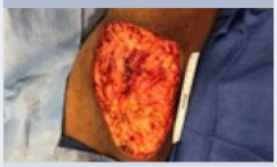
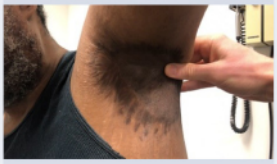
Rethink Complex Wound Closure with

NovoSorb® BTM Biodegradable Temporising Matrix

Hidradenitis suppurativa

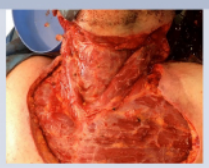


Post resection

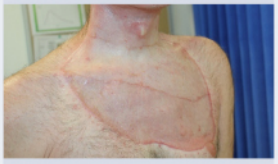


1 year post treatment

Necrotising fasciitis



Post serial debridement



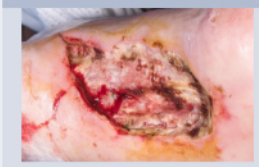
3 months post treatment

An implantable bilayered synthetic dermal matrix designed to facilitate complex wound closure

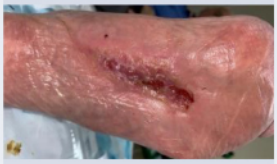
Learn more about NovoSorb® BTM and how it could benefit your patients

Discover more

Ischemia related gangrene wound

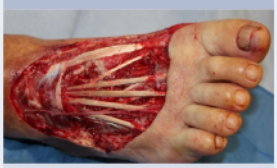


Post initial debridement

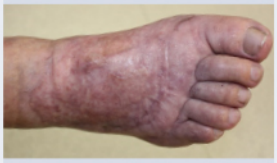


5 months post treatment

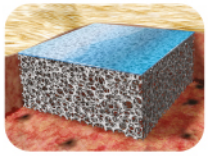
Traumatic degloving



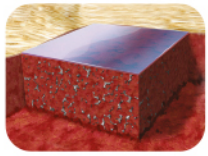
Post debridement



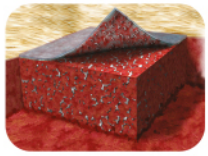
9 months post treatment



Application of NovoSorb BTM to wound bed



Integration of the matrix via cellular migration, neovascularisation, and collagen production



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ORIGINAL ARTICLE

IWJ WILEY

A non-randomised pragmatic trial for the early detection and prevention of surgical wound complications using an advanced hydropolymer wound dressing and smartphone technology: The EDISON trial protocol

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Funding information
University of Western Australia

Abstract

Total hip or knee arthroplasty is a highly effective intervention for treating the symptoms of degenerative joint disease or osteoarthritis (OA), often an unwelcome consequence of obesity. A safe and common surgical procedure, hip and knee arthroplasty procedures are not immune to the occurrence of postoperative complications such as surgical site infection (SSI) or surgical wound dehiscence (SWD). While published rates of SSI following hip or knee arthroplasty are low, 1% to 2% in some cases, it is the resulting wound complication and its clinical management and the impact on patient well-being and return to daily life for the 1% to 2% that is of concern. Postoperative complications such as SSI are a major cost driver to the health care system following arthroplasty and often result in extended lengths of stay, readmission for further surgery, primary and community nursing visits, and are a costly burden to health care settings. Early identification of a wound complication through post-discharge surveillance using a fully transparent dressing and smartphone technology and patient education may

Abbreviations: CONSORT, consolidated standards of reporting trials; CRF, case report form; SPIRIT, standard protocol items recommendations for interventional trials; SSI, surgical site infection; SWC, surgical wound complications; SWD, surgical wound dehiscence; TKA, total knee arthroplasty; THA, total hip arthroplasty; QALYs, quality of life adjusted years; QoL, quality of life.

ameliorate contributing factors or reduce the likelihood of a complication occurring in the first instance. This clinical trial is a non-randomised pragmatic convenience sample carried out in 200 participants of both sexes receiving either a TKA or THA. There will be equal allocation to two groups (100 hips and 100 knees), with 50 in each allocation receiving the interventional dressing and 50 as control. The dressing will be applied prior to discharge and participants will be provided with education on postoperative wound care, when to contact home care nursing for a potential wound problem, and use of their smartphone to capture and send images of their incision site to the study nurses. Participants will also be followed up by home care nursing services at day 14 for suture removal and wound assessment. Participants will complete a patient-reported outcomes survey on day 14 and followed up on day 30 after surgery for wound assessment. The results of this trial may provide a novel pathway using a fully transparent dressing and digital technologies for the prevention of acute readmissions because of wound complications through early detection and intervention.

