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Published in:
International Journal of Nursing Studies

DOI:
[10.1016/j.ijnurstu.2023.104479](https://doi.org/10.1016/j.ijnurstu.2023.104479)

Publication date:
2023

Document Version
Publisher's PDF, also known as Version of record

[Link to publication in ResearchOnline](#)

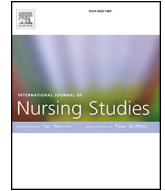
Citation for published version (Harvard):
Greenwood, C, Nixon, J, Nelson, EA, McGinnis, E & Randell, R 2023, 'Offloading devices for the prevention of heel pressure ulcers: a realist evaluation', *International Journal of Nursing Studies*, vol. 141, 104479.
<https://doi.org/10.1016/j.ijnurstu.2023.104479>

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Offloading devices for the prevention of heel pressure ulcers: A realist evaluation

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ARTICLE INFO

Article history:

Received 30 November 2022

Received in revised form 2 March 2023

Accepted 6 March 2023

Available online xxx

Keywords:

Devices

Heel pressure ulcer

Offloading

Prevention

Realist evaluation, tissue viability nurse specialist

ABSTRACT

Background: Heel pressure ulcers can cause pain, reduce mobility, lead to longer hospital stays and in severe cases can lead to sepsis, amputation, and death. Offloading boots are marketed as heel pressure ulcer prevention devices, working by removing pressure to the heel, yet there is little good quality evidence about their clinical effectiveness. Given that evidence is not guiding use of these devices, this study aims to explore, how, when, and why these devices are used in hospital settings.

Objective: To explore how offloading devices are used to prevent heel pressure ulcers, for whom and in what circumstances.

Methods: A realist evaluation was undertaken to explore the contexts, mechanisms, and outcomes that might influence how offloading devices are implemented and used in clinical practice for the prevention of heel pressure ulcers in hospitals. Eight Tissue Viability Nurse Specialists from across the UK (England, Wales, and Northern Ireland) were interviewed. Questions sought to elicit whether, and in what ways, initial theories about the use of heel pressure ulcers fitted with interviewee's experiences.

Results: Thirteen initial theories were refined into three programme theories about how offloading devices are used by nurses 'proactively' to prevent heel pressure ulcers, 'reactively' to treat and minimise deterioration of early-stage pressure ulcers, and patient factors that influence how these devices are used.

Conclusions: Offloading devices were used in clinical practice by all the interviewees. It was viewed that they were not suitable to be used by every patient, at every point in their inpatient journey, nor was it financially viable. However, the interviewees thought that identifying suitable 'at risk' patient groups that can maintain use of the devices could lead to proactive and cost-effective use of the devices.

This understanding of the contexts and mechanisms that influence the effective use of offloading devices has implications for clinical practice and design of clinical trials of offloading devices.

Tweetable abstract: How, for whom, and in what circumstances do offloading devices work to prevent heel pressure ulcers? Tissue viability nurses' perspectives.

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What is already known

- There is some evidence that heel offloading devices could help prevent heel pressure ulcers, however due to the low quality of existing trials, the certainty of the evidence is reduced
- Despite the lack of good quality evidence, offloading devices are widely used in clinical practice for heel pressure ulcer prevention

What this paper adds

- This paper explores how and why offloading devices are used in clinical practice, in the absence of a robust evidence base.
- Through knowing this can inform clinical practice and future clinical trials
- This is the first paper to use realist methodology to explore heel pressure ulcer prevention.

1. Introduction

Complex healthcare interventions are composed of multiple components. The behaviours of people who either deliver or receive the

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intervention can interact with one or more components resulting in a change in outcomes. Implementation of a new intervention, regardless of how simple it may seem from the outset, can become complex due to the dynamic nature of healthcare systems in which they are introduced (Anderson, 2008). Therefore, any evaluation of a complex intervention should increase our understanding of the components of the intervention and the behaviours of those that interact with it. An example of this is explored in this realist evaluation study: the use of offloading devices for the prevention of heel pressure ulcers.

Pressure ulcers, also known as pressure injuries, decubitus ulcers, pressure sores and bed sores, are defined as “a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear” (EPUAP et al., 2019). Pressure ulcers are a globally significant healthcare problem as they are largely viewed as an avoidable harm to patients. Not only can they be painful for patients, but they can also lead to complications such as infections that in extreme circumstances can lead to a major amputation or be fatal. Pressure ulcers can also be painful (Briggs et al., 2013; McGinnis et al., 2014a; Gorecki et al., 2011) and can have a massive impact upon quality of life (Gorecki et al., 2009).

The heel is reported as being the second most common body site, after the sacrum, for pressure ulcers to occur (Greenwood, 2020). The heel has a large fatty pad to the plantar aspect which is designed to withstand impact and pressure from the calcaneum (heel bone) during mobilisation or standing, with the bodyweight transmitted through the plantar surface of the foot. However, when a person is supine, then pressure is transmitted through the posterior heel, which has little padding between the skin and calcaneal bone (Cichowitz et al., 2009). Furthermore, the lower limb is prone to conditions such as peripheral arterial disease, neuropathy and oedema (McGinnis et al., 2014b), which are likely to make the heel more at risk for some patients compared to other body sites. Hence this skin site has specific characteristics which means it need to be considered carefully when studying pressure ulcer prevention and care.

There is consensus that elevating the foot off the bed (or ‘offloading’), so it is completely free of pressure, is the best way to prevent heel pressure ulcers (EPUAP et al., 2019). Heel offloading strategies include positioning pillows so that the heel is not touching the bed or using bespoke healthcare devices such as boots designed to completely suspend the heel whilst the patient is in bed.

A systematic review and meta-analysis found that offloading devices reduce the risk of developing heel pressure ulcers when compared to standard care, although no recommendations can be made due to the low to moderate quality evidence of the included trials (Greenwood et al., 2022). Regardless of this lack of high-quality evidence, these devices are widely used globally for heel pressure ulcer prevention, but what we do not know is, in the absence of robust clinical evidence, how, when, and why they are used in clinical practice. Clinical trials do not tend to consider the mechanical properties of heel-specific devices alongside the numerous variables, which can include both patient and nursing factors, that can influence how these devices are utilised in practice. Understanding this could improve clinical practice, inform the design of future clinical trials into the use of devices for pressure ulcer prevention, and provide key insights for the design of heel offloading devices.

2. Aim

To explore ‘what is it about offloading devices that works, for whom and in what circumstances’ (Pawson and Tilley, 1997) when used for the prevention of heel pressure ulcers in secondary care (urgent and planned care, primarily in hospitals).

3. Methods

Realist evaluation is a theory-driven approach that goes beyond exploring the effectiveness of an intervention, by providing an understanding of how contextual factors influence human decisions, actions

and responses to the intervention to explain why effectiveness varies across contexts (Pawson and Tilley, 1997). Realist evaluation acknowledges and incorporates the researcher’s knowledge in the development of theories, therefore the primary author’s (CG) knowledge and experiences of clinical practice, and a literature review of the current evidence (Greenwood et al., 2022) informed thirteen initial candidate theories. The theories are expressed in terms of context, mechanism, and outcome configurations; where a mechanism is fired in certain contexts to bring about the desired outcome (Wong et al., 2016). The ‘candidate’ theories were categorised as nursing factors (Table 1) and patient factors (Table 2) that might influence how offloading devices are implemented and used in secondary care. This study was undertaken in NHS hospitals, where care is free to all at the point of use.

In this study, theory elicitation was undertaken to refine, develop and add to these initial candidate theories by addressing contexts, mechanisms and outcomes, in order to develop into a realist programme theory (Pawson and Sridharan, 2010). This was carried out using a combination of data sources including interviews with stakeholders about their direct experience of the intervention, and a review of the existing literature identified during a systematic review (Greenwood et al., 2022).

Tissue Viability Nurse Specialists (nurses who assess and treat patients at risk of skin breakdown, or who have difficult to heal/non healing wounds) were identified as participants for this study as they are key stakeholders and clinical experts in pressure ulcer prevention with experience of using offloading devices in a variety of contexts. Participants were purposively sampled, and in-depth telephone interviews were conducted utilising the teacher learner cycle (Pawson and Tilley, 1997; Manzano, 2016). This is where the interviewer presents the theories, and the interviewee confirms, or falsifies, or refines the theory. Each interview was digitally audio-recorded and transcribed verbatim.

An iterative approach to data collection and analysis was taken. After each interview, a preliminary analysis was conducted by listening back to the interview and reading through the transcript to identify emergent themes and the topic guide amended to support further exploration of emergent themes in subsequent interviews. Once all interviews were completed, the transcripts and any relevant papers were inputted into NVIVO 12 (QSR International Pty Ltd., 2018). Thematic analysis was undertaken using a combination of inductive and deductive coding - using codes based on the theories whilst also open coding for the new themes that were identified, seeking out nuggets of information to explain the contexts, mechanisms and outcomes (Manzano, 2016; Wong et al., 2016).

4. Ethical approval

Ethical approval was gained through the University of Leeds School of Healthcare Research Ethics Committee (HREC15-014).

5. Results

Eight Tissue Viability Nurse Specialists were recruited (Table 3). The participants were all employed by the NHS in Secondary Care across the UK (England, Wales, and Northern Ireland). They had held a variety of posts including Clinical Nurse Specialists, Lead Nurses (team leader), and Nurse Consultant (advanced practice/leadership role), with a range of experience in Tissue Viability, varying from 2.5 years to over 20 years.

5.1. Programme theory 1: factors that lead to proactive use of devices for the prevention of heel pressure ulcers

5.1.1. Specialist knowledge

It was evident during the interviews that Tissue Viability Nurse Specialists have specialist knowledge with regard to the use of offloading devices and heel pressure ulcer prevention, which interviewees described as a resource utilised on a meso level by the organisation they

Table 1
Nursing factors that might influence how offloading devices are implemented.

