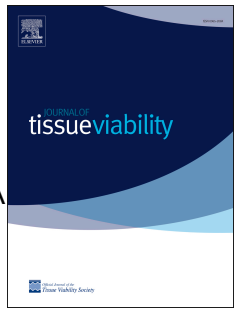

Process evaluation of an intervention to test the effectiveness of foam border dressings in preventing hospital-acquired sacral pressure injuries (the EEPOC trial): A protocol

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TITLE

Process evaluation of an intervention to test the effectiveness of foam border dressings in preventing hospital-acquired sacral pressure injuries (the EEPOC Trial): A protocol

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ABSTRACT

Background: Prophylactic foam border dressings are recommended for high-risk patients in addition to standard pressure injury prevention protocols despite limited high-quality evidence regarding their effectiveness. This protocol describes the process evaluation that will be undertaken alongside a multisite randomised controlled trial investigating the clinical and cost-effectiveness of these dressings in reducing hospital-acquired sacral pressure injury incidence.

Methods: This theory informed parallel process evaluation using qualitative and quantitative methods will be undertaken in medical and surgical units. To evaluate fidelity, recruitment, reach, dose delivered and received, and context, process data will include: research nurses' self-reported adherence to intervention protocols; semi-structured interviews with participants and research nurses and focus groups with nursing staff; participants' satisfaction and comfort with the dressings and perceived level of participation in pressure injury prevention; and nurses' attitudes toward pressure injury prevention. The proportion of the target population recruited, participant characteristics, and adherence to intervention protocols will be reported using descriptive statistics. Chi square or t-tests will compare differences in demographic characteristics between groups, and non-participants, and multivariate modelling will investigate potential moderators on the trial outcomes. Analysis of qualitative data will be guided by the Framework Method, which provides a clear, systematic process for developing themes.

Discussion: This process evaluation will provide valuable insights into mechanisms of impact and contextual and moderating factors influencing trial outcomes. Process data will enhance reproducibility of the intervention and trustworthiness of findings, and inform clinicians,

researchers, and policy makers about the extent to which foam border dressings can be feasibly implemented in clinical practice.

Trial registration: ACTRN12619000763145p.

Keywords Pressure injury, pressure ulcer, process evaluation, fidelity, protocol, randomised controlled trial, prophylactic dressings, sacral, medical, surgical

TITLE

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MANUSCRIPT

1. Introduction

Pressure injuries (PI) are defined as local skin or underlying tissue damage caused by pressure, shear and friction, with many considered preventable [1]. Hospital acquired pressure injuries (HAPI) result in significant negative consequences for patients and healthcare systems. A recent meta-analysis found that the global incidence of HAPI in adults was 8.4% [2]. HAPIs often develop over bony prominences and adversely affect patients' health both psychologically and physically including the potential for life threatening complications [1, 3]. The sacrum is the most common anatomical location for PI development, and these tend to be more severe and painful [1]. Healthcare costs associated with treating HAPI are also high [4, 5]. For example in the United States (US), PI has been estimated as costing approximately $26.8 billion (US) annually [6], accounts for 1.9% of Australia's public hospital expenditure (representing around AUD$2 billion) [4], and the estimated total cost of PI care in the United Kingdom (UK) has been reported to range £1.4-£2.1 billion, annually [7].

Painful and lengthy complications and escalating costs associated with HAPI have led health services prioritising pressure injury prevention (PIP) [8]. Existing clinical practice guidelines recommend PIP strategies such as regular PI risk assessment, skin inspection, regular repositioning, and the use of specialised support surfaces such as mattresses and seating cushions [1, 8]. Recently, five-layered foam dressings have been recommended in addition to standard PIP strategies [1]. These dressings improve tolerance to friction, shear, and

microclimate (e.g., by reducing alterations in skin moisture and preventing stretch or tear of the skin) [1, 9, 10].

A 2018 Cochrane review identified randomised controlled trials (RCT) investigating the effect of prophylactic foam dressings compared to usual care for PIP [11]. While the combined results favoured the use of prophylactic dressings, the authors' concluded evidence was uncertain due to high to unclear risk of bias and subsequent poor quality of existing studies [13]. Importantly, these studies did not collect process evaluation data, further limiting the findings repeatability and trustworthiness. Rigorous, multicentre trials in medical and surgical units are needed to determine if foam dressings are an effective PIP strategy [12]. Likewise, parallel process evaluations are needed to further explain the findings by evaluating intervention fidelity and contextual factors that can influence study outcomes [13-15].

