Clinical Trial Protocol

Introduction

Studies highlight that pressure injuries (PI) are a healthcare quality indicator and that healthcare workers need to expand their knowledge to adequately manage these wounds using the latest evidence-based information (Amir et al., 2017; Eberhardt et al., 2021). A focus on prophylactic dressings applied to patients' skin to prevent PIs has gained some traction in recent years to avoiding PIs however it is often referred to as an adjunct therapy with more studies to prevent PIs needing to be done (Cornish, 2017). Based on the above and informed by the findings of the systematic review (Chapter three), this chapter will describe a methodology for a clinical trial evaluating the use of barrier wipes to prevent PIs.

Research aim

To explore the effectiveness of barrier wipes on preventing pressure injuries for consumers in the residential aged care sector.

Primary objective

The study's primary objective is to investigate the effectiveness of a twice-daily application of a barrier wipe on the incidence of pressure injuries in residential aged care facility (RACF) consumers. The CONSORT statement for randomised controlled studies has been used to frame the structure of this chapter (CONSORT, 2010).

Methods

Design

A single blinded, multi-centre randomised controlled trial (RCT) study will be undertaken over eight months. A proposed study flowchart is identified in Appendix 2.

Settings

The setting will be residential aged care facilities (RACFs). Eligible facilities are RACFs in NSW and ACT funded and governed by the Uniting NSW and ACT group. These RACFs have a similar demographic consumer population and models of care to manage older people in aged care. An expression of interest will be sent to each RACF in the Uniting group. Twenty trial sites (RACFs) will be selected, prioritising those in a similar geographical location. This will

facilitate approximately 45 participants per site. A similar geographical location will facilitate ease of trial implementation and monitoring.

Participants

Participants will be recruited from the enrolled RACFs. Consumers in RACFs will be eligible for participation in the study if they meet the inclusion criteria outlined below.

Inclusion criteria

- ≥ 65 years old at the time of consent
- Living in a RACF
- Limited mobility defined as being able to stand to pivot transfer or less
- Ability to provide informed consent or informed consent obtained from the legal person responsible
- Those defined at risk for pressure injuries based off Waterlow scores (Appendix 1) (a score of 10 or higher).

Exclusion criteria

- <65 years old
- Any consumer with a current pressure injury to heels, buttocks, or sacrum. The reason for this is due to the inability to apply barrier wipes to a wound such as a PI.
- Not living in an enrolled RACF
- Those who are palliating and at end of life
- Those with sensitivities or allergies to any ingredients in the barrier wipe
- Those that are fully mobile or able to weight bear and mobilise and able to walk more than a metre. The rationale for this is that people who are fully mobile are at less risk for PIs.

Recruitment

Residential Aged Care Facilities who agree to participate will be briefed by the lead researcher (HR) on the trial via a virtual meeting (via Microsoft Teams). Once permission is sought the RACF will work with the PIPP lead within their location. The lead researcher will then hold a virtual meeting with the PIPP lead to orientate them to the project. Lastly the PIPP lead, relevant RACF care staff and the

research team will review all consent forms and consider eligibility. The PIPP lead will be given all details for the meeting by the lead researcher.

Recruitment of RACF

The participating head of regional operations manager will be asked to select RACF in their area who may wish to participate in the trial. The service managers onsite will approve their facility to participate. The deputy service manager will then be the person to coordinate all operational logistics. This will include ensuring stock availability, overseeing frontline workers to implement the trial, for the collection of local details such as Waterlow results, ensuring participants directly consenting have the cognition to do so based off cognitive assessments and diagnosis, participant completed consent forms, diagnosis checked for allergies and that any other paperwork are provided to the pressure injury prevention lead (PIPP) for Uniting NSW. The Registered Nurses (RN) at each facility will be responsible for completing all clinical assessments such as the Waterlow assessments for each participant and coordinating direct care staff to implement the trial.

Recruitment of Participants

Once all details are completed this will be forwarded to the PIPP lead who will identify potential participants based on the screening and outcome of the Waterlow tool as per the inclusion criteria (determined to be at risk for pressure injuries, score of 10+) (Appendix 1). Participants will then progress based on the inclusion criteria as reviewed by the PIPP lead. A participant information sheet will be provided to those eligible participants and their person responsible by the RNs and PIPP lead in person or via email. In this information sheet it will explain the trial using plain language and will include information about the trial design, its aims, objectives, possible risks, potential benefits, and options for withdrawing from the trial.

