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Assessing the feasibility and acceptability of developing and implementing a problem-solving training to improve symptoms of depression, anxiety and suicidal ideation

Submission date
03/02/2022

Recruitment status
No longer recruiting

Registration date
18/03/2022

Overall study status
Completed

Last Edited
23/03/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Problem-solving skills are important in helping people work out what to do when faced with a problem. A problem might be anything that is on your mind a lot, or something that you worry about. Lots of people have problems in life and sometimes these can be more difficult to address when in hospital We know that ignoring problems can have an impact on how people feel and behave and if left, you may find that they affect your physical and mental health. The aim of this study is to find out whether a brief problem-solving intervention can help to support people to feel better, act differently and take an active part in addressing problems whilst living in hospital.

Who can participate?
Patients aged over 18 years who are expected to be in hospital for the next 6 months with English as a first language, unless they are already involved in another study.

What does the study involve?
Participants will be asked to complete some questionnaires at the start and end of the study. These will measure whether the problem-solving skills have any impact on mental health, feelings of hopelessness and thoughts about suicide. Participants will be randomly allocated to receive either the problem-solving skills therapy plus usual care or just to receive usual care. Participants assigned to take part in the problem-solving skills therapy will be expected to attend 5 2-hour workshops in a group of up to ten other patients over the course of 1 week.

What are the possible benefits and risks of participating?
Participants will be given the opportunity to learn some new problem-solving skills which may help them cope better when faced with problems as an inpatient. It is unlikely that participants might feel upset or anxious during the study, but if they do feel upset they are free to leave at any time. Participants can also talk to a member of ward staff or the research team who will support them.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
April 2021 to December 2022

Who is funding the study?
Tees Esk and Wear Valleys NHS Foundation Trust (UK)

Who is the main contact?
Dr Amanda E Perry
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
302570

Study information

Scientific Title
Assessing the feasibility and acceptability of developing and implementing a problem-solving training: a randomised controlled trial to improve symptoms of depression, hopelessness and suicidal intent (In-patient Secure - Depression, Anxiety and Self-Harm [IS-DASH])

Acronym
IS-DASH

Study objectives
Problem-solving skills reduces symptoms of depression, hopelessness and suicidal intent in comparison to care as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Single-site interventional feasibility randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of depression, hopelessness and suicidal intent in patients in a secure in-patient hospital setting

Interventions
Participants are randomised to receive problem solving skills and care as usual vs care as usual only. Participants will be randomized by the York Trials Unit Randomization Service at the University of York. This web-based randomization process will randomize patients to one of the two arms of the trial based on a computer-generated code. The information will be stored on a secure server and access to the sequence will be confined to the Trial Manager. Allocation to the trial arms will be in the ratio of 1:1. The Trial Manager will access the treatment allocation for each patient by remote internet-based randomization. The group allocation will be disclosed to the Trial Manager after baseline data has been collected for each participant. The allocation outcome will be entered into the secure shared database so that all members of the research team can view the allocation.

The brief problem-solving intervention involves delivery of a well-established social problem-solving theory. The PI will deliver the intervention in groups of up to ten patients in a workshop lasting up to 2 hours, delivered over a 5-day period.

Intervention Type
Behavioural

Primary outcome(s)
The feasibility and acceptability of the trial to inform a future definitive trial, assessed using:
1. The recruitment rate of patients joining the trial
2. The retention of patients by estimating 3-month follow-up
3. The acceptability of the peer-led intervention in terms of adherence and attendance to the intervention and completion rates on questionnaires
4. Sample size calculated based on recruitment rates, outcomes and adherence
5. The acceptability determined by addressing barriers to implementation to develop an optimal plan for delivery of the complex intervention in the main trial

Data will be collected using a bespoke feasibility and acceptability questionnaire to cover: data on the number of eligible patients; numbers of those who consent to take part and withdraw (with reasons); follow-up and attrition rates, assess whether outcome data can be reliably and feasibly collected (completion rates); record the number of sessions attended and proportion that successfully complete; timing of the sessions and collect information from practitioners about what constitutes treatment as usual and measurement of acceptability and barriers to implementation for the definitive trial: during and up to 3 months post randomization.

Key secondary outcome(s)
1. Demographic characteristics measured using a bespoke questionnaire (including measurement of usual care) at baseline
2. Depression measured using the Patient Health Questionnaire (PHQ-9) at baseline and up to 3 months post randomization
3. Anxiety measured using the Generalised Anxiety Disorder Assessment (GAD-7) at baseline and up to 3 months post-randomization
4. Suicidal ideation measured using the Beck Suicidal Ideation Scale (BSSI) at baseline and up to 3 months post-randomization

Completion date
01/12/2022

Eligibility

Key inclusion criteria
1. Inpatient on forensic ward
2. English ability sufficient for understanding study materials without the need for a translator
3. Adult males and females >18 years of age
4. Remaining within the hospital for 6 months or more

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Individuals currently experiencing a mental health crisis
2. Individuals unable or unwilling to provide consent
3. Individuals that pose a risk to the research team
4. Individuals not remaining on the ward for the duration of the study
5. Individuals that are currently participating in another research intervention study

Date of first enrolment
01/05/2022

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
York Trials Unit
Health Sciences Department
University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Tees Esk and Wear Valleys NHS Foundation Trust

Results and Publications

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?
Protocol file	version 1	15/03/2022	16/03/2022	No	No
Protocol file	version 1	15/03/2022	23/03/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes