STUDY PROTOCOL

Co-developing, piloting, and evaluating a translational simulation (TS) delivery model for the promotion of psychological trauma-informed care (TIC) to improve service delivery within acute hospital settings: A Research Protocol

[version 1; peer review: 1 approved, 1 approved with reservations]

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Methods: Underpinned the Institute for Healthcare Improvement (IHI) Model for Improvement we will (i) co-design a TIC improvement programme for use in acute hospital settings using translational simulation (TS) approaches, (ii) implement TS4TIC in two acute hospital settings, and (iii) co-evaluate the effectiveness and acceptability of TS4TIC using co-defined outcome, process, and balancing indicators measured across iterative Plan, Do, Study, Act (PDSA) cycles.
Expected Outcome: The project's completion will result in a co-designed, open access *TS4TIC Toolkit*, consisting of a suite of TS scenarios and accompanying monitoring and training resources to guide the adaptation of this approach for use in other acute healthcare settings nationally and internationally.

Keywords

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This article is included in the Public and Patient Involvement collection.

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List of abbreviation

ACEs: Adverse Childhood Experiences

AIR: Adverse Incident Report

AMAU: Acute Medical Assessment Unit

CHI: Children's Health Ireland

CNMs: Clinical Nurse Managers

COVID-19: Coronavirus Disease 2019

DPIA: Data Protection Impact Assessments

DPO: Data Protection Officers

ED: Emergency Department

GDPR: General Data Protection Regulation

HHPA: Homeless Health Peer Advocate

HRB: Health Research Board

HSCP: Health and Social Care Profession.

HSE: Health Service Executive

IHI: Institute for Health Improvement

IHS: Inclusion Health Services

MMUH: Mater Misericordiae University Hospital

NDA: nondisclosure agreement

PDSA: Plan, Do, Study, Act

PPE: Personal Protective Equipment

PRG: Patient Representative Group

QI: Quality Improvement

RCPI: Royal college of Physicians of Ireland

RCQPS: Research Collaborative in Quality and Patient Safety

SEM: structural equation modelling

SJH: Saint James Hospital

TCD: Trinity College Dublin

TIC: Trauma Informed Care

TS: Translational Simulation

TS4TIC: Translational Simulation for Trauma Informed-Care

WP: Work Package

Introduction

Global estimates suggest that 70% of the general population have experienced at least one psychologically traumatic event in their lifetime, with 30.5% experiencing four or more events (Benjet *et al.,* 2016). When these traumas occur in childhood, in the form of physical, sexual and/or emotional abuse and/or profound neglect, bullying, witnessing war, community violence, as well as conditions such as drug abuse, spousal violence, and criminal activity in the household, they are referred to as adverse childhood experiences (ACEs) (WHO, 2020), (Felitti *et al.,* 2019). ACEs and frequent trauma exposure throughout the life course are associated with life-long negative physical and mental health effects (Lambert *et al.,* 2017), including a higher risk of auto-immune disorders, cardiovascular disease, and psychiatric conditions (Deschênes *et al.,* 2021; Dube *et al.,* 2009). More than half of people who seek psychiatric care have been assaulted, abandoned, neglected, raped as children, and/or have witnessed violence in their families (Van der Kolk, 2015). Trauma exposure is thus associated with relatively frequent hospitalisation and contact with emergency and other acute health departments, at considerable human and economic cost to Ireland's health system. Accordingly, acute hospital settings represent settings where hospital staff are in frequent contact with individuals who have experienced psychological trauma.

For those with a history of psychological trauma, accessing health services can be a triggering experience, which can manifest as challenging interactions between patients and staff, patients delaying or avoiding seeking care, which, in turn, can lead to patients being excluded from the service (O'Carroll & Wainwright, 2021), and overall poorer patient outcomes. Likewise, staff within health care services may have experienced their own psychological trauma, either in their personal lives (primary trauma) or through the course of their work (secondary trauma). Healthcare staff also face problems related to insecure employment contracts, burnout, moral injury, long working hours, fast-paced work, a shortage of health and care personnel, and the rise of administrative tasks (Kreh *et al.,* 2021; Lin *et al.,* 2021). Consequently, healthcare staff and systems alike are particularly vulnerable to critical events, such as the COVID-19 pandemic.

The COVID-19 pandemic resulted in elevated levels of patient and family distress related to disrupted visiting and end of-life experiences, anger at healthcare acquired COVID events, delays in treatment of non-COVID-19 conditions, all of which were likely compounded by a lack of face-to-face communication with healthcare providers (Fegert *et al.,* 2020; Isasi *et al.,* 2021). Given the noted psychological impacts of COVID-19 among patients and hospital staff (Billings *et al.,* 2021), there has never been a more pressing need to address emotional and psychological trauma within interactions between patients and staff (O'Carroll & Wainwright, 2019).

One promising avenue through which to mitigate the potentially deleterious effects of psychological trauma in health care settings is through the application of trauma-informed care (TIC) approaches. Within Hospital Settings, TIC has emerged as an important, low-cost, scalable strategy to improve experiences of people accessing care services (Muskett, 2014) and improve staff well-being, and has been widely applied in other fields (Maynard *et al.,* 2017) (e.g., education, child and family welfare, within prison systems, and among asylum seekers). Precipitating the development of TIC was the recognition that the indiscriminate use of certain practices (e.g., coercive practices, physical restraints prejudice) can be re-traumatising for individuals seeking health care services with traumatic histories (Carter, 2007). Improving quality of care and the overall patient experience therefore hinges on developing healthcare staff's understanding of the prevalence and

impact of psychological trauma and coming up with strategies to reduce potentially harmful interactions between those seeking health services and those delivering them (Emsley *et al.,* 2022).