Initial candidate theory	Context	Mechanism	Outcome pattern
1: Healthcare professionals with advanced knowledge of pressure ulcer prevention are more likely to appropriately implement an offloading device as a preventative measure	The specialist has more dedicated time to review the patient. Also, pressure ulcer prevention is a priority for the specialist as it is an area of expertise and something they do on a regular basis.	Resource: Specialist knowledge Reasoning: Specialist knowledge will lead to a more thorough and holistic risk assessment and will have more knowledge of the available resources	Patients are more likely to have a heel offloading device implemented when there is access to a specialist nurse with advanced knowledge
2: Nurses working in clinical areas that frequently care for patients at high risk of developing pressure ulcers are more likely to implement an offloading device as a preventative measure because pressure ulcer prevention becomes more of a clinical priority and staff are more experienced at managing at risk patients and aware of the resources available to them	Culture and ethos of the healthcare setting (with high risk of pressure ulcer development) makes pressure ulcer prevention more of a focus	Resource: Staff knowledge Reasoning: Patients being cared for in an environment where there are high numbers of at-risk patients means that pressure ulcer prevention is more of a priority and staff are more experienced in managing at risk patients and aware of the resources available to them/used to implementing them (i.e. – not just awareness).	Patients are more likely to have a heel offloading device implemented
3: Nurses are more likely to implement an offloading device if it is easily accessed within the care environment	Patients cared for in an environment where offloading devices are kept as ward stock or can be easily accessed	Resource: Offloading devices Reasoning: Nurses perceive that an intervention is needed immediately for patients at risk, and so respond by utilising offloading devices immediately following risk assessment	Increased utilisation of offloading devices in high-risk patients
4: If patients are moved frequently between different care environments then offloading devices are less likely to be utilised because of cost factors	Where it is anticipated that patients are going to be frequently moved between care environments	Resource: Offloading devices Reasoning: Nurses do not see it as a priority and something that can be left for the next person to deal with. If the offloading device is single patient use only, the nurses might see it as too much of a hassle to order or feel it should not come out of their budget and therefore the next ward can order the offloading device. If the offloading device is re-useable there is an ownership issue, and the ward are fearful that it will be sent with the patient and be lost.	Patients who frequently move between wards or who have a short-anticipated stay are less likely to have a heel offloading device.
5: Single patient use offloading devices, versus reusable devices, will be more desirable dependent on the care environment and priorities of the ward manager	Different patient groups in different care environments	Resource: Single use vs reusable offloading devices Reasoning: The financial priorities of the budget holder and patient types in their area will determine which offloading devices they will have available and how readily they will be available in that area	Implementing a plan of care appropriate to the patient becomes more about what is available and affordable rather than what is best for the patient, irrespective of cost
6: Offloading devices are more effective in patients with reduced consciousness	Patient with reduced consciousness (e.g., brain injury or sedated)	Resource: Offloading devices Reasoning: The patients will be unable to remove the offloading devices themselves/will not have an awareness of the offloading device	↑ compliance and effectiveness in care environments such as ICU
7: Nurses are more likely to utilise heel offloading devices as a response to pressure damage rather than as a preventative measure	Patients at risk of developing a heel pressure ulcer	Resource: Offloading devices Reasoning: Nurses are more likely to risk assess the patient as a whole and implement a total body device such as a mattress, rather than to risk assess individual body sites. It is only once pressure damage has occurred that they implement an offloading device	Offloading devices utilised more in patients with heel pressure ulcers rather than at risk patients.
8: If a powered air mattress is already in use, additional preventative methods are less likely to be utilised	Patients at high risk of developing a heel pressure ulcer	Resource: Powered air mattresses Reasoning Nurses knowledge, attitudes and opinions of mattresses will mean that they feel that this is sufficient to meet the patient's needs	↓ utilisation of offloading devices in settings or people with a powered mattress in place
9: Repositioning is a key component of pressure ulcer prevention but is less likely to take place if offloading devices are being utilised.	Care environment where nurses lack capacity to reposition patients and/or knowledge of the need for repositioning	Resource: Pressure relieving equipment including mattresses, cushions, and offloading devices Reasoning: Nurses are outsourcing to devices to replace need for frequent repositioning	Patients are repositioned less frequently and could in turn increase risk of developing a pressure ulcer. Care becomes focused on the device rather than the patient
10: Conversely, the offloading device is a physical reminder for nurses and the patients of their risk and therefore more attention is paid to this at-risk body site.	Patients at high risk of developing a heel pressure ulcer	Resource: Offloading devices Reasoning: The presence of the offloading device reminds the patients and nurses that the heel is an at-risk area, so more attention is paid to the heel	↓ heel pressure ulcer incidence because of a reduction in pressure, but also raises awareness of risk which leads to better self-care from the patient and more effective care from the nurse/carer

Table 2
Patient factors that influence how offloading devices are used.

Initial candidate theory	Context	Mechanism	Outcome pattern
11: Offloading devices are not suitable for use in patients who are at high risk of falls as they could become a fall hazard.	Patients at high risk developing a heel pressure ulcer and of falls, where falls prevention is more of a priority	Resource: Nurses knowledge and prioritisation Reasoning: Nurses perceive some offloading devices can be a fall hazard and so are reluctant to use them with patient at high risk of falls	↓ use of offloading devices in this patient group because falls prevention takes a priority over pressure ulcer prevention
12: Patients are not always compliant with the use of the offloading devices due to comfort factors	Patients at risk of developing a heel pressure ulcer with capacity to make decisions about their care.	Resource: Offloading devices Reasoning: Patients perceive the offloading device as bulky, hot, uncomfortable, or hindering self-movement and so are reluctant to use them	↓ compliance and usage of offloading devices
13: Risk assessments that involve the patient and/or carer are more likely to highlight specific risk factors/high risk areas leading to plan of care that is more patient specific and the patient will comply with	Risk assessments that take place in the presence of the patient and or carer	Resource: Offloading devices Reasoning: When nurses involve the patient and/or carers when performing a risk assessment and planning the patients care they will have a more comprehensive risk assessment and ↑ knowledge about the patient's pressure ulcer risk	An increased awareness of risk leads to an increased utilisation of interventions specific to the patient's need. By involving the patient in the care planning process, they will be more likely to comply

work in. This awareness and knowledge of the resources available was developed in part due to the dedicated time interviewees had to focus on pressure ulcer prevention, which in turn leads to a more proactive use of offloading devices. This could be through direct patient care, or through their influential role within their organisations. Interviewees felt they are perceived by both ward staff and the wider organisation as being a valuable resource for driving forward and influencing the initiation and use of offloading devices through training and education along with the development of guidelines and protocols.

In the absence of formal or published evidence, interviewees gained their specialist knowledge through networking, and utilising the knowledge of others as this quote demonstrates:

“...when I'm having to choose a device, I basically go by the manufacturer's advice but then [evaluate] it, and again with colleagues, see what [other organisations] have used, to see if they have [evaluated] it...no point if the device fails in another organisation, no point having a go in our Trust”

(P3, Clinical Nurse Specialist).

This suggests an element of trust in the other Tissue Viability Nurse Specialists that they have done a thorough and unbiased evaluation, as well as the context of the different organisations being similar enough for it to be relevant to their own.

5.1.2. Care environment

Interviewees described staff working in care environments that frequently cared for patients at high risk of developing pressure ulcers, as being more likely to implement an offloading device proactively for heel pressure ulcer prevention. Through knowledge of their organisations and patient risk factors, vascular, diabetes, orthopaedics, critical care, and care of the elderly were identified as environments that frequently cared for patients at high risk of developing heel pressure ulcers. These areas were where resources in the form of time, education, and devices would be focused as they could make the biggest impact and change in heel pressure ulcer rates, as this example shows.

Table 3
Participant details.

Participant number	Current role	Length in role (years)	Approx. acute patient population
P1	CNS ^a	3	1700 beds
P2	Lead nurse	20	1900 beds
P3	CNS	5	250 beds
P4	Lead nurse	20	900 beds
P5	Lead nurse	16	1000 beds
P6	Senior CNS	5	500 beds
P7	Senior CNS	2.5	800 beds
P8	Nurse consultant	17	400 beds

^a CNS = Clinical Nurse Specialist.

“So, for example the diabetic ward and the orthopaedic ward and [intensive care unit] probably are the highest risk areas... but they absolutely get [use of offloading devices] drummed into them”
(P8, Nurse Consultant).

Early implementation was viewed as essential for proactive use of devices, however there could be a reluctance due to cost for some care environments that saw a high turnover of patients, for example accident and emergency or admissions wards. In NHS hospitals, budgets are usually held by individual care environments/departments and therefore the cost of the device would come from their budget. Even if the device were to stay with the patient throughout their admission, if they were paid for out of an individual care environment's budget, this could influence device use as this quote demonstrates:

“...if we were going to try and implement heel offloading devices at point of entry to hospital, if they're deemed to be at risk, then it means that it could be [accident and emergency] or the medical admissions unit that were constantly buying them, even if they were using them for the rest of the stay in hospital”

(P5, Lead Nurse).

This quote demonstrates the impact that localised budgets have on perceptions of cost. The costs are borne by the hospital regardless of where the device is provided from. However, from the perspective of the interviewees, protecting an individual area's budget was a mechanism that could influence use, to the detriment of the patient. What is unknown is whether cost of the devices and localised budgets have a direct influence on how ward staff use the devices.

5.1.3. Single use versus reusable devices

Patient population, turnover and budgets were identified as influencing factors over whether single patient use, or reusable devices are used. Reusable devices can reduce costs where they were only required for a short period of time. However, this led to issues over 'ownership' of the devices as this interviewee gives an example of:

“...the ideal would be that the patient would come in and they would get given a pair of heel protectors and it would follow them through [their inpatient stay], but that's not how it works. We'd love to be able to do that, but there's just not the budget for those sorts of things. So, they are ward owned and the wards do, when they're not throwing them away because they think they're disposable, they do keep hold of them”

(P7, Senior Clinical Nurse Specialist).

There is also a potential training issue if staff are unable to distinguish between reusable and single use devices which needs to be considered when advocating reusable devices.

5.1.4. Accessibility of the device

During the interviews it was identified that busy ward environments where nurses had multiple competing priorities, if the device was stocked locally, it was more likely to be initiated in a timely manner. Delays in the supply process and poor communication could lead to delays in the device being initiated, or be a barrier to utilisation, which this interviewee gave an example of:

“In a busy environment, [ordering offloading devices] is just one more thing that they [nurses] have to sort out”

(P5, Lead Nurse).

In the absence of devices, pillows were frequently used as an alternative device. There is little evidence for the use of pillows as an offloading device, and as the patient moves it can be difficult to maintain offloading, which is a historical issue; as observed by *Tymec et al. (1997)*, but in practice pillows were discussed by the interviewees as being used as they are cheap and easy to access.

5.1.5. Repositioning

Interviewees viewed the most important component for pressure ulcer prevention was regular and effective repositioning as this quote demonstrates:

“Repositioning over anything is the most important aspect of pressure ulcer prevention, but if [the patient is] not repositioning for whatever reason or they're not repositioning effectively, if you've got heel devices in protecting the heels everyone's a winner are they not?”

(P7, Senior Clinical Nurse Specialist).

Barriers to ‘effective repositioning’ were discussed by several interviewees, giving examples such as the torso being turned but the heels

staying in the same place, patients declining repositioning, or their medical condition, as this quote describes:

“...when patients either are declining to be repositioned or maybe they can't be repositioned. For example, on the fractured neck of femur ward a lot of those patients when they first come back from surgery, they're either in pain initially ... they find [repositioning] uncomfortable. A lot of them are very elderly, they've got a lot of other co-morbidities, so [offloading devices] are an additional aid to repositioning”

(P6, Senior Clinical Nurse Specialist).

Where repositioning cannot be achieved as prescribed, these devices were viewed as an additional tool for proactively preventing heel pressure ulcers.

Summary of programme theory 1

For the outcome of heel pressure ulcer prevention, interviewees viewed the role of the Tissue Viability Nurse Specialists on the context of their wider organisation, through the mechanisms of identifying the need for offloading devices and to sourcing them. Interviewees also viewed the role of the Tissue Viability Nurse Specialist as being influential on the context of the wards through the mechanisms of leadership, training, and education, along with direct patient care and prescribing of offloading devices. Staff knowledge, identification of vulnerable patient groups, stock of devices, and costs were viewed as mechanisms that were influential on device use, as illustrated in *Fig. 1*.

5.2. Programme theory 2: factors that lead to reactive use of devices for the treatment of heel pressure ulcers and prevent further deterioration

As previously noted, the consensus from the interviewees was that repositioning was the most important aspect of pressure ulcer prevention,

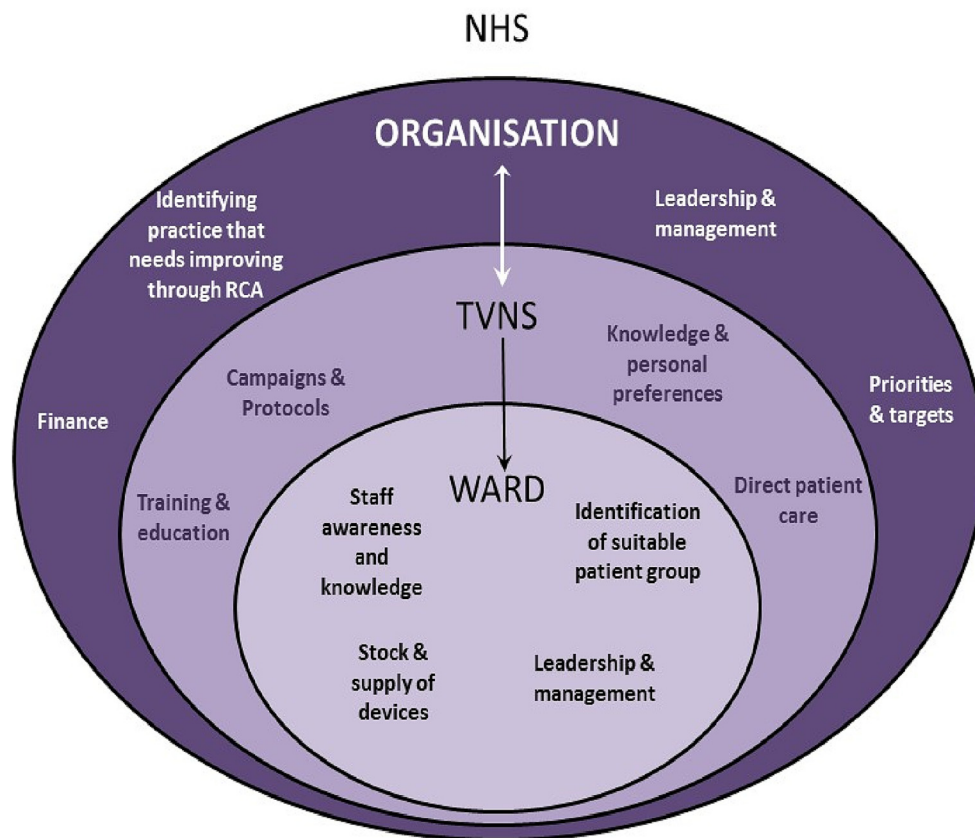


Fig. 1. Schema for programme theory 1 illustrating the mechanisms that influence the proactive use of offloading devices for heel pressure ulcer prevention in the contexts of the ward, the Tissue Viability Nurse Specialist, and the wider organisation.

although for patients who were deemed to be high risk, or where repositioning alone was insufficient, then additional interventions would be required. Offloading devices tended to be viewed as being a “third line” resource after repositioning and powered mattresses. Offloading devices would be initiated when repositioning could not be achieved as per the plan of care, or ‘reactively’ when there was evidence of vulnerable skin to the heels and therefore implemented to prevent deterioration.

5.2.1. Skin assessment

Using a device once a pressure ulcer has already developed was frequently viewed as a ‘reactive’ response, as this interviewee describes:

“...even though they have got the [offloading device kept as stock], they wouldn’t think to put it there as a preventative, again they would use it, but it would be a reactive response, so the advantage it furthers the staff on the ward in having the equipment there, is that from their perspective when the damage occurs they can put that offloader in place to stop any further deterioration, but they wouldn’t think to pro-actively put it in place”

(P1, Clinical Nurse Specialist).

It is possible that the skin damage acts as a visual mechanism, highlighting the patients’ level of risk. The reactive use of devices could be effective at reducing the risk of further deterioration if early signs of pressure damage are recognised, and the device is implemented at this point. Campaigns such as *React to Red Skin* (2019) teach the importance of early recognition of pressure damage, in the form of blanching or non-blanching erythema, and implementing preventative interventions.

All interviewees identified visual skin inspections as being a key component for pressure ulcer prevention, however if these are missed or inaccurate, then more severe pressure damage could occur prior to implementation of a device. Casts, bandages, and socks were identified as physical barriers to skin inspection, but some interviewees identified that heels could sometimes be missed for other reasons:

“I’m not convinced that skin inspection is always undertaken thoroughly for the heels. I think sacral areas tend to get a big focus and I think people sometimes forget about the heels”

(P5, Lead Nurse).

Skin assessment and the identification of early pressure damage acts as a reactive prompt for staff to initiate a heel offloading device, which can prevent further damage or deterioration.

There was no consensus as to whether heel offloading devices acted as a barrier or an aid to visual skin inspection, as both were theorised by the interviewees. Offloading devices could be a visual reminder for some staff that the heels are at risk and therefore need inspecting more frequently. In contrast, some interviewees felt that offloading devices could also be a barrier to skin inspection if staff did not want to remove the devices if this is viewed as time consuming, or if they were unaware of what the device was for or how to reapply them.

Summary of programme theory 2

Programme theory 2 explored the mechanism of reactively using offloading devices; where the outcome is to either prevent deterioration and/or treat a pre-existing heel pressure ulcer. It could be that staff only recognise the risk of heel pressure ulcer once there are visual signs of a pressure ulcer developing, and therefore initiate a device to prevent deterioration. This is not necessarily a negative way of using offloading devices, as in many cases the use of a dynamic mattress and repositioning are sufficient to meet the pressure ulcer preventative requirements of the patient, especially if the heel is raised off the bed. Where the context is early signs of a heel pressure ulcer, this can act as a visual prompt (mechanism) that the current plan is not meeting the patient’s needs, and therefore that this patient requires offloading (outcome).

Programme theories 1 and 2 informed Fig. 2, to illustrate the decision making in which offloading devices might be implemented in practice, both proactively and reactively.

5.3. Programme theory 3 – patient factors that influence how offloading devices are used

The first two theories focused on how these devices might be used in practice from the perspective of the Tissue Viability Nurse Specialist and ward staff. There are times where the use of devices is not desirable or possible from the perspective of individual patients, or certain patient groups.

5.3.1. Falls risk

When patients are at risk of both developing a heel pressure ulcer and at risk of falling, an informed decision is required as to whether the heel pressure ulcer risk or falls risk is the greatest risk to the patient. In most cases, interviewees viewed heel offloading as being a fall hazard in certain patient groups, and in these cases, they would not advocate the use of a device, as this quote illustrates:

“...if they cannot safely offload the heel... and they cannot keep the heels free from pressure because the patient is agitated or you know, is pretty mobile in the bed, then it’s safer to just nurse the heels on the mattress”

(P2, Lead Nurse).

Due to being a trip hazard, it was viewed that these devices should be only used for patients when they are in bed. There was a desire for a cheap device for ambulatory patients, but this was identified as a gap in the market as this interviewee discusses.

“We’re going out to tender in the next few weeks, and we’ve actually written in our tender spec[ification] that we’re looking for something suitable for ambulatory patients. But you and I both know that there probably is not anything out there, but you know, we’re asking the question”

(P4, Lead Nurse).

5.3.2. Patient comfort/preferences

Previous trials of offloading devices have described how patients found the devices ‘hot and bothersome’, bulky, and restricted free movement in bed, which ultimately affected compliance in their trials (Bååth et al., 2016; Donnelly et al., 2011; Gilcreast et al., 2005). These trials used different devices, so it is unknown whether these issues are confined to individual devices, however in order to effectively offload the heel whilst distributing the pressure across the lower limb, requires the devices to be padded and/or bulky. Whilst comfort is likely to be a high priority for patients, this was not always the case for ward staff. Campbell et al. (2010) used a nominal group process to select device use in their study, and patient comfort was ranked 5/7 in terms of importance. This was also discussed by one interviewee as being less of a priority:

“I’ve never thought about it from the device being comfortable actually [whether or not they will keep the device on]... I’d thought about it more that if the patient is less responsive, quite weak or sedated or some other medical condition going on, then they are less likely to fidget or kick it off”

(P1, Clinical Nurse Specialist).

Some interviewees reported ward staff attempting to improve comfort and compliance with the devices by using sheets or pillowcases to line the devices, however this could reduce the effectiveness of the devices through causing a hammocking effect which in turn increases the contact area at the heel. It was uncertain whether staff were aware that

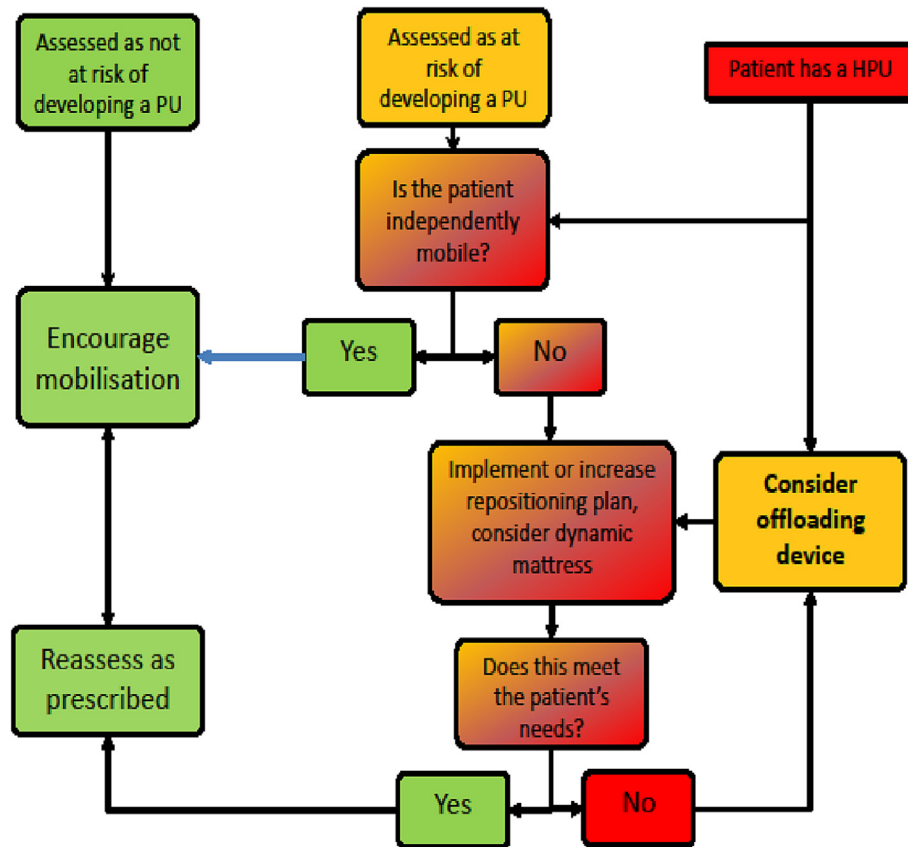


Fig. 2. Proposed model of how offloading devices are used in practice.

through doing this the devices became less effective, or if they viewed that using a less effective version of the device is better than nothing.

5.3.3. Recovery and rehabilitation

The consensus from the interviews was that offloading devices were most effective when used in an immobile limb – either because the patient was not conscious or mobile within the bed, for example in areas such as critical care or stroke wards. This patient group was considered at highest risk of developing a heel pressure ulcer and so should be offloaded, but there are also fewer patient factors that affect concordance such as sensation, comfort, or the patients' ability to remove the device. In these situations, pillows or reusable devices might be more effective as this participant discussed:

“So, wherever the patients are very high risk, I mean, have really high-risk factors and there is a risk that their legs could come off the pillow, then I would go for the higher end device. But I do think even for your high-risk patients, if they offload satisfactorily on a pillow then there's a place for that”

(P8, Nurse Consultant).

Offloading was viewed as not being suitable for all patients, at all points during their inpatient stay, but as a more fluid requirement, which should be frequently reassessed alongside their risk: in realist terms we should be asking “what device works for each patient, at each stage of their inpatient journey”. Therefore, in a patient who is recovering and becoming more mobile, offloading may become less of a necessity or could even become a hindrance, as this interviewee describes:

“So, for example if you've come in with a fractured neck of femur you do not want to move, and you might actually be very comfortable with your [offloading] boot in situ. But once you have had your surgery and you're starting to get a bit more mobile, pain is under

control, then you find that the boot is actually getting in your way of actually trying to be independent...so I think there's something about use in terms of where in the patient's journey”

(P2, Lead Nurse).

Summary of programme theory 3

Again, for the outcome of heel pressure ulcer prevention, individual patient factors/mechanisms need to be considered when implementing offloading devices, and whether it is suitable in the context of the different stages of their inpatient stay. Offloading was viewed as being most important in the context of acutely unwell and bedbound patients. Mobilising is an important part of the recovery process, and as the patient starts to mobilise the device could then become a hindrance or even a trip hazard. Concordance with offloading device use can be improved by considering individual patient preferences, where the patient is on their recovery journey and therefore current risk factors and working with the patient.

6. Discussion

The Tissue Viability Nurse Specialists interviewed viewed their role as being central to the proactive use of offloading devices. Their advanced knowledge and dedicated time to pressure ulcer prevention allowed them to identify patient populations and clinical areas where offloading devices would be beneficial. The interviewees would subsequently source the devices, taking cost and usability into consideration, and promote their use through training and education and prescribing their use for individual patients. There was a large focus by the interviewees on training and education, and this was often viewed as being a central component to their role, however the effectiveness of training

and education about pressure ulcer prevention in increasing staff knowledge and reduction in pressure ulcer rates remains uncertain (Porter-Armstrong et al., 2018). Further research is required on whether training and education increases device use through increasing knowledge, or if increasing staff's familiarity with the available devices and how to use and access them is sufficient. Other factors that were reported as leading to the proactive use of devices included ward leadership and the devices being readily available to the nursing team.

The reactive use of offloading devices as a response to early signs of heel pressure ulcer could prevent the development of severe heel pressure ulcer, however this required staff to understand heel specific risk factors and be able to recognise early skin changes such as blanching and non-blanching erythema in a timely manner. Studies have found that nurses' ability to recognise Category 1 pressure ulcers have been variable (Sternier et al., 2011; Vanderwee et al., 2006), and this does not take into account patients with darker skin tones where erythema is difficult to detect due to the higher concentrations of melanin in the skin. The heel can also be a more difficult area to visualise when the patient is in a supine position and capillary blood flow and reperfusion of the dermis can be masked by the thicker epidermis of the heel (Vanderwee et al., 2006).

The interviewees discussed concordance versus compliance with regard to the use of the devices and identified comfort factors as being a major factor that affected concordance, something that has been reflected in the literature (Bååth et al., 2016; Donnelly et al., 2011; Gilcreast et al., 2005).

It is important to understand more than just whether an intervention works, but how, why, when, and what it is that makes an intervention 'complex'. Research therefore needs to reflect the reality of clinical practice, which is a strength of this paper.

This is the first piece of research to use realist methods to focus specifically on heel pressure ulcer prevention. Realist evaluation was selected as it acknowledges the importance of incorporating the knowledge and clinical experience of the researcher.

A search of the grey literature, and the literature identified in a previous systematic review was undertaken alongside this study to contribute to theory refinement. Fifty potentially relevant articles were identified, although none contributed to the development of the programme theories, suggesting the paucity of research and evidence at the time that this study was undertaken.

6.1. Limitations

This study involved only one aspect of a Realist Evaluation: theory elicitation and refinement. This study is just from the perspective of eight Tissue Viability Nurse Specialists, who are not the primary care givers. It also did not explore the patients' perspectives which are an important element. Testing of these programme theories would further strengthen the findings of this study and help to address the gap in the perspectives from the patients and primary care givers.

6.2. Conclusions

The interviewees all discussed using offloading devices in clinical practice and felt there was a need for these devices.

This research has identified that offloading devices are not considered as a panacea: they are not suitable for every patient at every point in their inpatient journey. By identifying 'at risk' patient groups that are more likely to maintain offloading may lead to a more proactive and cost-effective use of devices.

Using devices reactively in patients where repositioning and dynamic mattress use is insufficient for pressure ulcer prevention, cannot be implemented, or where there are early signs of heel pressure ulcer is another recognised approach for using offloading devices.

Through interviewing experienced Tissue Viability Nurse Specialists, who have a vast amount of experience in utilising these devices in

clinical practice, this study has been able to gain an understanding of how, when, and why offloading devices are used. It is beyond the scope of this research study to be able to inform the design of these devices, and we cannot alter the experiences and perceptions of patients, however through understanding the contexts and mechanisms through which these devices are implemented and used in clinical practice can help to improve practice and inform future clinical trials.

CRedit authorship contribution statement

Clare Greenwood: Conceptualization, Methodology, Data collection and analysis, Writing- Original draft preparation.

Rebecca Randell: Overview of data analysis and validation, Supervision, Writing- Reviewing and Editing,

Jane Nixon, Andrea Nelson, and Elizabeth McGinnis: Supervision, Writing- Reviewing and Editing,

Funding

CG conducted this review as part of her PhD at the University of Leeds which was funded by a Charitable Grant from <https://leeds-cares.org/LeedsHospitalsCharity> (<https://www.leedshospitalscharity.org.uk/>) and Smith and Nephew Foundation. The funding body has no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Data availability

The datasets generated during and/or analysed during the current study are not publicly available as respondents were assured raw data would remain confidential and would not be shared.

Declaration of Competing Interest

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.

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