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Research paper

Acceptability of a behaviour change intervention to improve care of clinically deteriorating patients on acute hospital wards: A theory-based mixed-methods study

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ABSTRACT

Introduction: Patients who clinically deteriorate in acute hospital wards who do not receive optimal care are at risk of harm. Track-and-trigger tools have been implemented internationally to facilitate the detection of clinical deterioration and prompt a response. Despite these tools, patients continue to deteriorate without optimal care. To address this, a theory-based behaviour change intervention (the Promoting Recognition Of deterioraTion and EsCalaTion of care [PROTECT] intervention) was developed to promote detection and response behaviours from nursing staff. While the PROTECT intervention followed a robust development process, its acceptability to end-users (those who could receive or deliver it) was unknown.

Aim: The aim of this study was to prospectively evaluate the acceptability of the PROTECT intervention to end users in a research context.

Design: A mixed-method study was conducted with a sequential explanatory design underpinned by the theoretical framework of acceptability.

Methods: Ward-based nursing staff members and critical care outreach nurses from three hospitals were recruited. Research materials were developed using theoretical framework of acceptability constructs. Participants received a presentation about the PROTECT intervention before completing a questionnaire using a live poll. Questionnaire results, displayed in real time, guided which acceptability constructs were explored in a subsequent focus group. Participant's demographics and questionnaire data were reported descriptively. Qualitative data were analysed using Framework Method.

Results: Research was conducted with 19 participants. The PROTECT intervention was rated as (highly) acceptable for four constructs (*Affective Attitude, Perceived Effectiveness, Intervention Coherence, and Self-efficacy*) and less acceptable for three constructs (*Opportunity Costs [and Gains], Burden, and Ethicality*). Participants praised the intervention's multifaceted nature and the familiarity of components that aligned with the existing strategies. Concerns were raised about its potential for components to induce psychological harm and the burden of engaging with the intervention.

Conclusion: The PROTECT intervention was broadly rated as (very) acceptable, suggesting progression to delivery and piloting in acute hospitals is appropriate. Findings from this work will be used to refine the PROTECT intervention and inform development of the implementation package.

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1. Introduction

Clinical deterioration has been defined as the change in a patient's condition from one clinical state to a worse clinical state accompanying a greater risk of morbidity and mortality.¹ Findings from observational studies conducted across the world suggest that patients who clinically deteriorate without optimal care are at a greater risk of unplanned admission to an intensive care unit

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(ICU), cardiac arrest, or death—collectively termed serious adverse events (SAEs).² Suboptimal care of clinical deterioration also increases hospital length of stay incurring considerable financial costs to healthcare providers.² More than half of patients who clinically deteriorate exhibit objective signs detectable through routine monitoring of vital signs (e.g., heart rate, respiratory rate, blood pressure).³ There is also a tentative signal from the literature that a patient's perception of their own condition can predict deterioration before changes in vital signs are evident.⁴ Accurate monitoring and interpreting patients' vital signs and incorporating patient and family perspectives into clinical decision-making are approaches that healthcare staff can use to detect and respond to signs of clinical deterioration preventing SAEs.

To optimise care of clinically deteriorating patients, rapid response systems (RRSs) have been implemented in Australasia,¹ the United Kingdom (UK),⁵ Europe,⁶ North America,⁷ and in some low- and middle-income countries.⁸ These systems include separate but connected detection and response workflows^{9,10} with variation between organisations in how these two elements are operationalised. To strengthen the detection workflow of the RRS (also termed the *afferent limb*¹⁰), physiological track-and-trigger tools have been implemented internationally. These tools capitalise on the frequency of abnormal vital signs in clinically deteriorating patients, providing a signal when vital signs are deranged and prompting clinicians to act.¹¹ Noteworthy examples of these tools include the "Between-the-Flags" tool—implemented across New South Wales in Australia—¹² and the National Early Warning Score 2 (NEWS2)—implemented widely across the UK.¹³

The NEWS2 signals patient risk based on the total score (range: 0–20) aggregated from individual scores assigned to six routinely recorded vital signs (heart rate, blood pressure, respiratory rate, conscious level, temperature, and peripheral oxygen saturations).¹⁴ Once the aggregate NEWS2 is calculated, the patient's level of risk is stratified as low (score range: 0–4), medium (score range: 5–6), or high (score ≥ 7).¹⁴ Cohort studies of medical, surgical, and emergency department patients have demonstrated that a NEWS2 score ≥ 7 is independently associated with a higher risk of SAEs,^{15–17} with the NEWS2 demonstrating greatest reliability in predicting poor outcomes within 24 h of the score being recorded.¹⁸ When compared to other track-and-trigger tools used internationally, the NEWS2 demonstrates superior predictive performance¹⁹ which may explain why it has been broadly implemented in the UK and in other countries.