Randomised controlled trials are considered gold standard for evaluating cause-effect relationships between interventions and outcome(s) [16]. Yet, they provide limited information regarding the intervention's mechanism of impact. As such, there is growing recognition of the value of undertaking processes evaluations alongside intervention studies[13-15, 17, 18]. Yet, a recent scoping review of process evaluations undertaken alongside RCTs and c-RTs in the hospital setting identified only a small number of trials (n=14) reporting process evaluation findings [19]. The authors concluded there was a lack of standardised reporting of process evaluations and clear descriptions of if or how authors use theory to guide their evaluation was not evident [19].

Collecting parallel process data enables researchers to: (i) provide evidence of fidelity on intervention implementation; (ii) determine the proportion of the target population that received the intervention and their response; and (iii) understand contextual factors that may influence intervention delivery and outcomes [13-15]. Well planned process evaluations provide

detailed documentation that enable replication studies to be undertaken and information regarding the mechanism of action for significant or non-significant effects, thereby enhancing an intervention's validity [13-15, 17]. Collecting process data is particularly important for multi-site trials where it is necessary to determine whether interventions are implemented and received consistently across sites, and to understand contextual differences between sites [14]. That is, what works for whom, when, under what circumstances and importantly, why [13].

This protocol paper describes the proposed process evaluation being undertaken alongside the EEPOC Trial. Full details of the definitive trial and planned economic evaluation have been published elsewhere[20]. There are many benefits to publishing study protocols. Doing so promotes transparency, prevents study duplication, and provides an opportunity to share high quality and innovative study methodology[21]. Publishing study protocols also promotes accountability for authors to report their results in a timely manner and enables readers to determine the extent to which the trial was undertaken according to the original protocol[21].

2. Methods

2.1 The EEPOC Trial

The EEPOC Trial (EffEctiveness of Prophylactic fOam dressings in the prevention of saCral pressure injuries in at-risk hospitalised patients) is a multi-site RCT; data collection commenced at the first study site in July 2020. The EEPOC Trial is testing the clinical and cost effectiveness of a prophylactic silicone foam border dressing (Mepilex Border Sacrum®) compared to standard care for preventing sacral HAPI in at-risk hospitalised patients. The medical and surgical wards of three Australian hospitals are participating in the EEPOC Trial.

The EEPOC Trial process evaluation

2.2 Aims and design

This study protocol describes the multi-method, multi-site parallel process evaluation which aims to: 1) determine the extent to which intervention protocols are implemented as planned; 2) evaluate how the intervention is received by participants; 3) assess whether recruitment procedures are undertaken in accordance with protocols; 4) determine whether the intervention was delivered to a sufficient number of the target population; and finally, 5) explore contextual factors that may influence trial outcomes.

2.3 Evaluation frameworks

Guided by well-established frameworks for undertaking process evaluations [14, 18] and assessing implementation fidelity [15], this study employs both qualitative and quantitative methods to evaluate: (i) *Fidelity* – quality and extent to which the intervention is delivered as planned; (ii) *Recruitment* – procedures used to approach and attract participants; *(iii) Reach* – the proportion of eligible participants receiving the intervention; (iv) *Dose delivered* – amount or number of intended units of the intervention component delivered / provided by interventionists; (v) *Dose received* – the extent to which participants actively engage with and are receptive to the intervention; and (vi) *Context* – the physical, social, and political environment that can affect an intervention . Assessment of context is particularly important for this multi-site trial as existing hospital policies and practices for PIP may vary between sites, thus describing these factors will help explain their potential influence over trial outcomes. Components of the process evaluation are designed to both monitor difficulties during the trial to inform necessary adaptations (i.e., formative evaluation) and evaluate data at the conclusion of the trial (i.e., summative evaluation)[14]. Table 1 provides an overview of the study objectives, process evaluation components and their respective evaluation strategies.

Table 1 Overview of the parallel process evaluation components, study objectives and evaluation strategies

Evaluation component	Description	Objective(s)	Evaluation strategies
Context	Aspects of the intervention that may influence intervention implementation or study outcomes; includes contamination or extent to which the control group was exposed to the program [10]. Causal mechanism present within the context which acts to sustain the status quo, or potentiate effects [13]	Determine what contextual factors within and between sites affect either intervention implementation or the intervention outcome. Monitor extent to which the control group is exposed to the intervention.	▪ Semi-structured, face-to-face interviews with participants and research nurse and focus groups with nursing staff. ▪ Meeting minutes (e.g., from site visits, meetings, and other forms of communication (telephone, email) with senior nursing executives). ▪ Assess local artefacts that detail PIP strategies, resource use, PIP documentation, policy, and procedure(s). Assess nursing staff attitude toward PIP using the APuP instrument, validated for use by nursing staff [22].
Fidelity	Adherence to content and dose (i.e. frequency and duration), moderated by: facilitation strategies, quality of delivery and participant responsiveness [15].	Determine the extent to which the intervention is implemented consistently with research protocols and procedures (i.e., *Adherence to content/dose)*	*Adherence to content/dose* ▪ Research nurses self-report intervention delivery in REDCap including documentation of deviations from protocol. ▪ Photography audit checklist undertaken every month on 10% of photographs to evaluate quality of photographs (e.g. lighting, angle, distance) and photo modification to conceal dressing markings ▪ Research nurses document contamination of control group during daily outcome assessment via REDCap

Evaluation component	Description	Objective(s)	Evaluation strategies
		Enhance fidelity by using *facilitation strategies* and ensuring *quality of delivery.* Explore participants' and intervention personnel *responsiveness* to the intervention.	*Facilitation strategies* ▪ Standardised training for research nurses. ▪ Standard operating procedures manuals. ▪ Ongoing site support via periodical teleconferences and site visits ▪ Education resources and presentations provided for ward staff via in-services to relay information regarding the trial. *Quality of delivery* ▪ Monitoring of data collection logs by research team via REDCap. ▪ Semi-structured interviews with research nurses and focus groups with nursing staff to evaluate their experience of training and in-services to identify any gaps in content, knowledge, and skill development. ▪ Research nurses engage in peer evaluation of photography using the audit checklist as a guide (e.g., during training and multi-site meetings). *Participant responsiveness* ▪ Semi-structured interviews with participants and focus groups with nursing staff. ▪ Semi-structured interviews with research nurses ▪ Assess participant comfort and satisfaction with the intervention.
Dose delivered	Amount or number of intended units of each intervention or	Determine the extent to which the trial dressing is administered in	▪ Database (REDCap) for research nurses to record contacts with participants including intervention delivery (number of daily assessments completed per participant, number of applications

Evaluation component	Description	Objective(s)	Evaluation strategies
	component delivered or provided by interventionists [18]	accordance with protocol (e.g., number, frequency)	and reapplications of the dressing, whether the dressing is present at time of assessment, reasons why not). ▪ Monitor accuracy of data collection procedures via REDCap by research team ▪ Undertake semi-structured, face-to-face interviews with participants and research nurses.
Dose received (exposure)	**Exposure** - Extent to which participants actively engage and interact with, are receptive to, and/or use materials or resources; and **Satisfaction** - participant satisfaction with program, interaction with staff and/or investigators [18]	Determine participants' level of engagement in the intervention. Explore the acceptability of the intervention to both participants, intervention personnel and nursing staff. Understand how the participants react to the intervention. Assess participants' level of satisfaction and comfort with the sacral foam border dressing.	▪ Undertake semi-structured, face-to-face interviews with a sub-sample of participants. ▪ Evaluate participants perceptions of participation using the PPPIP scale. ▪ Measure participant satisfaction and comfort with the dressing.

Evaluation component	Description	Objective(s)	Evaluation strategies
Recruitment	Procedures used to approach and attract participants, including maintenance of participant involvement [20, 22]	Determine what planned and actual recruitment procedures were used to attract participants and describe barriers to recruiting participants. Determine if certain groups of individuals were more (or less) likely to be recruited. Determine if recruitment processes were consistently applied between and within sites.	▪ Research nurses to document challenges with screening and recruitment procedures (e.g. contextual factors such as patients being unavailable). ▪ Research nurses document reasons for non-participation/ why eligible patients may not have been approached for inclusion and monitor number of participants who are lost to follow-up and protocol deviations. ▪ Compare recruitment rates between sites ▪ Describe any differences in how patients are told about the study by research nurses across sites
Reach	Proportion of the intended target audience that participates in an intervention [14]. Includes documentation of barriers to participation and representativeness	Determine the proportion of eligible patients who are approached, recruited, randomised and complete the study. Determine the proportion of eligible patients who	▪ Research nurses keep accurate and detailed documentation of screening and recruitment procedures. ▪ Research nurses document the proportion of patients refusing to participate and reason for non-participation and participants who are lost to follow-up /missed data. ▪ Research nurses collect participant demographic data via REDCap, including characteristics of non-participants where they provide consent for this.