The consumer and/or person responsible will first need to give consent for any information to be shared during recruitment and screening. Consent forms will be provided by the RNs and will need to be completed prior to commencing. Details of the participants including phone number and address will be required and will be stored safely within the RACF electronic system iCare. During the recruitment process all details will be provided to the RNs of what to expect during the trial to ensure informed consent to participate with a focus on minimising active or passive coercion in all interactions. Decision making capacity of participants may change over the trial, therefore, the ability to withdraw from the trial will also be discussed.

The RACF care team will be asked to not overstate any possible benefits of the trial and not to discriminate in any of the selection requirements for potential participants.

Additional Information

Participants will be offered information sessions face to face or virtually via Microsoft Teams to discuss the trial at the commencement of the trial, mid-way and at the conclusion provided by the PIPP lead who will have been briefed by the lead researcher. Care staff will be provided with information for the application process of the wipes in a 30-minute videoconference via virtual platform (e.g. Microsoft teams) by the PIPP lead. This will cover how to apply the barrier wipe, what location to apply the wipes too (heels, sacrum, and buttocks), how often to apply the wipe (twice per day), where to dispose of the wipes (general waste bin, not flushable) and to allow the skin to dry after application. This allows for active communication and to ensure all questions are answered for participants and RACFs. The compliance documents will also be provided to the RACF for the product used in the trial; therapeutic goods administration approval and the safety data sheets.

Participant consent

As per the *National Statement on Ethical Conduct in Human Research* Element 3: "adequate time should be allowed for prospective participants to understand and consider what is proposed and for their questions and expression of concerns to be addressed by those obtaining their consent (NHMRC, 2018)." Thus, all participants will be given one week to consider their responses and can withdraw at any time. Additionally, general consent requirements, as outlined in the NHMRC (2018), will be followed throughout the development of the protocol. Specifically, consent will only be accepted when a participant and or authorising person has been fully informed of the purpose of the trial, that they understand how the findings will be presented and any other potential benefits to the participant, either directly or indirectly. The intervention and control groups will be clearly explained by the lead researcher to the PIPP lead who will then inform managers and registered staff, including outlining timeframes and time will be provided for questions to be asked.

All consent forms will delineate the rights of the participants and the responsibilities of the researchers. Participant consent will be collected in writing from each consumer and will be witnessed by a care provider at the RACF who is familiar with the participant's condition. Should a participant not wish to be involved in the trial and sign the consent, the researcher

acknowledges their right to do so, and this is respected. No reason for non-participation is required. Consent may also be withdrawn at any time during the trial without concerns. The researcher considers consent as an on-going process during the trial. Further to this, all activities during the trial will also include verbal consent to proceed, such as the twice daily application of barrier wipes. Should verbal consent not be obtained the activity will not proceed and the reason will be investigated and documented. All efforts to re-schedule the activity will be made in accordance with the participants wishes.

Should any emotional distress be noted during the trial such as when activities are attended, the care provider or researcher will seek guidance from the participant to continue or cease the activity. The researcher will respect any choice of the participant with consideration given to those with cognitive impairment. The care providers will also be aware of nonverbal signs of distress such as facial grimacing and agitation indicating potential discomfort and the activity will cease.

Person Responsible Consent

The Guardianship Tribunal of the NSW Civil and Administrative Tribunal (NCAT), at times will be involved in the care of people with impaired cognition. In the case that a participant is under the care of a guardianship tribunal, they will be consulted in the same way that person responsible would be.

Participant Withdrawal

Potential reasons for withdrawal may include death, illness, exit from facility for hospital or discharge or due to participant no longer wishing to be in the trial. These have been factored into attrition rates in the sample size calculation. The data analysis section provides detail on how missing data will be handled.

Participant Enrolment

Once all parties have agreed to join the trial and all have been screened to meet the inclusion criteria, signed consent forms will be provided to the lead researchers with the Waterlow assessments (Appendix 1). Once this has occurred the responsible general practitioner will be emailed a letter outlining the trial and the consumers participation, giving them an opportunity to discuss any concerns. Once these details are received the researchers will de-identify participants with an allocated ID number and the participants will be randomised into an

intervention and a control group. The ID number will be included on all documents for each participant.

Intervention

The intervention in this study is the use of a barrier wipe applied twice daily to the participants skin in conjunction with usual care. The barrier wipe will be applied to the heel, sacrum, and buttock areas after bathing in the morning and before retiring at night. These products will be distributed to the RACFs at the commencement of the study and monitored for re-stocking by the deputy service managers weekly. The barrier wipe that has been selected is based on best fit for aged skin as per the listed ingredients and will be pH neutral as recommended for this age group.

Barrier wipes will have the following characteristics:

- Dermatologically tested
- Lanolin free
- Skin neutral pH
- Contain dimethicone
- Long lasting
- Hypoallergenic
- Non-cytotoxic
- Alcohol free, sting free.

Barrier wipes will be used with an aim to provide a standard and consistent approach to the minimum application of a twice daily use. Using barrier wipes assists in the assessment of compliance with the compliance (fidelity) as wipe usage can be easily measured by counting the amount used and distributed. The intervention trial has been informed by reviewing the available literature and noting a gap in the prevention of pressure injuries.

Care staff from the RACF will be referred to as skin integrity advocates (SIAs) for this trial. They will be a mix of care service employees, enrolled nurses, registered nurses, and managers who have experience in supporting good skin hygiene. Skin integrity advocates will be required to support participants in the correct application of twice daily barrier wipes. Care staff will be provided clear instructions on how to apply the product. The care staff will apply the barrier

wipe to all consenting participants. The care staff will attend skin assessments monthly on the iCare electronic system to ascertain skin integrity. The PIPP lead will review the data via the Power BI system that automates anyone who has developed a PI from the iCare system.

Monthly video conferencing meetings will occur with available employees, inclusive of clinical managers within the RACF to trouble shoot any requirements, ensure stock is available and to ensure the study is on track. A key component of the intervention will be the tailored meetings and product education sessions delivered by the researcher and PIPP lead over the course of the trial. As part of the trial, RNs will monitor the facilities documentation platform to review each participants wound chart to determine the prevalence of PIs.

Control

The control in this study will focus on usual care. Care staff will continue to follow their standard practices of regular pressure area care, utilising appropriate support surfaces, assessment using validated tools and caring for the person holistically. As part of the trial, RNs will monitor the facilities documentation platform to review each participants wound chart to determine the prevalence of PIs.

Residential aged care facility support

The lead researcher will ensure that all Aged Care standards are respected and incorporated into care. The RACF will assist with participant screening, recruitment, and enrolment. The RACF will also provide support by rostering time for meetings and education sessions to occur.

Participant support & engagement

Consumer input and feedback will be sought at regular intervals during the trial at all stages via communication from the RACF care team. Should any concerns arise the research team will be notified, and the issue will be reviewed. All concerns raised will be documented with the outcome noted.

Fidelity

The fidelity of the intervention will be measured in two ways. The distribution and use of wipes (product use) will be collected and compared against the minimum requirement of the intervention.

Outcome(s)

The primary outcome will be the incidence of PI to heel, buttocks or sacrum per participant per year. Prospective assessment of participants by clinical staff each day for PIs will occur, consistent with current practice. Any stage of PIs to the heel, buttocks or sacrum will be recorded in a PI wound chart and skin assessments as usual practice within RACFs. At the end of each month, the PIPP lead will review the documentation and provide results to the lead researcher. The international recognised definition for a PI, including the 6 stages will be included (see definitions section). The date of PI onset will be recorded. Pressure injuries on the same participant at different anatomical locations will be counted as individual PIs. At the commencement of the study the participant will be reviewed via a skin assessment and deemed a participant if no existing PIs are located. New PIs that healed but reoccurred at the same anatomical site will be included as an outcome. The outcomes for this trial are summarised in Table 4.1.

Table 4. 1 Outcomes for the trial primary objective

Trial objective	Outcome	Measure
The primary objective of the study is to investigate the effectiveness of a twice daily application of a barrier wipe on the incidence of PIs in RACF consumers and to determine outcomes related to the implementation of the intervention including adherence, acceptability, barriers, and facilitators from the perspective of the older person.	Primary outcome	The incidence of PIs to sacrum, buttocks, and heels per participant per year. Each individual PI will be included.
	Secondary outcomes	The time in days to the first PI

Randomisation

Each week, for all participants who have consented that week, participants will be randomised in a 1:1 ratio and allocated to either the control or intervention group by a researcher. A researcher will prepare a concealed allocation schedule by computer randomisation. The lead researcher will have no further access to participant data.

Blinding

Participants will not be blinded to the study, as it will not be possible to deliver the intervention without them knowing. Care staff/RNs in each facility will be responsible for observing and collecting outcome data. RNs will upload any participant who develops a PI into the wound chart, this then generates a report via Power BI. Power BI shows data collected by room

number. The PIPP lead will then verify the PI diagnosis on iCare and then review Power BI and provide each participant with a PI to the lead researcher. The PIPP lead will not know whether the participant is allocated to a control or intervention group.

Statistical Methods

Sample size

The incidence of PIs reported in the literature is 1.33 (95% CI =1.29–1.37) per 1000 consumer days, with a standard deviation of 1.65 (Jorgensen et al, 2018). This is re-calculated to be 0.49 PIs per year (SD 0.60), assuming 365 days per year. For an eight-month study, we assumed a baseline incidence of 0.33, reducing to 0.196 for the intervention group, based on a relative reduction of 40%. A sample of 330 in each arm, achieves 80% power, with a type one error of 5%. Attrition needs to be considered in the context of the participants and setting. Allowing for an attrition rate of 30%, a sample of 429 is required in both intervention and control arms.

Data quality and missing data

Missing data will be minimised by following up with each participant weekly with expected high fidelity. Given the setting and participant demographics, participants may die during the study, thus resulting in missing data. The approach to missing data from non-completion of the study is two-fold. The primary approach will be to exclude the participant data from all analysis. A secondary approach is to include data were available and impute missing data. Imputation will be based on the characteristics of participants who have a full set of data.

Primary outcome analysis

An intention to treat analysis will be used for the primary outcome of the incidence of PI per participant per 100 consumer days. For PIs, to allow for multiple events to be counted, negative binomial regression will be used, which models the counts as a Poisson process but allows for overdispersion. This approach will be used to estimate incident rate ratios (and 95% CIs), also adjusting difference in baseline covariates.

Secondary outcome analysis

Time to first PI will be described using Kaplan Meier survival curves. A log rank (Mantell-Cox) test will be used to compare crude days to PI in the control and intervention arms. A Cox proportional hazard model will be developed to estimate the hazard of PI (yes or no), comparing those in the control and intervention arms. The proposed null hypothesis is that use if barrier

wipes do not increase the hazard of a PI. Differences identified at baseline using a univariate analysis will be included in prognostic variables, when comparing those in control and intervention groups, using a forward stepwise conditional (likelihood ratio) process.

Data collection

Once consent is gained, the participant will be registered and assigned a unique number to de-identify the person by a researcher. A record of the participants contact details against their ID number will be included on all documentation. All participants will be assessed by the RACF care team using the Waterlow PI risk assessment tool (Appendix 1) via the RACF electronic documentation system to ascertain risk level for PIs. Researchers will download all results and upload this to their data base on SharePoint. All participants will be assessed by the RACF care team using a skin assessment for each participant via the RACF electronic documentation system to ascertain skin integrity and rule out any PIs. Monthly skin assessments of all participants will be attended by the RACF care team via the RACF electronic documentation system to ascertain skin integrity.

The PIPP lead will download all results and provide these to the researchers to upload this to their data base on SharePoint. Those within the intervention group will be allocated barrier wipes by the RN. The ID number will be added to excel data collections held on SharePoint sites securely. For any participant who develops a pressure injury this will be added to the RACF wound charting electronic documentation system. The PIPP lead will download all results and provide these to the researchers who will upload this to their data base on SharePoint. All outcomes will be collected, de-identified and added to a data collection form by the PIPP lead. Data collection will occur through an electronic form using Uniting iCare system and Power BI. Data from these systems will be used to evaluate and record the number of PIs developed over the time of the trial. The PIPP lead will provide these details de-identified to the researchers. Statistical analysis will be supported by the Clinical Research Design, IT, and Statistical Support (CReDITSS) unit. An outline of the data for collection are summarised in Table 4.2.

Table 4. 2 Overview of data collection

Data	Timing of data collection	Recorded by	Collected by	Source	Research data storage

Demographics: - Age - Sex - Rural/remote or regional setting - Facility name / location - Diagnosis to determine cognitive status	Immediately prior to study commencement	Researcher	Researcher	Participant enrolment survey	University server
Participant risk factors: - PI risk assessment tool completion (Waterlow) - No. participants classified at risk - Skin assessment - Review of current wound charts to rule out current PIs to heels, sacrum and buttocks - Mobility status - Allergy status	Immediately prior to study commencement AND Skin assessments monthly	Care team as part of existing care	PIPP lead and given to Researcher	Review of medical notes (iCare and Power BI)	University server
Primary outcome data: - Date of PI - Anatomical location - Stage of PI - PI staging correct	Monthly	PIPP lead	Researcher	Review of medical notes (iCare and Power BI)	University server
Monitoring of barrier wipes to ensure correctly	Daily	RN	PIPP lead	Manual data collection form	University server

applied and distributed - Distribution of wipes to each participant (6 wipes per day; Each service of 45 participants will require 270 wipes per day - 10.8 packets)					

