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Clinical and cost effectiveness of a system for turning and positioning intensive care unit patients, when compared to usual care turning and positioning devices, for the prevention of hospital-acquired pressure injuries. A randomised controlled trial

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Abstract

Pressure injuries affect 13.1% to 45.5% of patients in the intensive care unit and lead to pain and discomfort for patients, burden on healthcare providers, and unnecessary cost to the health system. Turning and positioning systems offer improvements on usual care devices, however the evidence of the effectiveness of such systems is still emerging. We conducted an investigator initiated, prospective, single centre, two group, non-blinded, randomised controlled trial to determine the effectiveness of a system for turning and positioning intensive care unit patients, when compared to usual care turning and positioning devices, for preventing PIs. The trial was prematurely discontinued after enrolment of 78 participants due to COVID-19 pandemic related challenges and lower than expected enrolment rate. The study groups were comparable on baseline characteristics and adherence to the interventions was high. Four participants developed a PI (in the sacral, ischial tuberosity or buttock region), n = 2 each in the intervention and control group. Each participant developed one PI. As the trial is underpowered, these findings do not provide an indication of the clinical effectiveness of the interventions. There was no participant drop-out or withdrawal and there were no adverse events, device deficiencies, or adverse device effects identified or reported. The results of our study (in particular those pertaining to enrolment, intervention adherence and safety) provide considerations for future trials that seek to investigate how to prevent PIs among ICU patients.

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Key Messages

- pressure injuries (PIs) affect 13.1% to 45.5% of patients in the intensive care unit (ICU)
- turning and positioning systems offer improvements over usual care devices; however, the evidence of the effectiveness of such systems is still emerging
- we enrolled 78 patients in an investigator-initiated, prospective, single-centre, two-group, non-blinded, randomised controlled trial to determine the effectiveness of a system for turning and positioning ICU patients, when compared with usual care turning and positioning devices, for preventing PIs
- the results of our study (which was prematurely discontinued because of pandemic-related challenges and low enrolment rate) provide considerations for future trials that seek to investigate how to prevent PIs among ICU patients

1 | INTRODUCTION

Pressure injuries (PIs) are damage to the skin and soft tissue[1] caused by mechanical deformations (e.g., pressure and shear) usually over a bony prominence.[2] PIs can evolve into chronic wounds due to difficulty in healing over time.[3] PIs cause pain and suffering, predispose the person to infection, increase the length of hospital stay and cost, and sometimes cause premature death.[1]

PI rates in Australian intensive care units (ICUs) are high, with prevalence averaging around 13.6% in one state,[4] a figure that is consistent with international reports (ranging from 13.1% to 45.5%).[1] The right tail of this range suggests that PI prevention is a challenge and that improved outcomes are difficult to sustain. Although these rates have gone down from previous observations of PI rates in Australia,[5] the cost of PIs in acute care patients remains high at an estimated AU$9.11 billion in Australia.[6]

Preventing PIs is particularly important for ICU patients who are critically unwell and/or cannot move independently, and who are, therefore, at high risk of PI development.[7] Turning and positioning patients (which refers to moving the patient's body, eg, while they are in bed)[8] is well recognised as an essential intervention to prevent skin damage such as PIs.[9] Equipment is used to turn and position patients, specifically to ensure that they are placed in the desired position until the next turning and positioning event. Turning and positioning is usually conducted with a slide sheet for turning and pillows or wedges for positioning.[8]

Research and evaluation of turning and positioning of patients have largely focused on the best time intervals for turning and positioning[10] and direction regarding the best position to place the body to prevent PIs.[11] Such strategies cannot successfully prevent PIs if the body is not moved safely (minimising exposure to friction, shear, and pressure) and if the body position is not supported between position changes (to prevent the body returning to the previous position and sustaining ongoing unintended pressure to a specific area). The slide sheet was principally designed to address the occupational health and safety risks of staff but may provide some reduction in shear when positioning patients.[1] Pillows were designed for domestic use and not for positioning patients, and wedges are commonly used to stabilise the patient's body. These devices do not offer advanced structural characteristics that effectively redistribute pressure and alleviate internal localised, sustained tissue deformations, which is an essential requirement for PI prevention.[2] Turning and positioning systems offer some improvements over usual care devices; however, the evidence of effectiveness of these systems is still emerging.

An excellent example for the considerable knowledge gaps and lack of understanding of the currently known aetiology of PIs leading to a poor design or usage of a positioning device is the (still) commonly used donut-shaped head positioner (and similar positioners to allegedly protect the sacral region).[12] Donut-shaped head supports, primarily made of stiff gels, are commonly used to protect the occiput of patients who are stationary. To investigate the effects of a donut-shaped head positioner on the scalp tissues, Katzengold and Gefen[13] used a three-dimensional, anatomically realistic, finite element model of an adult head, to which they added a

donut-shaped gel head support. These authors then compared the occipital scalp tissue loads while the donut-shaped gel head positioner was in use with those associated with the Z-Flo fluidised head positioner (Mölnlycke Health Care, Gothenburg, Sweden) and a standard medical foam. The donut-shaped gel head positioner inflicted the greatest exposure to high (and therefore dangerous) occipital soft-tissue mechanical stresses among the tested positioners.

Katzengold and Gefen's[13] work demonstrated that though the donut-shaped gel head positioner is supposedly designed to move tissue loads away from the occiput and disperse them to the surrounding tissues, it fails to do this, in fact. Contrarily, this device concentrates on transferring the head-weight force through a relatively narrow ring of scalp tissues, thus increasing the risk of developing occipital PIs. A clinical study relying on this advanced biomechanical knowledge in collaboration with intensive care specialists indeed confirmed that the aforementioned fluidised positioning device is substantially more effective in reducing occipital PIs.[14]

The biomechanical efficacy of the Mölnlycke Tortoise Turning and Positioning System in minimising tissue deformations at anatomical regions at risk for a PI (eg the sacrum) has also been considered.[15] Using magnetic resonance imaging (MRI), the effect of pressure-preventive devices on sacral skeletal muscle, subcutaneous fat, and skin tissue deformations was determined. Changes in tissue thickness were compared when lying supine on a rigid surface (MRI table), lying on a standard foam mattress, lying on a mattress with prophylactic multi-layer dressing in situ, and lying on a standard foam mattress with prophylactic multi-layer dressing and a Mölnlycke Tortoise Turning and Positioning System in situ. The mattress, dressing, and the turning and positioning device, when applied together, resulted in significantly lower deformation of each soft-tissue layer and the total soft-tissue bulk with respect to the rigid MRI table ($P < .05$), suggesting that a combination of interventions may reduce sacral PI risk. These studies highlight that close collaboration between bioengineers and clinicians, such as demonstrated in the aforementioned work, is required to evaluate the design of PI prevention devices.[16]

Our previous research with patients involved two evaluations of the turning pad and fluidised positioner components of the Mölnlycke Tortoise Turning and Positioning System, and this system is the intervention used in the RCT reported in this paper. The first evaluation was an observational study of the maintenance of the 30°, side-lying, lateral tilt position among aged care residents when using a standard care pillow and the fluidised positioner.[17] We identified that the average side-lying angle with the pillow was 26.7 ° at baseline, 21.5° at 1 h, and 16.6° at 2 h, which compared with that of the positioner, which was 30.7° at baseline, 29.3° at 1 h, and 26.8° at 2 h. The main effects of condition and time were significant—condition: $F(1, 11) = 14.378$, $P < .001$, time: $F(2, 22) = 45.858$, $P < .001$, and there was a statistically significant interaction between the effects of condition and time on the average lateral tilt position, $F(2, 22) = 15.574$, $P < .001$.

A sub-component of our research included three case studies of the perspectives of aged care residents on turning and positioning using the Mölnlycke Tortoise Turning and Positioning System components.[18] Each participant rated the system components satisfying overall, and equally or more satisfying than the usual care devices. Residents used their own words to describe their perception and user experience of the bioengineering design principles implemented in the system components—turning pad: reduction of localised soft-tissue deformations through larger body-support surface contact areas, by either immersion or envelopment[13,15,19]; fluidised positioner: moulding to shape[13,15,19]—highlighting the importance of integrating bioengineering work with patient perspectives.

Our second study reported the feasibility of positioning immobile, critically ill patients at risk of PIs using the fluidised positioner, focusing on head and neck alignment of immobile patients.[20] Conducted in the same ICU as the RCT reported in this paper, the study identified factors of relevance for future trial design. The processes for screening patients for eligibility were successful (and this informed the screening processes for the RCT). However, there were delays in obtaining participant consent (this was not an issue in the RCT, as a waiver of the consent process was obtained).

1.1 | Study aim

The aim was to determine the clinical and cost effectiveness of a system for turning and positioning ICU patients, when compared with usual care turning and positioning devices used for preventing PIs. The research question was "Is a turning and positioning system more effective, when compared with usual care turning and positioning devices, in preventing hospital-acquired PIs among ICU patients?"

Following the enrolment of 78 participants, the study was placed on hold because of challenges in conducting the trial during the COVID-19 pandemic. The study was not restarted because of the low enrolment rate achieved until that time and the ongoing implications of the pandemic at the study site. We report our findings to share

the results and discuss feasibility aspects pertaining to the trial and in the spirit of addressing the reporting bias that occurs when RCTs are not reported.

2 | MATERIALS AND METHODS

2.1 | Design

The study was investigator-initiated, prospective, single-centre, two-group, non-blinded, RCT. The study was approved by the Austin Health Human Research Ethics Committee and was prospectively registered with the Australian and New Zealand Clinical Trials Registry on 4 February 2019 (ACTRN12619000156189). Participants were enrolled from 14 August 2019 to 27 May 2020.

2.2 | Hypotheses

1. Participants cared for with the turning and positioning system while in the ICU will have significantly fewer PIs than participants who are cared for with usual care turning and positioning devices.
2. The marginal cost of turning and positioning care, the treatment costs of PIs, and the average costs per person will be lower among participants who are cared for with the turning and positioning system compared with participants receiving usual care.

Given the premature discontinuation of the study, we report only descriptive results pertaining to hypothesis 1, as the value of results pertaining to cost is limited in the context of the cessation of the trial.

2.3 | Setting

The study setting was an ICU with 10–18 beds in Melbourne, Australia. At the time of the trial, the ICU admitted approximately 1200 patients each year, with an average of 100 patients each month. The average length of stay in the ICU at this time was 2 days. The ICU did not routinely use wound dressings as a PI prophylaxis measure at the time of the trial.

2.4 | Eligibility

The inclusion criteria were ≥18 years of age, ICU admission for critical illness or trauma, and high risk of PI development (a score of ≤12) according to the Braden Scale for predicting pressure sore risk.[21] The exclusion criteria were having a sacral, ischial tuberosity, or buttock PI; trauma to sacrum, ischial tuberosity, or buttock; suspected or actual spinal injury precluding the patient being turned or immobilised; having injuries that are not survivable or receiving palliation; and known sensitivity to nylon, polyester, polyurethane, or cotton.

On 24 April 2020, the trial eligibility criteria were changed in response to the emergence of COVID-19. From this time onwards, patients were ineligible to participate if they had a confirmed or suspected COVID-19 diagnosis. Patients cleared of COVID-19 were eligible if they met all other eligibility criteria. Patients were ineligible if cared for in the prone position (irrespective of diagnoses). Participants who did not have COVID-19 at the time of enrolment and who subsequently were diagnosed with COVID-19 were withdrawn from the study, as well as participants who did not have COVID-19 at the time of enrolment but were subsequently cared for in the prone position for treatment of COVID-19 or other respiratory condition(s). Any participants who had been cared for in the prone position had finished their participation in the study before these changes to the criteria were made. From this time onwards, no patients who had COVID-19 were otherwise eligible to participate; the one enrolled participant who had COVID-19 had completed participation in the study, and no participants were thereafter cared for in the prone position.

2.5 | Sample size and power analysis

The proposed sample for the study was n = 430 (n = 215 per study group). We calculated the sample size to detect a decrease in the ICU PI incidence rate of 5% (from 6.1% to 1.1%) in the intervention group. Using the formula for computing a sample size for a binary outcome and equal sample size in both the groups,[22] a sample size of n = 215 participants per group (n = 430 in total) was required. This calculation assumed α to be 0.05 and power to be 0.8 (β = 20). Review of PI data reports at the participating ICU (for the previous 2-year period) suggested that the sample would be achieved in an 18-month period.

2.6 | Site preparation

Study-funded research nurses (two ICU nurses who usually worked at the study site) were employed for a total of 4 days per week. The research nurses were trained in study processes, data collection, and PI assessment (to ensure consistency in PI identification and staging). The research nurses had completed Good Clinical

Practice (research) training. ICU staff (nurses and physiotherapists) were given in-person group education about the study and were trained to use the turning and positioning system during theoretical and practical training sessions delivered by the research team and industry representatives. The research nurses provided support and guidance to the staff regarding the use of devices as required during the trial.

2.7 | Screening and enrolment

The research nurses screened new ICU patients at the start of the work shift and throughout the day. Pending ICU admissions were identified for follow-up on arrival. Screening included reviewing patient information in the electronic medical health record, liaising with ICU nurses and doctors regarding eligibility criteria, and assessing the patient's skin to confirm that there was no existing PI in the sacral, ischial tuberosity, or buttock regions (which would exclude participation).

