# INTroducing A Care bundle To prevent pressure injury (INTACT) in at-risk patients: a protocol for a cluster randomised trial

Wendy Chaboyer[a,b,c], Tracey Bucknall[d,f], Joan Webster[a,g], Elizabeth McInnes[e,h], Merrilyn Banks[g], Marianne Wallis[b,i], Brigid M. Gillespie[a,b,c], Jennifer A. Whitty[a,c,j], Lukman Thalib[k,l], Shelley Roberts[a,b,c,*], Nicky Cullum[m]

[a] *NHMRC Centre of Research Excellence in Nursing, Griffith University, Australia*
[b] *Centre for Health Practice Innovation, Griffith University, Australia*
[c] *Menzies Health Institute Queensland, Griffith University, Australia*
[d] *Alfred Health, Australia*
[e] *School of Nursing, Midwifery and Paramedicine, Australian Catholic University, Australia*
[f] *School of Nursing and Midwifery, Deakin University, Australia*
[g] *Royal Brisbane and Women's Hospital, Australia*
[h] *Nursing Research Institute, St Vincent's Health Australia (Sydney), Australia*
[i] *University of the Sunshine Coast, Australia*
[j] *University of Queensland, Australia*
[k] *Faculty of Medicine, University of Kuwait, Kuwait*
[l] *Griffith University, Australia*
[m] *University of Manchester, United Kingdom*

***Corresponding author:** Shelley Roberts, NHMRC Centre of Research Excellence in Nursing, Griffith University, Australia. Phone: +617 55529557. E-mail: s.roberts@griffith.edu.au

**Author contributions:** WC, TB, JWe, EM, MW, BG, JWh, LT and NC contributed to study conception. All authors except SR contributed to study design. WC, TB, JWe, EM, MB, MW and BG contributed to data acquisition. All authors will contribute to data analysis and interpretation. All authors contributed to article drafting and revision, and have approved the final version of the manuscript.

**Conflict of interest:** The authors declare no conflict of interest.

**Funding:** This study is funded by the National Health and Medical Research Council (NHMRC) through a Project Grant (APP1058963).

**Ethics approval:** Ethical approval given by Queensland Health (reference number HREC/13/QGC/192).

**ABSTRACT**

*Background:* Pressure injuries are a significant clinical and economic issue, affecting both patients and the health care system. Many pressure injuries in hospitals are facility acquired, and are largely preventable. Despite growing evidence and directives for pressure injury prevention, implementation of preventative strategies is suboptimal, and pressure injuries remain a serious problem in hospitals.

*Objectives:* This study will test the effectiveness and cost-effectiveness of a patient-centred pressure injury prevention care bundle on the development of hospital acquired pressure injury in at-risk patients.

*Design:* This is a multi-site, parallel group cluster randomised trial. The hospital is the unit of randomisation.

*Methods:* Adult medical and surgical patients admitted to the study wards of eight hospitals who are (a) deemed to be at risk of pressure injury (i.e. have reduced mobility), (b) expected to stay in hospital for ≥48 hours, (c) admitted to hospital in the past 36 hours; and (d) able to provide informed consent will be eligible to participate. Consenting patients will receive either the pressure injury prevention care bundle or standard care. The care bundle contains three main messages: 1) keep moving; 2) look after your skin; and 3) eat a healthy diet. Nurses will receive education about the intervention. Patients will exit the study upon development of a pressure injury, hospital discharge or 28 days, whichever comes first; transfer to another hospital or transfer to critical care and mechanically ventilated. The primary outcome is incidence of hospital acquired pressure injury. Secondary outcomes are pressure injury stage, patient participation in care and health care costs. A health economic sub-study and a process evaluation will be undertaken alongside the trial. Data will be

analysed at the cluster (hospital) and patient level. Estimates of hospital acquired pressure injury incidence in each group, group differences and 95% CI and p values will be reported.

*Discussion:* To our knowledge, this is the first trial of an intervention to incorporate a number of pressure injury prevention strategies into a care bundle focusing on patient participation and nurse-patient partnership. The results of this study will provide important information on the effectiveness and cost-effectiveness of this intervention in preventing pressure injuries in at-risk patients. If the results confirm the utility of the developed care bundle, it could have a significant impact on clinical practice worldwide.

*Trial registration:* This trial is registered with the Australian New Zealand Clinical Trials Registry, ACTRN12613001343796.

**What is already known about the topic?**

- Pressure injury is a significant clinical and economic issue.
- Most hospital acquired pressure injuries are preventable.
- Strategies to prevent pressure injuries must be complex and multidimensional.

**What this paper adds**

- This paper proposes a protocol for a complex intervention for pressure injury prevention, i.e. a pressure injury prevention care bundle.
- The proposed care bundle includes three main messages: (1) keep moving; (2) look after your skin; and (3) eat a healthy diet.
- The care bundle incorporates patient participation in care and encourages nurse and patient partnership.

## BACKGROUND

A pressure injury (PI), also known as pressure ulcer, is defined as "localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear" (European Pressure Ulcer Advisory Panel et al., 2014). PIs are a major problem in hospitals, affecting approximately 10 – 30% of patients worldwide, depending on the country, setting, patient population and presence of pressure injury prevention (PIP) strategies (Banks et al., 2010, Gunningberg et al., 2013, Igarashi et al., 2013, James et al., 2010). The majority of PIs in the clinical setting are hospital acquired pressure injuries (HAPI) (Gallagher et al., 2008, Gunningberg et al., 2011, Lyder et al., 2012). Two European studies of nearly 2000 hospitalised patients reported PI prevalence between 15 – 19%, and 77 – 78% of these were HAPI (Gallagher et al., 2008, Gunningberg et al., 2011). In Australia, the incidence of HAPI is 7.4 – 17.4% (Mulligan et al., 2011).

PIs result in significant physical, social and physiological problems for patients, including pain, wound exudate and odour, decreased mobility and independence, poor body image and emotional issues (Gorecki et al., 2009, Gorecki et al., 2011, Latimer et al., 2014). They also place a large burden on the health care system, by increasing length of stay (Graves et al., 2005) and hospital costs (Graves and Zheng, 2014). In fact, a recent estimate of the total cost of PI in public and private hospitals in Australia in 2010-11 was US$1.64 billion (±US$1.05 billion) (Graves and Zheng, 2014). PI treatment costs are estimated to represent 1.9% of all public hospital expenditure in Australia (Nguyen et al., 2015). Considering the significant negative outcomes for both patients and hospitals, PIP is of high importance.

It is recognised that the majority of PI, particularly HAPI, are preventable (Australian Commission on Safety and Quality in Health Care, 2011, Ayello and Lyder, 2008, VanGilder et al., 2009). In 2008, the US Centres for Medicare and Medicaid Services ceased

reimbursing facilities for HAPIs, considering them “never events”, that is, preventable events that should never occur (Centers for Medicare and Medicaid Services 2007). Similarly, in the UK, facilities now incur financial penalties for failing to meet PIP goals, or receive financial incentives if goals are achieved (Department of Health, 2012). In Australia, Queensland public hospitals are fined AU$30,000 and AU$50,000 for stage III and IV HAPI, respectively (Queensland Government and Department of Health, 2014). Preventing PI is one of the Australian National Safety and Quality Health Service Standards, which are used to assess performance and accreditation of Australian health care facilities (Australian Commission on Safety and Quality in Health Care, 2011). The importance of PIP is also reflected in international PI guidelines (European Pressure Ulcer Advisory Panel et al., 2014). Due to the number of complex and inter-related risk factors for PI, preventative interventions must be complex and multifaceted (Coleman et al., 2013). Core PIP strategies include: encouraging mobility and appropriate support surfaces; good skin care; and nutritional assessment and intervention if required (European Pressure Ulcer Advisory Panel et al., 2014).

The evidence for improvements in HAPI rates with multifaceted PIP interventions is limited to quality improvement projects with a lack of large-scale RCTs. However, systematic reviews and theory suggest that a combination of quality improvement intervention strategies may reduce the incidence of PI in the hospital setting (Padula et al., 2014, Soban et al., 2011, Sullivan and Schoelles, 2013). Several core elements are consistent across studies, including staff education and information sharing, leadership, performance monitoring, and PI-specific interventions such as protocols, guidelines and risk assessment (Padula et al., 2014, Soban et al., 2011, Sullivan and Schoelles, 2013), emphasising the value of multifaceted interventions. One systematic review highlighted a need for further understanding around implementation, causal pathways and the role of context in PIP interventions (Soban et al., 2011), hence the importance of conducting definitive trials with adequate piloting and process evaluation.

A care bundle is a structured group of interventions based on clinical practice guidelines that improve processes of care, encourage compliance to guidelines, and have been shown to improve patient outcomes (Institute for Healthcare Improvement, 2014, Rello et al., 2011). One US group developed an 8-item PIP care bundle that included skin care, turning and nutritional assessment, directed at nursing staff, and although their annual PI prevalence data showed trends towards improvements in PI prevalence, no formal analysis was undertaken (Baldelli and Paciella, 2008). A cluster randomised trial (c-RT) in the Netherlands found that a patient safety care bundle was effective in reducing adverse events, specifically PIs, urinary tract infections and falls among hospital and nursing home patients (van Gaal et al., 2011). The study employed a multifaceted implementation strategy using staff education, patient involvement and feedback on processes and outcomes to simultaneously implement multiple best practice guidelines (i.e. for each adverse event) in study wards (van Gaal et al., 2011). To date, care bundles have mostly focused on guiding clinicians in their practice, yet evidence suggests involvement of patients and their families working alongside clinicians could be a major driver in the use of care bundles (Coulter, 2006, van Gaal et al., 2011).

Patient participation in their health care has been shown to reduce adverse events and improve patient safety (Weingart et al., 2011) and result in improved health outcomes (Arnetz et al., 2010, Dwamena et al., 2012). National and international groups such as the Australian Commission on Safety and Quality in Health Care (2011), US Joint Commission on Accreditation in Healthcare Organizations (2006) and the World Health Organisation (2007) advocate for consumer participation in health care. Importantly, “Partnering with consumers” is one of the 2011 Australian Safety and Quality Health Service Standards, and is expected to be applied in conjunction with the standard “Preventing and Managing Pressure Injuries” (Australian Commission on Safety and Quality in Health Care, 2011). Recent research on patient and health professional views about patient participation suggests that

many interventions work optimally when both the health professional and patient have a role in the initiative (Davis et al., 2012). However, rigorous studies that have examined the impact of patient-clinician partnerships on patient outcomes in the acute care setting are lacking (Coulter, 2006).

In summary, PIs contribute to significant burden for patients and the health care system. As many HAPI are considered preventable, strategies for PIP warrant special consideration, yet research suggests they are poorly implemented. A patient-centred PIP care bundle may be an effective approach to PIP, and is consistent with evidence on the benefits of care bundles and mandates for patient participation in care. Patients, who have a vested interest in PIP, may be an untapped resource to prompt timely use of PIP strategies.

Consequently, an innovative PIP strategy was developed (Chaboyer and Gillespie, 2014, Gillespie et al., 2014) that is intended to optimise efficacy and sustainability, namely a care bundle that incorporates patient participation in care, easy access to PIP information and nursing staff engagement. This paper reports the protocol currently being used to test this care bundle, namely the INTACT trial (INTroducing A Care bundle To prevent pressure injury in at-risk patients).

**Aims and hypotheses**

This study aims to provide rigorous evidence regarding the effect of a PIP care bundle on the development of HAPI in patients at risk of PI.

*Primary Hypothesis:* The incidence of HAPI in “at risk” hospitalised patients who receive a PIP care bundle will be lower than that in at risk hospitalised patients receiving standard care.

*Secondary Hypotheses:* The intervention group will have better outcomes than the standard care group in terms of: (a) PI stage, i.e., depth of tissue damage; (b) patient participation in care; and (c) healthcare costs.

All hypotheses apply to both the cluster level and the patient level (see data analysis).

