

WardSonar: a real-time measure of safety for mental health wards

Submission date 07/01/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 03/12/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Evidence shows there are large numbers of safety issues on acute mental health wards, frequently involving violence and self-harm, associated with increased costs, physical and psychological harm. Safety data is currently only collected retrospectively and very little is collected from the service user perspective. This study aims to co-design with service users and staff a technological intervention that collects data about the perception of safety from service users, in order to support staff to anticipate and avoid developing incidents.

Stakeholder and lay input has informed the development of this project, specifically through discussions with service users and co-applicant representation. We will link to existing stakeholder groups hosted by Leeds and York Partnership NHS Foundation Trust to support the project via co-app with lived experience. The key outputs of the research will be a new intervention in the form of a licenced product to enable the collection of and response to real-time service user-generated safety data. The research will produce traditional and non-traditional publications in a variety of media. Dissemination will target key stakeholders: mental health service providers, commissioners, regulators, practitioners, policy makers, and academic researchers and make effective use of social media. We will publish in high-impact open access academic journals and present and discuss our findings at conferences to a wide range of practitioners, academics, and service users. We will also devise and host a digitally supported dissemination event and invite representation from all stakeholders. The resulting product has the potential to improve safety and well-being for service users and staff on acute mental health wards, a key concern of the CQC and an NHS priority.

Who can participate?

Service users aged 16 years or above, who are a current inpatient of a mental health ward

What does the study involve?

The project has two phases and uses different methods during each phase. Phase 1 uses a co-design approach to developing the intervention, supported by an 'environmental scan' consisting of a scoping review and the collection and qualitative analysis of interview data. Phase 2 will be a mixed-methods process evaluation. A focused ethnography will explore how staff communicate and use safety data supported by interviews with service users and staff to

further understand feasibility and acceptability. We will simultaneously collect routine data including incidents, NHS mental health safety thermometer (if available), workforce and ward occupancy. Measures relating to safety culture and ward atmosphere will be completed pre and post intervention, as well as real-time measures of these concepts on three occasions. The synthesis of these data will assess the impact of the intervention on outcome measures; enhanced understanding of feasibility and acceptability.

What are the possible benefits and risks of participating?

The information participants provide will help us develop our research which might lead to improved safety on wards. We hope participants will find the subject of the interview and sharing your views interesting. Depending on their experiences participants may find talking about them upsetting, if this is the case we will ensure participants are provided with sources of support.

Where is the study run from?

University of Leeds (UK)

When is the study starting and how long is it expected to run for?

January 2020 to December 2022

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

Prof John Baker, J.Baker@leeds.ac.uk

Contact information

Type(s)

Principal Investigator

Contact name

Prof John Baker

Contact details

School of Healthcare

University of Leeds

Woodhouse Lane

Leeds

United Kingdom

LS2 9JT

+44 113 343 1271

j.baker@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

300833

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 300833, CPMS 50821

Study information

Scientific Title

Developing a service user centred co-designed patient safety intervention for acute mental health wards: A mixed methods process evaluation

Acronym

WardSonar

Study objectives

This project aims to co-design an intervention that improves patient safety on acute mental health wards through the collection of daily data about the perception of safety from service users to support staff in monitoring and improving the safety of the clinical environment. The intervention will be tested, and its' feasibility and acceptability explored.

To achieve these aims, we have the following objectives:

1. To co-design with service users and staff an intervention that will allow real-time monitoring of safety on acute mental health wards
2. To explore the feasibility and acceptability of capturing real-time feedback from service users about safety
3. To explore how staff use this information when reported during daily handovers (or other mechanisms)
4. To explore how the resulting data is related to existing quality and safety metrics
5. To explore how these data can be used longitudinally to promote safety

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/11/2021, East Midlands - Nottingham 2 Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 203 443 6294; nottingham2.rec@hra.nhs.uk), ref: 21/EM/0247

Study design

Mixed methods process evaluation

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Safety on mental health wards

Interventions

A mixed-methods process evaluation. A focused ethnography will explore how staff communicate and use safety data supported by interviews with service users and staff to further understand feasibility and acceptability. We will simultaneously collect routine data including incidents, NHS mental health safety thermometer (if available), workforce and ward occupancy. Measures relating to safety culture and ward atmosphere will be completed pre and post intervention, as well as real-time measures of these concepts on three occasions. The synthesis of these data will assess the impact of the intervention on outcome measures; enhanced understanding of feasibility and acceptability.

The digital intervention consists of up to four discrete 'products':

a service user recording interface to collect data;

healthcare staff dashboard for data analysis;

a ward interface for public consumption;

an Application Program Interface (API).

The primary tool asks services users to answer a series of questions about how safe they feel recorded on a hand held tablet. Data will be recorded in real-time and sent to an API for data processing. The dashboard will be the main interface used by staff to view data submitted by service users. It will primarily be accessed in specific, authorised locations, such as the ward office, and provide real-time snapshot data and greater informational insights through the use of interactive data visualisations. A simple ward interface may be created (subject to co-design) to communicate a subset of outcome measures for public consumption.

Intervention Type

Behavioural

Primary outcome measure

Quantitative evaluation of the 'effect' of the intervention on patient safety:

1. Continuous routine safety data (incidents, NHS mental health safety thermometer (monthly), workforce data, admissions/discharges, and ward occupancy and acuity)
2. Standard measures of culture and ward atmosphere (measures from the Agency for Healthcare Research and Quality (AHRQ), Hospital Survey on Patient Safety Culture (HSOPC), staff perceptions of 'ward atmosphere' using the EssenCES scale), pre and post intervention for each participating ward

Secondary outcome measures

Qualitative evaluation:

Undertake a focused ethnography to explore the use of the intervention across a variety of

wards and organisational settings. This combination of data will support an exploration of the intervention in terms of its' use within each context, the challenges of engaging with the intervention, unintended consequences (positive and negative, and how these are mitigated), as well as an understanding of the likely requirements for a future trial design (outcomes, challenges, supporting factors etc). This will be presented as a case study for each ward.

Overall study start date

01/01/2020

Completion date

30/12/2022

Eligibility

Key inclusion criteria

1. Service user aged over 16 years
2. Current inpatient of a mental health ward
3. Capacity to consent to participate in research
4. Able to communicate in spoken English

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

6 wards, all patients per ward (approx 120 patients) and all members of the MDT.

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

10/01/2022

Date of final enrolment

01/10/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Leeds and York Partnership NHS Foundation Trust
2150 Century Way
Thorpe Park
Leeds
United Kingdom
LS15 8ZB

Study participating centre
Lynfield Mount Hospital
Bradford District Care Foundation Trust
Heights Lane
Bradford
United Kingdom
BD9 6DP

Sponsor information

Organisation
University of Leeds

Sponsor details
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT
+44 (0)113 2431751
governance-ethics@leeds.ac.uk

Sponsor type
University/education

Website
<http://www.leeds.ac.uk/>

ROR
<https://ror.org/024mrx33>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

30/12/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		01/05/2024	28/05/2024	Yes	No
Results article	Service-user patient safety perceptions, incidents and subsequent contagion	28/11/2024	03/12/2024	Yes	No