Only necessary information for the trial will be collected such as consent forms, PI status from skin assessments, PI risk from Waterlow assessments and data obtained from iCare and Power BI. All data will be stored electronically on a password protected university server. The RACF care team will complete all clinical assessments and documentation in the usual way using their electronic documentation system iCare. Researchers will have access to this system to extract data as needed. All access, transfer and management of participant clinical records will be handled safely, confidentially and in accordance with legislative requirements. This will include only keeping accurate, up to date, objective, and factual records. The researchers will use the Universities SharePoint site to hold all data via a cloud system and will update this weekly. This will also maximise security. Prior to commencing the trial, the RACF care team will attend an information session on how to collect data and where to secure this to ensure quality control and assurance.

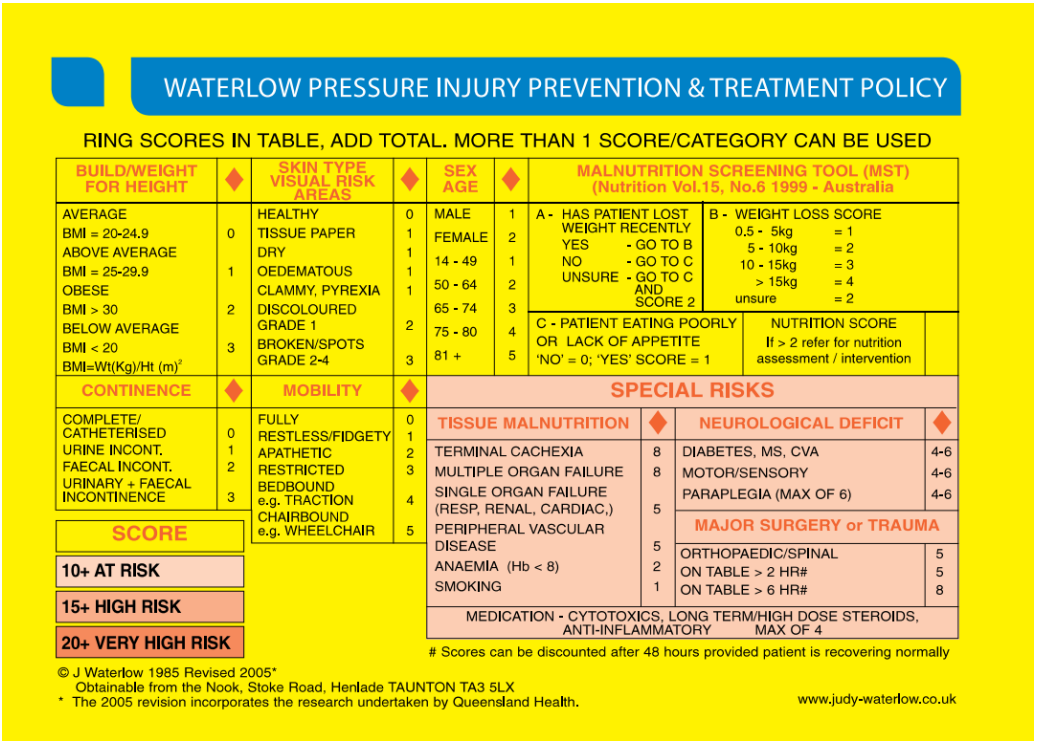
All interactions with RACF care team and participants will be made clear and declared with notice. Interactions will consider the environment to ensure all participants are comfortable and confidentiality can be maintained. All data will be stored for 15 years post publication as per the NHMRC guidelines, on the university secured server (NHMRC, 2018). No data will be shared prior to the trial publication.

Conclusion

This protocol has presented the method used including the design and setting. Participant information and the recruitment process has been provided. The statistical methods have been identified as well as a summary of data collection required.

Appendix 1: Waterlow assessment / Uniting Modified Waterlow Assessment

Pressure Injury risk assessments can assist the health care worker as an additional tool to ascertain those at risk of developing PI. The Waterlow assessment can be seen in the image below including the Waterlow assessment used at Uniting NSW and ACT.



WATERLOW PRESSURE INJURY PREVENTION & TREATMENT POLICY

RING SCORES IN TABLE, ADD TOTAL. MORE THAN 1 SCORE/CATEGORY CAN BE USED

BUILD/WEIGHT FOR HEIGHT		SKIN TYPE VISUAL RISK AREAS		SEX AGE		MALNUTRITION SCREENING TOOL (MST) (Nutrition Vol.15, No.6 1999 - Australia	
AVERAGE		HEALTHY	0	MALE	1	A - HAS PATIENT LOST WEIGHT RECENTLY	B - WEIGHT LOSS SCORE
BMI = 20-24.9	0	TISSUE PAPER	1	FEMALE	2	YES - GO TO B	0.5 - 5kg = 1
ABOVE AVERAGE		DRY	1	14 - 49	1	NO - GO TO C	5 - 10kg = 2
BMI = 25-29.9	1	OEDEMATOUS	1	50 - 64	2	UNSURE - GO TO C AND SCORE 2	10 - 15kg = 3
OBESE		CLAMMY, PYREXIA	1	65 - 74	3		> 15kg = 4
BMI > 30	2	DISCOLOURED GRADE 1	2	75 - 80	4	C - PATIENT EATING POORLY OR LACK OF APPETITE 'NO' = 0; 'YES' SCORE = 1	unsure = 2
BELOW AVERAGE				81 +	5		NUTRITION SCORE If > 2 refer for nutrition assessment / intervention
BMI < 20	3	BROKEN/SPOTS GRADE 2-4	3				
BMI=Wt(Kg)/Ht (m)^2							

CONTINENCE		MOBILITY	
COMPLETE/ CATHETERISED	0	FULLY	0
URINE INCONT.	1	RESTLESS/FIDGETY	1
FAECAL INCONT.	2	APATHETIC	2
URINARY + FAECAL INCONTINENCE	3	RESTRICTED	3
		BEDBOUND e.g. TRACTION	4
		CHAIRBOUND e.g. WHEELCHAIR	5

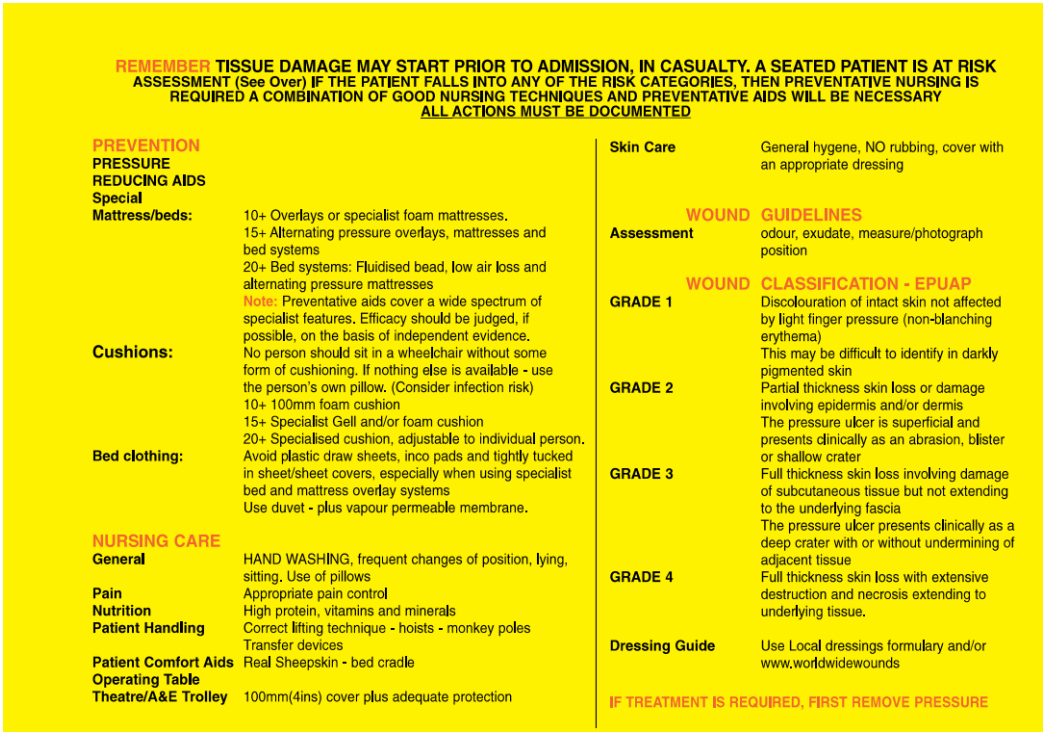
SPECIAL RISKS

TISSUE MALNUTRITION		NEUROLOGICAL DEFICIT	
TERMINAL CACHEXIA	8	DIABETES, MS, CVA	4-6
MULTIPLE ORGAN FAILURE	8	MOTOR/SENSORY	4-6
SINGLE ORGAN FAILURE (RESP, RENAL, CARDIAC,)	5	PARAPLEGIA (MAX OF 6)	4-6
PERIPHERAL VASCULAR DISEASE	5	**MAJOR SURGERY or TRAUMA**	
ANAEMIA (Hb < 8)	2	ORTHOPAEDIC/SPINAL	5
SMOKING	1	ON TABLE > 2 HR#	5
		ON TABLE > 6 HR#	8