2.8 | Consent

A waiver of the consent process was developed in alignment with the National Statement on Ethical Conduct of Research and more specifically the relevant considerations for people who are highly dependent on medical care and receiving intensive care.[23] This process was approved by the HREC, and the participant and/or their legally authorised representative was advised of the patient's enrolment in the study as soon as practicable. A brochure was provided to the next of kin, which included information about the trial and the option to withdraw from the study. When practicable, a research nurse spoke with the patient and/or their legally authorised representative about the study and answered any questions.

2.9 | Randomization

Participants were randomly assigned, in a 1:1 ratio, to the intervention group or the control group. A random generation sequence was developed by a statistician (independent of the study) using Microsoft EXCEL and was blinded to the intervention allocation by the use of labels "Intervention A" and "Intervention B" in place of the identifying names of the equipment and devices. A consecutively numbered envelope system was used, and the envelopes were stored in the ICU. A research nurse retrieved and opened the next randomisation envelope when a patient was screened as eligible and enrolled in the study.

2.10 | Blinding

The ICU staff and study participants were not blinded, as there was no way to conceal the intervention given the visible nature of the usual care devices and the turning and positioning system.

2.11 | Standard care

Both groups of the study participants received standard care including the usual time schedule for turning and positioning of patients (two-hourly or as required according to clinician assessment); all participants were placed on a Hill-Rom TotalCare P500 intensive care bed, and the usual ICU staff provided turning and positioning care. Bariatric care was provided to patients on the basis of their body size and/or weight and included the use of non-standard equipment (such as a larger bed) and more staff to provide care (such as when turning and positioning). All participants were examined by one of the research nurses to identify the development of any hospital-acquired PIs to the participants' sacral, ischial tuberosity, or buttock regions.

2.12 | Treatment

The difference between the two study groups was in the devices used for turning and positioning. The intervention group participants had the turning and positioning devices applied immediately upon enrolment or at the first scheduled positioning event following enrolment. The control group participants continued to use devices that were already in use (slide sheet, pillows, and foam wedges).

2.12.1 | Control group: Care with usual care turning and positioning devices

Slide sheets (nylon material) were used to turn the participant from side to side and to move the participant up and down the bed. The slide sheet did not remain under the patient. Pillows and wedges were used to maintain the patient's body position when in the side-lying position. The type of pillow and wedge were not standardised; however, pillows in use typically had a foam or synthetic inner filling encased in a stitched or seam-welded impermeable cover made of polyester, vinyl, plastic, or polyvinyl chloride (PVC). The foam wedges used were typically the wedge triangle pillow (DEARJANE MEDICAL) made of memory foam with a waterproof

Slide sheet

Pillow

Wedge

FIGURE 1 Usual care turning and positioning devices.

cover (size 20 cm × 20 cm × 40 cm). The slide sheets, pillows, and wedges in use were standard ICU equipment (Figure 1).

2.12.2 | Intervention group: Care with the turning and positioning system

The Mölnlycke Tortoise Turning and Positioning System has two components: a turning pad and a fluidised positioner. The former is used to turn the patient from side to side and move the patient up and down the bed, and it remains under the patient while in bed. The latter is used to maintain the patient's body position when lying on side. The system components are approved by the Australian Therapeutic Goods Administration as low-risk devices (approval numbers 282 958 and 282 967, respectively) and for the therapeutic purpose described in this study. The system is available in "standard" and "bariatric" versions with a weight limit of 400 kg for both. The bariatric version of the system includes a larger turning pad (for use on a wider bed) and a larger fluidised positioner (for use with larger patients; Figure 2).

The turning pad is made of nylon, polyester, polyurethane, and cotton. The turning pad has indicators for where to position the patient's body on the pad for optimal placement and has ergonomic handles. The main body of the pad has a low-pressure air chamber designed to adapt to the patient's body by positive air displacement. This feature is designed to redistribute pressure over a larger surface area. The turning pad was not to be used with a hoist and was only used in the bed.

The fluidised positioner is comprised of a polyurethane bag, which predominantly contains polydimethylsiloxane (a viscous fluid mix). The fluidised positioner can be moulded by hand to the shape required for each specific use, is designed to maintain the shape it is moulded into and not flatten over time, and can subsequently be remoulded to the shape required for the next position change. The positioner can be used with specialised beds and mattresses. Both components of the turning and positioning system are non-latex and

Turning pad

Fluidized positioner

FIGURE 2 Intervention turning and positioning system.

diethylhexyl phthalate (DEHP)-free. Linen, for example a sheet, is used between the patient and the turning pad and the fluidised positioner. Both components are cleaned with hospital-approved disinfectants. The system is for single-patient use and to be discarded after 90 days of use.