Once clinical deterioration is detected and care escalated, the response element of the RRS (also termed the *efferent limb*¹⁰) is activated. The response may be provided by ward-based clinicians and/or practitioners from a designated response team, e.g., a critical care outreach, medical emergency, or rapid response team.¹¹ Systematic review findings suggest that involvement of a response team protects clinically deteriorating patients from poor outcomes.⁷ However, for the patient to benefit from the involvement of these teams requires ward nurses to recognise clinical deterioration and escalate care appropriately. Despite implementation of RRSs, there is evidence that safety-critical detection and response behaviours are not consistently enacted by ward nurses, resulting in avoidable deaths in some clinically deteriorating patients.^{2,20} Patient harm resulting from failure to detect clinical deterioration and appropriately escalate care to a designated response team is referred to as *afferent limb failure*.^{21–23}

To optimise care of clinically deteriorating patients and mitigate the risk of afferent limb failure, a behaviour change intervention was developed using the theory-based approach proposed by French et al.²⁴ The development work included three

(completed and published) work packages with the broad intent to (i) report the specific behaviours that needed to be changed and therefore targeted by the intervention⁵; (ii) empirically examine barriers and facilitators to the target behaviours using a theoretical framework of behaviour change²⁵; and (iii) use findings from the first two work packages to populate the intervention with theoretically informed content.²⁶ The output of this development work was a draft intervention for delivery to ward-based nursing staff including registered nurses (RNs) and unregistered support staff, e.g., healthcare assistants (HCAs) (or comparable roles internationally). The Promoting Recognition Of deterioraTion and EsCa-lation of care (PROTECT) intervention was designed to enhance nurses' detection behaviours by promoting effective use of track-and-trigger tools and consideration of patient and family perspectives. It encourages staff to respond to concerns and escalate care when necessary. Although the intervention was developed in the UK, where the NEWS2 is the track-and-trigger tool, the safety-critical behaviours it targets—detection and escalation of care—are potentially applicable across different contexts and settings where other track-and-trigger systems are used.

PROTECT is populated with a training package and 12 behaviour change techniques (BCTs).²⁶ BCTs are observable, replicable elements of behaviour change interventions that work by modifying attitudes, beliefs, and/or intentions.²⁷ Each BCT is classified with a unique label and identification number drawn from the literature.²⁸ Observable and replicable BCTs are recognised as different from the strategies used to deliver them.²⁷ For the PROTECT intervention, the concrete strategies for delivering BCTs are referred to as *delivery approaches* and the combination of a BCT and its delivery approach is termed an *intervention component*. Some components of the PROTECT intervention will be delivered in the context of a workshop and some in the ward environment. The intervention components of PROTECT and the delivery context are described in Table 1.

Acceptability is recognised as a necessary condition for intervention delivery as it influences the extent to which end users (i.e., intervention deliverers and/or recipients) engage with an intervention and whether it can be implemented with adequate fidelity (i.e., delivered as intended).²⁹ Given its importance, Sekhon et al.³⁰ conducted a multiphase study to define acceptability and develop a theoretical framework that could be used to (prospectively or retrospectively) assess the acceptability of healthcare interventions to end users. Acceptability was defined as "*the extent to which users and receivers of an intervention consider it appropriate based on anticipated or experiential cognitive and emotional responses to it*".³⁰ The theoretical framework of acceptability (TFA) includes seven constructs underpinning the concept of acceptability which are *Affective Attitude, Burden, Ethicality, Intervention Coherence, Opportunity Costs, Perceived Effectiveness, and Self-efficacy*.^{30,31} The TFA has been used to empirically examine the acceptability of healthcare interventions³¹ including those delivered in critical care settings.^{32,33} More recently, researchers who have used the TFA to examine acceptability of healthcare interventions have recommended two revisions to the framework: (i) redefining *Opportunity Costs* to *Opportunity Costs and Gains* to align with the other TFA constructs that have both positive and negative aspects and (ii) including a new construct, *Perceived Safety and Risk*.³¹ See Table 2 for definitions of all TFA constructs.

To maximise productivity and reduce research waste, it is recommended that intervention acceptability be assessed in a research context before progressing to evaluation in a healthcare environment (i.e., as part of a pilot study).²⁹ The aim of this research was to prospectively evaluate the acceptability of the

Table 1

A description of the content of the PROTECT intervention.

Delivery context	Intervention components	
	BCT label (and unique identifier) ²⁸	Delivery approach
Workshop	Training package (not a BCT)	Staff ^a members receive a 1.5-h training package during the workshop focusing on the use of NEWS2, the evidence underpinning NEWS2, and its strengths and limitations.
	Consider pros and cons (007069)	Staff members are asked to consider pros/cons of monitoring vital signs and escalating care in line with NEWS2 and discuss this with peers.
	Induce anticipated regret (007067)	Staff members are asked to imagine the remorse they might feel if a patient came to harm because actions were not taken in line with NEWS2 protocol.
	Increase salience of consequences (007068)	Staff members are shown two video clips featuring (i) a patient discussing the consequences of delayed and timely escalation of care and (ii) an HCA speaking about the consequences of being dismissed by an RN when they escalate care.
	Prompt comparative imagining of future outcomes (007070)	HCA's are asked to imagine possible outcomes (for them and the patient) of early, delayed, or no notification to an RN about a high NEWS2. HCA's are paired with RNs to reflect on this.
	Identify self as a role model (007158)	RNs are prompted to imagine responding to NEWS2 appropriately and think about who they might be setting a good example for.
	Action planning (007010)	HCA's complete "if-then" statements by producing responses to hypothetical scenarios and discussing their responses as a group.
Workshop and ward setting	Increase awareness of others' approval (007074)	In the workshop , staff members are shown a video clip of a respected and credible CCON speaking about their approval of prompt escalation of care and close monitoring of patients with an elevated NEWS2. In the ward , in response to an appropriate escalation of care for a patient with a high NEWS2, CCONs will provide in-person positive feedback to RNs and/or email positive feedback to ward managers to be disseminated at safety huddles.
	Add objects to the indirectly experienced environment (007164)	Three pieces of equipment may be added to wards: (i) Blood Pressure (BP)/peripheral oxygen saturations (SpO ₂) machines; (ii) a digital thermometer with a timer for counting respiratory rate; and/or (iii) clocks with second hands for counting respiratory rate.
Ward setting	Indirectly restructure the social environment (050347)	Staff will attend brief safety huddles, facilitated by the nurse-in-charge, at least once per shift which will provide opportunities for staff to raise concerns about clinically deteriorating patients.
	Provide positive social consequence for behaviour (007265)	During safety huddles, the nurse-in-charge will praise staff for raising concerns. AND In response to an appropriate escalation of care for a patient with a high NEWS2 score, CCONs will provide in-person positive feedback to RNs and/or email positive feedback to ward managers to be disseminated at safety huddles.
	Deliver informational support (007042)	Staff will be identified and developed to be champions to support their peers. Champions would have greater knowledge of NEWS2, care of clinically deteriorating patients, and relevant local policies/procedures.
	Prompt intended action (007080)	Laminated signs will be attached to monitoring equipment reminding HCA's to escalate concerns to RNs.

BCT: behaviour change technique; CCON: critical care outreach nurse; HCA: healthcare assistant; NEWS2: National Early Warning Score 2; PROTECT: Promoting Recognition Of deterioration and Escalation of care; RN: registered nurse.

^a Staff indicates that **both RNs and HCAs** should receive the BCT. Where this is not the case, the target recipient is specified.

PROTECT intervention to potential end users and use findings to refine the intervention prior to piloting it in acute hospital wards.

2. Methods

2.1. Design

A mixed-methods study informed by the TFA was conducted. The design is sequential explanatory³⁴ as quantitative findings

from a TFA-informed questionnaire (delivered to participants using a live poll) guided which constructs of acceptability were qualitatively explored in focus groups.

2.2. Setting

Sites were three acute hospitals in greater London, UK. Sites 1 and 3 were large specialist referral centres, while site 2 was a district general hospital. The PROTECT intervention was developed through research conducted at site 1. All three hospitals had RRSs

Table 2

Definitions of theoretical framework of acceptability (TFA) constructs.

TFA construct	Definition ^a
Affective attitude	How an individual feels about the intervention
Burden	The perceived amount of effort that is required to participate in the intervention
Ethicality	The extent to which the intervention has good fit with an individual's value system
Intervention coherence	The extent to which the participant understands the intervention and how it works
Opportunity costs or gains	The extent to which benefits, profits or values must be given up, or are gained by engaging in the intervention
Perceived effectiveness	The extent to which the intervention is perceived as likely to achieve its purpose
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention
Perceived safety and risk	The perceived, or experienced, threats and hazards, or feelings of safety, encountered when participating in the intervention

^a Definitions obtained from the studies by Sekhon et al.³⁰ and Paynter et al.³¹

which included the use of NEWS2 and a critical care outreach team to respond to clinically deteriorating patients outside of the ICU. The RRS had been operational for 23 years in site 1, 18 years in site 2, and 4 years in site 3.

2.3. Participants

RNs and HCAs working in acute wards (excluding the ICU, emergency department, and operating theatres) were invited to participate as they represent potential recipients of the PROTECT intervention. Critical care outreach nurses (CCONs) were also invited as they represent potential deliverers of the intervention. Staff members were contacted via email and prompted to contact a researcher (SM) to opt in to the study.

2.4. Data collection

Using published guidance,³⁵ a questionnaire was developed that included one item linked to each TFA construct.³⁰ For example, “It is clear to me how the [workshop-/ward-based] components of the intervention will help improve care of clinically deteriorating patients” (linked to the TFA construct *Intervention Coherence*) and “How much effort will it take to engage with the [workshop-/ward-based] component of the intervention?” (linked to the TFA construct *Burden*). For each item, participants were asked to rate their level of agreement from 1 to 5, with higher scores reflecting more favourable responses. The final list of questionnaire items ([supplementary file 1](#)) was scrutinised by a TFA expert (MS) before being loaded onto an online polling platform (Poll Everywhere). A focus group topic guide was developed also informed by the TFA constructs³⁰ ([supplementary file 2](#)). The topic guide and live poll were piloted with members of an acute and critical care research group, and revisions were made based on pilot participant's feedback.

Delivery of the questionnaire and the subsequent focus group discussions took place in-person in a prebooked room within or adjacent to the hospital building. Focus groups were audio recorded and transcribed verbatim for analysis. Transcripts were not returned to participants for comment. Focus groups were facilitated by a member of the research team (SM) with experience of conducting qualitative research in the fields of behavioural and implementation science but with no prior involvement in the development of the PROTECT intervention and no pre-existing relationships with participants. A second member of the research team (DS) was present to provide practical and administrative support (e.g., issuing consent forms, collecting participant's demographic information, and operating audio-recording equipment) and to take field notes. After participants had been welcomed, given consent, and introductions were complete, the following procedure was followed: (i) the facilitator used a PowerPoint presentation to provide a descriptive overview of the components of the PROTECT intervention that would be delivered in a workshop context; (ii) participants were asked to access the online poll using their mobile phone or digital device and respond to seven questions aligned to TFA constructs; (iii) once polling was complete, anonymised poll responses were then displayed graphically (see [supplementary file 3](#)) to participants using live feedback from the Poll Everywhere platform; (iv) to ease participants into the focus group discussion, the opening question after the poll was linked to a TFA construct with a favourable response from the group; and (v) thereafter, questions centred on TFA constructs with less favourable responses and on adjustments that could be made to make intervention components more acceptable. Prompts were used throughout to encourage dissenting views and the participation of all group

members. After a short break, steps 1–5 were repeated for components of the PROTECT intervention that would be delivered in the ward setting.

2.5. Data analysis

Participant demographic information and results from the TFA polling tasks were reported descriptively using frequencies, percentages, medians, and interquartile ranges (IQRs).

Qualitative data were analysed using Framework Method³⁶ and a combined deductive and inductive approach. Audio recordings were professionally transcribed, and subsequently, the primary analyst (SM) familiarised himself with the data. Transcripts were systematically and deductively coded using the seven TFA constructs³⁰ plus the *Perceived Safety and Risk* construct³¹ as the coding categories. To ensure robust and defensible coding, a single transcript was randomly selected and independently coded by two members of the research team (DS and SM) using published definitions of TFA constructs.³⁰ Disagreements in coding were reconciled through discussion and debate. Where consensus could not be easily achieved, a third member of the research team (MS) with significant expertise in the TFA was consulted. A single researcher (SM) performed all subsequent coding independently with the opportunity to discuss uncertainties with other researchers (DS and MS) throughout the process. A codebook including construct definitions and example quotations was developed and refined iteratively throughout the coding process.

Once all transcripts were coded, high-level “belief statements” were inductively synthesised to represent the views of participants expressed in coded segments (see guidance by Atkins et al.³⁷). Belief statements were interrogated for shared meaning and grouped to form the initial themes (by SM). The initial themes, codes, and associated quotations were copied into a table to create a framework matrix organised by the TFA constructs. During the development of the framework matrix, analytic memos³⁶ were written (by SM) to capture ideas about the content and labelling of themes and potential relationships between the data. The framework matrix and analytic memos were scrutinised by all members of the research team (DS and MS), and a final framework matrix was developed. Median scores for each acceptability construct were then jointly displayed alongside the qualitative themes and reviewed (by DS, SM, and MS) to identify how the qualitative data confirmed, challenged, or expanded the quantitative findings.³⁴

2.6. Ethical approval

The study received favourable opinion from the City St George's, University of London nursing proportionate research ethics committee (reference: ETH2324-1480), the Health Research Authority (reference: 24/HRA/1405), and local research and development departments from each of the three hospital sites.

3. Results

3.1. Participants

Three focus groups were conducted from October to November 2024, with a total of 19 participants. The number of participants in each focus group ranged from four to 10. Each focus group lasted 2 h. Participant characteristics are presented in [Table 3](#).

Table 3
Participant characteristics.

	Site frequency (%)			
	1	2	3	Total (all sites)
Job role				
Senior registered nurse	2 (50)	4 (40)	3 (60)	9 (47)
Registered nurse	2 (50)	4 (40)	2 (40)	8 (42)
Healthcare assistant		2 (20)		2 (11)
Workplace				
Critical care outreach	2 (50)	3 (30)	2 (50)	7 (36)
Endocrinology			2 (33)	2 (11)
Haematology	1 (25)		1 (17)	2 (11)
Internal medicine	1 (25)			1 (5)
Surgical care		2 (20)		2 (11)
Respiratory care		5 (50)		5 (26)
Gender				
Female	2 (50)	10 (100)	5 (83.3)	17 (89)
Male	2 (50)			2 (11)
Years of experience				
Range	3–9	0.5–13.5	2–8	0.5–13.5
Mean	5	4.9	4	4.65

3.2. TFA questionnaire results

For the intervention components delivered in a workshop, the median acceptability score—ranging from 1 (very unacceptable) to 5 (very acceptable)—across all seven TFA constructs was 4 (IQR: 1), and for the intervention components delivered in the ward setting, it was 5 (IQR: 3). TFA constructs with the highest median acceptability scores were *Affective Attitude* and *Perceived Effectiveness*, while constructs with the lowest median acceptability scores were *Burden* and *Ethicality* (Fig. 1).

3.3. Summary of qualitative themes and integration with quantitative data

Based on eight theoretical constructs, including the more recently proposed *Perceived Safety & Risk* construct,³¹ 16 themes were included in the final framework matrix. Theme labels were constructed to capture valence, indicating whether participants expressed positive, negative, or mixed views about the acceptability of the PROTECT intervention. There was complete agreement between the quantitative and qualitative findings for the *Affective Attitude* and *Perceived Effectiveness* constructs (Fig. 1) as all themes were positive. These findings indicated that participants generally liked the PROTECT intervention and understood how it could influence staff behaviour and improve the care of clinically deteriorating patients. While the median acceptability score for the *Opportunity Costs and Gains* construct was 4 for both workshop- and ward-based components of the intervention, the qualitative data revealed differing participant views on this construct. In this way, the quantitative data were both confirmed and challenged by the qualitative findings. In keeping with our study aim, we devoted more time during focus groups to discussing the TFA constructs that participants rated as less acceptable in the live poll—namely *Burden* and *Ethicality*. By gathering more detailed qualitative data on these constructs, we were able to expand our understanding of why participants' questionnaire scores were lower in these areas. Consequently, these constructs, alongside *Opportunity Costs and Gains* (where participants' views varied), form the focus of the narrative summary that follows. During analysis, the importance of the *Perceived Safety*

	Theoretical Constructs							
	<i>Affective Attitude</i>	<i>Perceived Effectiveness</i>	<i>Intervention Coherence</i>	<i>Self-Efficacy</i>	<i>Opportunity Costs & Gains</i>	<i>Burden</i>	<i>Ethicality</i>	<i>Perceived Safety & Risk</i>
Median acceptability scores (1-5)	5*, 5†	5*, 5†	4*, 5†	4*, 5†	4*, 4†	4*, 2†	2*, 2†	-
Themes	1. PROTECT is good (+) 2. PROTECT is familiar or like usual practice (+)	3. PROTECT may have a positive impact on practice (+)	4. PROTECT may improve awareness and understanding of the consequences of (in)appropriate care (+) 5. PROTECT may improve communication related to clinical deterioration (+) 6. PROTECT is a good fit to address issues in practice (+)	7. Staff will be able to engage in the PROTECT workshop (+)	8. Engaging in PROTECT requires staff to give up time they could be devoting to other work (-) 9. PROTECT is valuable or needed (+) 10. PROTECT does not interfere with other priorities as its components are part of the job (+)	11. Changing behaviours targeted by PROTECT will (not) require effort (+/-) 12. It requires time and effort to prepare sites to implement PROTECT (-)	13. PROTECT may make staff reflect on the ethicality of inappropriate care (+/-) 14. PROTECT has (no) ethical consequences in its focus on improving care related to clinical deterioration (+/-)	15. PROTECT workshop may induce strong emotions or trigger difficult memories (-) 16. Staff may not feel psychologically safe to share concerns or experiences around clinical deterioration, encouraged by PROTECT (-)

Key:

Median acceptability scores range from 1 = very unacceptable to 5 = very acceptable

*Relates to workshop-based components of PROTECT, †Relates to ward-based components of PROTECT

‘+’, ‘-’, or ‘+/-’ symbols indicate whether quotes within the theme reflected greater, lesser, or mixed views of intervention acceptability

Constructs with a solid outline are original TFA domains (included in the questionnaire). The construct with a dashed outline was not included in the questionnaire but was used for deductive coding.

Fig. 1. Joint display of findings including theoretical constructs, median acceptability scores, and themes. PROTECT: Promoting Recognition Of deterioraTion and EsCaTion of care; TFA: theoretical framework of acceptability.

and Risk construct became evident justifying why it has also been summarised in greater depth. A full overview of the themes developed within each construct, alongside example quotes, is presented in [supplementary file 4](#).

3.4. Burden

Themes within this construct related to both the effort required to engage with specific intervention components and the effort to prepare hospital sites to implement the intervention. Participants described several sources where effort would be required to engage with the intervention including reflecting on practice in the workshop, restructuring ward routines, and changing how staff members communicate with one another (e.g., challenging less appropriate care and providing positive feedback).

"I found when I'm looking at the ward-based components, there's a lot of factors that are going to be making it difficult to be practicable", RN1, site 3.

By contrast, participants also spoke about how it should not require much effort to engage with the PROTECT intervention as its components reflected parts of their day-to-day work.

"No [the ward-based component] wouldn't take a lot of effort. If it's—I think, like the whole point is that it shouldn't—your job shouldn't be an effort", HCA1, site 2.

Preparing the hospital to implement the PROTECT intervention was also perceived as requiring time and effort. Aspects discussed as requiring effort included scheduling staff to attend the workshop, setting up safety huddles so they are carried out consistently, and developing staff champions.

"Making a rota and having nine HCAs on the floor. It would take a lot of effort for me to say I'm going to take this person off there", RN1, site 1.

3.5. Ethicality

Participants primarily focused on how engaging with the intervention could prompt staff to reflect on the ethicality of their usual practice, rather than the ethicality of engaging with PROTECT itself. Participants spoke about how the intervention could raise awareness of the moral imperative for staff in managing clinical deterioration, prompting reflection on whether their usual care met ethical standards.

"Moral or ethical, I was thinking of like for those who don't actually record the resps [respiratory rate], and just put, 17, 16. Is that a true reflection? Are you being honest? Are you actually putting down the correct documentation? Will the patient be treated properly? Will any issues be addressed? So, I was thinking more along that line of honesty", HCA2, site 2.

Several participants indicated that there were no moral or ethical consequences to the PROTECT intervention as its components align with the expectations of their job role and that it would not have ethical consequences different to usual practice.

"I feel like the ward-based component, a lot of this should be ingrained. A lot of this is the job", CCON2, site 1.

An aspect of the PROTECT intervention that participants suggested had ethical consequences was encouraging staff to challenge colleagues about potentially inappropriate care. Participants noted that this could be intimidating, particularly for junior staff, who might struggle to question more senior colleagues. Some participants spoke about how the intervention's focus on adhering to NEWS2 could introduce ethical dilemmas, such as how to respect patient autonomy when they refuse vital signs.

"Thinking a patient [with new confusion] says to you outright, 'I don't want a set of obs [observations] done', but they've got a respiratory failure and actually the respiratory rate's high. Is it then ethical?", CCON2, site 1.

3.6. Opportunity costs and gains

Within this construct, themes highlighted both potential costs and gains of engaging with the PROTECT intervention. Participants spoke about how engaging with PROTECT might reduce the time available for other work activities. Specifically, attending the workshop and engaging with ward-based components (e.g., building the champion role) were seen as taking time away from other tasks, raising staffing and safety concerns.

"In my ward, in particular, we have very complex patients and when you have a lot of workload building, it's difficult to find that time that we're talking about", RN1, site 3.

Some emphasised that if implemented poorly, the intervention could interfere with other duties. Participants spoke about the importance of the PROTECT intervention being prioritised sufficiently to be implemented successfully. Suggestions to support this included ensuring the workshop is advertised appropriately and not scheduled on a clinical day for staff, having cover for staff working on wards to attend the workshop, and having organisational support.

"Sometimes meetings do come up, but it's how you, you know, communicate with the service. Ask me to attend that meeting and tell them that this is very important for me to attend", HCA2, site 2.

Many participants felt that the PROTECT intervention aligned with existing priorities, particularly patient safety, and highlighted the need for interventions to improve the use of NEWS2.

"[PROTECT is] something completely vital in this day and age, where we look at something like the NEWS scoring system", CCON3, site 2.

Participants also discussed how components of the PROTECT intervention are part of their typical job and thus were not seen as interfering with other priorities.

"I mean, observations are being done [...] we're just asking them to be done more accurately [...] organising safety huddles, they're already being done [...] from my point of view, this is, doesn't really impact on your work life", CCON1, site 2.

3.7. Perceived safety and risk

Themes in this construct were related to the potential for the workshop component to cause emotional harm and how staff may not feel psychologically safe to share experiences in reflective discussions about clinical deterioration. Many aspects of the

workshop that encourage staff to reflect on inappropriate care were highlighted as having the potential to cause distress or trigger difficult memories, including the reflective activities, considering future regret, and impactful videos about the consequences of delayed escalation of care.

"Some of the scenarios, they might be familiar with, and they may have been in a similar situation which they encountered in their working life. They might find the kind of sometimes might be kind of they went through a stressful situation like that they went through and trigger their memories", CCON2, site 2.

Some participants worried about staff burnout and for the workshop to lead staff to feel guilty about their practice. Participants highlighted the importance of creating a safe space, ensuring facilitators are mindful of the potential for recipients to experience emotional distress, briefing participants on what to expect from the workshop, and giving them an opportunity to ask questions in advance.

"[You] might be pulling quite stressed, burnt-out staff into an intervention from busy wards where they feel that they're not coping anyway ... It'd be good, like pregame like to pregame them a little bit and give them a warning shot as to you know, how they're—because you're asking them to be vulnerable, aren't you?", CCON1, site 1.

Despite these concerns, several participants saw the reflective activities from the PROTECT workshop as potentially powerful strategies to induce behaviour change.

"Because you're reflecting on things that happen or outcomes for your patient, then that's a powerful learning tool" CCON2, site 3.

"The pros outweigh the cons [of providing details of real-life case studies in which an adverse event occurred], but we just must be mindful of the cons as well". RN1, site 3.

4. Discussion

The PROTECT intervention was developed to support nursing staff to enact a cluster of behaviours that could improve care for clinically deteriorating patients. We issued questionnaires informed by the TFA using a live poll and conducted three focus groups using a topic guide—also underpinned by the TFA—to prospectively explore the acceptability of the PROTECT intervention to 19 nursing staff members who were potential end-users of the intervention. Using mixed methods to examine acceptability prior to delivery (i.e., anticipated acceptability) has provided information that could be used to refine the intervention and inform an implementation strategy.

In a polling task, participants of our focus groups rated both workshop- and ward-based components of the PROTECT intervention as acceptable or very acceptable in five of the seven TFA constructs (*Affective Attitude, Perceived Effectiveness, Intervention Coherence, Self-Efficacy, Opportunity Costs, and Gains*). Broadly, this signals that our diverse group of participants understood and appreciated the intervention design and believed in its potential to improve the care of clinically deteriorating patients. From their conceptual framework of "implementability" of healthcare interventions, Klaic et al.²⁹ recommend that acceptability be assessed in the research context and that progression to intervention delivery should follow if acceptability is adequate. Our findings suggest that the PROTECT intervention is sufficiently acceptable to progress to piloting in the acute ward setting.

Piloting would enable us to explore acceptability of PROTECT to those who have experienced the intervention rather than assessing anticipated acceptability,³⁰ as we have demonstrated in this work. A pilot study would also enable us to explore other components of implementation including fidelity and, subsequently, feasibility²⁹ and to make further refinements before preparing to evaluate the impact of the PROTECT intervention on patient outcomes.

The TFA constructs rated lowest by our participants for both the workshop- and ward-based components of PROTECT were *Burden* and *Ethicality*. The same two constructs were also reported as problematic in an acceptability study, underpinned by the TFA, nested within a feasibility trial to evaluate a temperature management strategy for critically ill children.³² Collectively, our findings suggest that these two constructs may be particularly pertinent when considering implementation of complex interventions in acute and critical care settings where staff must navigate competing priorities and undertake complex work that is physically, cognitively, and ethically demanding.³⁸ Despite a willingness to engage with the PROTECT intervention, several of our participants identified potential implementation challenges related to lack of staff, high workload, and competing priorities. Strong leadership, a conducive culture, and appropriate staffing levels are required to ensure nursing staff can adequately engage with patient safety interventions such as PROTECT.³⁹

The addition of *Perceived Safety and Risk* alongside other TFA constructs has been advocated for exploring the acceptability of interventions implemented in healthcare environments.³¹ This construct has been used in acceptability studies to code data related to the perceived risks of *physical harm* from engaging with interventions including a novel surgical pathway³¹ and a physiotherapist-led prone positioning bundle for the ICU.³³ From this work, we have illustrated how the *Perceived Safety and Risk* construct may be applied more broadly to elucidate risks of moral injury and threats to psychological safety from engaging with patient safety interventions.

The most contentious elements of the PROTECT intervention were the proposed workshop-based components that involve prompting nursing staff to imagine the potential consequences and/or their feelings, should a patient come to harm due to afferent limb failure. Several participants raised concerns about the *ethicality* of these reflective components and felt that they could create distress in recipients by triggering memories of patients they had cared for and situations where they may not have been able to provide optimal care and afferent limb failure occurred. These findings are broadly consistent with a wider body of literature describing second-victim phenomenon. The term "second victim" refers to healthcare professionals who are psychologically affected when a patient in their care comes to harm.⁴⁰ In the context of afferent limb failure, the clinically deteriorating patient who does not receive optimal care and their family are the first victims, while the healthcare staff involved in their care are the second victims.⁴¹ While the term itself has been criticised, there is an expanding body of literature reporting the effect of being a second victim and exploring approaches to mitigate its negative impact on staff wellbeing and retention. Broadly, a theme across the body of literature is that staff involved in a patient safety incident should be provided with opportunities to discuss and reflect upon it in a supportive environment⁴² to maximise learning and reduce the risk of further patient safety incidents and ongoing distress and absenteeism.

Prompting reflection on clinical deterioration events is associated with a degree of risk, as articulated by our focus group participants. However, it is conceivable that if the reflective activities from the workshop components of the PROTECT

intervention are facilitated effectively, and a high level of support is provided, they could impact positively on intervention recipients. The challenge from an implementation standpoint will be ensuring that the same high level of support is available to all ward nursing staff who attend the PROTECT workshop. If it is not practical to consistently provide this level of support, it may be preferable and safer to remove the less-acceptable elements of the intervention rather than risking harm to some intervention recipients. Focusing on specific BCTs (Table 1), the BCT participants highlighted most frequently as problematic was *Induce Anticipated Regret*. This BCT works by modifying *beliefs about consequences*, that is, modifying recipients' perceptions of what will be achieved or lost by enacting the relevant behaviour/s.⁴³ The *Consider Pros and Cons* BCT has the same reported mechanism of action⁴³ but was not considered as controversial by our participants. Practically, this means we could remove the *Induce Anticipated Regret* BCT to improve acceptability with the assurance that the *Consider Pros and Cons* BCT will target staff behaviour through the same broad mechanism of action ensuring the theoretical integrity of the intervention is maintained.

4.1. Strengths and limitations

To the best of our knowledge, this is the first example of the TFA being used to empirically examine the acceptability of a theory-based intervention that has the broad intent of improving care of clinically deteriorating patients in acute hospitals. We used a methodologically innovative approach delivering an online poll immediately before a focus group discussion to rapidly identify which TFA constructs participants considered less acceptable. This enabled us to explore the less acceptable components of PROTECT in greater depth and identify opportunities to refine the intervention to increase acceptability. While this may have limited our findings in some areas (i.e., acceptability constructs with higher acceptability score were not explored in depth), we argue that these methods maximised productivity enabling us to meet our aim and objectives in a relatively short focus group. Given our participants were all frontline nursing staff with busy work schedules, we consider this a strength.

Broadly, we achieved our aim of recruiting a relatively diverse sample of potential providers and recipients of the intervention to participate in a focus group. However, we were only able to recruit two HCAs from a single site compared to 17 RNs. Consequently, it is very likely that the views of these important stakeholders are less well reflected in our findings. Similarly, we did not include ward doctors in our sample. While ward doctors are not end-users of the PROTECT intervention, it is well reported in the international literature that medical staff members frequently provide the initial response to a clinically deteriorating patient once care has been escalated.¹¹ Consequently, it is plausible that delivery of this intervention will impact on their workload. The small number of HCAs and lack of medical staff in our sample are noteworthy limitations of our work. Looking forward, our plan is to assess intervention acceptability longitudinally while piloting the intervention on acute wards. During this proposed research, we will ensure purposeful recruitment of HCAs and ward-based doctors to ensure their views are captured and used to further refine the intervention and the implementation package.

5. Conclusion

We used a theory-based approach to explore the prospective acceptability of PROTECT—a behaviour change intervention that aims to improve care of clinically deteriorating patients. Broadly, intervention components for delivery to nursing staff in a

workshop and in the acute ward setting were found to be (very) acceptable by potential end-users. Consistent with other published research, concerns were raised about the physical, cognitive, and emotional burden of engaging with an intervention that aims to support care of critically ill patients. We offer new insights into the potential risks and benefits of activities where nursing staff members are prompted to reflect on their practice in caring for clinically deteriorating patients and illustrate how this may be reconciled through the removal of specific intervention components considered less acceptable. From previous research, we demonstrated that it is possible to use a theory-based approach²⁴ to model a complex intervention to improve care of clinically deteriorating patients. In this research, we have deepened our understanding by using a theoretical framework to explore prospective acceptability of the same intervention. Our work illustrates how theory may be applied sequentially and at different stages of a research program that focuses on designing and refining a behaviour change intervention. Further research is required to understand the acceptability of the intervention following delivery in a healthcare setting and to explore the fidelity and feasibility of implementation.²⁹

CRedit authorship contribution statement

Duncan Smith: Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Stephen McIntyre:** Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing – review & editing. **Man-deep Sekhon:** Validation, Writing – review & editing.

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Declaration of competing interests

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Supplementary Data

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