KEYWORDS

early detection, orthopaedic surgery, prevention, SSI surveillance, surgical site infection, telemedicine, wound infection

Key Messages

- Pragmatic trial design allows for rapid translation of study findings into clinical practice.
- Prevention of surgial wound complications can be optimised through early detection and diagnosis.
- Timely and focused patient education allows a patient to take an active role in early detection of a surgical wound complication.

1 | INTRODUCTION

Background and rationale: Total hip or knee arthroplasty is a highly effective intervention for treating the symptoms of degenerative joint disease or osteoarthritis (OA), often an unwelcome consequence of obesity.[1,2] The global prevalence of obesity is increasing,[3-6] and it is reported that obese individuals have 1.5 to 2 times the risk of developing knee OA compared with non-obese population.[7] Coupled with the increase of obesity is a forecast rise in the number of knee and hip joint arthroplasty procedures, in Australia and internationally.[8,9] Currently, in Australia, the numbers of total knee arthroplasty (TKA) and total hip arthroplasty (THA) procedures for OA are forecast to exceed 161 000 and 79 000 procedures by 2030.[8] This is an extraordinary increase of 275% and 208% on 2013 numbers.[8] It is anticipated the total cost to the Australian health care system will reach $AUD5.3 billion, of which $AUD3.54 billion relates to the private sector.[8] Beyond the growth in the ageing population, high rates of obesity are considered one of the major drivers for the increase of OA-related joint replacement.[10-13]

A safe and common surgical procedure, hip and knee arthroplasty procedures are not immune to the occurrence of postoperative complications such as surgical site infection (SSI) or surgical wound dehiscence (SWD). While published rates of SSI following hip or knee arthroplasty are low, 1–2% in some cases,[14,15] it is the resulting wound complication and its clinical management and the impact on patient well-being and return to daily life for the 1% to 2% that is of considerable concern. Complications such as SSI and/or dehiscence following TKA and THA often result in extended lengths of stay, readmission for further surgery, primary and community nursing visits, and are a costly burden to health care settings. Gow et al (2016) recently reported a mean cost of NZD $40 121 per patient with a postoperative SSI following joint arthroplasty, and a mean length of stay in the acute care setting of 42 days.[16] Likewise, in Australia, postoperative complications such as SSI are a major cost driver to the health care system following arthroplasty.[17] Peel et al (2015) recently reported an increase in costs by 61% for patients who incur an SSI after arthroplasty, with estimates of an additional $97 million AUD to the acute health care setting within the first

30 days after surgery.[17] Early identification of a wound complication and implementation of prevention strategies may ameliorate contributing factors or reduce the likelihood of a complication occurring in the first instance.

Surgical wound complications following hip and knee arthroplasty in obese patients: To address the evidence gap for the early identification and prevention of postoperative wound complications in obese patients following hip or knee arthroplasty, a non-randomised pragmatic trial is proposed. This study will use an advanced transparent hydropolymer wound dressing coupled with the ability to capture digital images of the incisional wound via smartphone technology. Enabling the patient to send digital images of their incision line to a clinician to monitor their surgical wound healing progress remotely will enable early identification and prevention of a surgical wound complication. The use of a patient-to-provider smartphone technology with digital images allows remote assessment by the clinician without dressing removal, or patient attendance in the outpatient clinic, or presentation to the primary health care setting. Unless otherwise indicated, the patient's wound can be remotely monitored to full closure. Furthermore, the use of this self-care model empowers the patient in their wound healing. More importantly, this will facilitate the early identification of a wound complication and allow the clinician to intervene during this critical time point. It is the early identification and prevention of a catastrophic wound event that is key to improving surgical wound healing.

This study will determine the feasibility of such a model in early identification and prevention of surgical wound complications. Early identification and rapid treatment has the potential to reduce the number of hospital readmissions because of escalation of a catastrophic wound breakdown.