## METHODS/DESIGN

### Study design

This study is a multi-site, parallel group cluster randomised trial (c-RT). The unit of randomisation will be hospitals to prevent contamination between groups. Wards cannot be randomised as there is substantial patient movement between wards. Patients will receive either the intervention or standard care. The primary outcome is incidence of HAPI, and secondary outcomes are PI stage, patient participation in care and health care costs. Patients will exit the study upon: reaching study day 28; development of a PI; hospital discharge; transfer to another hospital; or transfer to critical care and requiring mechanical ventilation. An economic sub-study will evaluate the cost effectiveness of the intervention compared to routine care. A project manager (based at a university) will coordinate overall management of the project. Their role will entail assisting with the development of the database, coordinating ethics applications, overseeing and/or delivering research assistant training, site monitoring both during start up and during the trial, assessment of data quality. At each site, a study investigator who is a senior researcher and four separate groups of research assistants will be involved: (1) to recruit patients; (2) to deliver the intervention; (3) to collect data for the economic evaluation; and (4) to collect daily data to assess the outcomes (incidence of HAPI). The trial has been approved by the Queensland Health Human Research Ethics Committee (reference number HREC/13/QGC/192), and by five hospitals and one university.

The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613001343796) and is funded by the National Health and Medical Research Council (APP1058963).

**Setting**

To be eligible for the study, hospitals must (a) be metropolitan referral hospitals that cater for diverse patient adult populations and case-mix groups; (b) offer acute medical and surgical and rehabilitative services; and (c) have 200 or more beds. All patients from wards except day-surgery, critical care, emergency, maternity, paediatrics, mental health and dialysis units will be eligible to participate. There will be 5-15 wards able to participate at each site, which ensures diverse geographical, unit size and sub specialty representation. Methodological and pragmatic issues were considered in determining the number of sites. A total of eight acute care hospitals in Queensland, New South Wales and Victoria, Australia, have agreed to participate.

Randomisation

Generation of the allocation sequence and random 1:1 block allocation of hospitals to intervention or control group will be undertaken using a central randomisation service not involved in the study in any way. Hospitals will be stratified by the current HAPI rates as reported in each hospital. Allocation based on clusters will be concealed until the intervention is assigned. A statistician, not involved in recruitment and blinded to groups (treatment/ control) will generate a series of random number lists for 4, 6, 8, 10 and 12 wards. The lists will then be sent to recruiters, who will determine the number of wards they will recruit from and the order in which wards will be approached. Hospitals will be informed of which arm of the study they are randomised to on completion of data collection. The chief investigators and

interventionists will not be blinded to group allocation but the recruiters, outcome assessors and analysts will be blinded. These latter research assistants will be informed about group allocation at the end of the data collection.

**Participants**

A consecutive sample of patients in the study wards who meet all inclusion and no exclusion criteria will be recruited into the sample.

*Inclusion criteria*: (i) adults admitted to a study ward; (ii) expected hospital length of stay of ≥48 hours; (iii) at risk of PI as measured by limited mobility (i.e. requiring physical or mechanical assistance to reposition or ambulate); (iv) able to read English; and (v) able to provide informed consent.

*Exclusion criteria:* (i) previous participation in this trial; (ii) admitted to the hospital for >36 hours prior to recruitment; and (iii) palliative or dying patients.

Recruitment

We plan to commence recruiting at one site, to test procedures and other processes before recruitment commences at other sites. For each site, a computer-generated ward randomisation schedule will be developed and used to determine the order of approaching wards for recruitment of patients. This is to ensure that all wards in a particular institution are fairly represented. The number of wards approached each week will depend on recruitment rates at that site. The recruiters, from Monday to Friday, will screen eligibility of all patients admitted to study wards using a screening tool reflecting the inclusion and exclusion criteria. Patients will only be screened once. The nurse unit manager will ask potential participants if they are willing to be approached about this study, and if patients agree, they will be

consecutively approached by recruiters according to the ward randomisation schedule. Verbal and written information about the study will be provided before seeking consent from the patient. Recruitment will continue until 200 patients have been recruited at each site. The trial period (i.e. time from first recruitment to final completion) is expected to be nine months. Figure 1 shows anticipated participant flow through the study.

Sample Size

The incidence of HAPI in Australian hospitals ranges from 7.4% – 17.4% (Mulligan et al., 2011). A Cochrane review on support surfaces reporting a meta-analysis of five studies indicated a reduction in PI in at risk patients (RR 0.40, 95% CI 0.21 – 0.74) (McInnes et al., 2012). In our sample size estimate we have taken a conservative approach of incidence of 10% HAPI (control) with an expected reduction of 50% or an absolute reduction of 5% (from 10% to 5%) in the intervention group and an intra-class correlation of 0.001, the actual intra-class correlation in another c-RT of a PIP strategy (Moore et al., 2011). To obtain 90% power with a two-sided $\alpha$ level of 0.05, 8 hospitals with 169 patients per hospital are required (PASS – Power Analysis and Sample Size system, NCSS, Utah). Thus, the total sample required will be 1,352. Data from our pilot study indicated an attrition rate of just over 10%, hence additional patients will be recruited for a total sample of 1,600 (n = 200 per site).

**Intervention**

The intervention is a PIP care bundle aimed at both the individual (patient) and the cluster (hospital). It includes three main messages to promote patient participation in PIP care: (1) keep moving; (2) look after your skin; and (3) eat a healthy diet, which will be delivered to patients through a brochure, poster and DVD. Nurses will also receive training on

encouraging patients to engage in PIP self-care activities. Table 1 contains details of the intervention components and materials.

The PIP care bundle is based on the Institute of Healthcare Improvement recommendations that care bundles should be evidence based and straightforward, encompassing 3-5 items (Institute for Healthcare Improvement, 2014). The intervention will be delivered by dedicated health professionals (predominantly registered nurses) with a specific interest in wound care to both patients and nurses (patient and cluster level). Implementing the intervention will involve: (a) one-to-one patient training including watching a 5 min DVD; (b) an information brochure on PI; (c) poster reminders; and (d) training of nursing staff to promote partnering with patients in PIP care and the care bundle. Interventionists will deliver the PIP care bundle to patients shortly after recruitment and will provide both patient education and nurse training throughout the study. Thus the intervention is patient-centred and reflects partnership between patients and nurses in the delivery of care. The intervention was previously developed and piloted in an acute tertiary hospital setting (Chaboyer and Gillespie, 2014, Gillespie et al., 2014). Awareness of the INTACT trial will be raised through a range of strategies such as hospital newsletters, e-mails and forums. A trial-specific education programme targeting all nurses in study wards will be implemented to ensure clinical staff understand and support the study. A run-in period of two months will include formal group inservices and informal discussions with staff to ensure those at intervention sites understand the intervention and engage in partnering with patients in PIP strategies, and those at control sites are aware of the study. This training will commence prior to data collection and will continue as deemed necessary throughout recruitment depending on ward staff turnover. Ideally, all nurses on study wards will receive the training at least once. The study investigator at each site will be responsible for organising training at that site.