MEDICATION - CYTOTOXICS, LONG TERM/HIGH DOSE STEROIDS, ANTI-INFLAMMATORY MAX OF 4

SCORE
10+ AT RISK
15+ HIGH RISK
20+ VERY HIGH RISK

Scores can be discounted after 48 hours provided patient is recovering normally



REMEMBER TISSUE DAMAGE MAY START PRIOR TO ADMISSION, IN CASUALTY. A SEATED PATIENT IS AT RISK
ASSESSMENT (See Over) IF THE PATIENT FALLS INTO ANY OF THE RISK CATEGORIES, THEN PREVENTATIVE NURSING IS REQUIRED A COMBINATION OF GOOD NURSING TECHNIQUES AND PREVENTATIVE AIDS WILL BE NECESSARY
ALL ACTIONS MUST BE DOCUMENTED

PREVENTION

PRESSURE REDUCING AIDS

Special Mattress/beds:
10+ Overlays or specialist foam mattresses.
15+ Alternating pressure overlays, mattresses and bed systems
20+ Bed systems: Fluidised bead, low air loss and alternating pressure mattresses
Note: Preventative aids cover a wide spectrum of specialist features. Efficacy should be judged, if possible, on the basis of independent evidence.

Cushions:
No person should sit in a wheelchair without some form of cushioning. If nothing else is available - use the person's own pillow. (Consider infection risk)
10+ 100mm foam cushion
15+ Specialist Gell and/or foam cushion
20+ Specialised cushion, adjustable to individual person.

Bed clothing:
Avoid plastic draw sheets, inco pads and tightly tucked in sheet/sheet covers, especially when using specialist bed and mattress overlay systems
Use duvet - plus vapour permeable membrane.

NURSING CARE

General HAND WASHING, frequent changes of position, lying, sitting. Use of pillows
Pain Appropriate pain control
Nutrition High protein, vitamins and minerals
Patient Handling Correct lifting technique - hoists - monkey poles Transfer devices
Patient Comfort Aids Real Sheepskin - bed cradle
Operating Table Theatre/A&E Trolley 100mm(4ins) cover plus adequate protection

Skin Care General hygene, NO rubbing, cover with an appropriate dressing

WOUND GUIDELINES

Assessment odour, exudate, measure/photograph position

WOUND CLASSIFICATION - EPUAP

GRADE 1 Discolouration of intact skin not affected by light finger pressure (non-blanching erythema)
This may be difficult to identify in darkly pigmented skin

GRADE 2 Partial thickness skin loss or damage involving epidermis and/or dermis
The pressure ulcer is superficial and presents clinically as an abrasion, blister or shallow crater

GRADE 3 Full thickness skin loss involving damage of subcutaneous tissue but not extending to the underlying fascia
The pressure ulcer presents clinically as a deep crater with or without undermining of adjacent tissue

GRADE 4 Full thickness skin loss with extensive destruction and necrosis extending to underlying tissue.

Dressing Guide Use Local dressings formulary and/or www.worldwidewounds

IF TREATMENT IS REQUIRED, FIRST REMOVE PRESSURE

Images sourced from Waterlow (2005)

Uniting Modified Waterlow Assessment SECTION ONE	Score	
Gender at birth *(select one only)*		
Male	1	
Female	2	
Age		
14 – 49	1	
50 – 64	2	
65 – 74	3	
75 – 80	4	
81+	5	
Build/Weight for Height (BMI=weight in Kg/height in m^2) *(select one only)*		
Average – BMI 20-24.9	0	
Above average – BMI 25-29.9	1	
Obese – BMI > 30	2	
Below average – BMI < 20	3	
Continence *(select one only)*		
Complete/catheterised	0	
Incontinent urine	1	
Incontinent faeces	2	
Urinary and faecally incontinent	3	
None of the above	0	
	Section One Total Score	

SECTION TWO

More than one response can be selected for each of the questions below. You will need to add the score from Section One with the total from Section Two

Skin Type – Visual Risks Area *(More than one score/category can be used)*		
Healthy	0	
Tissue paper (thin/fragile)	1	
Dry (appears flaky)	1	
Oedematous (puffy)	1	
Clammy (moist to touch)/pyrexia	1	
Discoloured (bruising/mottled)	2	
Broken spots(grade 2 – 4)	3	
Mobility *(More than one score/category can be used)*		
Fully mobile	0	
Restless/fidgety	1	
Apathetic (sedated/depressed/reluctant to move)	2	
Restricted (restricted by severe pain or disease)	3	
Bedbound (unconscious/unable to change position/traction)	4	
Chair bound (unable to leave chair without assistance)	5	

NUTRITION: If score for Nutrition is 2 or more then refer for nutrition assessment/ intervention

Malnutrition Screening Tool (MST) [i]

Has the resident lost weight recently?

Yes – go to B *No – go to C* *Unsure - go to C and score = 2*

B: Weight Loss		
0.5 – 5 kgs	1	
5 – 10 kgs	2	
10 – 15 kgs	3	
>15kgs	4	
C: Resident eating poorly or lack of appetite		
Unsure	2	
Yes	1	
No	0	

If score is greater than 2 refer to Dietician for assessment/intervention

[ ] Yes –referred for nutrition assessment/ intervention as total score for MST section is greater than 2

[ ] No –referral not required as total score for MST section is less than 2

SPECIAL RISKS		
Tissue Malnutrition *(More than one score/category can be used)*		
Multiple organ failure	8	
Terminal cachexia	8	
Single organ failure e.g. cardiac, renal, respiratory	5	
Peripheral vascular disease	5	
Anaemia = Hb < 8	2	
Smoking	1	
None of the above	0	
Neurological Deficit *(More than one score/category can be used)*	***Max score = 6***	
Diabetes / MS / CVA	4-6	
Motor/ sensory	4-6	
Paraplegia	4-6	
Surgery/Trauma *(More than one score / category can be used. Scores can be discounted after 48 hours, provided patient is recovering normally)*		
On table > 6 hours	8	
Orthopaedic/ below waist/spinal *(up to 48 hours post op)*	5	
On table > 2 hours *(up to 48 hours post op)*	5	
None of the above	0	
Medication	***Max score = 4***	
Cytotoxic, anti-inflammatory, long term/high dose steroid *Max 4*	4	
Section Two Total Score		

Section One Total Score	
Section Two Total Score	
Add scores for Section One and Section Two in this space	

Risk Rating (Tick one only)	Score	Resident' s Risk
Resident is not at risk of pressure injury	Less than 10	
Resident is at risk of pressure injury	10+	
Resident is at HIGH risk of pressure injury	15+	
Resident is at VERY HIGH risk of pressure injury	20+	

To be used in conjunction with Waterlow Risk Assessment[ii]

Directives (*Tick all that apply)*

- ☐ Consult with dietician to provide high protein oral nutritional supplements in addition to regular diet - consider food first
- ☐ Frequent skin care interventions are required to manage excessive moisture.
- ☐ Provide transfer assistance devices (e.g. overhead handle) to promote independent patient transferring and reduce shear forces and friction
- ☐ A dynamic support device is required
- ☐ Use a support cushion when seated in a chair or wheelchair, *for example ROHO*
- ☐ Resident to be repositioned at least 4 times/day
- ☐ Resident to be repositioned at least 6 times/day
- ☐ Resident to be repositioned as often as required to ensure erythema that may be present has resolved within 20 minutes of being repositioned
- ☐ Resident to be positioned at 30° lateral inclination when positioning side to side
- ☐ Resident to be positioned at 30° recumbent inclination when in recumbent position
- ☐ When repositioning in any position always check the position of the heels and other bony prominences
- ☐ Select and fit heel pressure off-loading devices appropriately with due consideration and monitoring of the micro-climate when enclosing heels
- ☐ Use a medical grade sheepskin as an adjunct or when a high specification reactive (constant low pressure) or active (alternating pressure) support surface is unavailable/not tolerated.

☐ Other: *What other interventions not listed above are appropriate?*

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.....

.....

What are the goals for this resident in pressure injury management?

Tick all that apply

- ☐ To promote pressure injury prevention
- ☐ To provide optimal care to residents with pressure injuries
- ☐ Resident is free from further skin breakdown
- ☐ Residents skin remains in tact
- ☐ Resident has optimal skin care routine

This assessment was completed by:

Name	Signature & Designation	Date

Assessment sourced with permission from internal documents within Uniting (2020)

Appendix 2: CONSORT Flowchart

Using the CONSORT flowchart system an outline of the study will be used for adding in all details and can be seen below in Appendix 3.