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Formal title: Prophylactic dressing to minimise sacral pressure injuries in high risk hospitalised patients: A pilot study.

Running head: **P**ressure **I**njury **P**revention **P**ilot **S**tudy (PIPPS)

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ABSTRACT

Aim. In this paper we describe a trial protocol used to assess feasibility related to: study administration (recruitment, randomisation, retention, compliance, eligibility criteria, suitability of protocol instructions and data collection questionnaires); resource and data management (suitability of site, time and budget allocation, management of personnel and data); intervention fidelity (treatment dose, violations) and effect size.

Background. Pressure injury can lead to increases in hospital length of stay and cost. The sacrum is identified as one of the most common anatomical pressure injury sites for hospitalised patients. Silicone foam border dressings have been proposed as one strategy to reduce pressure injury incidence, however rigorous testing of benefit in a general medical-surgical population is required.

Design. Randomised controlled trial.

Methods. Eighty patients will be recruited after assessment of high risk of pressure injury in a large tertiary hospital in south-east Queensland, Australia. Eligible, consenting participants will be randomly allocated to either a control group (routine care) or an intervention group (routine care and a sacral prophylactic dressing). The primary outcomes comprise feasibility criteria as identified above. The secondary measure is the presence and severity of sacral pressure injury via blind assessment of digital photographs. Hospital and university ethics approval was received in October 2013.

Discussion. Prophylactic dressings applied to the sacrum may be an effective method for reducing pressure injury in high risk general medical-surgical patients. However more rigorous studies to confirm benefit are required. This pilot study will determine the feasibility and effect size to inform a larger randomised controlled trial.

Keywords acute care, prevention, pressure injury, sacrum, silicone foam border dressing, nursing, pilot study, feasibility

Trial registration Registered with the Australian and New Zealand Clinical Trials - ACTRN12613001328763 http://www.ANZCTR.org.au/ACTRN12613001328763.aspx

SUMMARY STATEMENT

Why is this study needed?

- Previous studies report prophylactic dressings are effective in reducing PI in intensive care/high dependency patient populations.
- Findings from published studies are inconsistent; this may be due to the observational focus of research and/or design limitations related to limited allocation concealment, blind assessment and a lack of control of relevant confounding factors.
- This is the first randomised controlled trial to test allocation concealment and blind assessment of PI using photography in a hospitalised general medical-surgical patient population.

INTRODUCTION

Acutely and chronically ill patients are at high risk of developing pressure injuries (PI) during their hospitalisation (Allman *et al.* 1999, Brindle & Wegelin 2012, Chaiken 2012, Jenkins & O'Neal 2010, Meyers 2010). Hospital acquired PI may cause pain, discomfort and immobility for patients, increase the risk of infection, complications and prolong the length of hospital admission at considerable cost (Allman *et al.* 1999, VanGilder *et al.* 2009).

Pressure injuries continue to impact patients and health services. According to recent Australian data, the rate of hospital acquired PI was between 7.4-17.4% (Mulligan *et al.* 2011). In the state of Queensland, the rate of hospital acquired PI in 2011 was 8.8% for all patients and 15.1% for patients with restricted mobility (Centre for Healthcare Improvement 2012). Although current data regarding the cost of PI per patient are not available Graves, Birrell & Whitby (2005) predicted the cost of PI in Australian public hospitals in 2001-02 was AU$285 million with 398,000 bed days used. In the UK the total annual cost of PI management reported by Bennett and colleagues (2004) was GB£1.4-2.1 billion equating to 4% of total healthcare expenditure, while the average cost of a PI in the United States' health care system has been estimated at between US$37,000 to $70,000 per patient (Armstrong *et al.* 2008, Weir 2009). The Queensland Government recently introduced a system of financial penalty for severe PI with stage 3 PI costing individual health services AU$30,000 and $50,000 for identified stage 4 PI (Miles *et al.* 2013). Prevention of PI therefore represents a national and international priority in terms of patient outcome and economic efficiency.