2.13 | Primary outcome

The incidence of PIs was expressed as the total number of PIs developed in both the intervention and control groups during the study period. A PI was defined as "a localized injury to the skin and/or underlying tissue usually over a bony prominence, due to pressure, or pressure in combination with shear",[24] and PIs were classified according to these guidelines (which were current at the time of the registration of the study).

2.14 | Measurement and data collection

Initial data were collected by a research nurse immediately following enrolment. Data included enrolment date, participants' demographics, characteristics of the participant's ICU stay, admission classification, treatments, physiological variables [including mean arterial pressure (mmHg), temperature (C°), heart rate (beats per minute), fraction of inspired oxygen (fraction/percentage)], the Braden Scale pressure risk assessment score,[21] continence status, body mass index and classification, bariatric status

(this is a flag for the classification of care provision), and health-related constraints on positioning. The Braden Score was assessed by a research nurse, and other initial data were collected from the electronic medical record and paper records that are usually completed by care providers at the bed side.

Ongoing data were collected by a research nurse daily (during the four weekdays that the research nurses worked) commencing the day after the enrolment day. Data included use of allocated intervention, any resolved unblancheable erythema, PIs occurring (and the PI stage and location), and end-of-study date. Direct observation of the participants' skin (during usual turning and positioning care) was made by a research nurse to identify the presence or absence of PIs and resolved, unblancheable erythema. Direct observation of the bed was made by a research nurse to identify whether or not the allocated intervention was in use. Other ongoing data were collected from the electronic medical record and paper records that are usually completed by care providers at the bed side. Participation in the study and data collection ceased upon discharge from the ICU; development of a sacral, ischial tuberosity, or buttock PI; or death.

2.15 | Analysis

Study data were collected by the research nurses using REDCap electronic data capture tools[25,26] hosted at the University of Melbourne. The analysis was based on the intention-to-treat protocol[27]; therefore, all patients randomised to the intervention were analysed regardless of any protocol violations. The person conducting the analysis was not blinded. The aim was to compare the development of PIs per group and PIs by anatomical site per group using Fisher's exact test and to conduct a survival analysis to determine the difference in PI incidence development rates per group and time to provide a hazard ratio (HR) between the groups. However, descriptive statistics were employed (the analysis was conducted in Microsoft EXCEL 2019) given that the study was discontinued prematurely and sample size was not achieved. Results pertaining to feasibility of the trial were also reported to enable understanding and discussion of factors for consideration for future trial design and implementation.

3 | RESULTS

The ICU staff (n = 48, nurses and physiotherapists) were educated about the study and trained to use the turning and positioning system. Participants were enrolled from 14 August 2019 to 27 May 2020 (41 weeks). In total, 598 patients were screened for inclusion in the study, and a further 124 patients were recorded as not screened due to being discharged from the ICU before screening could occur. The total number of participants enrolled was 78, a rate of 1.9 participants per week (Figure 3).

3.1 | Baseline characteristics

The groups were comparable at baseline with respect to demographic, physiological, and pressure risk-related characteristics and illness type (Table 1).

3.2 | Time in study

The period of the study was 5 days on average, and this result was similar between the groups (4 days in the intervention group and 6 days in the control group) (Table 2).

3.3 | Adherence to the intervention

All the participants received the allocated devices upon enrolment. In total, 15 participants (6 from the intervention group and 9 from the control group) were classified as requiring bariatric care. In these cases, the intervention group participants received the bariatric version of the turning and positioning devices and the control group participants used pillows and wedges as usual, noting that more of these devices (pillows and wedges) may be used when positioning larger bodies.

After enrolment, the allocated devices were found to be in use on 98% of the occasions when adherence to the intervention was assessed (257 of 262 assessments). The finding was similar between the two groups (97% in the intervention group and 99% in the control group) (Table 3).

The reasons for non-use by the intervention group participants (two participants on three occasions in total) included the turning pad being soiled overnight due to incontinence and being removed by staff (a new turning pad was placed in situ the following morning) and the turning and positioning system being removed overnight as the participant was proned (2 days later, when proning ceased, the system was placed back in situ). The reasons for non-use by the control group participants (two participants on two occasions in total) included that the participants were mobilising when assessment occurred.