Providing TIC requires that health care organisations invest in workforce and professional development as well as organisational and practices changes. Unfortunately, few healthcare staff in Ireland are trained in TIC and there remains a clear knowledge gap on the effectiveness and best methods of training in TIC within the healthcare sector (Bruce *et al.,* 2018). Moreover, where TIC is implemented within the health sector, few have placed healthcare staff and patients with lived experiences of psychological trauma at the centre of TIC training design and evaluation (Emsley *et al.,* 2022).

The current research therefore aims to address these gaps by developing a novel, stakeholder- developed, socially innovative improvement programme for TIC within acute healthcare settings (TS4TIC). Central to the development of this improvement programme is combining the well-established Institute for Health Improvement (IHI) model for improvement with a novel healthcare training and improvement technique known as translational simulation (TS). The IHI model for improvement consists of accelerating improvement through iterative cycles of change. The model consistently applies the Deming wheel (also known as the Shewhart cycle or the Plan, Do, Study and Act (PDSA) process). TS uses team-based, in-situ simulation of challenging scenarios to improve patient care and healthcare systems through interventional, testing, and diagnostic functions. TS is co-created by members of the team and, in this instance, patients. By focusing on real clinical problems, such as those regularly recounted by staff and patients in each context, TS can address issues beyond procedural or knowledge-based training to improve and simulate improvement and thus address some of the previously noted challenges in improving healthcare (Dixon-Woods, 2019). The iterative nature of TS further aligns with clinical governance and quality improvement (QI) services in healthcare institutions and, indeed, TS is thought to be most effective when integrated within an institutional QI programme (Dixon-Woods, 2019).

Objectives and deliverables

Taken together, the project aim will be achieved through the completion of the following research objectives: (i) co-design a TIC improvement programme for use in acute hospital settings using translational simulation (TS) approaches (TS4TIC), (ii) implement TS4TIC in two acute hospital settings, and (iii) co-evaluate the effectiveness and acceptability of TS4TIC using co-defined outcome, process, and balancing indicators measured across iterative Plan, Do, Study, Act (PDSA) cycles. Table 1 summarises the deliverables that are expected to emerge from these three research objectives, in addition to two additional management and dissemination objectives:

Methods

Context

St James's Hospital (SJH), Dublin, is an inner-city hospital in a catchment area with a high level of socioeconomic deprivation (Conway *et al.,* 2016; Walsh *et al.,* 2004). Within SJH, more than 10% of people attending the Emergency Department (ED) and/or admitted to acute medical wards are experiencing homelessness or otherwise considered under-served and socially excluded populations (Ní Cheallaigh *et al.,* 2017). SJH's emergency department (ED) and an acute medical admission unit (AMAU) were thus chosen as specific locations identified by both hospital staff and patients as the first touchpoints for many patients with the hospital's services.

Sample size and sampling strategies

The challenges presented by trying to provide care for patients who have likely experienced complex and prolonged psychological trauma are, from our preparatory discussions with SJH staff, felt by all patient-facing staff. Accordingly, the TS4TIC sampling frame is comprised of all staff working in the ED and AMAU, including receptionists/administrators (n=17), security staff (n=55), nurses and health care attendants

Table 1. Summary of deliverables emerging from management, dissemination and research objectives.

	Expected deliverables per objective
Deliverable 2.1	Finalise research protocol and submit to HRB Open Research
Deliverable 3.1	Finalise compendium of improvement indicators
Deliverable 4.1	Make necessary iterations to pre-brief materials, simulation scenarios and TS4TIC Toolkit
Deliverable 4.2	Prioritisation of change(s) to current practices, reflected in a Road Map towards making SJH a 'Trauma-aware/ sensitive Hospital'.
Deliverable 4.3	Manuscript preparation publication(s) describing the results of the evaluation of TS4TIC. Submission of a minimum of two publications to peer-reviewed journals
Deliverable 4.4	Publication of freely available TS4TIC toolkit with accompanying training materials
Deliverable 4.5	Delivery of a workshop on how to co-create and co-deliver research with persons with lived experiences of psychological trauma

(n=145), catering staff (n=4), cleaning staff (n=10), porters (n=4), medical teams (n=73), and health and social care professionals (n=10.5), such as physiotherapists and social workers. All N=318 staff rostered to the ED and the AMUA will thus be informed of the study in months 3-4 and invited to take part in the simulation-based training. Recruitment will be led by members of the existing TS4TIC project team, which consists of representatives from each of these groups, who will act as gatekeepers and invite potential participants to take part in the project. Likewise, collaborators with lived expertise of psychological trauma and those who represent them, who are also represented within the TS4TIC project team, will also be recruited as potential participants.

Study procedures and improvement models

The co-development and subsequent evaluation of TS4TIC will be achieved using a mixed-methods, collaborative approach. Specifically, the IHI Model for Improvement will be used to guide the (i) co-design of a TIC improvement programme using translational simulation (TS) approaches (WP 1), (ii) implementation of TS4TIC in acute hospital settings (WP2), and (iii) co-evaluation (WP3) of the effectiveness and acceptability of TS4TIC using co-defined outcome, process, and balancing indicators measured across two successive Plan, Do, Study, Act (PDSA) cycles.

TS uses team-based, in-situ simulation of challenging staff/patient interaction scenarios to improve patient care and the healthcare systems. Specifically, TS (i) diagnoses safety and performance issues and (ii) delivers simulation-based interventions within relevant context (Nickson *et al.*, 2021). The focus of TS is thus on team behaviours and systems-level learning and change with an increase in individuals' awareness. Consequently, within TS, the importance of both diagnosing and understanding the context and learning in context are stressed from the outset and changes are made to the system following and through each iterative simulation cycle (see Figure 1).