This study will also implement a quality of life (QoL) assessment to determine the cost- and health-related quality of life. This study will also investigate the patient's perception of wound healing after surgery using a fit-for-purpose questionnaire. Quantitative and qualitative methods will be engaged to deliver a mixed methods approach to determine the patient's perception of their wound healing, a shortfall in the current research. Finally, we aim to determine the cost-effectiveness of the intervention relative to the control using a stepped health economic analysis, concluding with a cost-utility analysis reporting a cost per quality-adjusted life year (QALY).

2 | OBJECTIVES

The study aims to investigate the utility of a transparent advanced wound dressing that may potentially facilitate the early identification and prevention of a surgical wound complication following hip or knee arthroplasty. In partnership with the attending physician and home care nursing services, the patient is able to send images to the clinician for assessment using smartphone technology. The clinician may advise the patient to present to clinic for review or not depending upon symptoms and visualisation of the incision line. This study tests a novel clinical pathway for the early identification and prevention of postoperative surgical wound complications (SSI and/or SWD) in an orthopaedic surgery population. The study aims to reduce not only the number of surgical wound complications (SWCs) through early identification and appropriate management but also to reduce the number of hospital readmissions because of undiagnosed and untreated wound complications after hip and knee arthroplasty.

The study objectives are as follows:

1. To investigate the role of an advanced transparent hydropolymer wound dressing, which allows full visibility of the incision line to identify early indicators for a wound complication without dressing removal. Using digital images captured via smartphone technology by the patient and sent to the health care provider (HCP), this may facilitate early identification and prevention of postoperative SWCs in an orthopaedic surgery population.
2. To determine the clinical feasibility of a novel clinical early identification pathway for postoperative prevention and management of SWCs.
3. Conduct a QoL study to determine the cost-effectiveness of the intervention relative to the control using a stepped health economic analysis.
4. Conduct a fit-for-purpose survey to capture the patient's perceptions of wound healing following orthopaedic surgery.

3 | TRIAL DESIGN

This study is a prospective pragmatic parallel non-randomised trial based on a convenience sample of 200 consecutive participants; (hips n = 100, knees n = 100). The conduct of the trial is shown below in the trial CONSORT (Figure 1). This trial was prospectively registered with the Australia and New Zealand Clinical Trials Registry ACTRN12620000004965p. WHO UTN: U1111-1239-9961.

4 | METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Study setting: Participants will be sourced from patients attending a metropolitan private hospital for an elective total knee or hip replacement. English-speaking patients who are to undergo an elective total knee replacement will be invited to participate in the study. Potential participants

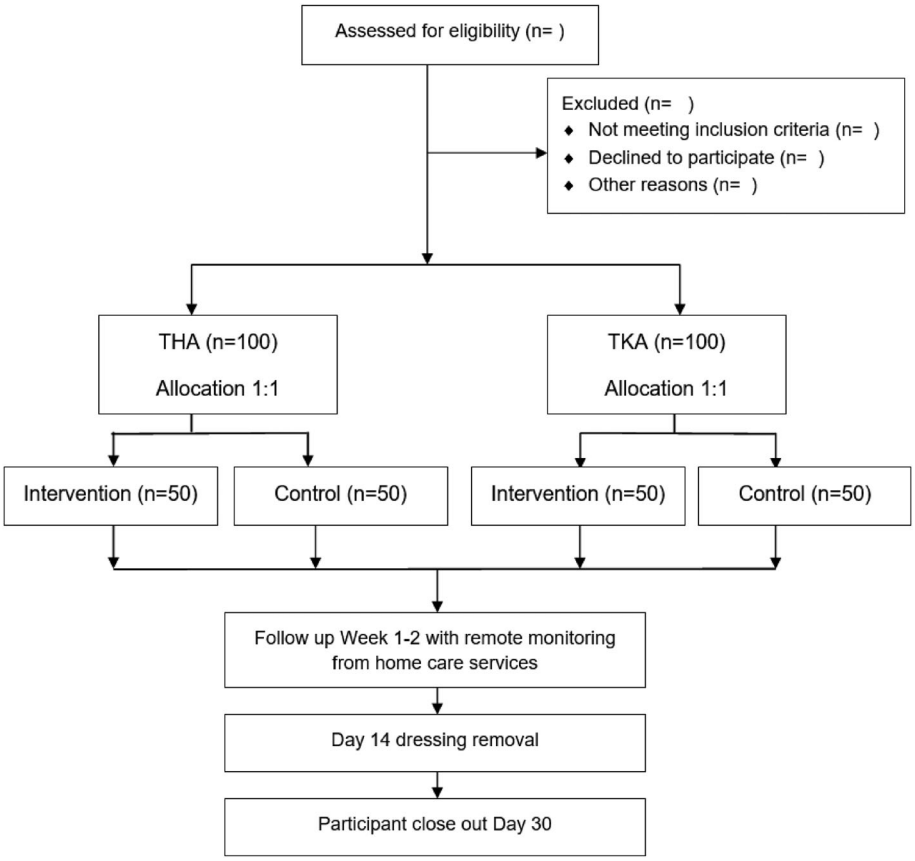

FIGURE 1 CONSORT for EDISON participant flow. (Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Trials. 2010;11:32. PMID: 20334632)

will be invited to participate during the initial surgical consult with the orthopaedic surgeon/trial coordinator; written informed consent will be sought prior to enrolment.

Eligibility criteria:

Inclusion criteria: Consenting adults scheduled to undergo a scheduled elective TKA with access to smartphone technology.

Exclusion criteria: Non-consenting patients, urgent or emergency admissions, allergy to hydropolymer dressing.

Written informed consent will be sought from the potential participant by the trial coordinator following informing the patient of the study and invitation to participate.

Additional consent provisions for collection and use of participant data and biological specimens: There are no plans for ancillary studies following this trial.

5 | INTERVENTIONS

Explanation for the choice of comparators: The transparent hydropolymer dressing is currently used in clinical practice, and is an advanced wound care dressing indicated for use in acute and chronic wound care. The transparent hydropolymer dressing is a sterile, bacteria, virus and waterproof, transparent polymer dressing for the treatment of surgical and other acute wounds. It consists of a semi-permeable polyurethane film with a skin-friendly adhesive border and an absorbent hydropolymer gel pad that is clear. The transparent dressing enables visual wound inspection without removing the dressing and thus facilitates undisturbed wound healing. This is an advanced wound care dressing already used in clinical practice for acute and chronic wounds. The dressing will be placed over the participant's incision site following closure of the incision and prior to discharge from the hospital. The participant will receive education (verbal and written provided by the study RA/CNC) on the dressing and how to manage this dressing in the home. Control participants will receive standard care. Standard care consists of a non-visible film and pad dressing. The participants will also receive an information sheet on warning signs of potential wound breakdown, how to take and send a digital image of the incision at home, and next steps if required. The dressing wear time for the study period is 14 days. Participants will be followed up during the following time points following discharge: Week 1, day 14 and Day 30, if not contacted earlier by the participant. On completion of the QoL and the Bluebell Wound Survey, the participant will be closed out of the trial.

Intervention description: This study will investigate the role of an advanced transparent hydropolymer wound dressing, which allows full visibility of the incision

line to identify early indicators for a wound complication without dressing removal. The transparent hydropolymer dressing, currently used in clinical practice, is an advanced wound care dressing indicated for use in acute and chronic wound care. As the hydropolymer gel pad absorbs exudate and supports optimal wound healing through partial hydration, this dressing is suitable for dry and low exuding wounds. The skin-friendly, shower-proof adhesive border ensures secure fixation. The high permeability of the film dressing to water vapour and oxygen helps to prevent build-up of fluid and maceration. The dressing protects the wound from friction and shear and provides a barrier to bacteria, virus and external contaminants. The dressing is indicated for dry and low exuding acute wounds such as surgical wounds, superficial partial-thickness burns, skin donor sites, lacerations and abrasions. The dressing is available in several sizes: 5 × 7 cm, 7 × 10 cm, 8 × 15 cm, 10 × 24 cm, 10 × 35 cm. The dressings are sterile packed and are available in boxes of 5 and 10 individual dressings

Criteria for discontinuing or modifying allocated interventions are[1]clinical observed and patient-reported allergy or reaction to the dressing,[2] and participant withdrawal from the study. The protocol does not allow for modification of the intervention.

Strategies to improve adherence to interventions: The participants will be closely monitored as part of the discharge surveillance programme at the study site. Postoperative weeks 1–6 participants will be contacted by the study RN via a phone call to follow up on their wound healing. A scripted phone call will ask questions of the participant in relation to their wound healing and dressing. The hospital post-discharge surveillance programme and wound care protocol will also be adhered to.

Relevant concomitant care permitted or prohibited during the trial: During the trial, normal wound care assessment and management is permitted. There are no changes to any concomitant care provided by a healthcare professional.

Provisions for post-trial care: There is no anticipated harm and compensation for participation in this study. Following completion of trial participation, patients will continue to receive the standard of care, if required, and provided by their health care professional.

Outcomes: This study uses a composite outcome approach. Primary clinical endpoint: SSI as per the CDC definition and/or surgical wound dehiscence (Y/N) as classified using the Sandy/WUWHS SWD Grading System. The Southampton Wound Score system will also be used.

Secondary outcome includes the patient-reported wound healing outcomes using the Bluebelle Wound Healing Questionnaire and the EQ-5D Survey.

Primary clinical endpoint: Number of SWCs in each group. SSI as per the CDC definition and/or SWD (Y/N) as classified using the Sandy/WUWHS SWD Grading System.

EuroQol EQ-5D-5L: The EuroQol EQ-5D is a validated measure of health-related QoL, comprising a five-dimension health status classification system and a separate visual analogue scale.[17]The EQ-5D consists of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each with either three or five levels. We will use the five-level version of the instrument, which is likely to be more sensitive to small but important changes in health-related QoL.[18] The responses will be converted into an index score, and total QALYs for each woman will be obtained by estimating the area under the curve defined by their baseline and final EQ-5D-5L responses.[19]

Bluebelle wound questionnaire: A specific fit-for-purpose validated wound experience questionnaire will be used to evaluate the participants' experience in relation to their wound healing following surgery.[20] The Bluebelle WHQ is an 18-item questionnaire for the assessment of SSI in closed primary wounds. It is a single measure designed for completion by patients, or health care professionals during a period of up to 30 days after discharge from hospital. The questionnaire includes items to assess signs, symptoms and wound care interventions indicative of SSI. Response categories include an ordinal scale to capture symptom severity. Development of the measure involved patients and professionals using robust methodology. This survey tool has been used extensively in the United Kingdom to describe the patients' experience with wound healing in the post-discharge period.[21-23] Permission was sought and granted by the authors of the Bluebelle Group to use the wound experience questionnaire for the EDISON study.

Participant timeline: Participants' schedule as per EDISON trial is given in Table 1.

Sample size: The sample is a consecutive series of eligible participants. As this is a prospective pragmatic study, a powered sample is not required. The planned number of participants is 200.

Recruitment: Potential participants will be screened for eligibility by the lead surgeon and RA. Following identification of eligible participants, the potential participant will be informed of the study and invited to participate. All participants are included in the analysis.

6 | ASSIGNMENT OF INTERVENTIONS: ALLOCATION

Sequence generation: Not applicable.

TABLE 1 Schedule of events—EDISON trial

Study assessments	Screening	Study period			
Visits	**Baseline**	**DOS**	**Discharge**	**Day 7**	**Day 14**
Day post-op		0	3 ± 1 days	7 ± 2 days	14 ± 2 days
Informed consent	X				
Inclusion/exclusion criteria	X				
Demographic data	X				
Medical history	X				
Prior medication history	X				
Height	X				
Weight	X		X		
Investigational product application			X		
Education on dressing—discharge			X		
Participant photos of incision site[1]				X	X
Adverse event reporting			X	X	X
Assessment for surgical site infection as per CDC[2] definition *if indicated*				X	X
Wound healing assessment Southampton wound score[3] *if indicated*				X	X
Surgical wound dehiscence grading[4] *if indicated*				X	X
Bluebelle patient survey[5] & QoL (QoL EQ-5D)[6]					X
End of study (Window open until 30 days post-surgery)					X