Evaluation component	Description	Objective(s)	Evaluation strategies
	of individuals who are willing to participate [18].	refuse to participate and why they refuse. Determine the proportion of recruited patients who do not complete the study and reasons why. Describe the demographic characteristics of those who did and did not participate in the trial.	

APuP = Attitude toward Pressure Ulcer Prevention; BMI = Body Mass Index; CTC = Clinical Trial Coordinator; PI = Principal Investigator; PIP = Pressure Injury Prevention, PPPIP =Patient Participation in Pressure Injury Prevention scale; REDCap =Research Electronic Data CAPture

2.4 Setting and sample

The EEPOC Trial and parallel process evaluation are being undertaken in three Australian metropolitan tertiary hospitals. A consecutive sample of eligible participants admitted to the medical and surgical wards of participating hospitals are recruited and randomised to receive either the intervention and routine PIP care or routine PIP care only. As part of the process evaluation, a sub-sample of trial participants, nursing staff and trial research nurses working in the study wards will also be invited to participate in semi-structured interviews or focus groups and to complete relevant questionnaires (described in detail below).

2.5 Data collection

2.5.1 Context

Both qualitative and quantitative methods will be used to collect process data relevant to context. A quantitative evaluation of context will be achieved by using the validated Attitudes toward Pressure ulcer Prevention (APuP) instrument, which was developed in Belgium to assess nursing staff attitudes toward PIP [22]. Example questions include: "I feel confident in my ability to prevent pressure ulcers", "pressure ulcer prevention should be a priority, and "I have an important role in pressure ulcer prevention". The APuP will be completed by all willing (or all consenting) nursing staff working in the participating hospital medical and surgical units. A purposive sample of nursing staff who complete the APuP questionnaire will also be invited to participate in a focus group to explore their perceptions and awareness of the intervention and perceived effectiveness / impact of the intervention. One focus group will be undertaken at each site by a trained research assistant; approximately 8 to 12 staff members will be recruited to participate in each focus groups, which will last approximately 45 minutes

(depending on feasibility in terms of staffing constraints) and will be digitally recorded and transcribed verbatim. Focus groups are the chosen method as they are suitable for exploring potential issues with, and gauging individuals' perceptions of a program or product, and can generate rich, user-friendly data [23]. All trial research nurses will also be invited to participate in semi-structured, face-to-face interviews to explore any barriers and/or facilitators to intervention implementation. Interview guides for both the semi-structured interviews and focus groups will be developed based on guidelines and previous literature, including findings from the pilot RCT [24], and will be tested prior to full implementation. Finally, a review of site-specific hospital strategies, campaigns, policy documents and clinical procedure guidelines will also be undertaken and data relevant to site-specific PIP strategies (e.g. repositioning regimes, types of support mattresses used) will be collected.

2.5.2 Fidelity

Assessment of fidelity is guided by the Implementation Fidelity Framework [15] . To quantify fidelity, the research nurses' self-report adherence to intervention implementation via REDcap, which includes documentation of intervention delivery and any deviations from the trial protocol (with reason). Several facilitation strategies are being used to optimise and standardise intervention implementation. The research team have developed detailed standard operating procedure manuals to ensure blinding, random group assignment, and intervention delivery occur as planned. Further, research nurses participate in training activities including a series of presentations and interactive activities to provide a detailed description of all aspects of the trial. Research nurses' feedback on procedures, manuals and data collection instruments are also sought. To enhance awareness of the intervention in participating wards, information flyers are displayed throughout the wards, medical records

indicate those participants who are enrolled in the trial and in-services are delivered to nursing staff.

Participant responsiveness to the intervention can have an important impact on implementation fidelity [15]. Trial participants' comfort and satisfaction with the dressing is evaluated using a single item on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). Their perception of participation in PIP is also assessed using the seven-item Patient Participation in Pressure Injury Prevention (PPPIP) validated scale [25]. The PPPIP was psychometrically tested and validated among an Australian sample of acute care patients (n=688) and demonstrated acceptable levels of construct validity and reliability [25].