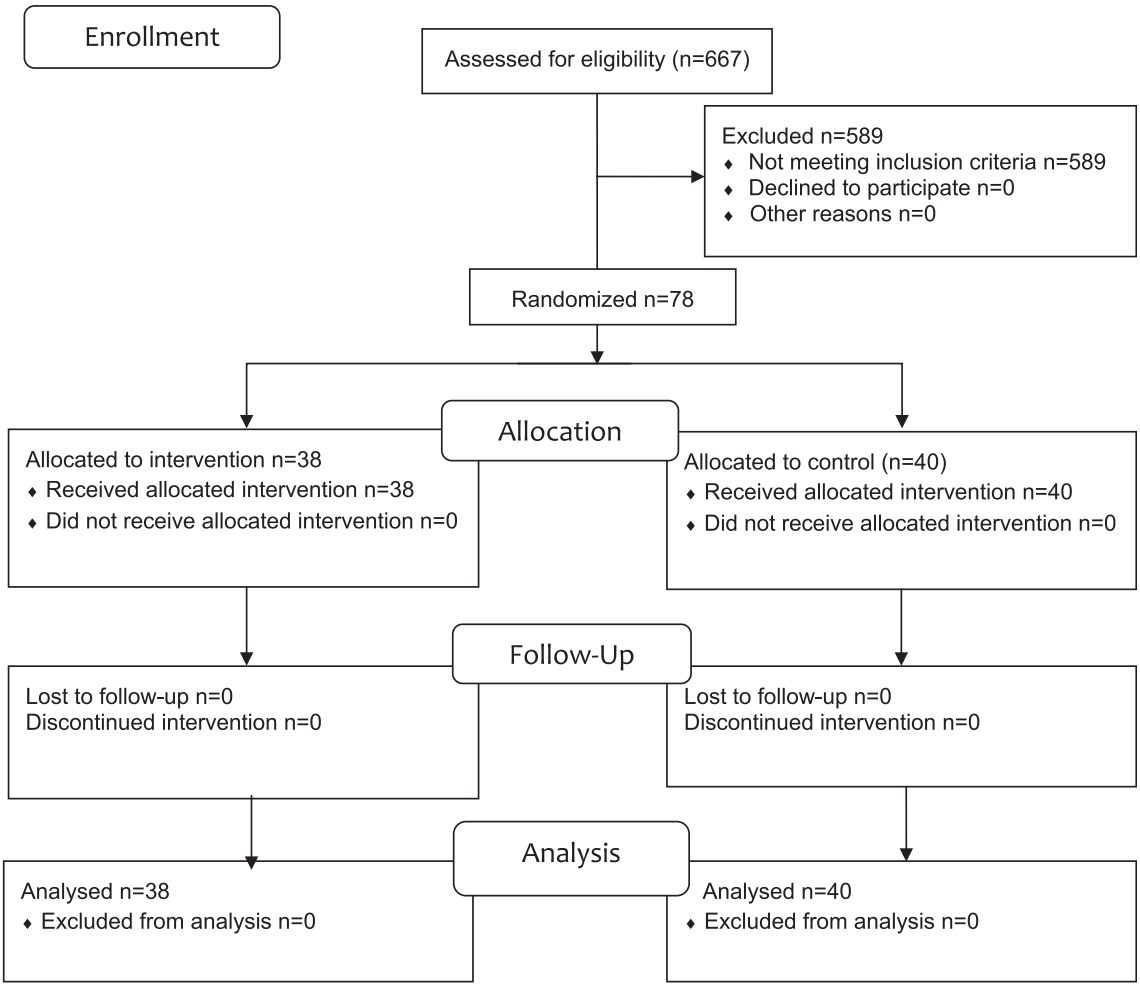

FIGURE 3 CONSORT flow-chart.[25]

Information regarding any constraints on positioning was collected, and in the case of the intervention group, one participant could not be repositioned on the left side of the body due to respiratory failure; for another, haemodynamic compromise was listed as a constraining factor; and for yet another, being proned was noted. In the case of the control group, being proned was listed as a constraining factor for one participant.

3.4 | Incidence of PIs

The total number of patients who developed a PI in the sacral, ischial tuberosity, or buttock region was n = 4 (n = 2 in both intervention and control groups). Each participant developed one PI in the regions of interest (sacral, ischial tuberosities, and buttocks) (Table 4). In total, eight participants (three in the intervention group and five in the control group) had been assessed prior to enrolment as having non-blanchable erythema that had resolved.

3.5 | Participant events

There was no drop-out of participants, and no participants withdrew from the study. There were no adverse events, device deficiencies, adverse device effects, serious adverse events, or serious adverse device effects identified or reported. In total, 12 participants died during the trial (n = 7 in the intervention group and n = 5 in the control group). There was no unexplained mortality for which the intervention was not excluded as a contributing factor.

4 | DISCUSSION

This study aimed to measure the clinical and cost effectiveness of a system for turning and positioning ICU patients, when compared with usual care turning and positioning devices, for the prevention of hospital-acquired PIs. The trial was preceded by establishment of the biomechanical efficacy of the Mölnlycke Tortoise

TABLE 1 Participants' baseline characteristics ($n = 78$).

	Intervention ($n = 38$)				Control ($n = 40$)			
	Mean	(SD)	Median	(IQR)	Mean	(SD)	Median	(IQR)
Age (years)	57	(18)	58	(46–70)	58	(16.4)	60	(49–73)
Sex (M/F)	24/14				26/14			
Physiological variables								
Temperature (°C)	36.3	(1.2)			36.5	(1.6)		
MAP (mmHg)	68	(14)	65	(60–74)	69	(14.4)	65	(60–70)
Heart rate (bpm)	93	(28)			93	(33.4)		
FiO_2 (%)	75				79			
ICU admission origin								
Emergency Department	21				19			
Ward	8				7			
Operating theatre	4				10			
Cath lab	3				3			
External transfer	2				1			
ICU admission type								
Critical illness	36				40			
Trauma	2				0			
Mechanical ventilation	33				38			
COVID-19	0				1			
Braden Scale score	9	(1.5)	9	(8–10)	9	(1.4)	9	(9–17)
BMI	34	(16.1)	29	(25–41)	32	(7.2)	34	(29–36)

Abbreviations: BMI, body mass index; FiO_2, fraction of inhaled oxygen expressed as a decimal value; ICU, intensive care unit; MAP, mean arterial pressure.

TABLE 2 Time in study (days) ($n = 78$).

Time in study (days) (n = 78)					
Intervention (n = 38)		Control (n = 40)		Total (n = 78)	
Mean and range	SD	Mean and range	SD	Mean and range	SD
4 (1–14)	(3.6)	6 (1–39)	(6.3)	5 (1–39)	(5.2)

TABLE 3 Adherence to the intervention.

Adherence to the intervention (n = 262 assessments)			
Intervention (n = 109)		Control (n = 153)	
Yes	No	Yes	No
106	3	151	2

Turning and Positioning System components in minimising tissue deformations at anatomical regions at risk for a PI,[12-16,19,28] evaluations with patients,[17,18] and a feasibility study conducted at the study site,[20] all of which informed our design and recruitment strategy. The number of patients enrolled in the trial was lower than expected, and the COVID-19 pandemic presented implementation challenges that could not be overcome. The trial was prematurely discontinued following enrolment of 78 participants.

Non-achievement of sample is a common occurrence in RCTs generally,[29] reported in trials that involve patients who have wounds[30] and in research conducted to prevent PIs in the ICU setting in Australia.[31] It is important to note that this evidence precedes the COVID-19 pandemic; however, the issue of non-achievement of sample may be further inflated because of the known impacts of such unprecedented events in healthcare services (eg staffing challenges) and impacts that remain unknown to date.

One factor associated with low enrolment in wound-related RCTs is a mismatch between anticipated and

TABLE 4 Patients who developed a PI, characteristics and time to development (n = 4).

	Group	Anatomical location	PI stage	Timing to development (days post enrolment day)
A	Intervention	Sacrum	2	Day 1 in trial
B[a]	Intervention	Right buttock	1	Day 14 in trial
C	Control	Sacrum	Unstageable	Day 16 in trial
D[b]	Control[a]	Sacrum	2	Day 2 in trial

[a]Participant B had respiratory failure resulting in not being positioned on the left side of the body from Day 2 to Day 9.
[b]Participant D had COVID-19 (enrolled before the trial eligibility changed to exclude COVID-19 patients from participation). This participant had been previously assessed as having non-blancheable erythema at the sacrum, which resolved after being positioned off the affected area. This participant had been proned for 16 h prior to identification of the PI.

actual eligible patients.[30,31] Based on our screening data (pre-trial/pre-COVID-19 and during the trial), this is a likely explanation for the sub-optimal enrolment in our study. However, an admission rate of 25% less than the anticipated rate to the ICU during the study period and 17% of patients not screened for inclusion only in part explains this outcome. Another factor is reliance on surrogates to consent for ICU patients to participate in trials and the gap that can occur between eligibility and obtaining consent.[32] This issue did contribute to low recruitment in one of our earlier studies[20]; however, it was not a factor in this trial because of the waiver of the consent process that was employed.

The trial commencing after the winter season (the peak season for admissions and acuity in the ICU) and concluding before the following year's winter season likely stymied enrolment and this is a consideration for others who are developing recruitment strategies for RCTs conducted in the ICU. The impact of the research nurses working four weekdays is a consideration with respect to potentially missed participants; however, it is suggested that such missed patients would have likely been ineligible (if discharged from the ICU on day 1 or 2 of their stay, these patients would have likely been more mobile and, therefore, not at high risk of PI development). The merit of employing research staff to screen and recruit patients 7 days a week and for more hours each day should be carefully considered given the significant cost implications (weekend and after-hour pay rates, which are considerably higher than weekday rates) and the risk that this approach may not result in a higher recruitment rate.

Feasibility and/or pilot studies[33] are considered essential precursors to the conduct of larger definitive trials, and the results of such studies provide justification for future research and therefore help minimise research waste. The studies that we conducted prior to the trial (and our pre-trial screening of patient data) did not indicate that our sample would be unachievable, and our previous research led to critical learnings that informed our trial design and implementation. For the benefit of future research, effort should be made in investigating and reporting barriers to and enablers and predictors of achievement of sample in PI studies conducted in the ICU. This evidence should be synthesised and presented in a form that is useful to others who are planning clinical trials and developing recruitment strategies. Such guidance would also be highly valuable beyond the ICU setting given the high risk of discontinuation of trials due to slow recruitment in acute care more generally.[34]

Intervention adherence was high with all study participants receiving the allocated intervention, and subsequent checking of adherence identified that the allocated intervention was in use on 98% of the occasions assessed. The reasons for the few occasions of non-use were reasonable, and in all cases where the devices should have been reinstituted, this occurred in a timely manner. This is a positive finding given that all participants receiving an allocated intervention in non-drug trials is reported to be a rare occurrence and subsequent intervention adherence is typically lower.[35] This finding speaks to the feasibility of using the usual turning and positioning devices and the turning and positioning system in future research.

Of the 78 participants, four developed one PI each (two participants each in the intervention and control group). Given that the trial is underpowered, these findings do not provide an indication of the clinical effectiveness of the interventions. The case of PI "D" warrants discussion given that the participant had COVID-19, had been previously proned, and developed a sacral PI. This case highlights that there is still much to discover about the impact of COVID-19 on PI development. The COVID-19 virus is associated with cytokine storm, inflammation, endothelial damage, ischaemia, and coagulation and micro-thrombotic events which distort the tissues,[36] and there is suggestion that purpuric or non-blanchable purple lesions, where the skin is not broken and which develop on areas of the body not exposed to pressure, may be a result of vascular inflammation or

microthrombi and not pressure as is typically conceptualised.[37] However, of note, PI "D" was a Stage 2 PI, a presentation that is not consistent with this theory.

From a participant safety perspective, the trial was uneventful in terms of drop-out and withdrawal (regarding these events, there was none). Additionally, there were no issues reported or identified with the devices used in the study and no unexplained mortality for which the intervention was not excluded as a contributing factor. These findings speak to the overall safety of the interventions, acceptability of the study, and completeness of participation and monitoring.

The inability to complete the trial, given the positive findings relating to intervention adherence and monitoring, is disappointing, though not unexpected in the context of a global pandemic impacting ICU admissions, workforce, and the feasibility of clinical trials. Although the results of the trial do not provide evidence of the effectiveness of the interventions, they do provide useful information for researchers who are planning and/or conducting similar research with patients who have PIs in the ICU setting and during times of unprecedented disruption to service delivery that occurs during a pandemic. National health register analyses have proven that the prevalence of chronic wounds significantly increased in 2020 with the breakout of the COVID-19 pandemic[38] and, importantly, there is no certainty that wound rates would return to the pre-pandemic levels; hence, even though the COVID-19 conditions were extreme (not only in the aspect of enrollment to this study but in other aspects as well), relevance is likely to remain in the post-pandemic era.

4.1 | Limitations

Study limitations include that the study was conducted at a single site, which limits the generalisability of the study findings. The inability to blind the participant and the research nurses (assessors) to the intervention is a further limitation, one that would be difficult to resolve given the visible nature of the usual care devices and the turning and positioning devices.

5 | CONCLUSION

ICU patients are at high risk of developing PIs. Turning and positioning is an essential intervention to prevent PIs; however, the effectiveness of turning and positioning devices for PI prevention has not yet been established. The results of our study (in particular those pertaining to enrolment, intervention adherence, and safety) provide considerations for future trials that seek to investigate how to prevent PIs among ICU patients.

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CONFLICT OF INTEREST STATEMENT

Suzanne Kapp has received research funds for investigator-initiated studies and has been invited by Mölnlycke Health Care to speak at conferences and symposia. Nick Santamaria and Amit Gefen are consultants to Mölnlycke Health Care and members of its Global Pressure Ulcer/Injury Advisory Board, and have received research funds from Mölnlycke. Mölnlycke has not controlled (or regulated) the research carried out by Nick Santamaria and Amit Gefen. William Padula declares Personal Fees and Equity Holdings with Monument Analytics, LLC.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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