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Exploring a new approach to preventing self-harm in psychiatric inpatient hospitals

Submission date
13/05/2024

Recruitment status
No longer recruiting

Registration date
17/06/2024

Overall study status
Completed

Last Edited
03/09/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Suicide is a leading cause of death for all age groups and a growing public health concern. Literature suggests asking about suicidal ideation reduces it, additionally risk of suicide is dynamic and not linear, with fluctuations throughout a day, week month or even lifespan. Hence interventions must match this. Just In Time Adaptive Interventions (JITAI) use real time information to intervene just in time and are used to respond to varying needs over time. Hence this study will aim to evaluate the feasibility of using a just in time approach to aim to reduce suicidal self-harm in NHS inpatient psychiatric settings.

Who can participate?
Staff and patients at participating wards will be eligible to participate. With exception to patients who lack capacity, whose first language is not English (the booklet is currently only available in English) or are in seclusion. Agency staff will be unable to participate as it is highly unlikely they will return to the same ward during the course of the trial.

What does the study involve?
The study uses a booklet- based intervention. Staff on participating wards are invited to training to learn about the background of the study, how to receive consent from patients and how to use the study booklet with patients.
Staff then advertise and recruit eligible patients to the study, once recruited, patient participants start to use the booklet. This involves the patient completing daily questionnaires within the booklet in 1:1 sessions with participating staff, which asks questions pertaining to wellbeing, frequency of suicidal ideation and distress levels. Scores are plotted in charts within the booklet. If the score indicates high risk, staff will then initiate routine risk assessment and management procedures using prompts provided to them during training.

What are the possible benefits and risks of participating?
The project is a new way of monitoring risks on the ward and can help staff to intervene early. Whilst there are no immediate benefits for people participating in the project, it is hoped that this work will help us to see if this type of intervention method can be used in inpatient settings in the NHS and will provide us with enough data to do a preliminary randomised control trial.

The questionaries ask about topics that may be upsetting. If patients are distressed by the content of the questionnaires, they can speak to the staff member in their 1:1 Session. If any of the questions cause staff distress this can be discussed and dealt with in clinical supervision. Additionally, staff can attend weekly staff support sessions in addition to clinical supervision and workplace wellbeing. Staff can also contact the psychologist or ward manager for additional support and signposting if needed.

Where is the study run from?
Rotherham Doncaster and South Humber NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2022 to August 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).
MindLife (UK)

Who is the main contact?
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Dr Jaime Delgadillo, j.delgadillo@sheffield.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324004

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56194, IRAS 324004

Study information

Scientific Title
Feasibility trial of a Just-in-Time Adaptive Intervention (JITAI) to prevent self-harm events in an inpatient care setting

Acronym
JITAI

Study objectives
To evaluate the feasibility of a just in time adaptive intervention (JITAI) to prevent suicidal self-harm events in NHS psychiatric inpatient care settings.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/09/2023, West of Scotland Research Ethics Service (Ward11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 23/WS/0087

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Suicidal self-harm

Interventions
Participating inpatient care wards across two NHS Trusts will be randomly assigned to two groups. Participants will be randomised and then take part in the same 4-month intervention at a different time (phase one is up to month 4 and phase two from month 4 to month 8), depending on their group assignment.

During the first phase months 1-4 of the study, Group 1 will have immediate access to JITAI training and booklet. Group 2 will serve as a delayed intervention control during this phase. After 4 months, during the second phase, Group 2 will be trained and will have access to JITAI and a booklet. During this second phase, Group 1 will continue to use JITAI.

Participants will be of two types- staff participants and patient participants.

At the start of each phase staff participants within the assigned group will attend training which will provide information on the daily measures being used as well as the JITAI intervention and how they can view the data input by patients to respond. So at this time point, zero staff participants assigned to wards in group one will attend the training. Staff in group 2 will attend training before the start of phase 2- 4 months after the study starts.

The JITAI intervention works based on daily Routine Outcome Monitoring (ROM) and when these indicate things are not going well, this triggers an intervention. The patient participant completes daily ROM using a web-based secure survey, which asks questions about well-being, frequency of suicidal ideation and distress levels. Ward staff review this data daily to assess changes in the patient's well-being and risk factors. If the feedback provided by the JITAI algorithm indicates high risk, staff will then initiate routine risk assessment and management procedures. It's much the same as if you were continuously monitoring a cardiac patient's heart rate during a post-operative (emergency) hospital stay – the technology alerts clinicians to critical changes in cardiac rhythm leading to immediate emergency procedures.

This stepped wedge trial design assumes that significant differences in the primary clinical outcome (e.g., number of self-harm incidents during 4 months) would be found after phase 1 (primary hypothesis test A). No significant differences would be found after phase 2 (secondary hypothesis test B) or after 12 months (secondary hypothesis test C). The present feasibility study seeks to evaluate whether implementing such an intervention (JITAI) and collecting data is at all feasible within this stepped wedge design. The absolute number of self-harm incidents will be collected for each 4-month interval.

Intervention Type
Behavioural

Primary outcome measure
Staff self-evaluation of the efficacy of risk assessment will be measured using the Risk Assessment and Management Self-Efficacy Scale (RAMSES) at the start of the trial, month 4 and month 8

Secondary outcome measures
Measured at admission:
1. The Depression Anxiety Stress Scale, DASS-21
2. The Health of the Nation Outcome Scales (HoNOS)
3. Quality of life enjoyment and satisfaction questionnaire (Q-LES-Q)
4. Alcohol Use Disorders Identification Test AUDIT-10

Measured daily:
1. The Daily Index (DI-5)
2. World Health Organisation Wellbeing Index (WB-10)
3. Items from the Perceived Mastery Scale (PM)

Qualitative interviews will be conducted with some participating staff at the end of the study to gain views on experiences of using the JITAI method in clinical practice and the barriers and enablers to this.

Overall study start date
01/12/2022

Completion date
30/08/2024

Eligibility

Key inclusion criteria
1. Between the ages of 18 - 65 years
2. Inpatient on one of the participating wards
3. Staff participants must be permanent members of staff
4. Staff participants must have completed all the relevant mandatory Trust risk management training
5. Staff member on one of the participating wards who have attended JITAI training

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 16-24; UK Sample Size: 16-24

Key exclusion criteria
1. Not fluent in English
2. Patients who are in seclusion
3. Patients assessed not to have the capacity to consent to take part- only participants deemed to have the mental capacity to provide informed consent will be included, this may fluctuate, so we can include patients who may gain capacity during the active phase of data collection
4. Agency staff members

Date of first enrolment
22/11/2023

Date of final enrolment
30/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Health & Social Care NHS Foundation Trust
Centre Court
Atlas Way
Sheffield
United Kingdom
S4 7QQ

Study participating centre
Rotherham Doncaster and South Humber NHS Foundation Trust
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Sponsor information

Organisation
Rotherham Doncaster and South Humber NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Funder Name
Mindlife UK LTD

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/08/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the chief investigator, Professor Jaime Delgadillo (j.delgadillo@sheffield.ac.uk), in a CSV file alongside a data dictionary. The data will be shared with qualified researchers who pre-register their planned secondary analysis plan, for a time-limited period dependent on the planned secondary analyses, in a fully anonymised format and in compliance with the conditions of ethical approval and informed consent provided by participants.

IPD sharing plan summary

Available on request