**Standard care**

For the duration of the trial, patients in the control group hospitals will receive the standard care provided for PIP on the particular ward. It is likely that standard care may vary from hospital to hospital and even between wards; consequently, we will document 'standard care' at each recruiting site. Patients in intervention group hospitals will also receive standard PIP care along with the intervention.

**Blinding**

Selection bias is a potential issue when undertaking cluster trials, especially when individual participants are recruited (Giraudeau and Ravaud, 2009). In order to minimise this potential bias, three strategies will be employed. Firstly, as described previously, recruiters will use a randomly generated ward list to determine the order by which they will approach wards during recruitment. Secondly, recruiters will not be the same individuals as those delivering the intervention. Finally, we will blind the recruiters to the actual intervention. The patient information and consent forms only state we will be examining various PIP strategies and in training recruiters will also be told this. Recruiters at each site will also be trained at their own hospital only. Full blinding in this study is difficult due to the study design (i.e. patients participating in their care) and the need for informed consent. However recruiters, nursing staff and patients will only be told broad details of their arm of the study, for example that the study involves documenting PI and various strategies for PIP, and will be unaware that the study is a c-RT. All research assistant groups (recruiters, interventionists and outcome assessors) will be blinded to study design and hypotheses, and will be trained separately to avoid the intervention being known to all groups. Outcome assessors will be blinded to group allocation and will be assigned to one hospital only. Success of outcome assessor blinding

will be assessed at the end of the study using the James Blinding Index (James et al., 1996). Finally, data analysts will be blinded to group allocation.

**Research assistant training and treatment fidelity**

All research assistants will undergo separate and group specific onsite training tailored to their role to ensure consistency across all sites. All research assistants will use standardised procedure manuals providing specific detail on their roles and data collection, plans for dealing with intervention fidelity issues and monitoring the delivery of the intervention. Participants in all groups will receive identical information and instructions regarding the study, except for the actual intervention.

**Data collection**

One research assistant will recruit the patients, obtain consent and collect demographic and clinical data. A second research assistant will deliver the intervention. Trained outcome assessors will collect daily data and assess the outcomes (blind to allocation). An electronic case record form will be developed to capture cluster level and patient level data and will be completed by the recruiter and/or the project manager. At the cluster level, the number of hospital beds, most recent HAPI rate and hospital PIP resources will be collected at baseline. At the individual patient level, demographic and clinical data such as gender, diagnosis, body mass index and risk factors for PI will be collected at baseline. This patient data will be collected from the medical records and the patient. The use of any other PIP interventions (i.e. as part of standard care) for each patient such as pressure relieving devices, special diets etc. will be recorded from the daily care plan, medical records or by direct observation by the outcome assessor. The outcome assessors will monitor and collect the same information on

actual PIP interventions delivered to patients in the control wards as for patients in the intervention wards.

**Outcome assessment**

The primary outcome is incidence of HAPI, and secondary outcomes are pressure injury stage, patient participation in care and health care costs. Patients will reach the trial endpoints of: development of a pressure injury, hospital discharge or 28 days, whichever comes first; transfer to another hospital or transfer to critical care requiring mechanical ventilation. The outcome assessors, who will be trained in skin assessment, will visually inspect the skin of all participants daily to determine if a PI is present, and if so, its stage. This skin assessment will follow international consensus guidelines for assessing PI (European Pressure Ulcer Advisory Panel et al., 2014). Each site will be funded for one half-time equivalent outcome assessor position plus weekend half-time, however due to staffing logistics (i.e. holidays, sick leave), 3–4 outcome assessors will be trained per site and are anticipated to be used using a roster system. All outcome assessors will receive a full day training in outcome assessment and data collection. This training will include theory and practice related to full skin integrity assessment, PI identification and staging. All assessors will undertake a test under exam conditions in which they will be asked to observe high definition photographs of PIs and determine whether the photograph shows a PI and if so, what stage. Inter-rater reliability of outcome assessors will be assessed using Fleiss Kappa for multiple raters on the primary outcome (presence of a PI) and secondary outcome (stage of PI). Research suggests that with training, excellent inter-rater reliability (Kappa 1.0, i.e. 100% agreement between trained clinical trials nurses and their team leader) can be achieved (Nixon et al., 2005). During the trial, monitoring will occur, with the project manager using source data to verify the date entered into the electronic case report form. The outcome assessor will also collect data for

secondary outcomes including patients' responses to the patient participation scale (Weingart et al., 2011) when patients reach the trial endpoint. This scale measures patient participation in inpatient care by asking seven questions around patients' knowledge and understanding of medical conditions and procedures, ability to access health professionals and participate in decision making, and hospital experiences (Weingart et al., 2011).

**Process evaluation**

A process evaluation will be undertaken alongside the trial to explain discrepancies between expected and observed outcomes and provide insight into why the intervention is successful or not (Craig et al., 2008). A framework for designing and reporting process evaluations for c-RTs will be employed (Grant et al., 2013). This framework consists of a number of elements for evaluating processes, including recruitment and reach, intervention delivery, response to intervention, maintenance, context, outcomes and theory (Grant et al., 2013). In the process evaluation of the INTACT trial, recruitment and reach will be descriptively analysed using screening log data from all study sites (i.e. total number of patients screened vs. recruited). Intervention delivery to clusters (nurses) and individuals (patients) will be measured by keeping inservice logs of staff training and documenting delivery of each intervention component to individuals at all interventions sites. Response to the intervention will be explored at the cluster and individual level through nurse and patient interviews. The possibility of maintenance of the intervention (i.e. translation into clinical practice) will be explored in nurse interviews. Context will be considered at a local, state and national level regarding PIP care by reviewing hospital policies and procedures, state penalties and national standards. Unintended consequences will be assessed through any changes in policy, processes or routine care at each site.

**Cost and resource use data**

A trial-based economic evaluation will be undertaken from the health system perspective to compare the direct healthcare costs and effects of a care bundle for PIP, relative to standard care. The resource utilisation data to be recorded and costed are summarised in Table 2. Costs related to provision of the care bundle such as time to educate patients and train nursing staff and costs of developing resources such as brochures, posters and DVDs will be collected for all trial participants, as will length of hospital stay. During a 4-week observational sub-study, micro-costing data will be collected by a separate research assistant, which will allow the calculation of direct costs to the hospital for pressure-related assessment and prevention for each participant across all sites. This sub-study sample is expected to represent 320 participants (20% of the trial cohort) and will be sufficient to indicate the mean and distribution of costs related to implementation and other PIP strategies used for each patient. The sub-study will determine the number of repositioning episodes per participant, number of clinical staff required for repositioning, and the nurse time required per turn. Other resource use related to PIP such as the use of special mattresses, skincare products and incontinence care will also be recorded for this sub-study. These resource use data will be collected by directly observing the patients in the sub-study and auditing medical records. Direct costs (AU$ 2014) will then be allocated to each resource unit using standard costing sources. These data from the substudy will be used alongside intervention and length of stay data to estimate the total resource use and direct healthcare cost per participant for the two groups over the entire study period.

**Data analysis**

Blinded analyses of primary and secondary outcome measures will be undertaken at cluster level and patient level. Our primary hypothesis will be tested at the individual patient level

but adjusted for the cluster structure as per the recommendation of Cochrane methods on the analyses of c-RT. Generalised Estimation Equations (GEE) models, hierarchical or generalised mixed models and multi-level models will be used to adjust for clustering of patient-level data. Within each approach, simple analyses such as t-tests, Chi-square tests or more complex approaches such as multivariate Cox regression models will be considered. Both allow for the effect of the intervention on the incidence of HAPI and other secondary outcomes to be tested; however, only complex analyses allow adjustment for potential covariates. Adjustment for individual patient covariates will occur in the appropriate level of analyses using GEE or multi-level models.

*Cluster level analysis:* The incidence rates per 1000 hospitalised days between intervention and standard care groups will be compared at cluster level. Estimates of the HAPI incidence in each group, group differences as well as the 95% CI and p values will be reported. Other outcomes will also be compared at the cluster levels between the intervention and control group. Baseline variables and other covariates will be compared between the two groups to ensure the intervention and control groups do not differ in their baseline characters.

*Patient Level Analysis:* Patient level analyses will primarily account for the intra-cluster correlation, thus increasing the statistical power of the analysis. Cluster adjusted Z-tests (to compare the proportion between the intervention and control groups) or t-tests (to compare means) will be undertaken to avoid spuriously low p-value and overly narrow confidence levels, over-emphasizing the impact of the intervention. However, the more comprehensive inferences in our study will be based on the use of modelling techniques to incorporate patient level data adjusted for nested structure. Cox regression with robust standard error will be used to estimate the rate ratios given the incidence rate per person time is the main outcome in this study. Robust standard error accounts for the correlation outcome within each

hospital. Cox regression will also adjust for a number of pre-specified covariates in comparing the incidence of HAPI between the intervention and standard care group. These modelling techniques allow the direct correlation within clusters to be modelled explicitly, and many potential confounding factors will be included in the model when comparing the effect of the intervention. Such models will be developed for primary and secondary outcomes. We will use STATA for the analyses of our data. An intention to treat analysis will be used but we will also undertake a per protocol analysis to elucidate differences in outcomes depending on the intended vs. actual intervention received.

*Cost-effectiveness Analysis:* Detailed within-trial resource utilisation and costs will be used to undertake a stepped economic evaluation and estimate (i) the comparative per patient HAPI related healthcare prevention costs for each group, and (ii) the comparative incremental cost of preventing an additional case of HAPI. As the duration of the trial is less than one year, discounting will not be applied to costs or benefits. Hierarchical modelling approaches and cluster-adjusted non-parametric bootstrapping techniques will be employed to compare mean difference in the total costs between groups, and to estimate a confidence interval around the mean (Bachmann et al., 2007). In addition, a cost-effectiveness analysis will be undertaken based on the primary outcome measure (incidence of HAPI), to estimate the incremental cost per additional person remaining free from PI.

## DISCUSSION

This study will provide important information on the effectiveness of a patient-centred PIP care bundle to reduce the incidence and severity of HAPI in at-risk patients, improve patient participation in their care and reduce associated health care costs. To our knowledge, this is the first randomised study to incorporate a number of recognised PIP strategies into a care bundle with a focus on patient engagement and nurse-patient partnership. This is a novel

approach to a significant clinical problem. It is multifaceted, patient-focused and expected to maximise effectiveness and sustainability.

PIP is of high importance considering the significant patient consequences and economic burden to hospitals. As noted by an international Expert Wound Care Advisory Panel, PI research lags behind that in other areas of medicine and very few RCTs have been conducted (Armstrong et al., 2008). Whilst recent systematic reviews show promising evidence around care bundles (i.e. a set of evidence based practices) for PIP (Soban et al., 2011, Sullivan and Schoelles, 2013), it has been suggested that further research is needed to better understand implementation, mechanisms (or causal pathways) and the role of context in intervention success or failure (Soban et al., 2011). This proposed c-RT will be cutting edge. If it confirms the utility of a patient centred PIP care bundle, it could change practice worldwide.

This study has a number of strengths, including its robust design. Cluster randomisation (i.e. by hospital) will ensure there is no contamination between study groups. Thorough training of interventionists and data collectors will optimise fidelity and reliability. Whilst blinding of patients is not possible due to the need for informed consent, blinding of data collectors and nurses to study design and hypotheses, and blinding of outcome assessors and data analysts to group allocation will minimise bias. The study also has a strong theoretical base. Care bundles have been shown to improve patient outcomes and are based on core practice guidelines (Institute for Healthcare Improvement, 2014, Rello et al., 2011). Patient participation in their health care results in improved outcomes and responses to interventions, and is promoted by leading healthcare organisations worldwide (Australian Commission on Safety and Quality in Health Care, 2011, Joint Commission on Accreditation in Healthcare Organizations, 2006, World Health Organisation, 2007). The inclusion of an economic sub-study will strengthen the impact of the findings by providing meaningful cost-analysis data,

and may inform recommendations on the adoption of the intervention for PIP in clinical practice. Finally, the inclusion of a process evaluation will provide important information on implementation and give insight into why the intervention is successful or not and how it may be optimised.

Challenges in this trial may include: (1) reaching recruitment targets, but we plan to increase the number of wards participating at each site if required; (2) when patients are unexpectedly discharged, resulting in missing outcome data, although we have considered hospital discharge practice in timing outcome assessments; (3) ensuring the blinding of research assistants (including outcome assessors) to study site group allocation, but we will assess their perception of group allocation; and (4) avoiding selection bias, however this will be addressed by using a ward randomisation schedule and recruiting consecutive patients according to the schedule.

The results of this study will be presented at local hospital, patient safety and university fora, and a press release will be prepared. Abstracts will be submitted to major international meetings such as patient safety, nursing and medicine and published in high-ranking health services and medical/nursing journals. The results will have international application and implications for clinical practice and nursing education. If successful, testing of the intervention internationally would be indicated, and it should be rapidly adopted and cited in Australian core practice guidelines.

**Trial status**

At the time of manuscript submission, data collection has commenced at all study sites.

## References


Armstrong, D.G., Ayello, E.A., Capitulo, K.L., Fowler, E., Krasner, D.L., Levine, J.M., Sibbald, R.G., Smith, A.P., 2008. New opportunities to improve pressure ulcer prevention and treatment: implications of the CMS inpatient hospital care present on admission indicators/hospital-acquired conditions policy: a consensus paper from the International Expert Wound Care Advisory Panel. Advances in Skin & Wound Care 21 (10), 469-478.

Arnetz, J.E., Winblad, U., Höglund, A.T., Lindahl, B., Spångberg, K., Wallentin, L., Wang, Y., Ager, J., Arnetz, B.B., 2010. Is patient involvement during hospitalization for acute myocardial infarction associated with post discharge treatment outcome? An exploratory study. Health Expectations 13 (3), 298-311.

Australian Commission on Safety and Quality in Health Care, 2011. National safety and quality health service standards. ACSQHC, Sydney.

Ayello, E.A., Lyder, C.H., 2008. A new era of pressure ulcer accountability in acute care. Advances in Skin & Wound Care 21 (3), 134-140.

Bachmann, M.O., Fairall, L., Clark, A., Mugford, M., 2007. Methods for analyzing cost effectiveness data from cluster randomized trials. Cost effectiveness and resource allocation 5 (1), 12.

Baldelli, P., Paciella, M., 2008. Creation and implementation of a pressure ulcer prevention bundle improves patient outcomes. American Journal of Medical Quality 23 (2), 136-142.

Banks, M.D., Graves, N., Bauer, J.D., Ash, S., 2010. The costs arising from pressure ulcers attributable to malnutrition. Clinical Nutrition 29 (2), 180-186.

Centers for Medicare, Medicaid Services 2007. Medicare program: changes to the hospital inpatient prospective payment systems and fiscal year 2008 rates. Federal Register 72 (162), 47129.

Chaboyer, W., Gillespie, B.M., 2014. Understanding nurses' views on a pressure ulcer prevention care bundle: a first step towards successful implementation. Journal of clinical nursing 23 (23-24), 3415-3423.

Coleman, S., Gorecki, C., Nelson, E.A., Closs, S.J., Defloor, T., Halfens, R., Farrin, A., Brown, J., Schoonhoven, L., Nixon, J., 2013. Patient risk factors for pressure ulcer development: systematic review. International Journal of Nursing Studies 50 (7), 974-1003.

Coulter, A., 2006. Engaging patients in their healthcare: how is the UK doing relative to other countries? , Oxford, UK.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M., 2008. Developing and evaluating complex interventions: the new Medical Research Council guidance. International Journal of Nursing Studies 50 (5), 587-592.

Davis, R.E., Pinto, A., Sevdalis, N., Vincent, C., Massey, R., Darzi, A., 2012. Patients' and health care professionals' attitudes towards the PINK patient safety video. Journal of Evaluation in Clinical Practice 18 (4), 848-853.

Department of Health, 2012. Delivering the NHS Safety Thermometer Commissioning for Quality and Innovation 2012/13: a preliminary guide to delivering 'harm free' care. London.

Dwamena, F., Holmes-Rovner, M., Gaulden, C.M., Jorgenson, S., Sadigh, G., Sikorskii, A., Lewin, S., Smith, R.C., Coffey, J., Olomu, A., 2012. Interventions for providers to promote a patient-centred approach in clinical consultations. Cochrane Database Syst Rev 12.

European Pressure Ulcer Advisory Panel, National Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2014. Prevention and treatment of pressure ulcers: quick reference guide. Perth, Australia.

Gallagher, P., Barry, P., Hartigan, I., McCluskey, P., O'Connor, K., O'Connor, M., 2008. Prevalence of pressure ulcers in three university teaching hospitals in Ireland. Journal of Tissue Viability 17 (4), 103-109.

Gillespie, B.M., Chaboyer, W., Sykes, M., O'Brien, J., Brandis, S., 2014. Development and pilot testing of a patient-participatory pressure ulcer prevention care bundle. Journal of Nursing Care Quality 29 (1), 74-82.
Giraudeau, B., Ravaud, P., 2009. Preventing bias in cluster randomised trials. PLoS medicine 6 (5), e1000065.
Gorecki, C., Brown, J.M., Nelson, E.A., Briggs, M., Schoonhoven, L., Dealey, C., Defloor, T., Nixon, J., European Quality of Life Pressure Ulcer Project group, 2009. Impact of pressure ulcers on quality of life in older patients: a systematic review. Journal of the American Geriatrics Society 57 (7), 1175-1183.
Gorecki, C., Closs, S.J., Nixon, J., Briggs, M., 2011. Patient-reported pressure ulcer pain: a mixed-methods systematic review. Journal of Pain and Symptom Management 42 (3), 443-459.
Grant, A., Treweek, S., Dreischulte, T., Foy, R., Guthrie, B., 2013. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. Trials 14 (1), 15.
Graves, N., Birrell, F., Whitby, M., 2005. Effect of pressure ulcers on length of hospital stay. Infection Control and Hospital Epidemiology 26 (3), 293-297.
Graves, N., Zheng, H., 2014. Modelling the direct health care costs of chronic wounds in Australia. Wound Practice and Research 22 (1), 20-33.
Gunningberg, L., Hommel, A., Bååth, C., Idvall, E., 2013. The first national pressure ulcer prevalence survey in county council and municipality settings in Sweden. Journal of Evaluation in Clinical Practice 19 (5), 862-867.
Gunningberg, L., Stotts, N.A., Idvall, E., 2011. Hospital-acquired pressure ulcers in two Swedish County Councils: cross-sectional data as the foundation for future quality improvement. International Wound Journal 8 (5), 465-473.
Igarashi, A., Yamamoto-Mitani, N., Gushiken, Y., Takai, Y., Tanaka, M., Okamoto, Y., 2013. Prevalence and incidence of pressure ulcers in Japanese long-term-care hospitals. Archives of Gerontology and Geriatrics 56 (1), 220-226.
Independent Hospital Pricing Authority, 2014. Nationally efficient price determination 2014-2015. Darlinghurst NSW.
Institute for Healthcare Improvement, 2014. What is a bundle?
James, J., Evans, J.A., Young, T., Clark, M., 2010. Pressure ulcer prevalence across Welsh orthopaedic units and community hospitals: surveys based on the European Pressure Ulcer Advisory Panel minimum data set. International Wound Journal 7 (3), 147-152.
James, K.E., Bloch, D.A., Lee, K.K., Kraemer, H.C., Fuller, R.K., 1996. An index for assessing blindness in a multi centre clinical trial: Disulfiram for alcohol cessation: a VA cooperative study. Statistics in Medicine 15 (13), 1421-1434.
Joint Commission on Accreditation in Healthcare Organizations, 2006. Patient-inclusive care: encouraging patients to be active participants in their care. Joint Commission Perspectives on Patient Safety 5 (11), 1-8.
Latimer, S., Chaboyer, W., Gillespie, B., 2014. Patient participation in pressure injury prevention: giving patient's a voice. Scandinavian Journal of Caring Sciences 28 (4), 648-656.
Lyder, C.H., Wang, Y., Metersky, M., Curry, M., Kliman, R., Verzier, N.R., Hunt, D.R., 2012. Hospital-acquired pressure ulcers: results from the National Medicare Patient Safety Monitoring System Study. Journal of the American Geriatrics Society 60 (9), 1603-1608.
McInnes, E., Jammali-Blasi, A., Bell-Syer, S., Dumville, J., Cullum, N., 2012. Preventing pressure ulcers—are pressure-redistributing support surfaces effective? A Cochrane systematic review and meta-analysis. International Journal of Nursing Studies 49 (3), 345-359.
Moore, Z., Cowman, S., Conroy, R.M., 2011. A randomised controlled clinical trial of repositioning, using the 30 tilt, for the prevention of pressure ulcers. Journal of Clinical Nursing 20 (17-18), 2633-2644.

Mulligan, S., Prentice, J., Scott, L., 2011. WoundsWest wound prevalence survey state-wide overview report. Perth, WA.

Nguyen, K.-H., Chaboyer, W., Whitty, J., 2015. Pressure injury in Australian public hospitals: a cost of illness study. Australian Health Review 39 (3), 329-336.

Nixon, J., Thorpe, H., Barrow, H., Phillips, A., Andrea Nelson, E., Mason, S.A., Cullum, N., 2005. Reliability of pressure ulcer classification and diagnosis. Journal of Advanced Nursing 50 (6), 613-623.

Padula, W.V., Mishra, M.K., Makic, M.B.F., Valuck, R.J., 2014. A framework of quality improvement interventions to implement evidence-based practices for pressure ulcer prevention. Advances in Skin & Wound Care 27 (6), 280-284.

Queensland Government, Department of Health, 2014. Health funding principles and guidelines 2013-14.

Rello, J., Chastre, J., Cornaglia, G., Masterton, R., 2011. A European care bundle for management of ventilator-associated pneumonia. Journal of Critical Care 26 (1), 3-10.

Soban, L.M., Hempel, S., Munjas, B.A., Miles, J., Rubenstein, L.V., 2011. Preventing pressure ulcers in hospitals: a systematic review of nurse-focused quality improvement interventions. Joint Commission Journal on Quality and Patient Safety 37 (6), 245.

Sullivan, N., Schoelles, K.M., 2013. Preventing in-facility pressure ulcers as a patient safety strategy: a systematic review. Annals of Internal Medicine 158 (5_Part_2), 410-416.

van Gaal, B.G.I., Schoonhoven, L., Mintjes, J.A.J., Borm, G.F., Hulscher, M.E.J.L., Defloor, T., Habets, H., Voss, A., Vloet, L.C.M., Koopmans, R.T.C.M., van Achterberg, T., 2011. Fewer adverse events as a result of the SAFE or SORRY? programme in hospitals and nursing homes. Part I: Primary outcome of a cluster randomised trial. International Journal of Nursing Studies 48 (9), 1040-1048.

VanGilder, C., Amlung, S., Harrison, P., Meyer, S., 2009. Results of the 2008 - 2009 International Pressure Ulcer Prevalence Survey and a 3-year, acute care, unit-specific analysis. Ostomy and Wound Management 55 (11), 39.

Weingart, S.N., Zhu, J., Chiappetta, L., Stuver, S.O., Schneider, E.C., Epstein, A.M., David-Kasdan, J.A., Annas, C.L., Fowler, F.J., Weissman, J.S., 2011. Hospitalized patients' participation and its impact on quality of care and patient safety. International Journal for Quality in Health Care, mzr002.

Weingart, S.N., Zhu, J., Chiappetta, L., Stuver, S.O., Schneider, E.C., Epstein, A.M., David-Kasdan, J.A., Annas, C.L., Fowler, F.J., Weissman, J.S., 2011. Hospitalized patients' participation and its impact on quality of care and patient safety. International Journal for Quality in Health Care 23 (3), 269-277.

World Health Organisation, 2007. Patients for patient safety. Geneva.

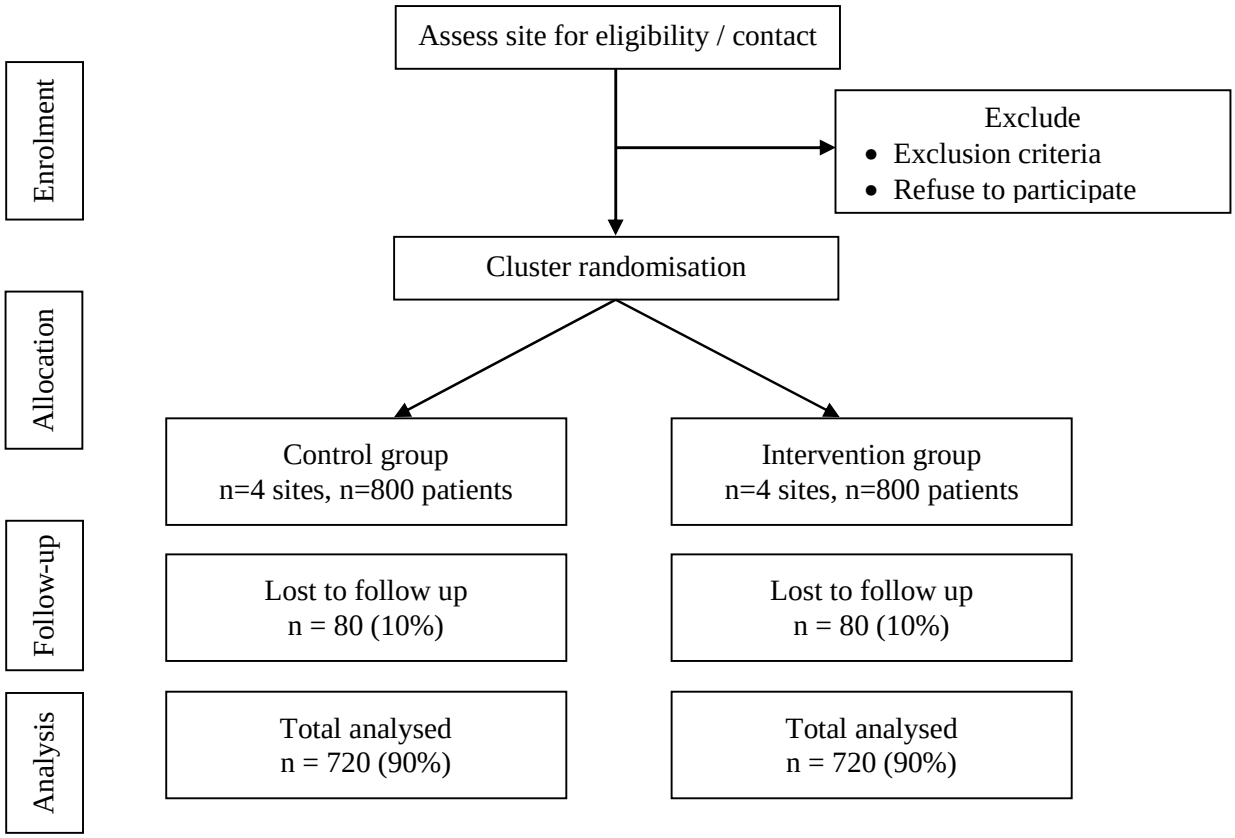


Figure 1: Anticipated participant flow through study

**Table 1: Content of patient education**

| Message | Summary of content |
|---|---|
| 1. Keep moving | • Change position whilst in bed or in a chair<br>• Use pillows for support or ask staff for help when changing position<br>• Keep active by going for walks if possible |
| 2. Look after your skin | • Advise staff of pain, tenderness, redness or blistering over bony areas<br>• Keep skin, clothes and bedding clean and dry<br>• Use moisturising lotion and mild cleanser or moisturising soap to prevent drying out of skin<br>• Special equipment (i.e. air mattresses, pressure relieving cushions, booties) may be used to reduce pressure |
| 3. Eat a healthy diet | • Good nutrition is important for skin protection and wound healing<br>• Ensure good protein sources (examples given) for skin maintenance<br>• Drink plenty of fluids for hydration<br>• Consult with a dietitian or nutritionist<br>• Take nutrition supplements as prescribed |

Note: The intervention materials include a detailed brochure, which will be explained to patients by interventionists; a five minute DVD; and a poster, summarising the three key messages.

**Table 2: Summary of resource data collection and costing methods**

| Resource to be measured | Data collection and costing method | Source for unit cost |
|---|---|---|
| PIPCB Intervention | | |
| Materials including poster, brochure, DVD | Fixed cost, averaged across all trial participants | Commercial provider |
| Staff time for patient education and nurse training | Recorded by RA for all patients in trial and estimated from nurse training sessions | Staff salary hourly rates (including on-costs) |
| PIP strategies | | |
| Clinical staff time for turning | Observational sub-study: number of nurses per turn, turns per patient and time per turn observed, confirmed with patient, and recorded by RA | Staff salary hourly rates (including on-costs) |
| PIP products (including mattresses, wedges, rings and cushions; skincare products; incontinence care; dressings for PIP) | Observational sub-study: observed, confirmed with patient, and recorded by RA | Hospital cost centre |
| Dietitian consult for the purpose of PIP | Observational sub-study: patient notes, confirmed with patient, and recorded by RA | Staff salary hourly rates (including on-costs) |
| Hospital length of stay | Length of stay recorded by RA for all patients in trial | Independent Hospital Pricing Authority (2014) |