Taken together, the novel combination of TS with the IHI Model for Improvement and Deming's PDSA cycles will allow for the co-development of a TS4TIC improvement programme (Plan), to carry out the TS4TIC scenarios (Do), to observe and learn from the processes and outcomes of TS4TIC (Study), and to determine what modifications should be made to the next iteration of the TS4TIC improvement programme (Act). PDSA cycles were chosen as the preferred methodology as (i) they are highly compatible with the stages of TS (Goodyear-Smith *et al.*, 2015) and (ii) when used correctly, they present an externally valid and pragmatic scientific method for testing changes in complex systems (Braithwaite *et al.*, 2018; Taylor *et al.*, 2014). Moreover, while recent calls (Nickson *et al.*, 2021) have been made to combine TS with PDSAs to achieve greater system change, to the best of our knowledge, this is the first study to trial this approach (see Figure 2).

The IHI model of improvement figure was adapted by converting the improvement steps to black and white for a clear readability. The PDSA circle and the model for improvement phases in the table above it remained unchanged.

Important to note here that consistent with participatory approaches, all research procedures are subject to change as a result of ongoing learning and extensive participant consultation. And while preliminary discussions with key stakeholders' groups took place to inform the initial design of the project, we acknowledge the possibility of changes occurring to this

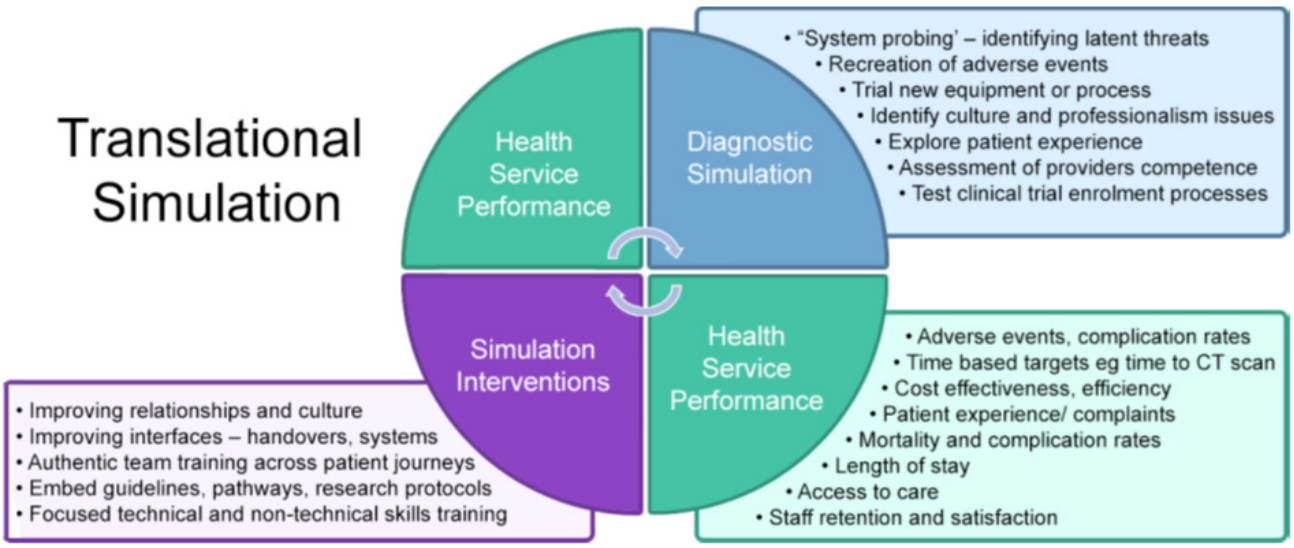

Figure 1. Stages of implementing translational simulation has been reproduced with permission from (Brazil, 2017).

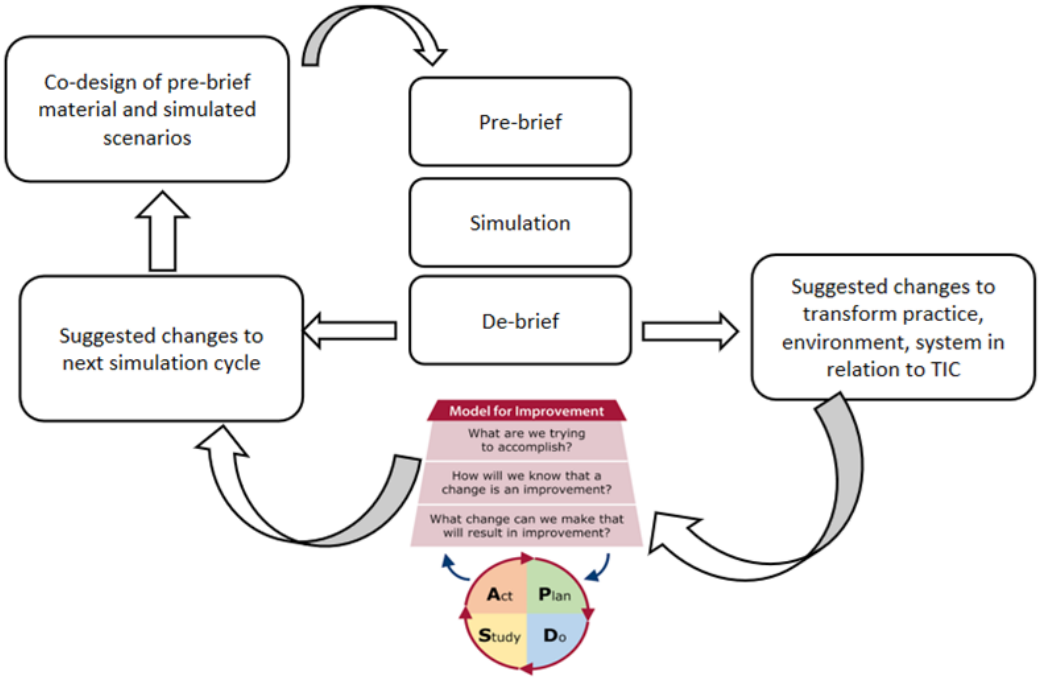

Figure 2. Adapted from the Institute for Health Improvement (IHI) model for improvement.

study's protocol as the research unfolds. In its initial design, however, TS4TIC's research objectives and deliverables are expected to be achieved through the completion of three research-specific work packages (WP1-3). The activities planned under each of these work packages are described in greater detail below:

Work Package (WP) 1: To co-design a translational simulation-based trauma-informed awareness, training, and improvement programme (TS4TIC) for use within an acute hospital setting

PDSA Cycle 1, Step 1 - Plan

Comparable to the diagnosis stage of TS, the first PDSA Cycle will focus on co-designing (i) scenarios to include in the initial version of the TS4TIC improvement programme (towards achieving research objective 1) and (ii) the evaluation procedures to assess the impact and acceptability of implementing the TS4TIC improvement programme (towards achieving research objective 3). In addition to the planning already underway as a result of early engagement with collaborators, further activities that will take place during PDSA Cycle 1, Step 1 include:

(1.1) Completion of a scoping review (Month 4) to clarify: What do we mean by trauma-informed care within acute hospital settings? This review will be used to (i) improve conceptual clarity and (ii) ensure a shared understanding of TIC amongst the study team.

(1.2) Completion of an internal review of existing quality and safety issues related to psychological trauma within SJH, delivered in Month 6. The internal review will be achieved through (i) a review of existing Adverse Incident Report (AIR) data and historic patient experience feedback data (Months 2-3) and (ii) we have hosted our first of five Workshop Series with participants (Months 4-6). The content of TS4TIC will thus be identified through 'system probing' (Brazil, 2017) approaches, where latent threats are identified, adverse events are recreated, culture and professionalism issues are identified, and patient experiences are explored.

(1.3) Using the results from the scoping review and internal review, we will co-design pre-brief materials, with accompanying co-designed simulation scenarios. Again, participant consultations during a second workshop hosted in Months 5-7 will ask: Which of these challenge(s) do we prioritise solving to achieve measurable improvement? Consistent with TS approaches, possible challenges may include issues with relationships and culture, handover systems, team training, guidelines, pathways, and technical and non-technical skills. These suggested challenges will thus inform the content of 15-20 participant-driven simulation scenarios designed to highlight the importance of psychological trauma-awareness/sensitive leading to TIC. The simulation scenarios will particularly focus on 'diagnosis', e.g., identifying system factors along the patient journey from the door of ED to the AMAU which impact negatively on the experience of care for patients

with lived experience of psychological trauma. These may include challenges with tasks, tools, technologies, individuals, team, organisation and environmental factors. Together, these pre-brief materials and accompanying scenarios will form an initial version of the TS4TIC Toolkit.

(1.4) Once the initial content of the TS4TIC Toolkit is developed, we will identify which facilitators, participants, and observers are most appropriate to take part within each co-designed scenario (Month 7). Here, we ask: Which stakeholder(s) should be represented within each co-designed scenario? Different scenarios may, for example, require the participation of various staff including security, reception, triage nurse, doctor, nurses, Health and Social Care Professionals (HSCPs), and porters, among others. Careful attention will be paid to ensuring ethnicity and gender balances appropriate representation across the scenarios. The inclusion of hospital staff as co-applicants will ensure that scenario facilitators, participants, and observers are easily and rapidly engaged.

(1.5) A set of common evaluation measures for use as part of TS4TIC's co-evaluation procedures (i.e., in fulfilment of research objective 2) will be agreed upon. This activity thus asks: What changes, or degree of change, would we need to observe to deem the TS4TIC intervention a success? Consistent with the TS systems approach, participants will be encouraged to draw on the results of the scoping review and internal review, to develop indicators of success, including indicators of effectiveness and acceptability, at individual (i.e., service user, service provider), team, unit, organisational, and system levels. In addition, indicators will be developed as part of process, outcome, and balancing (i.e., knock-on effects or unintended consequences to other parts of the health system) evaluations, again co-designed from the outset with both Socially Excluded Persons (SEP) and Health Care Workers (HCWs) involvement. These indicators will thus inform the measurement tools adopted throughout the evaluative component of TS4TIC (i.e., in fulfilment of research objectives 2 and 3) and will eventually inform the development of the TS4TIC Compendium of Improvement Indicators as a component of the TS4TIC Toolkit.

(1.6) A baseline assessment will take place during Months 8-9, based on the indicators co-identified and described under Activity 1.5, will take place with all participants prior to the commencement of any simulation-based activities.

WP 2: To iteratively implement TS4TIC in an ED and AMAU setting

PDSA cycles of improvement will take place. Here we give an outline of what the first two cycles might look like. Further cycles-within-cycles will also emerge through the research.

PDSA Cycle 1, Step 2 - Do

(2.1) Finalised research protocol is being submitted to HRB Open Research, for consideration as an open access publication.

(2.2) Implementation of the scenarios, co-designed under Activity 1.3, will take place within SJH between Months 10-12, at locations and times agreed in advance. Aligned with TS approaches, the four main types of learning targeted by the scenarios will be: Individual, Team, Unit-Level and/or Organisational learning. Each of these learning levels will therefore be reflected in our evaluation (see: PDSA Cycle 1 - Step 3 - Study). Implementation of these scenarios will follow a general format, aligned with broader TS approaches, as outlined below. Approximately 7-10 participants and at least one actor will take part in each scenario, with each scenario lasting 20 minutes. The scenarios will take place in or adjacent to the clinical spaces. It is envisaged that approximately 15-20 scenarios will be run in this step.

Scenarios will run as follows:
Firstly, all scenarios will include a safety check, whereby clinical nurse managers (CNMs)/shift leaders will be identified and will be asked to confirm that they agree for the simulation to proceed, and staff participation will also be confirmed. Consistent with TS principles, this ensures that simulation scenarios offer a safe place for participants, allowing behaviours and practices to take place without interfering with departmental work or procedures, while also ensuring staff and patient privacy. A final safety check to ensure that there are no potential serious risks from proceeding (e.g. that staff are not required for a major emergency) will be done before commencing, in order to create a psychological safe environment for all stakeholders (Rudolph *et al.,* 2014). Participants will have been asked to sign a nondisclosure agreement (NDA) and the importance of confidentiality will be reiterated before the scenario begins, to prevent information on this study from being shared with others which ultimately protects the confidentiality subscribed to in this intervention.

Secondly, each scenario will follow a 5/7/8 Model, designed as a total of 20 minutes of learning. As part of the 5/7/8 Model, the first five minutes are spent completing a simulation pre-brief, which might include introductions, a discussion of the objectives, roles, and expectations of the simulation, a confidentiality reminder, a reminder of the resources available should a participant become distressed, and the completion of a 'fiction contract', whereby the latter involves seeking a voluntary contract from the learner, or participant, to act as if the simulation were real. The next seven minutes are then spent in the simulation, whereby all participants act in their authentic roles. For ethical reasons, we envisage that actors with lived experience of social exclusion will act the part of patients with lived experiences of trauma. Pre- and de-briefing and psychological support for the actors and health staff will be provided by the co-authors. With the permission of participants, all simulations will be video recorded for data collection purposes. Participants are given the opportunity to pause and repeat parts of the simulation if desired (i.e., Time Out).

Finally, the last eight minutes are spent on reflective practices and recapping what occurred during the simulation (Eppich & Cheng, 2015). The facilitators will clarify that the

reflective sessions or practices focus on systems rather than individuals, and the analysis phase will ultimately be used to focus on a variety of performance domains which may include decision-making, communication, resource utilisation, situational awareness, and teamwork. The debrief, as with other elements of the simulation, remains confidential within the team. During the debriefing and recap, participants (including actors) will be asked to summarise the case, identify things that went well, areas and opportunities for improvement, and points for actions and responsibilities. Moreover, participants will be asked to reflect on (i) what can the team learn? (ii) what can the unit learn? and (iii) what can the hospital or organisation learn? Finally, participants will be asked to reflect on how the simulation may have differential implications for men and women, ensuring that gender is considered across the various scenarios. The debriefing and recap will also be used to inform future TS cycles, such that the scenarios themselves can also be further adapted to maximise the learning experience. In this way, the TS cycles very much mirror the PDSA cycles, as complementary approaches.

Smaller improvement projects will fall out of the TS and these will be run through smaller iterative PDSA cycles where appropriate.

WP 3: To co-evaluate the effectiveness and acceptability of TS4TIC in improving quality of care within an acute hospital setting

PDSA Cycle 1 - Step 3 - Study

Co-evaluating the effectiveness and acceptability of (TS4TIC) for use within an acute hospital setting will involve the analysis and synthesis of a series of agreed upon (i) process, (ii) outcome, and (iii) balancing measures across Individual (staff and patients), Team, Unit and/or Organisational levels. Here, balancing measures are included to explore the potential, unintended, or unforeseen effects of introducing TS4TIC, including across the wider hospital system. Step 3 of the first PDSA cycle is thus marked by the following activities:

(3.1) In keeping with co-design principles, researchers and key stakeholders including persons with lived experiences of trauma, front-line staff, hospital and Health Services Executive (HSE) management and the study team, will co-determine how the TS4TIC training is evaluated (Goodyear-Smith *et al.*, 2015). For indicative purposes, we will include a list of *potential* indicators and, where applicable, accompanying validated measures that may be used to assess the efficacy and acceptability of TS4TIC, in fulfilment of our research objective 3. These are, however, subject to change following the outcome of Activity 1.5 (i.e., agreement on a set of common evaluation measures). Ultimately, these indicators will thus form the basis of the TS4TIC Compendium of Improvement Indicators, the initial version of which will be delivered in Month 13.

(3.2) Participants (recruited from a potential N=318 participants) who will have taken part in the baseline evaluation will complete a follow-up questionnaire containing indicators measured using scale-based tools by Month 14.

(3.3) Key informant interviews with individuals taking part in the simulations will take place by Month 15. Interviews will focus on participants' experiences of having taken part in the scenarios, what they found worked to reinforce their learning, and how the process of developing TS4TIC could be improved. Individuals will be asked to provide feedback on TIC patient interactions in the clinical environment following simulation training.

(3.4) Expert interviews (e.g., senior management, the hospital Patient Representative Group (PRG), Patient Experience Lead) will take place with other stakeholders by Month 15, who, after reviewing the recordings of the simulation, will be asked to consider whether and if so, how, the various simulations might be improved in order to enhance individual, team, unit-level and organisational learning. Interviewees will also be asked to consider where, within their existing practices and workflows, might the TS4TIC improvement programme best be implemented.

(3.5) Analysis of observational data collected during the implementation of the various scenarios as part of TS4TIC, including observations made during the debriefing and recap step. Together, data will be used to evaluate learnings of the team, diagnosis of the system, identify any suggested changes to the context, as well as the perceived impact on the quality of the care experience for patients and staff.

(3.6) Data will be analysed using the data analysis methods described under PDSA Cycle 2, Step 3, below by Month 15, and written up across a minimum of two manuscripts for submission to peer-reviewed journals.

WP4: To co-produce and disseminate a TS4TIC Toolkit for the acute hospital sector

PDSA Cycle 1 - Step 4 - Act

Initial results from the analysis of initial outcome, process, and balancing data will then be discussed through:

(4.1) Workshop Series 3 in Months 16-17, which aims to collect and collate feedback and reflection. Specifically, the purpose of these workshops will be to identify suggestions of key practical and procedural changes to current practices emerging from the learnings of the scenarios that participants believe will lead to improvements in quality of care. Here, we ask: What changes do we need to make to improve the delivery of care experienced by patients and staff who have experienced psychological trauma? These changes will be explored using ED patient journeys, which involve several interactions, including with other patients and various staff including security, reception, triage nurse, doctor, nurses, HSCPs, and porters, among others. Possible changes may occur at the level of handover systems, training, guidelines, pathways, and technical and non-technical skill building. These may also include changes to tasks, tools, and technologies.