Background

The sacrum is identified as one of the most common anatomical pressure injury sites (Brindle & Wegelin 2012, Centre for Healthcare Improvement 2012, Chaiken 2012, Walsh *et al.* 2012). Prevention strategies such as the use of prophylactic silicone foam border dressings

in very high risk critical care or high dependency patients have resulted in a reduction in their incidence (Brindle & Wegelin 2012, Chaiken 2012, Walsh *et al.* 2012, Santamaria *et al.* 2013). However these results may be difficult to replicate in a hospitalised general medical-surgical population due to their focus on intensive care/high dependency settings and, unreliable due to their observational design and/or methodological limitations related to deficient allocation concealment, blind assessment and lack of control of confounding factors (Schulz 2008, Brindle & Wegelin 2012, Chaiken 2012, Santamaria *et al.* 2013, Walsh *et al.* 2012). Furthermore, the authors of a recent Cochrane Review who examined dressings and topical agents used in the prevention of PI recommended more data about the effectiveness of silicone foam bordered dressings was required (Moore & Webster 2011). Thus more rigorous testing of the dressing in a general medical-surgical population is required.

THE STUDY

Aims

The objective for this pilot study is to evaluate the feasibility of undertaking a RCT to assess effectiveness against pre-defined criteria. Pilot studies are not suitable for hypothesis testing (Leon *et al.* 2011). Rather they are useful in evaluating the feasibility of an intervention as a pre-requisite strategy for a larger study in relation to: study administration (recruitment processes including refusals, randomisation, retention rates, compliance, eligibility criteria, suitability of protocol instructions and data collection questionnaires); resource and data management considerations (related to suitability of site, time and budget allocation; management of personnel and data); intervention fidelity (comprising treatment dose, effect and identification of violations) and effect size (Thabane *et al.* 2010, Lancaster *et al.* 2004, Leon *et al.* 2011). It is therefore essential pilot studies are conducted with the same rigor and scrutiny as larger trials to avoid bias and misleading results (Arnold *et al.* 2009).

The specific aims of this pilot phase are to:

1. Assess the feasibility of conducting a RCT using pre-determined feasibility criteria comprising recruitment, retention, management of personnel and data and intervention fidelity;
2. Use pilot data to refine the intervention protocol and research strategies;
3. Test the effectiveness of blind assessment and data collection;
4. Enable sample size estimations for a larger RCT (Leon *et al.* 2011).

Design

The researchers will adhere to the Good Clinical Practice and Consolidated Standards of Reporting Trials (CONSORT) guidelines for parallel group trials (Moher *et al.* 2010) and test feasibility of using an RCT design over 8-12 months. The study period is realistic due to the high level of patient acuity in the study venue and the often rapid onset of PI in acutely ill patients (Gefen 2008). All participants assessed as being high to very high risk of PI will be randomly assigned to either the routine care or dressing group, or routine care group and receive routine care as per hospital policy, regardless of their allocation. In the participating health care facility, routine care for patients assessed as having a high risk of PI consists of regular skin observation and nursing care via use of a pressure redistribution overlay on a standard mattress, or removal of a standard mattress and replacement with a pressure redistributing mattress, possible multi-disciplinary review and second hourly repositioning.

Participants

Non-probability consecutive sampling will include all eligible adult patients admitted to specific admission entry points and continue until 80 patients are randomised. Patients who meet the following inclusion criteria will be eligible for recruitment into the study:

- ≥18 years of age (the study venue is an adult-focused tertiary health facility);
- Able to provide written informed consent either in person or via their family member or legal guardian (National Health and Medical Research Council 2007). Approval to seek proxy consent has been granted by the Queensland Civil and Administrative Tribunal.
- Assessed as being at high risk or greater of PI (as per a risk assessment score of 15+ using the Waterlow Scale at admission entry points into the general medical-surgical context as per hospital policy.
- Expected hospital length of stay ≥72hrs following recruitment;

Exclusion criteria include:

- Suspected or actual spinal injury which prevents the patient being repositioned;
- Lower back surgery (lumbar spine) which prevents the application of a sacral dressing;
- Existing sacral PI, injury or allergy in the sacral area at the time of hospital admission;
- Faecal incontinence at the time of hospital admission;
- Unable to speak or understand English with no interpreter present.

Outcomes

While the aims of this study are to test the feasibility of the protocol and related processes to inform a larger trial, the main outcome of the program of research is to reduce the prevalence and severity of PI in high risk hospitalised patients. The National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) pressure injury and staging classification system (National Pressure Ulcer Advisory Panel (NPUAP) 2009) (as reported in the Pan Pacific Clinical Practice Guideline for the Prevention and

Management of Pressure Injury (Australian Wound Management Association 2012), will be used to guide the assessment of PI. Assessment of patients in both groups will be conducted by a blind nurse assessor via high resolution photographs and occur every third day coinciding with dressing removal in intervention participants (Walsh *et al.* 2012, Brindle & Wegelin 2012, Chaiken 2012, Santamaria *et al.* 2013) and/or on discharge from the ward. Secondary endpoints are identified in Table 1.

Study process

General medical-surgical patients will be screened for eligibility into the study by the Research Nurse at specified admission entry points. Routine PI risk assessment using the Waterlow Scale will be conducted by nursing staff when patients are admitted to the facility and thereafter, as per hospital policy. The Waterlow assessment relies on the rating of 8 categories including build and weight for height, visual assessment of the skin, age, gender, continence, mobility, measure of malnutrition and several 'special risk factors' (tissue malnutrition, neurological deficits, major surgery and certain medications) (Webster *et al.* 2010a). A score of 15 or above is considered the cut-off point for high risk of PI and a score of 20 or above as very high risk (Webster *et al.* 2010a). In the study site, patents assessed as high risk of PI have specific interventions provided to decrease the risk of PI; these are outlined in the hospital wide Risk Assessment Management Flowchart. Furthermore, all registered and enrolled nurses at the study venue are required to undertake annual pressure injury assessment training using the National Database of Nursing Quality Indicators (NDNQI) PI classification system.

Entry points to the study will be via the Surgical Care Unit (SCU), the Emergency Department (ED) or the participating medical and surgical wards. Patients are increasingly admitted to wards via ED in short time periods due to the National Emergency Access Target

(National Health Performance Authority 2012). The aim of the strategy is to ensure patients presenting to an Australian public hospital ED will either physically leave the ED for admission to hospital, be referred to another hospital for treatment or be discharged home within 4 hours.

To contain the number of wards participating in this feasibility study only orthopedic patient cases and medical admissions will be screened and approached. Screening at the point of admission will ensure patients are assessed for risk of PI and study eligibility and then randomised to either the control or intervention group on admission to hospital. Prospective participants or their family member or legal guardian will be told about the study at an appropriate time during their admission and provided with sufficient time to read the information, consider their participation and provide informed consent.

Intervention

When consented and randomly allocated to a study group, recruited patients will have demographic and health status characteristics recorded including age, gender, diagnosis or surgery, source of admission, mobility status, body mass index, health comorbidities, current smoking status, Waterlow score, existing PI (other than sacral) and history of PI. A high resolution photograph of each participant's sacrum will be taken at this point as a baseline reference point. Each recruited patient's name and hospital information (date of birth, unique record number and contact phone number) will be detailed in a separate document (participant key) and only be available to the Research Nurse to ensure patient confidentiality.

If allocated to the 'routine care and dressing group' the Research Nurse will apply a silicone foam border dressing to the patient's sacrum and document the participants consent and study enrollment in their health record. Patients allocated to the routine care group will

continue to receive routine care, as per hospital policy. All patients enrolled in the study will have their sacrum/dressing assessed at least once a day and preferably each shift (every 8 hours) by the Research Nurse or RNs caring for the patient as per hospital policy recommendations. For participants in the dressing group, the dressing will be assessed at least once a day and replaced every 3 days or sooner if it becomes loose or soiled. The sacral dressing will also be removed in instances of skin reaction, faecal incontinence and patient-rated discomfort. Skin reaction will be reported via the standard hospital incident reporting process as an adverse event. The dressings will continue to be used for intervention group patients until their discharge from the study ward or until the patient is mobilising independently, whichever is sooner.

The dressings being used are specifically designed and shaped for the sacral area. They are comfortable and hypoallergenic according the manufacturer's advice. The silicone layer ensures that the dressing can be changed without damaging the wound or surrounding skin or exposing the patient to additional pain thereby minimising the risk for maceration. Furthermore, the dressing can be lifted and adjusted or removed and reapplied to allow for regular observation, without losing its adherent properties. The dressing is also showerproof to allow it to remain insitu for several days (Molnlycke Health Care). There are several reports of quality improvement projects where sacral foam dressings to prevent PI have been changed every 3 days or twice a week safely and with good effect (Brindle 2010, Brindle & Wegelin 2012, Chaiken 2012, Walsh *et al.* 2012). Therefore this feasibility study will allow, where possible, prophylactic silicone foam dressings to remain intact for up to three days before replacement.

Sample size

A total of 80 patients (40 per group) will be recruited and randomised to the study. Although this number will be insufficient to determine effect, it will be appropriate to determine feasibility and sufficient to yield estimate of effect size to inform planning of a larger trial (Arnold *et al.* 2009, Hertzog 2008, Leon *et al.* 2011, Thabane *et al.* 2010). Figure 1 presents the CONSORT diagram of the study.

Randomisation

Following eligibility assessment and consent, the Research Nurse will login to a clinical trials coordinating website to obtain an online code for random allocation of patients to either the 'routine care or dressing group' or the 'routine care group'. Randomisation will involve a stratified approach to ensure even distribution of participants' diagnostic category (medical and surgical), as well as a 1:1 ratio with random block sizes. This method of group allocation will ensure concealment of allocation prior to randomisation.

Blinding

As all members of the research team, nursing staff and patient participants will be aware of allocation to either the intervention or control group, only the outcome assessor(s) will be blinded to group allocation. At each 72 hour point following baseline photograph, a high resolution digital photograph will be taken of each participant's sacrum. De-identified and coded photographs will be emailed to blind assessors to ensure they are completely removed from the participating wards.

Two suitably qualified blind assessors have been engaged to evaluate photographs. Prior to the commencement of the trial, inter-rater reliability of their PI staging was assessed. Further inter-rater assessment of 20 photographs will be undertaken, with the results of each

of the two blind assessors compared with an expert assessor from the Stomal Therapy and Wound Management Department, a specialist nursing-led service at the participating health service.

Data analyses

Eligible patient and recruitment numbers, participant numbers at each measurement wave and attrition data will be reported using a CONSORT style approach (Moher *et al.* 2010). Prior to conducting any statistical analysis, variables will be checked for outliers, distributional properties, missing values and any observable errors in recording, coding or data entry. Sample attrition will be managed via intention-to-treat analysis to ensure an unbiased comparison of the groups produced by randomisation. Cohen's weighted kappa test will estimate inter-rater reliability. A score of ≥ 0.7 will be considered acceptable.

Statistical and clinical comparisons of baseline demographics and clinical characteristics will be undertaken to test for any substantial differences between the intervention and routine care group. Descriptive results will be reported using summary statistics, depending on the level and distribution of the data. Continuous/interval data will be expressed as mean ± standard deviation or median ± interquartile range based on normality of data and categorical data will be presented as counts and percentages. Analysis will specifically address the primary and secondary outcome measures and be performed using SPSS version 21. Confidence intervals of 95% will be used for all descriptive tests.

Ethical considerations

This pilot trial will be conducted in accordance with the Helsinki declaration (2008) and [Australian] National Health and Medical Research Council's National Statement Guidelines (2007). Ethical approval has been granted by the health service and university

human research ethics committees and proxy consent by family member and/or legal guardian approved by the Queensland Civil and Administrative Tribunal. Participants and/or their family member or legal guardian will be provided full details of the study purpose, benefits and risks and the nature of their potential involvement. Written consent will be sought from each patient or their family member or legal guardian prior to randomisation. Participants or their family member or legal guardian will be advised that they can withdraw from the study at any time and that withdrawal will not jeopardise any treatment or relationship with the hospital. Revocation of Consent Forms will be provided to each participant as a means of withdrawal.

There are no reported instances of harm to participants as a result of treatment with similar dressings applied to the sacrum (Brindle 2010, Brindle & Wegelin 2012, Chaiken 2012, Walsh *et al.* 2012). However several measures have been included in this study to ensure patient safety and level of comfort. For example in instances of persistent faecal incontinence or identification of a PI on a sacrum of a patient in the intervention group the prophylactic dressing will be removed and ongoing care will be provided as per hospital policy and reported via the hospital incident reporting process. Furthermore all cases of PI and skin reaction in the routine care and dressing group will be reported to the ethics committee as adverse events.

All data will be stored in locked or password protected facilities for 15 years. Publications and presentations will be prepared in a manner that maintains the confidentiality and anonymity of all study participants.

This study is registered with the Australian and New Zealand Clinical Trials: ACTRN12613001328763 http://www.ANZCTR.org.au/ACTRN12613001328763.aspx

Validity and reliability / Rigour

Results from randomised control trials can be useful in drawing conclusions about the effects of health care interventions if appropriate attention is directed towards ensuring validity and reliability of design (random group allocation, allocation concealment and blind assessment) and relevance to the population of interest (Rothwell 2006). In this study participants will be randomised to group via a random computer-generated process to eliminate the possibility of selection bias (Schulz 2008, Kendall 2003). Although investigators, clinicians and participants will be aware of group allocation due to the presence or absence of a dressing, allocation concealment will be possible via the use of remote blind assessors who will evaluate the outcome measurement (assessment of the sacrum) via the use of de-identified photography (Kendall 2003, Schulz 2008).

Careful consideration has been made to target a hospitalised general medical-surgical population using a non-probability sampling approach via inclusion and exclusion criteria. Data generated for this pilot study will therefore include success of recruitment approaches, recruitment rate (number of participants available who meet the eligibility criteria and their willingness to participate) and methodological issues related to applying the intervention or measuring outcome variables (Kendall 2003).

As feasibility criteria are being tested, quality control measures in place to reduce errors will also be tested. These include the development of a procedure manual, peer reviewed data collection forms and documented protocol revisions. All data collected will be checked for accuracy and timeliness as identified in the secondary outcomes and analysis plan.

DISCUSSION

Although there is considerable evidence to suggest prophylactic dressings are effective in reducing the prevalence and severity of PI, it is limited due to its focus on intensive care/high dependency patients as well as design constraints related to deficient allocation concealment and/or blind assessment. To our knowledge this is the first study to be conducted in hospitalised general medical-surgical patients, with both random allocation of participants and blind assessment of the primary outcome via the use of photography.

The general medical-surgical clinical focus of this pilot study is significant. The majority of published clinical studies examining the effectiveness of prophylaxis for the prevention of PI have been set in critical care contexts (Brindle & Wegelin 2012, Chaiken 2012, Santamaria *et al.* 2013, Walsh *et al.* 2012). These settings are often self-contained and specialise in providing concentrated care for immobile critically ill patients characterised by one-on-one or high dependency nurse to patient ratios. The success of prophylactic dressings in the prevention of PI may therefore be a result of highly controlled patient care. General medical-surgical contexts are quite different to critical care settings due to their high patient turnover and acuity as well as multiple links to different wards and services. As a result, hospital acquired PI in these generalised health environments continues to challenge quality outcomes for patients and health services (Allman *et al.* 1999, VanGilder *et al.* 2009).

The unpredictable nature of generalised heath settings necessitated the revision of study inclusion criteria. The initial protocol required a risk assessment of PI score using the Waterlow scale of 20+ or very high risk. However, early experience in this study and further review of evidence related to the assessment of risk of pressure injury (PI) suggests patients assessed as very high risk of PI are often critically ill and require intensive care. As this pilot study is focused on a different patient population (that is hospitalised general medical-surgical patients), extending the criteria to include patients with a high, as well as very high

risk of developing PI acknowledges the range of health statuses in this population. Broadening the Waterlow score for this study also incorporates the recommendation of the Waterlow Scale's creator to use knowledgeable clinical judgement when assessing PI risk factors (Waterlow 2005). Thus the inclusion criteria related to the Waterlow score has been expanded to include patients assessed as being at high risk of PI or greater (a score of 15+).

Site of spinal surgery has also been considered when determining the suitability of some patients for the study. Patients undergoing lumbar spine surgery cannot have a dressing applied to their sacrum as the dressing extends up from the tailbone over the lower back covering the surgical incision site. Patients having lower spine surgery are therefore now excluded from this pilot study.

The outcome measurement in many PI prevention studies has not been assessed by a blind assessor (Brindle & Wegelin 2012, Chaiken 2012, Santamaria *et al.* 2013, Walsh *et al.* 2012), representing a significant limitation in this body of research. The use of digital photography to assess PI therefore represents a practical solution to the problem of blinding (Baumgarten *et al.* 2009) and has demonstrated a high degree of validity for stage 2 PI and above (Baumgarten *et al.* 2009) and inter-rate reliability (Defloor & Schoonhoven 2004). There are identified limitations with the use of photographs, particularly in relation to detection of stage 1 PI and PI in patients with darkly pigmented skin (Baumgarten *et al.* 2009). However limitations associated with assessment of stage 1 PI can also exist with direct physical assessment (Australian Wound Management Association 2012).

Limitations

The Waterlow Scale features frequently in literature relating to PI prevention. While some authors have found the tool to be a useful instrument for the evaluation of risk in patients (Sayar *et al.* 2009), others have found it inadequate without independent assessment

of the patient's overall health context (Brindle & Wegelin 2012, Guy 2012, Webster *et al.* 2010b). Limitations associated with the scale have been mitigated in this study via purposeful clinician judgment based on the patient's overall health context.

CONCLUSION

Silicone foam border dressings have been proposed to prevent sacral PI, however further rigorous research that includes random group allocation and blind assessment in a hospitalised general medical-surgical patient population is needed to establish the benefits of combining these dressings with existing routine nursing care in the prevention of PI. This study will be the first conducted in a hospitalised general medical-surgical patient population. De-identified photographs of participant's sacrum will be used to enable blind assessment and results will inform the feasibility of progressing to a larger definitive RCT.

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Table 1 Secondary endpoints

a) Percentage of patients who are approached
b) Percentage of eligible patients who meet the eligibility criteria
c) Percentage of eligible patients who do not meet the eligibility criteria and are excluded from the study
d) Percentage of eligible patients recruited and consented
e) Percentage of eligible patients who refuse to participate (and why they refused)
f) Percentage of patients who are randomised
g) Percentage of recruited patients who complete the study
h) Percentage of recruited patients who do not complete the study
i) Reasons recruited patients were not able to complete the study
j) Baseline characteristics of participants including age, gender, diagnosis or surgery, site of admission, mobility status, body mass index, health comorbidities, current smoking status, Waterlow score, existing PI (other than sacral) and history of PI
k) Average duration (in hours) of applied sacral dressings
l) Reasons for sacral dressing dislodgement and removal
m) Patient perception of the comfort of the sacral dressing
n) Suitability of site including admission points (based on recruitment data, specifically the number individuals approached and the number recruited) and chosen wards (based on reasons for participant non-completion data) in the divisions of medicine and surgery
o) Suitability of time and budget allocation (based on rate of recruitment, use of dressings and judicious budget management)
p) Effectiveness of preparation/ training/support provided to nursing staff (in participating admission points and wards in the division of medicine and surgery), research nurses and blind nurse assessors
q) Suitability of data collection tools for nursing staff, research nurses and blind nurse assessors
r) Incidence of group allocation identification by blind assessor
s) Evaluation of inter-rate reliability of PI assessment by blind assessor (based on repeat assessment by member of the Stomal Therapy and Wound Management Department

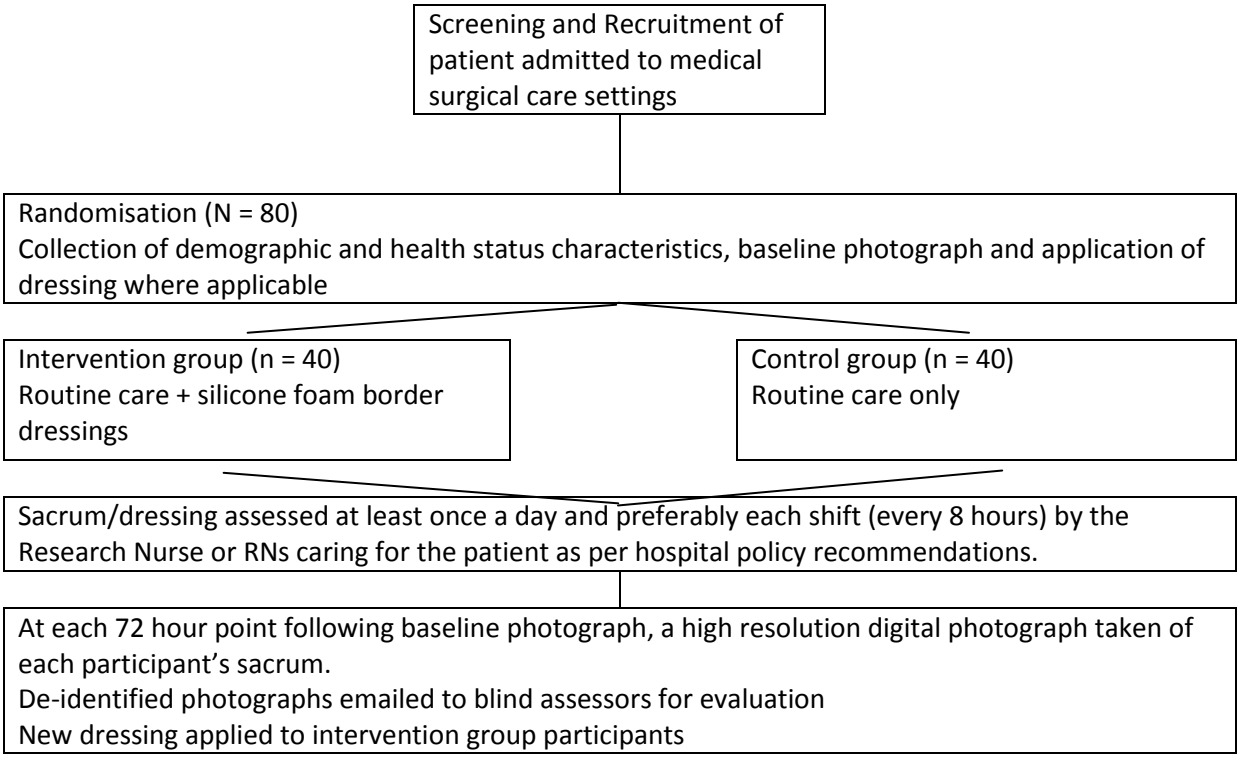

Figure 1 The CONSORT diagram showing participant flow through the study