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The effect of a patient centred care bundle intervention on pressure ulcer incidence (INTACT): A cluster randomised trial

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ABSTRACT

Background: Hospital-acquired pressure ulcers are a serious patient safety concern, associated with poor patient outcomes and high healthcare costs. They are also viewed as an indicator of nursing care quality.
Objective: To evaluate the effectiveness of a pressure ulcer prevention care bundle in preventing hospital-acquired pressure ulcers among at risk patients.
Design: Pragmatic cluster randomised trial.
Setting: Eight tertiary referral hospitals with >200 beds each in three Australian states.
Participants: 1600 patients (200/hospital) were recruited. Patients were eligible if they were: ≥18 years old; at risk of pressure ulcer because of limited mobility; expected to stay in hospital ≥48 h and able to read English.
Methods: Hospitals (clusters) were stratified in two groups by recent pressure ulcer rates and randomised within strata to either a pressure ulcer prevention care bundle or standard care. The care bundle was theoretically and empirically based on patient participation and clinical practice guidelines. It was multi-component, with three messages for patients' participation in pressure ulcer prevention care: keep moving; look after your skin; and eat a healthy diet. Training aids for patients included a DVD, brochure and poster. Nurses in intervention hospitals were trained in partnering with patients in their pressure ulcer prevention care. The statistician, recruiters, and outcome assessors were blinded to group allocation and interventionists blinded to the study hypotheses, tested at both the cluster and patient level. The primary outcome, incidence of hospital-acquired pressure ulcers, which applied to both the cluster and individual participant level, was measured by daily skin inspection.
Results: Four clusters were randomised to each group and 799 patients per group analysed. The intraclass correlation coefficient was 0.035. After adjusting for clustering and pre-specified covariates (age, pressure ulcer present at baseline, body mass index, reason for admission, residence and number of comorbidities on admission), the hazard ratio for new pressure ulcers developed (pressure ulcer prevention care bundle relative to standard care) was 0.58 (95% CI: 0.25, 1.33; $p = 0.198$). No adverse events or harms were reported.
Conclusions: Although the pressure ulcer prevention care bundle was associated with a large reduction in the hazard of ulceration, there was a high degree of uncertainty around this estimate and the difference

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What is already known about the topic?

- A Cochrane review shows complex interventions focusing on both providers and patients and using condition-specific materials have beneficial effects on health behaviour.
- Four recent reviews conclude negative associations between multi-component pressure ulcer prevention interventions or programs and the development of pressure ulcers but the studies reviewed were mostly small, single site, non-RCTs with numerous other limitations.
- The 2014 international clinical practice guidelines for pressure ulcer prevention recommend patients understand both their pressure ulcer risk and prevention strategies and recommend patients work with healthcare providers to develop individualised pressure ulcer prevention plans and actively participate in pressure ulcer prevention.

What this paper adds

- A simple, multi-component pressure ulcer prevention care bundle focusing on active patient participation in pressure ulcer prevention can be delivered to patients in about 10 min.
- It is feasible to use the gold standard skin inspection method to detect pressure ulcers in large trials.
- Uncertainty remains as to whether the pressure ulcer prevention care bundle reduces pressure ulcers. The pressure ulcer prevention care bundle may be effective.

1. Background

Hospital-acquired (HA) pressure ulcers (PU) are associated with poorer patient outcomes (Gorecki et al., 2009) extended hospital length of stay and greater healthcare costs (Nguyen et al., 2015; Russo and Elixhauser, 2006). HAPU prevalence in the general hospital population is approximately 15% in the UK (Briggs et al., 2013) Sweden (Gunningberg et al., 2013) Belgium (Vanderwee et al., 2011) and Australia (Mulligan et al., 2011); but varies according to PU definitions and detection methodologies. For example, a review of medical charts in a US study identified only 4.5% HAPU prevalence (Lyder et al., 2012), which is much lower than results reported in studies using skin assessment (Briggs et al., 2013, Brito et al., 2013; Gunningberg et al., 2013; Mulligan et al., 2011; Vanderwee et al., 2011). HAPU are recognised as an indicator of the quality of nursing care (Arnetz and Arnetz, 2009) and a preventable adverse events (Latimer et al., 2016; Webster et al., 2011; Winters et al., 2016). In fact, the US Medicare and Medicaid Services ceased reimbursing facilities for HAPUs in 2007 (Cene et al., 2016).

There are a number of prognostic factors for HAPU; the most well-recognised is restricted mobility (Adams et al., 2009; Baumgarten et al., 2006; Coleman et al., 2013; Nonnemacher et al., 2009). Other factors predictive of PU include increasing age (Baumgarten et al., 2006; Coleman et al., 2013; Nonnemacher et al., 2009) previous or current PU (Coleman et al., 2013; Nonnemacher et al., 2009) nursing home residence (Baumgarten et al., 2006) and multiple comorbidities (Coleman et al., 2013; Fogerty et al., 2008). Cornerstones of pressure ulcer prevention (PUP) evidence-based guidelines include risk assessment, support surfaces, regular repositioning, good skin care and adequate nutrition (Australian Wound Management Association, 2012; European Pressure Ulcer Advisory Panel et al., 2014); yet uptake of PUP guidelines is suboptimal (Aasen et al., 2012; Soban et al., 2011; Vanderwee et al., 2011).

There is growing evidence for the benefits of care bundles for improving uptake of guidelines in areas including infection (Pronovost et al., 2006) falls (McInnes et al., 2014) stroke care (Middleton et al., 2011) and PUs (Baldelli and Paciella, 2008; Mathiesen et al., 2013). However, no PUP care bundles have been tested rigorously in randomised trials. A care bundle is "a small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually" (Resar et al., 2012). Strategies to engage patients more effectively in their care are also developing momentum (Dwamena et al., 2012; Vaismoradi et al., 2015). In the area of PUP, the 2014 international clinical practice guidelines for PUP recommend patients understand both their PU risk and prevention strategies. They also recommend patients to work with healthcare providers to develop individualised PUP plans and to actively participate in PUP (European Pressure Ulcer Advisory Panel et al., 2014).

Given the promising evidence around patient participation and care bundles, a patient-centred PUP care bundle (PUPCB) that aimed to increase active patient participation in PUP by helping them understand more about PUs including preventative strategies, was designed and tested using a cluster randomised trial (c-RT) design. A cluster design was required to prevent contamination between intervention and control patients, and between patients and nurses moving or working across units. The care bundle was informed by the concept of patient participation in care (Sahlsten et al., 2008), PUP clinical practice guidelines (Australian Wound Management Association, 2012), and five systematic reviews on PUP (Chou et al., 2013; Niederhauser et al., 2012; Reddy et al., 2006; Soban et al., 2011; Sullivan and Schoelles, 2013). The prevalence, cost and negative outcomes associated with PUs as well as the evidence that implementation of PUP strategies is suboptimal, along with emerging evidence of the benefits of patient participation and the use of care bundles, provided the rationale for this study.

The primary hypothesis was: the incidence rate of HAPU in at risk hospitalised patients who receive a PUPCB will be lower than that in those receiving standard care and was tested at both the cluster and individual patient level. The secondary hypotheses, tested at the individual patient level, were: (1) Patients who receive a PUPCB will have less severe HAPU than those who receive standard care; and (2) Patients at risk of PU who receive the PUPCB will report higher patient participation in PUP than those who receive standard care. An economic analysis will be published separately.

2. Materials and methods

2.1. Trial design and participants

This study, entitled INTroducing <u>A</u> <u>C</u>are bundle <u>T</u>o prevent pressure ulcers (the INTACT trial), was a pragmatic c-RT. The trial protocol has been published (Chaboyer et al., 2015). Cluster eligibility criteria were either public or private tertiary referral hospitals with more than 200 beds that had acute medical, surgical and rehabilitative services. Eight hospitals in three Australian states were approached and all agreed to participate. Adherence to

clinical practice guideline recommendations for PUP at the study sites prior to the trial was unknown for most sites, although a study conducted at two of the sites about 3 years prior to the INTACT trial identified variation in adherence (Latimer et al., 2016). Patients were eligible if they were: aged $\geq$18 years; had an expected hospital length of stay of $\geq$48 h; at risk of PU as measured by limited mobility (i.e. requiring physical or mechanical assistance to reposition or ambulate); able to read English and provide informed consent. Patients were excluded if they were: admitted to the hospital for >36 h prior to recruitment; admitted to day surgery, critical care, emergency, maternity, paediatrics, mental health or dialysis; previous trial participants; palliative, or receiving end of life care. A screening log was kept to identify patients who did and who did not meet the inclusion criteria. Limited mobility rather than a PU risk assessment score was used by recruiters to screen for eligibility. Limited mobility reflected the need for either human assistance or equipment such as walkers, wheelchairs and monkey bars for mobilisation or repositioning, and was assessed by recruiters, making a judgement based on observation, and discussion with patient. Previous research indicates limited mobility is a strong risk factor (Adams et al., 2009; Baumgarten et al., 2006; Coleman et al., 2013; Nonnemacher et al., 2009) and the use of clinical judgement has also been shown to be able to identify patients at risk of PU (Webster et al., 2011). Written consent was obtained from all participants after the hospital was randomised, however participants (and the recruiting nurse) were blind to the hospital allocation at recruitment to minimise selection bias. Patients reached the trial endpoint when they: developed a new HAPU of any stage including those caused by devices; were discharged from hospital; reached 28 days; were transferred to another hospital or to critical care requiring mechanical ventilation; or died. This trial was registered with the Australian New Zealand Clinical Trials Registry (registration number ACTRN12613001343796) and was approved by the hospitals' and universities' human research ethics committees. All participants were given a study information sheet and signed a consent form.

2.2. Randomisation, concealment and blinding

Hospitals were stratified in two groups by their most recent PU prevalence rates (highest four and lowest four), although we are aware of potential limitations in the accuracy and currency of these data. It was not possible to stratify hospitals by other characteristics such as size, given a sample of only eight. De-identified stratification details were provided to a central randomisation service not involved in the study. Random number generating software was used to randomise hospitals (clusters) within strata, with random 1:1 block allocation of hospitals to intervention or control group. Allocation was concealed until all sites had confirmed participation. Hospital staff were not informed about the comparator intervention nor the group allocation. To further limit the possibility of selection bias, a statistician not associated with recruitment generated a random number list, which was used to determine the order in which recruiters approached the wards to recruit participants. Initial recruitment targeted four medical/surgical wards at each hospital, but if weekly recruitment targets of 10 patients/week were not being met, further wards were included in the trial. Recruitment and outcome assessment research assistants (RAs) were masked to the trial design and group allocation. Patients were blinded to group allocation, although they and the nursing staff were aware patients were in a study examining PU prevention strategies and subsequent development of PUs. Intervention RAs were blinded to the study hypotheses. The trial statistician was blinded to group allocation.

2.3. Intervention

The intervention group received standard care and the PUPCB. Its development was guided by the Medical Research Council Framework for the development of complex interventions (Craig et al., 2011) and based on the Institute of Healthcare Improvement's description of care bundles (Resar et al., 2012). The PUPCB was theoretically founded on the concept of patient participation, one aspect of patient centred care (Sahlsten et al., 2008), and empirically founded on the PUP clinical practice guidelines (Australian Wound Management Association, 2012), and five systematic reviews on PUP (Chou et al., 2013; Niederhauser et al., 2012; Reddy et al., 2006; Soban et al., 2011; Sullivan and Schoelles, 2013). As described in a Cochrane review, one aspect of patient centred care involves sharing control of interventions or management of health problems with patients (Dwamena et al., 2012). The patient centred PUPCB was multifaceted (Shekelle et al., 2013) directed at both the cluster (nurses on participating hospital wards) and individual (patients).

The patient component was developed with the input of end-users, including consumers, nurses and a variety of other health care professionals. A more detailed description of its development and feasibility testing has been previously published (Chaboyer and Gillespie, 2014; Gillespie et al., 2014). A 5-min DVD, information brochure and poster on PUP were the resources used to educate patients and promote their participation in PUP. The poster had photographs and three messages: 1) keep moving; 2) look after your skin; and 3) eat a healthy diet. The DVD and brochure focused on these same three messages and used the same photographs but provided detailed information about each message. Face-to-face patient education was provided once to patients at their bedsides within 24 h of being enrolled in the study (i.e. within 50 h of hospital admission). Thus, each patient received the intervention from one intervention RA and there was no follow-up or reinforcement of the training. At each site, one intervention RA was employed for four hours per day each of five week days (because patients were only recruited on weekdays). The intervention RAs were nurses or dietitians with over five years of acute care experience, whose role in the study was to deliver the intervention. These intervention RAs received one day of face-to-face training in intervention delivery. Patients watched the DVD and then the RA reviewed the brochure with the patient. Together, they determined where to position the poster. Patients were encouraged to ask questions throughout the session. The RA recorded the session duration and the intervention components delivered to the patient.

The PUPCB component aimed at nurses focused on information about patient participation in care as well as the content of the patient component. Between four and eight formal sessions, lasting 15–30 min, were conducted for nurses at each intervention site (depending on the number of study wards at that site) prior to and during data collection, reaching 38–66 participants at each site. A Powerpoint presentation session included an overview of the study, patient participation and the three target messages. Nurses were provided with copies of the educational resources. Ad hoc, one-on-one education sessions were provided to nurses who missed the group education sessions. Research nurses responded to any additional questions that arose throughout the study.

2.4. Control

Standard care was provided at all sites (i.e. both control and intervention sites), in line with regional guidelines (Australian Wound Management Association, 2012). All control and intervention sites met the national PU health service standard, which involved screening patients on admission and implementing PUP

interventions when clinically indicated. All control and intervention sites had hospital wide PUP committees, annual prevalence audits, and ward and hospital level PU reporting. For control sites, Powerpoint presentations or hard copies of the presentation were used to provide ward nurses (in groups) with an overview of the data collection at the site. Informal, individualised information sessions were also provided to nurses throughout the study.

2.5. Data collection

Data on the number of beds and hospital-wide PUP strategies were collected for each hospital at the start of the trial. There were two groups of RAs employed at each site as data collectors. Recruiters, who consented patients, also collected baseline patient demographic and clinical data, including diagnosis and risk factors for PU from medical records. Outcome assessors recorded daily patient skin status and collected information on other PUP care/ strategies the patient received (from medical records or direct observation). These strategies included a documented repositioning regimen and nutrition care plan, the use of various pressure relieving devices, and the use of skin care products such as barrier creams. All data were entered directly into a web-based electronic case record form using tablet computers.

2.6. Outcome assessment

The primary outcome was incidence of new HAPU and pertained to both the individiual patient and cluster. It was defined as number of new PU of any stage per 1000 patient follow up days. As the study was an open cohort, patient days of follow up varied. There were two secondary outcomes; severity of HAPU and patient participation in PUP. Severity of HAPU was classified according to the international PU Classification System (Stage 1 nonblanching erythema; Stage II partial thickness skin loss; Stage III full thickness skin loss; Stage IV full thickness tissue loss; Unstageable, deep tissue injury with depth unknown (European Pressure Ulcer Advisory Panel et al., 2014). Patient participation in PUP in care was measured when the patient neared (or reached) the trial endpoint by a validated seven-item participation in care scale (Weingart et al., 2011) modified to reflect participation in PUP, with higher scores reflecting higher levels of participation.

The outcome asssessor RAs, who were nurses or nursing students trained in skin assessment, visually inspected the skin of all participants daily and recorded the outcome in a standardised way. The RA training was one day in length (Stankiewicz et al., 2016), with a 10-item paper and pencil test administered after the training to assess participants' ability to identify photographed PUs and their stages. Of the 25 outcome assessors across all sites, inter-rater reliability testing indicated acceptable levels of agreement. Fleiss Kappa for the primary outcome, presence of a new HAPU was 0.923 (p < 0.001) and for the secondary outcome, HAPU stage, was 0.635 (p < 0.001). A Kappa above 0.60 is considered substantial agreement and above 0.80 almost perfect agreement (Landis and Koch, 1977).

2.7. Statistical analysis

An a priori sample size calculation was undertaken. Sample size calculations for cluster trials requires consideration of the extent to which data collected within a site may be correlated, (i.e. patients in one hospital may have similar data because their settings are the same) referred to as the intraclass correlation coefficient (ICC). Based on a previous study (Moore et al., 2011) we assumed an ICC of 0.001. We estimated the trial would have greater than 90% power with a two tailed alpha of 0.05 to detect 50% relative difference (5% absolute difference) from 10% to 5% in HAPU with

eight clusters of 169 patients each. Intention-to-treat analyses were undertaken by a statistician (LT) blinded to group allocation. All patients who were randomised were analysed in the groups to which they were randomised. Patients who withdrew or were lost to follow up were analysed based on their last skin inspection. There are specific recommendations against significance testing for baseline differences in c-RT (Wright et al., 2015), therefore we did not undertake this kind of statistical comparison of our baseline data.

HAPU incidences were computed taking into account their time to event nature; that is, the variable lengths of time patients were in the trial (recruitment to study endpoint) was accounted for in the analysis. The pre-specified primary analysis was at the level of the individual patient, but we also pre-specified cluster level analysis. For the patient level analysis, hazard ratios (HR) were computed using Cox proportional hazards models and their corresponding 95% confidence intervals (CI) using cluster adjusted robust standard errors (SE) (Rogers, 1993). Cox models are used to explore relationships between an outcome and explanatory variables, taking into consideration the time it has taken for this outcome to occur. A hazard ratio is derived from the Cox model and is an estimate of the ratio of the hazard rate in the intervention versus the control groups. Possible deviation from the proportional hazards assumption of the model using the non-proportionality test on the basis of the Schoenfeldt residuals was checked. In addition to crude HR, estimates were adjusted for pre-specified factors that are related in the literature or clinically to risk of pressure ulcers (age, PU present at baseline, body mass index, reason for admission, residence and number of comorbidities on admission). Body mass index was recoded to healthy (18.5–25.0) and not healthy (below 18.5 or above 25.0) for this analysis. At the cluster level, the total number of HAPU was divided by the total cumulative person days that the patients stayed in each cluster resulting in incidence rates in the two groups, which took into consideration the time the patient was in the trial. Incidence rate in treatment clusters was then divided by that of the control clusters to compute incidence rate ratio (with 95% CI).

For secondary outcomes, frequency of HAPU severity was compared between the two groups using cluster-adjusted chi-square test, while patient participation in PU care was compared between groups using cluster adjusted independent *t*-test. We used STATA version 13.1 (Stata Statistical Software, College Station, TX; Stata Corp LP) for statistical analyses.

3. Results

Eight tertiary hospitals agreed to participate (Fig. 1). Of 2377 eligible patients (1209 Intervention; 1168 Control), 777 (33%) declined to participate (409 [34%] Intervention; 368 [32%] Control) resulting in 1600 consenting patients (800 Intervention; 800 Control), with one patient in each group excluded after recruitment because they were confused and consented in error. The median number of wards used to recruit patients per site was 7 with 1338 of 1600 patients (84%) recruited from four medical/ surgical at each hospital. In total, 50/1598 (3.1%) patients withdrew and 74/1598 (4.6%) were lost to follow up. 768 (96%) patients in the intervention group received the PUPCB, which took a mean (±SD) length of time of 9.5 ± 5.4 min to deliver. There were no protocol violations in the control group; all 799 received standard care. Data collection began 23 June 2014 and was completed by 11 May 2015.

Baseline characteristics of the two groups are displayed in Table 1. It appeared participants in the PUPCB group were more frequently medical admissions, less likely to have been admitted from assisted living, were more likely to have neurological comorbidities, were less likely to have cancer and were less likely to have PU at baseline than the control group.
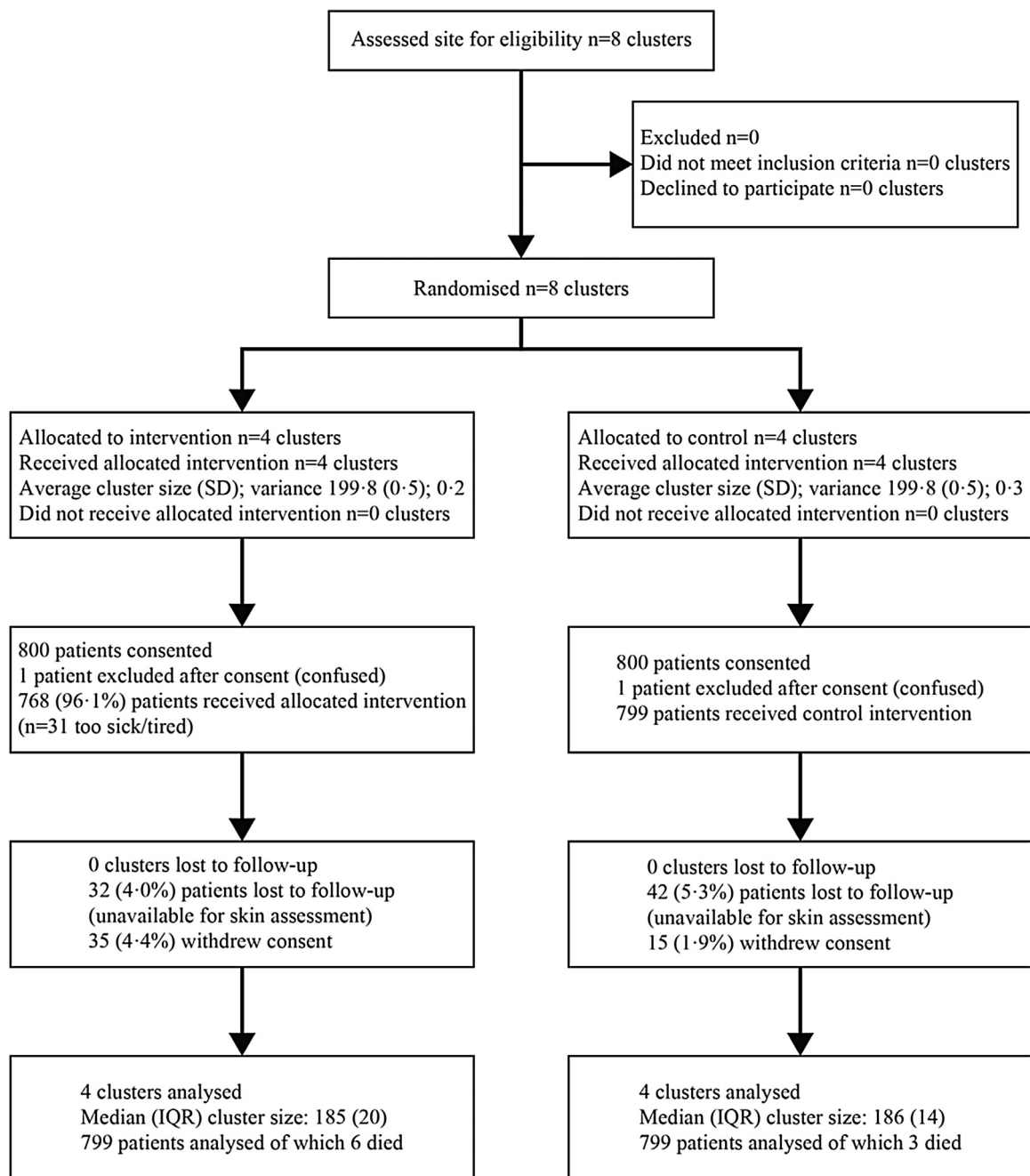
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Allocated to intervention n=4 clusters Received allocated intervention n=4 clusters Average cluster size (SD); variance 199·8 (0·5); 0·2 Did not receive allocated intervention n=0 clusters	Allocated to control n=4 clusters Received allocated intervention n=4 clusters Average cluster size (SD); variance 199·8 (0·5); 0·3 Did not receive allocated intervention n=0 clusters
800 patients consented 1 patient excluded after consent (confused) 768 (96·1%) patients received allocated intervention (n=31 too sick/tired)	800 patients consented 1 patient excluded after consent (confused) 799 patients received control intervention
0 clusters lost to follow-up 32 (4·0%) patients lost to follow-up (unavailable for skin assessment) 35 (4·4%) withdrew consent	0 clusters lost to follow-up 42 (5·3%) patients lost to follow-up (unavailable for skin assessment) 15 (1·9%) withdrew consent
4 clusters analysed Median (IQR) cluster size: 185 (20) 799 patients analysed of which 6 died	4 clusters analysed Median (IQR) cluster size: 186 (14) 799 patients analysed of which 3 died

Fig. 1. Participant flow through study.

All 1598 patients were included in the analysis; patients who withdrew or were lost to follow up were censored and their last observed skin assessment was used as the outcome (i.e., no PU). Forty nine patients (6.1%) in the PUPCB group and 84 (10.5%) in the control group developed a HAPU. Total follow-up was 9265 days for all patients (PUPCB group 5080 days; control group 4185 days). The HAPU incidence rate across the whole sample was 14.4 per 1000 person-days; 9.6 per 1000 person-days in the PUPCB group and 20.1 per 1000 person-days in the control group (incidence rate ratio 0.48; 95% CI: 0.33, 0.69; $p < 0.0001$).

The crude hazard ratio of 0.48 (95% CI: 0.20, 1.21) indicated a 52% reduction in the risk of HAPU associated with the intervention compared with standard care; this difference was not statistically significant. After adjustment for pre-specified covariates (age, baseline PU, BMI, type of admission (surgical, medical cancer),

residing in an aged care residence that provides assistance for daily living and number of comorbidities at admission), the effect was slightly attenuated: HR 0.58 (95% CI: 0.25, 1.33). The ICC of a HAPU event was estimated to be 0.035 (95% asymptotic CI 0.0000, 0.0765), higher than that used to determine the sample size.

After adjusting for the clustering, there was no significant difference between intervention and control groups in the severity of new PU (Table 2) or in patient participation in PUP (mean (SD) scores on the PU care scale: Intervention 3.3 (0.77), Control 3.0 (0.97), $p = 0.124$). No adverse events or harms were reported.

4. Discussion

This c-RT recruited 1600 at-risk patients in eight Australian public and private hospitals in three states. Incidence of HAPU was

Table 1

Baseline demographics and clinical characteristics of the sample.

Sample Baseline Characteristics	Intervention (n = 799) N (%)	Control (n = 799) N (%)
Female	393 (49.2%)	434 (54.3%)
Admitted from an aged care residence (assisted living)	41 (5.1%)	62 (7.8%)
Admission type		
Surgical	232 (29.0%)	316 (39.5%)
Medical	558 (69.8%)	463 (57.9%)
Cancer	9 (1.1%)	20 (2.5%)
Type of co-morbidity[a]		
Cardiovascular disease	400 (50.1%)	367 (49.7%)
Respiratory condition	190 (23.8%)	170 (21.3%)
Diabetes	168 (21.1%)	153 (19.1%)
Neurological	136 (17.0%)	105 (13.1%)
Malignancy/carcinoma	96 (12.0%)	129 (16.1%)
Renal disease	91 (11.4%)	106 (13.3%)
Peripheral vascular disease	108 (13.5%)	50 (6.3%)
Cerebral vascular accident	65 (8.1%)	94 (11.8%)
Dermatitis or eczema	51 (6.4%)	29 (3.6%)
Documented malnutrition on admission	13 (1.6%)	13 (1.6%)
Number of co-morbidities		
One	207 (25.9%)	232 (29.0%)
Two	197 (24.7%)	193 (24.2%)
Three or more	207 (25.9%)	181 (22.6%)
Current Smoker	50 (6.3%)	49 (6.1%)
PU present on baseline[b]	60 (7.7%)	95 (12.0%)
	Median (IQR) Range	Median (IQR) Range
Age (years)	70.0 (20.0) 18.0–100.0	74.0 (22.0) 19.0–104.0
Body Mass Index	27.4 (7.4) 13.1–65.7	27.0 (7.6) 14.5–69.4
Hospital length of stay (days)	6.0 (5.0) 1–77	5.0 (5.0) 1–97
Days in study (days)	4.0 (4.0) 0.5–28	4.0 (4.0) 0.5–28
Cluster Characteristics	N	N
Public hospital	3	3
Private hospital	1	1
Number of hospital beds (Median, IQR)	359 (499)	659 (201)
Range	270–929	508–750
Hospital wide PUP committee	4	4
Annual PU audit	4	4
PUP policy and procedures	4	4
PUP in hospital orientation for new graduates	3	4

PU = Pressure Ulcer. PUP = Pressure Ulcer Prevention. IQR = Interquartile Range.

[a] 2 missing in Intervention Group.

[b] 22 Missing in Intervention Group, 5 in Control Group.

measured using the gold standard skin inspection method. The intervention was patient-centred, structured and is replicable, and outcome assessment was prospective and daily, overcoming limitations in relying on medical record documentation of presence of PU. Whilst the control group had about twice the incidence of HAPU as the PUPCB group (unadjusted, hospital level data), there was no statistically significant effect of PUPCB on PU incidence at the participant level once prognostic factors and clustering had been accounted for. There is a high degree of uncertainty in our results that may be explained by the larger than expected ICC (0.035 rather than the 0.001 anticipated) and the small number of clusters randomised (four in each group).

It is possible the PUPCB had no effect but, given the large reduction in the hazard of pressure ulceration and the reduction in the incidence rate ratio, it is premature to reject this as an ineffective intervention. The patient level analysis shows there is great uncertainty regarding whether the intervention reduced HAPU relative to usual care. While the PUPCB reflected best practice evidence, it was also founded on patient participation in PUP. It is possible that the 'dose' of the training of both patients and nursing staff to facilitate this participation was not sufficient to enable active patient engagement. There is a growing body of evidence regarding the challenges experienced by acute care nurses in supporting patient participation. Some of these

Table 2

Stages of new pressure ulcers.

Stages	Intervention n = 799 N (%)	Control n = 799 N (%)	Cluster adjusted P value
Stage 1	28 (3.5)	60 (7.5)	0.644
Stage 2	16 (2.0)	19 (2.4)	
Un-stageable	5 (0.6)	5 (0.6)	

challenges included both patient condition and their varying preferences for active participation and nurses' individual mannerisms and willingness to partner with patients (Tobiano et al., 2015). There is also a recognition that nurses are ready to share some of their power and relinquish some of their control to allow patients to actively participate in their care (Sahlsten et al., 2008). Thus, the finding that there was no clear difference between the PUPCB and control groups may be because the PUP intervention did not provide adequate training or ongoing support to nurses about how to engage patients in PUP. Ultimately this means nurses may not have 'allowed' or facilitated patients' contribution to PUP. It is also possible that 'one off' training of patients was not enough to help them understand PUs better nor help them to participate in PUP. As recommended by a recent IJNS editorial (Balzer and Kottner, 2015), we also undertook a process evaluation of the intervention, which may provide more insights into what worked and didn't work for both patients and nurses. This notion is supported by the finding that there were no group differences in perceptions of participation in PUP.

The body of evidence from previous studies testing multi-component interventions to prevent HAPUs demonstrates mixed results. For example, a review of the use of multicomponent strategies in 26 US studies identified that 11 studies demonstrated statistical significance (Sullivan and Schoelles, 2013) yet only three were randomised trials. Most of the 24 studies in another review of PUP programs reported improvements in HAPU but the reviewers noted p-values reflecting statistical significance was rarely reported and none were randomised trials (Niederhauser et al., 2012). Consistent with these mixed review findings, the confidence intervals in our patient level analysis indicate there may be a reduction of 75% or an increase of 33% in HAPU rates if our PUPCB is used.

There are several possible alternative explanations for why the crude cluster level incidence rate ratio showed the PUPCB had a significant effect other than that it worked. It is possible that hospital practices between the two groups differed, with PUPCB hospitals providing higher quality care, possibly explaining the positive cluster level findings. We cannot explore this further as we do not have data on pre-trial adherence to PUP clinical practice guidelines by site. However, both PUPCB and control hospitals had similar hospital wide practices such as PUP committees, annual prevalence audits etc., and sites were randomly allocated to groups. All hospitals met the national quality and safety standard for PUP. Additionally, while some prognostic factors such as neurological conditions and peripheral vascular disease appeared higher in the intervention group; surgical admissions, and PU present at baseline appeared higher in the control group. Hence, is difficult to judge how these differences may have affected the results. Another possible explanation for the significant crude effect at cluster level is that this analysis takes no account of any differences in the types of patients admitted to the hospitals, and if participants in the intervention group hospitals were fundamentally less likely to develop pressure ulcers, there would be an apparent treatment effect.

A Cochrane review concluded that complex interventions aimed at both the provider and patient that included condition-specific educational materials had beneficial effects on health behaviours and health outcomes however, the risk of bias across the 43 randomised trials reviewed varied (Dwamena et al., 2012). The PUPCB tested had these characteristics of aiming the intervention at both the provider and patient, and use of condition-specific educational materials. Additionally, a large evidence-based assessment of patient safety strategies (Shekelle et al., 2013) concluded that multi-component interventions to prevent PU had sufficient evidence and were strongly encouraged to be adopted into clinical practice. Consequently it remains

plausible that a patient-focused PUPCB may reduce the risk of pressure ulceration in hospitalised patients but it would require a much larger (and very costly) study to demonstrate such an effect if it exists. In fact, a post hoc power analysis showed with recruiting 200 patients per site, the study would have required 28 hospitals per group at a statistical power of 80% to detect a statistically significant difference similar to that found in this study, if the ICC was 0.035.

4.1. Strengths and limitations

This is the first rigorous multisite c-RT of a patient centred PUPCB targeting both patients and staff behaviours. It was a pragmatic study and minimised contamination through the use of the cluster design. Recruitment of a range of at risk patients occurred in eight Australian public and private hospitals in three states. Hospitals were randomised by a central randomisation service, independent of the researchers and because selection bias is a major concern for cluster trials (Giraudeau and Ravaud, 2009), the order in which recruiters approached study wards was randomised as well. As noted in a recent editorial (Balzer and Kottner, 2015) and several systematic reviews, most other large studies report point prevalence or frequencies, often based on chart audit data, and most have not targeted at-risk patients (Chou et al., 2013; Niederhauser et al., 2012; Soban et al., 2011; Sullivan and Schoelles, 2013). The current study included all PUs, whereas some studies have excluded Stage 1 PU. Another strength was that outcome assessors were independent to the recruiters and interventionists; they were blinded to the study hypotheses, were trained and assessed patients' skin seven days per week. Excellent engagement was achieved (8/8 clusters approached agreed to participate); no clusters dropped out; and there was only a modest number of study participants lost to follow up.

The main limitation of this study is the low statistical power due to the small number of clusters and the higher than anticipated ICC. PUP studies are notoriously difficult to conduct in a robust and efficient manner. Whilst PU incidence rates are relatively low, hundreds of thousands of hospitalised patients are at risk at any point in time. The identification of PU is to some extent objective but poor documentation precludes the use of routine data. This means that good studies are extremely costly to mount as large numbers of outcome assessors who are masked to treatment group are required. An adequately powered study would have required 48 more hospitals (i.e. a total of 56 hospitals), each employing 3–4 data collectors, with huge quality control and budget implications. Another approach would be to consider the extent to which wards within hospitals could be randomised. However potentially this could result in contamination across groups. Alternatively, specific groups of high risk populations such as people with spinal cord injuries could be targeted as suggested in a recent IJNS editorial (Balzer and Kottner, 2015), although this might extend the time needed for recruitment.

Another limitation was the apparent baseline differences in the groups. For example, there were about a third more PU at baseline in the control group, which suggests they may have been more at risk of developing new PUs. However, in the patient level analysis we adjusted for this and several other potential differences between the groups in the patient level analysis. This study was conceptualised as a study about prevention of PU, thus patients were not followed up once they developed a HAPU. Following up patients may provide additional understanding about PU treatment and the natural history of how PUs progress or heal.

While a strength of the PUPCB is that the patient component was rigorously developed using a recognised framework, the component that was aimed at the nurses only involved staff education at a single time period with no other ongoing support.

Associated with this, we did not have ethical approval to collect data on the nursing staff, therefore we do not know the proportion of staff who received formal or informal training on the care bundle. It is possible that for nurses to successfully partner with patients for PUP, ongoing active support may have been required. Another potential limitation is the fact that patients received the education only once (soon after hospitalisation). It is always possible that it may have been more effective if the main messages were reinforced throughout the study period. The process evaluation, an independent study of the intervention, may provide a better understanding of the components of the intervention including the barriers and facilitators to uptake (Chaboyer et al., 2015). Finally, we did not collect observational data on the extent to which patients actually participated in their PUP, only asking them in the survey. It is possible that some patients may not have engaged in their PUP despite the intervention.

In conclusion, hospitals that used the PUPCB had a crude incidence rate for HAPU of about half that of control hospitals that provided standard care, but after adjustment for prognostic variables at the patient level, the effect was not statistically significant. The PUPCB reflects the move to partner with patients in their care and is simple to implement, but it is possible it requires more ongoing reinforcement to be effective. While the findings are inconclusive, the fact that the PUPCB is based on the current best evidence suggests that it may be a tool nurses can use to assist them in providing patient care.

Conflicts of interest

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Ethical approval

This study was approved by the following Human Research Ethics Committees: Gold Coast Health HREC/13/QGC/192 The Alfred Hospital 202/14 St Vincent's Private Hospital (Sydney) 14/109 Griffith University 2014/196 University of the Sunshine Coast A/14/628 University of Queensland 2014001380.

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