PDSA Cycle 2 - Step 1 - Plan

A second PDSA Cycle will then take place to further inform and refine the content of the TS4TIC improvement programme.

A key outcome of this step is therefore a revised version of the simulation scenarios for inclusion in the TS4TIC Toolkit, co-produced with continued user and stakeholder involvement. Key questions for all participants at this stage include: What are we trying to accomplish? How will we accomplish it? and how will we know when we have accomplished it? Therefore, whereas the first PDSA cycle was used to generate simulation scenarios based on existing challenges, this second PDSA cycle is 'solution-based', whereby simulation scenarios focus on implementing solutions to the problems identified in PDSA Cycle 1. In keeping with a participatory methodology, and the collaborative nature of TIC, this second planning stage will also include a series of workshops to:

(5.1) Prioritise which change(s) to current practices should be carried out. The purpose of this step is thus to build consensus on the order in which changes need to occur to improve quality of care using a psychological trauma-aware or trauma-sensitive approach with the view of becoming trauma-informed. The outcome of this activity will be used to generate a Road Map for making SJH a "Trauma-Informed Hospital".

(5.2) Make iterations and improvements to the co-designed pre-brief materials and accompanying simulation scenarios. These refined scenarios will thus result in the co-developed TS4TIC Toolkit, in fulfilment of research objective 1. Consistent with TS approaches, these revised simulations will focus on improving systems and processes (e.g., different behavioural approaches, communication styles or workflows), rather than individual or team knowledge and skills, such that learning is *translational*.

(5.3) Where appropriate, we will identify whether changes are needed to the facilitators, participants, and observers to take part within each revised scenario. This may require the recruitment of additional participants to the research.

(5.4) Revising the list of indicators used to determine the effectiveness and acceptability of the TS4TIC improvement programme in order to co-produce the TS4TIC Compendium of Improvement Indicators, as a component of the TS4TIC Toolkit.

PDSA Cycle 2 - Step 2 - Do

(6.1) The second 'do' step of TS4TIC will therefore consist of a series of revised simulation-based scenarios, refined based on the outcomes of PDSA Cycle 2 in fulfilment of research objective 2. These revised scenarios will focus on implementing the solutions identified in PDSA Cycle 1 Step 4 and will again be implemented as described in PDSA Cycle 1 - Step 2.

Importantly, these simulations will be intervention-based simulations and will focus on changing and improving the ED and AMAU systems of care. While some of the prioritised changes will be made possible through simulation; others will be 'Just Do It' type changes; some will require their own PDSA cycles and others still will be notified to the SJH management team as large-scale system changes.

PDSA Cycle 2 - Step 3 - Study

The second 'study' step of TS4TIC will consist of:

(7.1) Re-administering the evaluation measures, as described in PDSA Cycle 1 Step 3, with a particular focus on the longer-term sustainability of TS4TIC and on the implementation of systems-level changes identified as necessary in PDSA Cycles 1 and 2.

Data analysis

(7.2) Analysing data. As evaluation measures will likely include a mixture of quantitative (i.e., scale-based questionnaires) and qualitative (i.e., key informant interviews, focus group discussions) approaches, potential data analysis across outcome, process, and balancing data may include:

Questionnaire data will be analysed using structural equation modelling (SEM) procedures, using a robust maximum likelihood (MLR) (Schafer & Graham, 2002), as an estimation process to assess within arm (i.e., SJH participants) changes over time across the various indicators of success. Data analysis will be done using Mplus Version 8.2 (Muthén & Muthén, 2017). Specifically, within arm changes will be assessed across baseline and follow-up assessments, with a minimum of two assessments and changes over time will be assessed by comparing a null or 'constrained' model where all variable means are constrained to be equal to a second, 'unconstrained' model where means are freely estimated. Improvement in model fit will be tested using the loglikelihood difference test, whereby a significant chi-square (X^2) result is indicative that an unconstrained model is better than the constrained model, meaning that the null hypothesis of equal means can be rejected (Hoffman, 2015). The 'model test' feature in Mplus, which allows constraints to be tested using the Wald X2 test, will then be used to test pairwise comparisons across the assessment periods. Analyses will be conducted considering the stratification and clustering of the data at unit-level (i.e., TS simulation groups) using the 'complex analysis' function.

Interview data will be analysed using content analysis (CA), where the aim is to organise, generate meaning, and produce conclusions based on arrangements of the data. All interview transcripts will be transcribed verbatim and imported into NVivo for analysis. CA was chosen as it can be used to analyse various written data sources and because its methods are flexible and non-epistemologically circumscribed and can therefore be performed within different research traditions (Bengtsson, 2016). Here, CA will be conducted inductively and concerned with identifying common content across the different hospital staff and patient groups and to get a sense of the common preference for specific recommendations such that the results generated are applicable to SJH as an overall organisation, and therefore relevant to other acute hospital settings. First, interview transcripts and observational data will be used to create initial content codes to form a coding scheme, not guided by any theoretical framework, by reading through and taking notes, as an initial, informal coding process. Next, related codes will be merged to form a content category as part

of a broader categorisation process based on them reflecting related ideas or opinions that were discussed across interviews and therefore deemed as relevant themes. The final coding list containing more general and overarching themes and accompanying explanations of each theme will be created and data summarised under these broader themes for the purposes of feeding back to participants.

The results from both interview and questionnaire data will tell us if TIC awareness has potential for improvement through this intervention (Brazil, 2017; Nickson *et al.*, 2021) and ultimately improving patient care and the healthcare system at large. We are hoping to learn also from the results if the intervention can be replicated within other hospitals that include consultations with service users to improve their patients' outcome through a TIC awareness with all hospital staff.

Ethical statement

This intervention has been approved by the School of Psychology, Research Ethics Committee from Trinity College Dublin, University of Dublin [Approval No. SPREC032022-03] and the St James's Hospital (SJH)/TUH joint research ethics committee [Approval No. 2515]. Consent will be obtained from participants either electronically (in the case of the surveys being completed online) or in paper form (in the case of interviews or where surveys are completed in person). Quantitative surveys will be anonymised, and data will only be entered using each participant's unique identification number. Qualitative data will be pseudo-anonymised by assigning respondents a pseudonym and by redacting any references to names, job titles, and specific locations.

Plan for dissemination

Aligned with our anticipated impact and leveraging the interdisciplinarity and cross-sector nature of our wide network of collaborators, our dissemination plan emphasises knowledge translation at a local, national, and international scale across health, educational, academic, and political settings. Accordingly, dissemination of findings arising from TS4TIC as well as the final TS4TIC Toolkit will take place on a continuous basis through our group's ongoing participation across a range of conferences, committees, and associations. This includes, but is not limited to, dissemination at the All-Ireland Inclusion Health Forum, DoH National Patient Safety Conference, the National Emergency Programme and Acute Medicine Programme's annual scientific meetings, National Acute Medicine Conference, Safety in Health Systems network, the UK Faculty of Homelessness and Inclusion Health, and the Royal College of Physicians and of Surgeons of Ireland. Knowledge will also be translated into improved practices for both health and education. This will occur through improved training within the National Emergency Programme and Acute Medicine Specialist Registrar training, among undergraduates in TCD's School of Medicine, and within the post-graduate training and continuing professional development programmes delivered by the Royal College of Physicians and the Royal College of Surgeons of Ireland; through imparting the knowledge of how to conduct TS and related PDSA cycles within ED and AMAU, such that this approach can be sustained within the organisation; through the design and delivery of a publicly available, co-led workshop on 'How to co-create and co-deliver research with people with lived experiences of psychological trauma?' in Month 23, through regular discussion within internal hospital meetings (i.e. Medical and Nursing Grand Rounds, Clinical Nurse Manager Monthly Meetings); and through the growing national and international community engaged in translational simulation (or transformational simulation as it is called in the NHS). Findings will also be shared to inform practices and responses within other acute contexts (i.e., humanitarian emergencies) through the Research Network of the International Federation of the Red Cross Red Crescent-National Societies. Academically, knowledge and findings generated from this work will inform novel theoretical and methodological approaches within the patient safety community. Work will also be presented at the National Patient Safety Conference and results will be submitted for a minimum of three publications within high-impact, Open Access peer-reviewed journals, and disseminated at a minimum of two international health systems conferences (i.e., Health Systems Global). Politically, some co-authors engage extensively with policy makers in the Department of Health (DoH) in Ireland and with politicians at Ministerial level, have given seminars on Inclusion Health (DoH), contributed to policy documents on Inclusion Health and homelessness (DoH), and have engaged with Sláintecare. These channels will continue to be used to ensure the findings of the study are reflected in national policy development.

(7.3) Preparation of co-authored publication(s) reporting on the evidence for the effectiveness and acceptability of TS4TIC, in fulfilment of research objective 3.

(8.1) Results from further analysis of outcome, process, and balancing data will again be discussed to solicit further feedback and reflection sessions. The purpose of these latter sessions will be to identify further changes that need to be integrated into the final version of the TS4TIC Toolkit. This step will thus build on the findings of PDSA cycles 1 and 2 to finalise the translational simulation improvement programme for trauma-informed care (TS4TIC) for improved quality of care experience for both patients and staff in acute hospital settings, in fulfilment of our research aim.

(8.2) If needed, the Quality and Safety Improvement Directorate in SJH will support testing out additional changes in sub-project PDSA cycles. For example, the two cycles may result in the identification of areas that need to be addressed at an organisational level (e.g., organisational wide risks), issues that require intervention at a unit level (e.g., environmental factors), or areas that would benefit from a future PDSA approach. Given that participants will have obtained first-hand knowledge and experience carrying out the PDSA cycles and designing the TS scenarios, they will have the skills required to conduct additional sub-project PDSA cycles outside of the grant period.

(8.3) Publication of the final, freely available, TS4TIC Toolkit and finalisation of accompanying materials (i.e., training materials, compendium of indicators, to an open access platform (i.e., TS4TIC Website) for wider use and uptake.

(8.4) Dissemination of the TS4TIC Toolkit through our network of co-applicants and collaborators.

(8.5) Delivery of a workshop on how to co-create and co-deliver research with persons with lived experiences of psychological trauma.

The above activities will be undergirded by a Management Work Package (WP5) and by a commitment to the highest possible ethical standards (WP6).

4.5 Public and Patient and Carer Involvement

Inclusion and empowerment of people who have experienced trauma and social exclusion is at the core of Inclusion Health (IH), and participatory approaches used in this study include their participation in the SJH, IH, and QI group and the development of the Homeless Health Peer Advocate (HHPA) programme. Key aspects to consider include awareness of the imbalance power dynamic, possible issues with literacy and the need to prove practical and psychological support to persons with lived experiences of trauma to ensure that they are fully empowered to participate (Ní Shé *et al.*, 2019). TS4TIC also addresses the needs of front-line health workers, and they are also involved in all phases of the project. Details of PPI involvement (done and planned) across all work packages are detailed in Table 2 below.

Table 2. Public and Patient Involvement (PPI) Consideration by work package.

Work Package	Public and Patient Involvement
1 (co-Design)	Persons with lived experience of psychological trauma and front-line health staff highlighted the need for TS4TIC. Their views were sought during the writing of the application through formal (small group workshop with HHPAs) and informal mechanisms (informal discussions with health staff in nursing, security, medical, administrative roles). Existing participants who have been recruited through the HHPA programme and are all male, White and Irish. Collaborator RH identified potential participants originating from the Global South and we actively recruited a female to ensure diversity. Health staff and persons with lived experience of psychological trauma co-identified the problems, co-created the simulation scenarios, and decided on evaluation measures in partnership. Persons with lived experiences of trauma will participate in coaching the actors (who themselves will have lived experience of social exclusion) for the scenarios.
2 (Implement)	Building on their engagement in WP1, health staff and persons with lived experience of psychological trauma may act as facilitators and observers across the various simulations and lead reflections and/or be responsible for identifying problems and/or solutions arising in the scenarios. Health staff will participate in the scenarios.
3 (Evaluate)	Health staff and persons with lived experience of psychological trauma will co-determine how the TS4TIC training is evaluated including identifying and ranking indicators of the efficacy and acceptability of the intervention. Health staff and persons with lived experience of psychological trauma will determine questions for interviews and/or surveys of patients and staff and may, if they wish, interview and/or carry out assessments.
4 (co-Produce, Dissemination and Public Engagement)	Health staff and persons with lived experience of psychological trauma will (i) be involved in media coverage and (ii) contribute to the writing and review of the final TS4TIC Toolkit, accompanying training materials, and compendium of Improvement Indicators. They will also contribute ideas and review suggestions for dissemination within the health community and within socially and racially excluded communities, some of whom face discrimination. This may include the HHPAs designing and hosting workshops or information sessions on TS4TIC in community services (e.g. Merchants Quay Ireland, De Paul services, Spirasi, family homeless hubs).
5 (Manage)	Persons with lived experience of psychological trauma and health staff will participate in the Project Steering Committee.
6 (Ethics)	CNC and PM will be responsible for identifying and managing any adverse experiences resulting from participating in TS4TIC. All participants involved in the project will be encouraged to voice any concerns at any stage to the study team, or, if more acceptable, to the HHPA co-ordinator who can act as an independent, confidential support.

Data availability

No data associated with this article.

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Open Peer Review

Current Peer Review Status: ? ✓

Version 1

Reviewer Report 08 November 2023

https://doi.org/10.21956/hrbopenres.15015.r36675

✓ **Alicia Mendez**

Boston University, Boston, Massachusetts, USA

Thank you for the opportunity to read and review this research protocol. This protocol details the implementation of a mixed-methods, community-involved translational simulation/study using trauma informed principles in acute hospital settings. Overall, it is well-written, thorough, and the authors appear dedicated to including and centering all stakeholders in their research and dissemination. I am eager to learn what the results will show. The bulk of my feedback is intended to aid the authors in centering patients/those with lived experience of trauma. As of now, it is not clear that patients are included in the sample and/or stakeholder group. This can be ameliorated by noting earlier in the protocol that they are being included in the sample and by describing more thoroughly who makes up the PRG and those with "lived experiences of trauma."

1. For citations "WHO" and "Felitti," spell out WHO and combine with Felitti into one parenthesis.

2. At the end of this sentence add a citation or two about healthcare workers and vicarious trauma: "Likewise, staff within health care services may have experienced their own psychological trauma, either in their personal lives (primary trauma) or through the course of their work (secondary trauma)." Consider the first three added citations[1-3].

3. In the introduction it says that "TS is co-created by members of the team and, in this instance, patients." Yet, no one on in the sample is a patient. Make it clear in the introduction that your sample will not include patients, but other examples have.

4. Related to point 3, WP3 note that some stakeholders included will have "lived experiences of trauma." This reads like a good opportunity to include patients or people who have sought care at these hospitals – is the PRG included here? Please clarify who this means – does this mean front-line staff or hospital executives who have lived experiences of trauma or someone else? If it does not mean people who have sought care at these hospitals, consider recruiting and including them.

5. Please clarify who is part of the Patient Representative Group.

6. WP2: “Finally, participants will be asked to reflect on how the simulation may have differential implications for men and women, ensuring that gender is considered across the various scenarios.” Please indicate how you will include scenarios with gender diverse individuals (transmen or women, nonbinary people).

7. WP3: Because this study is evaluating trauma-informed work, it is important the research process itself also engage in a reflective process. Alessi & Kahn (2022) provide a good framework for trauma-informed research guidelines for qualitative research. Much of your steps are aligned with their guidelines so including it may aid in justifying your process.

8. 4.5 Public and Patient and Carer Involvement – Not sure why the heading includes the number “4.5”

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Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Trauma-informed care, intergenerational trauma, child sexual abuse, posttraumatic growth

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 01 November 2023

https://doi.org/10.21956/hrbopenres.15015.r36674

?

Patricia M Speck
University of Alabama at Birmingham School of Nursing, Birmingham, Alabama, USA

The authors plan to create a quality improvement project using the method by Deming (PDSA), and involving psychologically traumatized stakeholders from the community to implement trauma informed care in an acute care hospital. The evidence for need is presented and solid and includes seminal evidentiary support as well as current understanding of the relationship between psychological trauma and excellence in provision of care by healthcare workers.

As understood by this reviewer, the intervention is stakeholder input in trauma informed care education, development of policies to support trauma informed care interactions, and simulation training to support behavioral change. Lacking is the definition and expectation of what constitutes trauma informed care behavior or behavioral change or a plan for measurement.

Is stakeholder involvement enough to validate the actions in simulations or is there an evidence based guide on recognition of and interaction with patients experiencing psychological trauma? Since trust is the first principle in trauma informed care, what in the simulation helps establish trust of the patient in the worker pool? How does the patient-worker relationship give voice and choice to the patient pool, who in this case is stated as disadvantaged? What are the methods proposed to support behavioral changes promoting collaboration and empowerment, mutuality, culture, gender, and other patient characteristics?

Without specificity about these particular granular actions and behavioral change on behalf of the worker toward the patient in an acute care setting, education about trauma informed care principles is unlikely to change behavior. Without reported data, this reviewer is recommending more information for future reviewers to be satisfied with the design and method to test worker interventions that support trauma informed care principles and strategies. The quality improvement project is a great start and much needed, not only for our patients but between and among workers. With granular detail for behavioral change measured through observation and stakeholder feedback, the protocol has potential for testing in multiple sites. Respectfully submitted.

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Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Forensic nursing, trauma informed care, trauma and health outcomes

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.