[1]Informed consent will be obtained prior to any study procedures being performed. Photographs of the dressing application site will be taken prior to discharge. In the event of a local skin reaction, additional photos of the area may be taken by the participant and sent to the attending physician/clinical CNC to evaluate or verify the findings.
[2]CDC Surgical site infection definition https://www.cdc.gov/infectioncontrol/guidelines/ssi/index.html.
[3]The Southampton Wound Score will be used to assess wound infection and severity. Wilson A et al (2004) Surgical wound infection as a performance indicator: agreement of common definitions of wound infection in 4773 patients. *BMJ* (https://pubmed.ncbi.nlm.nih.gov/15367425/).
[4]In the event a surgical wound dehiscence occurs, a grading of the dehiscence will be scored as per the WUWHS SWD Grading System ttps://www.woundsinternational.com/resources/details/consensus-document-surgical-wound-dehiscence-improving-prevention-and-outcomes.
[5]Bluebelle Wound Experience Questionnaire (Validation of the Bluebelle Wound Healing Questionnaire for assessment of surgical site infection in closed primary wounds after hospital discharge *Br J Surg* 2019 Feb;106 (3):226–235. doi: 10.1002/bjs.11008.
[6]The participant will be required to complete the patient survey EQ-5D either electronically or via mail. (https://euroqol.org/eq-5d-instruments/).

Concealment mechanism: Not applicable.

Implementation: The research nurse will enrol consented participants and allocate the participant using equal allocation to either the intervention or control arm of the study.

7 | ASSIGNMENT OF INTERVENTIONS: BLINDING

Who will be blinded: Because of the nature of the dressings being different in appearance and over the incision line of the participant, it is not possible to blind the participant to the group they are allocated to.

Procedure for unblinding if needed: The trial is open label, therefore no unblinding procedure is required.

8 | DATA COLLECTION AND MANAGEMENT

Plans for assessment and collection of outcomes: Case report forms will record participant-related characteristics (age, weight, BMI, smoking, non-smoker, previous knee replacement, immunosuppressed, anticoagulation therapy) as well as pre-existing comorbidities (diabetes, peripheral arterial disease, cardiovascular disease) and intraoperative

related factors (closure method, sutures/glue) will be collected. The case report forms will also record the wound characteristics; incision healed (Y/N); dehiscence, if so extent and depth as per the WUWHS SWD Grading System, surgical site infection (Y/N) and type as per CDC definition, scarring (type keloid, non-keloid) and the Southampton Wound Score on of the incisional wound. This information will be recorded by study personnel at the specified follow-up time points. Source data will be de-identified, aggregated and entered into a software program (SPSS V30 IBM) for further analysis. Electronic data will undergo interim validation checks (random sample) by an independent observer to ensure accuracy and identify any errors, which will be cross-checked with source documentation for entry errors. This will be conducted on a monthly basis for the duration of the data collection phase.

Plans to promote participant retention and complete follow-up: Postoperative weeks 1 to 6 participants will be contacted by the study RA/CTC via a phone call to follow up on their wound healing. A scripted phone call will ask questions of the participant in relation to their wound healing and dressing.

Data management: Source data will be de-identified, aggregated and entered into a software program (SPSS V30 IBM) for further analysis. Source data will be stored in a locked filing cabinet in a locked office at the hospital site. Data will be retained for 5 years and destroyed as per the UWA Data Management Policy.

Confidentiality: Risk of disclosure of personal information is minimal as the investigators will adhere to Section 95A Australian Privacy Act: data are recorded in aggregate form only. Source documentation will be kept separate from the study database. Data collected will be de-identified and coded accordingly. To manage the risk of disclosure of personal information, data collected will be de-identified, and source documentation will be stored in a locked filing cabinet in a locked office onsite. Only study the PI and CPI and study statistician are permitted access to the data as data custodians of the study.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use: There are no plans for the collection of biological specimens in this study.

9 | STATISTICAL METHODS

Statistical methods for primary and secondary outcomes: Baseline descriptive statistics of the sample will be conducted. Statistical methods to be used will be descriptive statistics and test for significance between groups, nominal and categorical data (Chi-squared and Fisher's exact test).

Interim analyses: One interim analysis is planned as per monitoring requirements.

Methods for additional analyses (eg, subgroup analyses): There are no subgroup analyses planned.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data: Any missing data will be recorded in the source documentation as 'missing' and in the electronic record as binary (999).

Plans to give access to the full protocol, participant-level data and statistical code: The datasets used and/or analysed during the current study can be made available by the corresponding author upon reasonable request and in agreement with the research collaboration and data transfer guidelines of the University of Western Australia.

10 | OVERSIGHT AND MONITORING

Composition of the coordinating centre and trial steering committee: This is a single-centre study designed, performed and coordinated by the University of Western Australia in Murdoch University and St John of God Healthcare. Daily trial support is provided Principal Investigator: supervision of trial, related regulatory and ethical compliance.

Site Principal Investigator and study physician: supervision of trial at site and medical governance of participants, identifies potential recruits, ensures follow-up according to protocol.

Trial coordinator: informed consent, study visits, data capture, safeguard quality and data.

Study wound care (acute setting) senior nurse: remote or physical consultation and wound assessment.

Study wound care (home services) nurses: remote or physical consultation, wound assessment, data capture, ensures follow-up according to protocol. The study team meets weekly.

Composition of the data monitoring committee, its role and reporting structure: The Data Safety Monitoring Board (DSMB) will advocate for the ethical and safety interests of the participants while the trial progresses by making non-binding recommendations to the Trial Committee. A DSMB will be formed to monitor the study at interim periods: first third participants closed out ($n = 30$) and last quarter closed out. The DSMB consists of three independent reviewers: a statistician, surgeon and a nurse. The DSMB will be bound by the DSMB Terms of Reference and will provide a written report to the Trial Committee. The Trial Committee consists of the Principal investigator, research nurse and a biostatistician.

Adverse event reporting and harms: The trial will adhere to the TGA's definitions of adverse events for the duration of the trial. The trial will follow the processes as outlined in the NHMRC (2016) Safety monitoring and reporting in clinical trials involving therapeutic goods. http://www.NHMRC-guidance-safety-monitoring-and-reporting.pdf. The procedures for eliciting reports of and for recording and reporting adverse events include definitions of adverse events. *For further information on adverse events refer to the TGA* "The Australian Clinical Trial Handbook" 2018 and the NHMRC "Safety monitoring and reporting in clinical trials involving therapeutic goods" 2016.

While adverse events are not anticipated during this study, all standard site operating and reporting procedures will be adhered to in the event an adverse event occurs during the trial.

Frequency and plans for auditing trial conduct: The trial team will meet weekly to ensure the study is being conducted in accordance with the study protocol. All trial investigators will permit (following formal written request) trial-related monitoring, audits and regulatory inspections including local and external review, Human Research Ethics Committee and institutional governance review bodies as requested.

Plans for communicating important protocol amendments to relevant parties (eg, trial participants, ethical committees): In the event a protocol amendment is required, the standard procedure for notification will be adhered to. This involves submission of a protocol amendment to the HREC and awaiting approval. Once the approval has been granted, education on the changes, if required, will be used to communicate protocol changes to the investigators, research team and trial participants where relevant.

11 | DISSEMINATION PLANS

The trial has been registered with the ANZCTR: 12620000004965p. All publications and dissemination of trial findings will adhere to the International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals. Study findings will be reported at academic and scientific congress and meetings.

12 | DISCUSSION

To the best of our knowledge, this is the first study to use a completely transparent wound dressing for the early detection of postoperative incision complications in the home care setting. Moreover, the use of smartphone technology to allow communication between the patient and provider may lead to reduced admissions to the acute care setting where wound infections or breakdowns are managed in the home care setting.

13 | TRIAL STATUS

The anticipated commencement of recruitment of participants for this trial is February 2022. Recruitment is anticipated to continue until August 2022, with a 30-day follow-up period of all participants to be completed by September 2022. It is anticipated data analysis will be completed by November 2022. The authors confirm that all trial-related information and interventions used in this study are registered.

AUTHOR CONTRIBUTIONS

Kylie Sandy-Hodgetts is the Chief Investigator; she conceived the study, led the proposal and protocol development. Piers Yates, Steven Edmondson, Zaheerah Haywood, Richard Norman, Leigh Davies, Katrina Hulsdunk and Jessica Barlow contributed to study design and to development of the proposal. Kylie Sandy-Hodgetts was the lead trial methodologist. All authors read and approved the final manuscript.

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CONFLICT OF INTERESTS

Kylie Sandy-Hodgetts has received speaker honorariums from Essity BSN Hamburg, Molnlycke Healthcare, Gothenburg and Coloplast Australia. All other authors have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

The datasets used and/or analysed during the current study may be made available from the corresponding author upon reasonable request.

ETHICS STATEMENT

This study has been reviewed and approved by the St John of God Healthcare HREC #1843, under Version 3 EDISON_protocol_24062021. Written informed consent will be obtained from all participants.

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