BMJ Open

Evaluating the impact of a ward environment with 20 single occupancy rooms and two four-bedded bays on patient and staff experiences and outcomes in an acute NHS Trust: a mixed-methods study protocol

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To cite: Ataiyero Y, Stimpson E, Hall H, *et al*. Evaluating the impact of a ward environment with 20 single occupancy rooms and two four-bedded bays on patient and staff experiences and outcomes in an acute NHS Trust: a mixed-methods study protocol. *BMJ Open* 2024;**14**:e085528. doi:10.1136/bmjopen-2024-085528

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2024-085528).

Received 19 February 2024
Accepted 28 June 2024

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ABSTRACT

Introduction Traditionally, wards in acute care hospitals consist predominately of multioccupancy bays with some single rooms. There is an increasing global trend towards a higher proportion of single rooms in hospitals, with the UK National Health Service (NHS) advocating for single-room provision in all new hospital builds. There is limited evidence on the impact of a ward environment incorporating mostly single and some multioccupancy bays on patient care and organisational outcomes.

Methods and analyses This study will assess the impact of a newly designed 28-bedded ward environment, with 20 single rooms and two four-bedded bays, on patient and staff experiences and outcomes in an acute NHS Trust in East England. The study is divided into two work packages (WP)—WP1 is a quantitative data extraction of routinely collected patient and staff data while WP2 is a mixed-methods process evaluation consisting of one-to-one, in-depth, semistructured interviews with staff, qualitative observations of work processes on the ward and a quantitative data evaluation of routinely collected process evaluation data from patients and staff.

Ethics and dissemination Ethical approval was obtained from the UK Health Research Authority (IRAS ID: 334395). Study findings will be shared with key stakeholders, published in peer-reviewed high-impact journals and presented at relevant conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A multimethod study using innovative and interdisciplinary approaches to explore the impact of a new ward environment on patient and staff experiences and outcomes.
⇒ Using a mixed-methods approach provides an opportunity to gain rich and meaningful data from patients and staff over three different clinical areas.
⇒ Study findings will inform future hospital design in the research setting and potentially, other National Health Service Trusts.
⇒ Being a single-site study and the sampling technique in qualitative interviews may limit the transferability and applicability of study findings.

INTRODUCTION

Background

Given its commitment to constructing new hospitals, modernising primary care estates and supporting the mitigation of critical safety challenges in the UK National Health Service (NHS),[1] the Department of Health and Social Care earmarked James Paget University Hospitals NHS Foundation Trust (JPUH) for 'seed' funding for the construction of a new hospital between 2025 and 2030.[2] JPUH is one of the seven NHS hospitals affected by the deterioration of reinforced autoclaved aerated concrete (RAAC) materials.[3 4] Hence, to facilitate the effective removal of RAAC from existing clinical areas pending the design and construction of a new hospital, the 'concept ward' was built.

The concept ward is a hospital ward environment with a total bed occupancy of 28 beds consisting of 12 enhanced single rooms, eight standard single rooms and two four-bedded bays.[5] Among other others, the concept ward was also designed with dual bed head supplies for adult intensive care unit patients, a digital nurse call system connected directly to nurses' handheld gadgets, digital infrastructure installed for active management of medical equipment and future proofing for patient tracking, wayfinding solutions, mood lighting, touch down bases with multiroom

Figure 1 3D view of the Concept Ward, a 28-bedded ward comprising 20 single ensuite rooms and 2 four-bedded bays. 3D, three-dimensional.

observation and a well-being garden including outside therapy areas (see figure 1 for the concept ward layout).

The concept ward was built to facilitate the safe evacuation of clinical areas while remedial works are completed in these areas. This provides JPUH a unique opportunity to use the concept ward to inform the design of the proposed wards for the new hospital construction.

Study rationale

Hospital designs play a significant role in achieving high-quality patient care while balancing cost-effectiveness and users' (patients and staff) well-being.[6]

Traditionally, acute care hospitals have a combination of multioccupancy bays and limited single occupancy rooms.[7] However, there is an increasing global trend towards a higher proportion of single rooms,[8] with the NHS particularly advocating for single-room provision in all new hospital builds.[9] This growing shift towards single occupancy rooms has been linked to patients' preferences, with evidence suggesting that patients are likely to experience more privacy, confidentiality and improved dignity.[7 8 10 11] There are also increased prospects for family involvement in patients' care as well as improved infection prevention and control and consequently, reduced infection rates.[8 11 12] More so, healthcare professionals are able to tailor single occupancy rooms to the patients, thereby enhancing individualised care and patients' overall experiences of care.[6] However, a scoping review identified changes to work practices in relation to single occupancy rooms, resulting in less time for direct patient care and lonelier practice.[13] Increased walking distances, concerns for patient safety, quality of care and staffing levels, feelings of neglect and loneliness and reduced patient monitoring and surveillance have also been reported with respect to single occupancy rooms.[13–16]

Current evidence on the impact of wards that are predominantly made of single rooms yet have some multioccupancy bays on patient and staff experiences is limited, with most studies usually focusing on 100% single occupancy rooms. This is an important gap as the hospital environment can be central to patients' overall healthcare experiences, which in turn can impact their physical and/or mental well-being. More so, the hospital ward is a complex system which warrants careful consideration of the impact of the interplay between physical, psychological, social and design elements on patient and staff.[6] This complexity extends to sometimes competing outcomes, highlighting the need for healthcare environments to achieve a balance between the safe provision of healthcare delivery and enabling a productive workspace, with a positive experience for patients, their families[17] and staff alike.

Study aim

This study aims to assess the impact of a ward environment incorporating 20 single occupancy rooms and 2 four-bedded bays by analysing the ward, patient and staff experiences as a whole system, in up to three different clinical areas of care. The specific objectives are to:

1. Establish the effectiveness and impact of using the concept ward in a single acute NHS Trust.
2. Establish and evaluate the feasibility of using the concept ward and ascertain contextual factors that might impact its effectiveness through a mixed-method process evaluation.

To the best of our knowledge, this is the first study to use ergonomics approaches to understand how the work systems and processes in a 'concept' ward environment, across three different clinical areas of care, interact to achieve the outcomes on patient and staff experiences. It is anticipated that findings from this study will be instrumental to the future hospital construction at the research setting and other NHS Trusts.

METHODS AND ANALYSIS

Study design

This is a study protocol for a single-centre, multiward observational study with an embedded convergent mixed-methods process evaluation to ascertain the effectiveness and impact of the utilisation of the concept ward in one acute NHS Trust in East England. This study operates within the postpositivist paradigm, which recognises that multiple realities exist and that pluralistic approaches can be used to address the research aims.[18] This approach aligns with mixed-methods studies for richer and more nuanced understanding of the research aim. To enhance the overall validity and reliability of this study, both qualitative and quantitative research approaches will be triangulated. Triangulation reduces potential biases in any single approach, thereby offering a more robust picture of the study aim.

Study setting

This study will be conducted at JPUH, a hospital providing a range of general acute services and some specialised care to 250 000 residents in East England. Three selected clinical areas of care that are being decanted to the concept ward for at least a 12-week period while their ward areas undergo essential building repairs will be involved in this study.

Study duration

The active study period will commence in the last 2 weeks of the participating wards rotation in the concept ward up to and including 31 October 2024. Both qualitative interview and observational data will be collected in the same week for the three clinical areas rotating through the concept ward, ideally between weeks 12 and 14.

Work package 1: quantitative data evaluation

Objective

To determine the effectiveness and impact of the concept ward on patient and staff outcomes. These will include but not be limited to length of stay (LoS), readmission rate, staff and patient experience, nurse-sensitive indicators (ie, pressure ulcers, enhanced patient supervision) and staff sickness.

Eligibility criteria

No patients or staff will be actively recruited in this work package; it will use routinely collected administrative data, including service evaluation data that is collected as business as usual within the Trust. All eligible routinely collected data will be extracted from the Trust databases and anonymised with the aid of a computer software and exported as comma-separated values files. Only data of patients, and where applicable their parents and/or legal guardians, and staff who were placed on the participating wards will be eligible for extraction as part of this study. The data of people and staff who are in a clinical area that is not exposed to the concept ward and/or outside of the study period will be excluded.

Data collection

Quantitative data will come from three periods: before (prior to moving to the concept ward), during (time spent on the concept ward) and after (left the concept ward and returned to the originally clinical space).

Before period (prior to the move to the concept ward): (control)

Routinely collected administrative (patient and staff related) data, from each clinical area, will be extracted for at least an 8-year period prior to the clinical area moving to the concept ward (ie, 1 January 2015). The exact dates to be extracted over the 8-year period will be determined by the specific dates or period spent on the concept ward for each clinical area. These data will be compared with the during period to assess the impact of the study intervention. In addition, a second set of data that aligns with the postperiod will also be extracted and used to ascertain the impact on patient and staff outcomes of changing physical hospital locations for each of the clinical areas. This will represent the before period for both COVID-19 and moving to the concept ward. A further 30-day data (up to 30 days after moving to the concept ward) will be extracted to allow for readmissions for individuals admitted in the last month prior to the ward's move to concept ward. An 8-year unexposed period was chosen pragmatically to adjust for the impact of COVID-19 and reconfiguration of NHS services during the pandemic.

During period (the concept ward)

The 'during' period, per clinical area, will be defined by the clinical area being moved to the concept ward. The exposure period start date is dependent on the date each clinical area moves into the concept ward. Data will be extracted for the duration of time that the clinical area is in the concept ward. A further 30 days data will be extracted to allow for readmissions for individuals admitted within the overlapping period from the exposure and postexposure phases. The during period will be used to determine the start and end dates in both the preperiod and after period.

After period (once the clinical area leaves the concept ward)

The after period will commence once the clinical area leaves the concept ward and returns to its original ward base. The follow-up period will be for the same time that the ward was relocated from the date of the last day spent in the concept ward. A further 30 days data will be extracted to allow for readmissions for individuals

admitted within the overlapping period from the exposure and postexposure phases.

Data analysis

All statistical analyses will be performed by using STATA 18.0 and/or R software. Standard descriptive summaries will be presented according to the data type and prespecified subgroups including demographic data (ie, age, gender and deprivation) and by clinical area.

Primary outcomes

Hospital LoS and 30 days hospital readmission rates will be the main primary outcomes. LoS is defined as the number of days a patient spends in the hospital during a single admission, including time spent on the concept ward or original clinical ward. Readmission is defined as hospital admission that occurs within 30 days after discharge for the first admission.

Secondary outcomes

The study will also explore the effectiveness and impact of the concept ward on patient and staff outcomes, including but not limited to staff and patient experiences, nurse-sensitive indicators and staff sickness.

Generalised linear models (GLMs) will be used to explore the association between the outcomes and the intervention (ie, spending time on the concept ward). Age, gender, ethnicity, Index of Multiple Deprivation (IMD) and Charlson comorbidity score will be used to adjust for potential confounders. GLMs are flexible statistical modelling techniques for analysing a wide range of data types and distributions similar to the proposed routinely collected data to be analysed. Techniques such as gamma regression for positive continuous outcomes (eg, LoS) and Poisson regression for number of events (eg, readmission, sickness rates). In addition, these modelling techniques allow adjustment for potential confounders and have the ability to model the correlation structure inherent to the data. Univariate analysis will be used to identify variables to be included in a multivariable analysis using a p=0.2 as the cut-off point. Hypothesis tests will be two sided and considered to provide evidence for a significant difference if p values are less than 0.05 (5% significance level).

Work package 2: mixed-methods process evaluation

Process evaluations are conducted to explain any discrepancies between expected and observed outcomes, to understand how context influences outcomes and to provide insights to aid implementation. This work package aims to evaluate the feasibility of utilising the concept ward and ascertain contextual factors that might impact its effectiveness through mixed-method process evaluation.

Underpinning theoretical framework: the System Engineering Initiative for Patient Safety and Concepts for Applying Resilience Engineering models

This study will be underpinned by the SEIPS (System Engineering Initiative for Patient Safety) model, a theoretical model which integrates the concepts of human factors and systems engineering.[19] The SEIPS model offers a robust framework for understanding healthcare work systems, their interacting processes and intended and unintended outcomes.[20] Modern approaches to observing healthcare systems provide researchers with opportunities to capture what is termed 'work-as-done', or everyday clinical work as it is carried out. Successful care is known to be characterised by flexible and adaptive process in the face of multiple complex demand and capacity issues (termed 'resilient healthcare').[21] Hence, this study will also use the CARE (Concepts for Applying Resilience Engineering) model, which provides practical tools to apply insights from resilient healthcare to quality improvement.[22]

Previous work has incorporated the SEIPS elements into the CARE model which guides the study of successful task and process adaptation, thus accounting for both work system complexity and the interactions of different elements.[23] It is anticipated that insights gained from this work package will allow knowledge precipitation on human factors and ergonomics facilitating or impeding the utilisation of the concept ward, identifying how work processes and outcomes can be optimised in subsequent hospital ward design in a bid to enhance the experiences and outcomes of patients and staff.

Design

Using a mixed-methods process evaluation approach, the study will explore the acceptability and feasibility of delivering healthcare while using the concept ward. Data will be collected using three approaches: qualitative interviews, qualitative observational study and quantitative analysis of routinely collected data.

Qualitative interviews

Using semistructured interviewing technique, this study will explore the experiences of clinical staff working on the concept ward, with the aim of identifying (a) the contextual factors influencing patient and staff-related outcomes on the concept ward and (b) the necessary adaptations and adjustments to care that staff make to achieve positive outcomes.

Participant sampling and recruitment

Participants will be recruited based on maximum variation, a purposive sampling technique which ensures the heterogeneity of the study sample,[24] which will include staff of participating wards working on the concept ward during a stipulated study period. Potential participants will include a mix of staff working on the participating wards with varied skill mix and length of experience, including nurses, healthcare assistants, physiotherapists,

Table 1 Quantitative process evaluation

Data source	Data collected
Surveys, or other methods of data collection, undertaken by the Trust to monitor and/or evaluate the concept ward	Views on standards of care by staff and patients; experiences of care, privacy and dignity; utilisation of day room and garden space; effect of lighting and noise on staff and patient well-being; impact of increased digital for call bell system; quality of rest, sleep and activity opportunities; compliments and complaints by patients and their friends/family members.
Staff rotas (E-Roster) and standard operation producers for staffing levels	Clinical and non-clinical staffing model

ward clerks, etc. An invitation email containing a participant information sheet which will advise of the study purpose and participants' rights to participation and withdrawal will be shared with potential participants. To signify interest or clarify any queries they may have, potential participants can complete an initial contact form, providing contact details with which the qualitative researcher could reach them. Alternatively, potential participants could contact one of the research team using the contact details provided in the email.

Participation will be voluntary, and potential participants will be given at least 24 hours to consider their willingness to participate in qualitative interviews and complete an electronic consent form for research records. Interviews will be conducted between the 12th and 14th week of the clinical area being on the concept ward. Data will be collected in the same week for all three clinical areas rotating through the concept ward.

Data collection

Up to 10 one-to-one, in-depth semi-structured interviews with staff will be conducted per participating ward, to explore the process and their experiences of working in the concept ward.[25] Staff would have been exposed to the concept ward for at least 6 weeks to be eligible to participate in qualitative interviews. Interviews will be conducted ideally around the same weeks as observations. An interview schedule underpinned by the SEIPS and CARE models will guide qualitative discussions to ascertain how the work systems and their components interact with one another to influence patient and staff experiences and outcomes. See online supplemental file 1 for the interview schedule.

Lasting up to 60 min, interviews will be conducted either face to face (in a secure location within the study setting) or virtually, depending on logistics and participants' preferences. These will be recorded, audio and video recording for face-to-face and online interviews, respectively. Participants will be given up to 7 days to withdraw their data after which it will no longer be possible as data would have been anonymised and analysis would have commenced.

Data analysis plan

Audio (and/or video) recorded interviews will be transcribed verbatim. Transcripts will be analysed using a framework analysis method, a matrix-based approach which provides a clear and systematic structure from the initial data collection and management through to the development of explanatory accounts specific to the research.[26 27] Framework analysis consists of five interconnected stages from the initial data collection to providing insightful explanatory interpretations.[28] Data will be mapped to the theoretical frameworks underpinning this study (SEIPS and CARE models) to identify patterns, themes and relationships in the data. Data analysis will be conducted independently by two members of the research team, coming together to agree on key themes and resolving any differences thereby, enhancing rigour.

Qualitative observations

A direct non-participant overt observation of work within the concept ward including work system interactions (how teamwork, tools, design, processes are observed in care) will be conducted to assess how these fit with Ergonomic evidence and principles and influence observed patient and staff experiences and outcomes. Only the staff working on the concept ward will be observed in this study; patients will not be directly observed. Where necessary for clarity, staff may be asked questions or prompted to reflect on their work with regard to the observed interactions. Patients will not be asked any questions, nor any personal information taken from them. As recommended for work of this type, full descriptive field notes will be produced immediately after each observational session.[29]

Participant sampling and recruitment

This study will adopt the convenience sampling technique by recruiting participants who are on shift on the agreed days that the researcher is permitted to access the concept ward. As this study focuses on the interactions of the work systems on the concept ward which may potentially involve direct patient care, both the staff, patients and where applicable parents or legal guardians and consultees will be informed of the study and given the opportunity to either participate or not.

Posters containing key study information will be displayed at various locations in the hospital (including the concept ward) to advertise the study and advise patients and staff that the researcher may be present while they are on admission or on shift, respectively. Appropriate participant information sheets will also be shared with staff and patients, advising of the study purpose and their rights to voluntary participation and withdrawal as

Table 2 Summary of ethical considerations

Ethical component	Considerations	Work package
Right to approach, informed consent and right to opt-out	Where appropriate, potential participants for qualitative interviews will be approached in a way that does not breach their right to privacy and data protection, that is, the research team will not be provided any personally identifiable data (eg, contact details) of potential participants, without their prior consent. An invitation email will be drafted by Staffordshire University researchers and shared with the participating Trust for them to send out to the key stakeholders from the Trust. All potential participants who are invited to join the qualitative process evaluation will be provided with a participant information sheet. Potential participants will be given time to consider their willingness to participate and complete an electronic consent form for research records. Verbal consent will be obtained and recorded on the day of the interviews. For qualitative observations, patients and staff will be required to verbally consent prior to any study activity taking place. Should they wish to not be observed, verbal opt-out will be obtained and this will be documented in patient medical records. No record of staff opt-out will be recorded. For patients with limited or no mental capacity, their professional consultees will be approached and required to either verbally consent or decline observations, should they think the patients would want their care to be observed or not, respectively.	2
Right to withdraw	The participant information sheet will inform each participant that if they decide to take part, they will still be free to withdraw at any time and without giving a reason. Participants are also informed in the participant information sheet that if they do withdraw from the interviews, they will have up to 7 days after which data analysis would have commenced and it will be impossible for them to withdraw their data. For qualitative observations, participants will be able to withdraw from the study at any point during the observations; for patients with limited or no mental capacity, the researcher will watch out for facial and verbal cues of distress or disagreement to being in the room and they would leave immediately. However, it will be impossible to withdraw any already observed data due to its anonymous nature or once data analysis has commenced. For quantitative evaluation, all data will be extracted and anonymised by nominated members of the business intelligence team before being shared with the researchers for analysis.	2
Confidentiality and anonymity	Work package 1: No personally identifiable data will be shared with the research team. Personally identifiable data will only be accessed by individuals who have routine access to this data in the commission of their duties. Therefore, confidentiality will be maintained. Work package 2: Participation in the research will be confidential; the research team will not divulge the details of participants to anyone outside of the immediate research team unless safeguarding issues are raised. All data collected will be coded to ensure anonymity. Documents that include personally identifiable data will be stored separately from the coded research data and only the research team will be able to make the link between the two. This right to confidentiality and anonymity will be made clear in the participant information sheet. When results from the study become available, a summary report will also be sent out to participants who have requested a copy of the findings. The findings of the study may be used in conference presentations and journals. No named information about the participants will be published in any report of this study.	1, 2
Data protection and storage	The research team will abide by the UK General Data Protection Regulation (2018) and the Data Protection Act (2018). Nominated members of the business intelligence team will have the responsibility of retrieving and anonymising patient and staff-related data for the participating Trust before sharing the data with the research team. The NHS Trust will be given the option to transfer data by its preferred method as per Trust policy and procedure. If the NHS Trust does not have a preferred method, nominated individuals in the Trust will be able to deposit data into a secure Staffordshire University Microsoft Teams folder and their ability to access these folders will be for a limited period. All personally identifiable and research data will be stored separately within the Staffordshire University's secure SharePoint that requires a staff login to gain access. Participants who request a copy of the findings will need to share their email addresses which then become personally identifiable data. These will be kept up to when the study findings are written and sent out to such participants. This is only applicable to qualitative aspects of work package 2.	1, 2
Distress	For this study, proposed interviews and observations are not expected to cause any distress to participants, and no sensitive data will be collected. However, should this occur, participants will be encouraged to speak to the qualitative researcher, and they will be signposted to appropriate support within the Trust. For patients with limited or no mental capacity, the researcher will watch out for facial and verbal cues of distress or disagreement to being in the room and they would leave immediately. The staff providing care will identify appropriate support within the Trust for the patient.	2
Safeguarding	The data collected will remain confidential as indicated, however, prior to each interview and observation, the researcher will remind participants that in the event of disclosure of any safeguarding issue during interviews or if criminal activities were observed, these would be shared with the appropriate personnel. This will be made clear in the participant information sheet and prior to consent.	2

NHS, National Health Service.

well as the researcher's contact details for any queries or clarifications.

An invitation email will be sent to staff working on the concept ward, with a follow-up email sent to advertise the specific dates that the researcher will be present to undertake data collection. Verbal consent will be obtained from staff prior to commencing observations. Any staff who do not wish to be observed will be able to verbally opt-out of the study and the researcher will not follow them or observe their work. Before entering single rooms or bedsides in bays, the clinician who is being observed will verbally check that they are happy for the researcher to continue. This will constitute verbal consent. Written consent will not be obtained. Patients will also be able to verbally opt out of the study should they decline to have their care observed. For paediatric settings, where the child is less than 16 years of age, the child's parents or legal guardian will be able to opt out if they do not want their child's care processes observed. Children aged between 10 and less than 16 years of age, who have the ability to provide informed assent, will be given the opportunity to do so themselves, verbally.[30] For patients with limited or no mental capacity, their nominated professional consultees will be informed and provided with the study information sheet with which an informed decision will be made as to whether participation is appropriate. All verbal declines to observations will be documented in the patients' medical records and the researcher will not enter their rooms, be by their bedside or observe any staff providing care to them.

The researcher will respect patients' rights to autonomy and privacy and will leave the room if asked to do so. For patients with limited or no mental capacity, the researcher will watch out for facial and verbal cues of distress or disagreement to being in the room and they would leave immediately. Patients and where appropriate, their parents and/or legal guardians are free to verbally opt out at any time before or during the observations although it will not be possible to withdraw already collected observational data due to its anonymous nature and once data analysis and aggregation has commenced.

Data collection

The PETT (People, Environment, Tools and Tasks) Scan, a checklist and documentation tool will be employed to ensure a full consideration of the work systems including its people, environments, tools and tasks. Underpinned by the SEIPS model, PETT scans are commonly used to indicate the presence of barriers and/or facilitators for each of the PETT components or for component-component interactions.[31] See online supplemental file 2 for the PETT scan template.

During the observations, the researcher will have an observation sheet that will help them focus on what might be relevant to the study. Patients, and where appropriate their legal guardians and/or parents, consultees and staff can ask to see this if they wish. The researcher will only observe how the concept ward environment, equipment and people interact and influence care delivery and this may potentially involve how patient care is delivered. The researcher will take notes during or immediately after the observations and may ask staff questions to aid in further understanding of the interactions of the work systems and processes on the concept ward. No personal information will be collected, and it will not be possible to identify participants from any observational data collected. Questions asked of staff during observations will be subject to their capacity to respond and there will be no requirement at all to do so if unable or unwilling.

Observational sessions will be designed with staff to suit operational requirements. Around 18 hours of observation per ward (54 hours in total) is aimed for. Observation sessions will last around 3 hours each and cover where practicable (including but not limited to) handover periods, team meetings, everyday work of a range of senior ward staff and administrators, doctors, staff nurses and care assistants. Observations will be conducted between the 12th and 14th week of the clinical area being on the concept ward. Data will be collected in the same week for all three clinical areas rotating through the concept ward.

Data analysis plan

Observational data will be analysed using the framework analysis method, a matrix-based approach which provides a clear and systematic structure from the initial data collection and management through to the development of explanatory accounts specific to the research.[26 27] Framework analysis consists of five interconnected stages from the initial data collection to providing insightful explanatory interpretations.[28] Data will be mapped to the theoretical frameworks underpinning this study (SEIPS and CARE models) to identify patterns, themes and relationships in the data. Data analysis will be conducted independently by two members of the research team, coming together to agree on key themes, resolving any differences thereby, enhancing rigour. To provide a broader context for the observational data, findings will be triangulated with qualitative interview findings.

Quantitative process evaluation

As part of service evaluation, the study setting routinely collects patient and staff administration and survey data to explore their experiences of accessing healthcare and working in the Trust, respectively. These data will be retrospectively extracted, anonymised by the members of the direct care team before being shared with the research team. Hence, there will be no active recruitment of participants to collect quantitative process evaluation data.

Data collection

Quantitative data will include retrospective patient and staff administration data and surveys from the during period (time point when the clinical area is on the concept ward). The during period will be dependent on the dates when each clinical area moves into and out of the concept ward.

The minimum anonymised data items to be extracted are listed in the table 1.

Data analysis plan

Statistical analysis will be performed by using STATA and/or R software. Standard descriptive summaries and graphical plots will be presented for all collected data according to the data type and clinical area.

Data management

Data management will be UK General Data Protection Regulation (GDPR, 2018) compliant and handled in accordance with the Data Protection Act (2018) and Staffordshire University data storage policy.

Qualitative data including interview recordings and transcripts, observational data and field notes will be collected electronically and stored securely on a password protected; encrypted laptop owned by Staffordshire University. Other personally identifiable data such as consent forms will be collected digitally and stored within Microsoft Teams, on a SharePoint server owned and operated by Staffordshire University. Only the study team will have access to data, and these will be stored separately from anonymised research data.

Quantitative data will be extracted from the hospital database systems and downloaded onto a secure Trust computer for anonymisation. The Trust will be given the option to transfer data using its preferred method, as per Trust policy and procedure. If the Trust does not have a preferred method, the university will provide a facility to transfer the data securely. Currently, this uses a GDPR compliant Microsoft OneDrive facility where data can be deposited by named individuals in the participating trust for a limited period.

Anonymised data could be retained indefinitely, in accordance with open access data requirements but for at least 10 years following completion of the study. In this context, completion refers to the last relevant publication that becomes available.

Patient and public involvement

There are no patients and/or the public involvement in the study design; however, the project steering committee will consist of independent stakeholders including healthcare professional and patient and/or public representatives who will ensure that the study remains focused on patient and staff experiences and outcomes. The committee will meet bimonthly to provide overall project oversight.

Ethics and dissemination

Standardised ethical guidelines will apply throughout. Please see table 2 for the summary of the ethical considerations for this study. The study protocol underwent the Staffordshire University Independent Peer Review process and ethical approval was obtained from the UK Health Research Authority (IRAS ID: 334395). Study findings will be shared with key stakeholders including the collaborating NHS Trust, published in peer-reviewed high-impact journals and presented at relevant conferences.

Study strengths and limitations

The strength of this multimethod study lies in using innovative and interdisciplinary approaches to explore the impact of a new ward environment on patient and staff experiences and outcomes in an NHS Trust. This single ward in this single NHS Trust is proposed to be the design for not only all wards in the NHS Trust when it is rebuilt, but potentially all wards for new builds going forward. This research is critical to ensuring that the design of the concept ward going forward, is fit for purpose. Moreover, this research is designed to be grounded in the SEIPS and CARE models which have broader applicability and tendency to generate richer study findings given their potential for knowledge precipitation on human factors and ergonomics influencing the utilisation of the concept ward.

While it is a single ward location and may potentially limit the generalisability and transferability of study findings, multiple ward specialties are rotating through the environment over the study period (three specialties are being investigated). Qualitative interview participants will be recruited through maximum variation, a purposive sampling that ensures the heterogeneity of the study sample while the qualitative observations will employ convenience sampling, an approach designed to gather valuable insights into the study aim. We will triangulate findings from the qualitative interviews to provide a broader context for the qualitative observations. Triangulation helps us to reduce potential bias inherent in any single approach, offering a more robust picture of our research aim.[32] All qualitative and quantitative data collected will be triangulated to strengthen the overall validity and credibility of this research. We acknowledge the short-term nature of this study, given that the participating wards are just rotating through the concept ward while their original wards are being renovated. Hence, it is proposed that future research should explore the long-term impact of the ward environment on patient and staff experiences and outcomes.

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Contributors All listed authors made substantial contributions to the study design and development of this protocol, in accordance with the ICMJE criteria for authorship. Specifically, SJ, PM and JC conceptualised the project; SJ, YA, HAS, AD, VC and AR contributed to the study concept and design, and drafted the manuscript. PM, JC, HH, HA and ES made extensive contributions to the sections on participant recruitment and data collection processes. YA, HAS, AR and SJ revised the protocol extensively. All listed authors approved the final manuscript submitted for publication. SJ is the guarantor and is responsible for the overall content of the manuscript.

Funding This work is funded by James Paget University Hospitals NHS Foundation Trust.

Competing interests This study is funded by James Paget University Hospitals NHS Foundation Trust and some members of the research team namely ES, HA, HH, JC and PM are Trust employees with whom Staffordshire University team collaborated to facilitate data collection and access. The authors declare that they have no other competing interests.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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