Participant responsiveness will be explored using semi-structured, face-to-face interviews with a sub-sample of participants. Maximum variation purposive sampling will be used to recruit a diverse group of participants in terms of demographic and clinical factors (e.g. age, PI risk, admission type, number of commodities, previous PI history) [26]. Representativeness of the sample will also be enhanced by recruiting similar numbers of participants at each participating site. Approximately 25 to 30 participants will be interviewed (8 to 10 per site), however the sample size will also be guided by data saturation (i.e., when no new information is emerging from participants). Interviews will explore participants' experiences of the intervention, including perceptions of the intervention/dressing, any perceived barriers or facilitators, and what worked well and/or could have been done better. Interviews will last approximately 20 to 30 minutes and will be conducted in a private space in the hospital ward during their admission. Interviews will be digitally recorded and transcribed verbatim.

2.5.3 Recruitment

Recruitment refers to the procedures that are used to approach and attract potential participants [14]. Screening and recruitment instruments have been developed to enhance consistency with recruitment for the EEPOC Trial. This includes a standardised script for research nurses to refer to when approaching potential participants and providing information about the trial, as well as a visual flow diagram to follow. To identify potential differences in recruitment strategies between individuals and sites, observation of recruitment strategies and review of screening and recruitment data are undertaken by the Clinical Trial Coordinator to ensure compliance with protocols.

2.5.4 Reach

Measuring reach involves assessing the proportion of the target population that participate in the intervention. It also enables formative evaluation of potential barriers to participation [14]. To evaluate reach, recruitment and screening logs are regularly monitored to identify and address potential challenges. Research nurses are encouraged to document reasons for participant refusal or withdrawal where possible. These data are frequently reviewed and will be analysed at the conclusion of the trial to describe the proportion of eligible patients who are approached, recruited, and randomised, those who do not meet the eligibility criteria and are excluded from the study, and those who are eligible but refuse to participate. Differences in the demographic characteristics of eligible patients who are enrolled compared to those who are not enrolled in the trial will also be evaluated.

2.5.5 Dose delivered and received

As part of the process evaluation, strategies are employed to determine the extent to which the trial dressing is administered in accordance with protocol (e.g., number, frequency,

correct application). First, research nurses self-report intervention delivery via REDCap, including documentation of daily sacral skin assessments completed per participant, the number of applications/reapplications of the dressings, who applied the dressing (i.e., research nurse, nursing ward staff or other), whether the dressing is present at time of assessment, and if not, why. Further, data relating to the number of hours or days the dressing was applied for are collected as a measure of exposure to the intervention. The research team monitors data collection procedures via REDCap and intermittently cross-check these data with participant medical records. Interviews will be used to explore trial participants' level of engagement and acceptability of the intervention, and their perceptions of participation and level of satisfaction and comfort with the dressing.

2.6 Data analysis

2.6.1 Quantitative data

Quantitative data will be analysed using Statistical Package for the Social Sciences (SPSS) (IBM, Chicago, IL, USA)[27]. Descriptive statistics will be used to report the proportion of the target population included in the study and describe their characteristics. Chi square and/or t-tests will compare differences in demographic characteristics between participants in the intervention and control groups, and between participants and non-participants. Adherence to intervention components will be reported as frequencies and percentages (e.g., percent of daily outcome assessments completed, proportion of applications and reapplications of the dressing in accordance with protocols). Multivariate modelling techniques will be employed to investigate potential moderators on the treatment effect (e.g., dose of the intervention, incidence of HAPI), including contextual factors (e.g., results from the APuP and PPPIP surveys

and number/type of PIP strategies being used), participant characteristics and other clinical moderators.

2.6.2 Qualitative data

Qualitative data analysis will be guided by the Framework Method [28]. The Framework Method provides a clear, systematic process for developing themes based on the data by following seven key steps: transcription, familiarisation with the interview, coding, developing a working analytical framework, applying the analytical framework, charting data into the framework matrix, and interpreting the data [28]. This method has been selected because: 1) the systematic and structured approach makes this method suitable for analysing large amounts of qualitative data; 2) it can accommodate varying formats, such as interview transcripts, meeting minutes and field notes from observations; 3) this approach is useful for multidisciplinary research teams, where many researchers will be working on the project, with varying levels of experience with qualitative data analysis; and 4) the Framework Method is not grounded in a specific epistemological, philosophical, or theoretical position and is therefore adaptable depending on the qualitative approach and research question (e.g. can guide both inductive and deductive analyses, or a combination) [28]. The consolidated criteria for reporting qualitative research (COREQ) checklist will also be used to guide the conduct, analysis and reporting of this aspect of the process evaluation [29].

Several methods will be employed to enhance the rigour of qualitative data collection and analysis. Researchers will maintain clear and accurate records during data collection, analysis and reporting to provide an audit trail (e.g., via use of reflective journals and documenting memos) [30]. Further, coding will be undertaken by two members of the research team, independently and all members of the research team will be involved in the analysis and

interpretation of qualitative data [30]. Participants' accounts will be provided using rich verbatim quotes to support researchers' interpretation of the data, and maximum variation purposive sampling will ensure diversity of participants' perspectives [30]. Finally, reference to audio recorded interviews and verbatim transcripts throughout data analysis will enable researchers to check that emergent themes are consistent with participants' actual accounts [30].

3. Discussion

To the best of our knowledge, this is the first proposed process evaluation to be undertaken alongside an RCT investigating the effectiveness of foam dressings for PIP. This parallel process evaluation, guided by prominent frameworks [14, 15, 18], will provide valuable information regarding the potential mechanisms of impact and mediating factors influencing trial outcomes. Further, it will contribute to the limited body of evidence relating to process evaluations undertaken alongside RCTs in the acute hospital setting [19].

Findings from this study will inform clinicians, researchers, and policy writers about the extent to which the intervention may be applied to clinical practice [31]. If outcomes suggest the trial dressing is clinically and cost effective, the process evaluation can increase confidence in findings. For example, if trial outcomes identify significantly lower incidence rates of sacral HAPI in the intervention group compared to the control group, there may be greater confidence in the outcomes being the result of the intervention if there is evidence that fidelity to the intervention is high, and contextual factors are controlled for in statistical modelling. Conversely, if the intervention proves ineffective, process evaluation results will help to explain whether outcomes were the results of poor implementation of the intervention, or the intervention itself. If the intervention is not effective, but fidelity is found

158 to be low, researchers may conclude that poor fidelity has influenced outcomes. However, if
159 intervention fidelity is high, yet the dressing is found to be ineffective, it may be concluded
160 that these dressings are not effective and therefore should not be implemented as standard
161 practice in PIP. These conclusions will be informed by a detailed consideration of process data
162 alongside trial outcome data.

163 **Ethics approval and consent to participate:** Study protocol and procedures have been
164 approved by the Gold Coast Hospital and Health Services (HREC/2019/QGC/51088) and
165 Griffith University Human Research Ethics Committees (GU Ref No: 2019/685). Further,
166 Research Governance Offices at each participating site have reviewed and approved the trial.
167 Written informed consent will be obtained from all eligible participants. In the instance where
168 a participant is unable to provide written informed consent (e.g., due to cognitive
169 impairment), where possible, consent will be sought from the participant's proxy. This has
170 been approved by the Queensland Civil and Administrative Tribunal (QCAT).

171 **Competing interests:** The authors declare that they have no competing interests.

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173 Australia [APP11583879]. The funding body has no role in the design of the study not will
174 they have any role during its execution, analyses, interpretation of the data or decision to
175 submit results.

176 **Authors' contributions:** The authors confirm contribution to the paper as follows: study
177 conception and design: all authors; draft manuscript preparation: IL, BG and RW; all authors
178 reviewed and approved the final version of the manuscript.

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HIGHLIGHTS

- Hospital patients are at risk of pressure injuries and prevention is challenging
- Prophylactic dressings are an emerging pressure injury prevention strategy
- There is limited evidence for the effectiveness of these dressings
- Process evaluations are important to help explain study findings
- This protocol describes the process evaluation being undertaken alongside the EEPOC Trial
- Randomised controlled trials are considered gold standard
- Yet, they provide limited information about interventions' mechanism of impact
- processes evaluations are increasingly recognised as important
- They can provide evidence of fidelity, reach and contextual factors
- Results from this study will be considered alongside main trial outcomes

Declaration of interests

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: