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Suicide prevention for Emergency Department attendees with substance misuse

Submission date	Recruitment status	[ ] Prospectively registered
12/04/2023	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
14/04/2023	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
14/04/2023	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Research has shown that brief interventions may reduce the risk of suicide in people who present to a hospital emergency department (ED) after self-harm. However, while people with a substance use disorder (including alcohol) are at higher risk of suicide compared with people without, it is not known whether brief interventions reduce the risk of suicide or self-harm among this group. The research team have developed a brief telephone-based intervention that is designed to help people who present to ED after self-harm, and who have a substance use disorder. The main aim of this study is to test the feasibility and acceptability of the intervention.

Who can participate?
Individuals over the age of 18 years who have attended a hospital emergency department following a suicide attempt or act of self-harm and who have been using drugs and or alcohol

What does the study involve?
Participants complete a short set of questionnaires and participate in weekly telephone calls with liaison psychiatry staff over a 1-month period

What are the possible benefits and risks of participating?
By taking part in the intervention, patients receive follow-up support (delivered by telephone). The research team believes that the proposed study methods pose low to no risk for this patient group whose risks often remain high without any additional treatment intervention. All sessions of the intervention will be carried out by liaison psychiatry staff, who are clinically skilled and experienced in assessing and treating this patient population.

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

When is the study starting and how long is it expected to run for?
January 2020 to June 2022

Who is funding the study?
Bristol and Weston Hospitals Charity (UK)

Who is the main contact?
Prof. Paul Moran, paul.moran@bristol.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Paul Moran

ORCID ID
https://orcid.org/0000-0002-9257-8699

Contact details
Bristol Medical School
University of Bristol
Bristol
United Kingdom
BS8 2BN
+44 (0)117 33 14027
paul.moran@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
288891

Protocol serial number
IRAS 288891

Study information

Scientific Title
Suicide prevention care for Emergency Department attendees presenting with self-harm and concurrent substance misuse

Acronym
CONNECT

Study objectives
This study is assessing the acceptability, feasibility and safety of a brief intervention for people who present to hospital with self-harm and who have a history of drug and/or alcohol misuse

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/01/2021, South West - Frenchay Research Ethics Committee (Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8379; frenchay.rec@hra.nhs.uk), ref: 20/SW/0188

Study design
Non-randomized mixed-methods feasibility study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Prevention of suicide among hospital attenders presenting with self-harm and substance use

Interventions
This is a feasibility study of a new brief intervention for people who attend ED with self-harm and who have a history of substance misuse. The study incorporates the delivery of the intervention with a sample of patient participants, and interviews with staff and patients following the completion of treatment, to gather their views about their experiences of delivering/receiving treatment.

Staff training:
The study CI will train liaison psychiatry staff to deliver the intervention. A training session lasting approximately 90 minutes will be conducted at each hospital site: this will include familiarising staff with the study, the treatment manual and locally specific SOPs.

Recruitment of patients:
The research team will aim to recruit a convenience sample of up to 40 patients over a 12-month period. Eligible patients will be identified by liaison psychiatry (LP) staff during routine psychosocial assessments conducted in ED and will be asked whether they would like to take part. If patients wish to take part, LP staff will verbally explain the study to them, provide them with a participant information sheet, and take their written consent. At the point of recruitment, LP staff will record the patient's contact details, to enable the delivery of the follow-up sessions of the intervention, which will be delivered by telephone. They will explain the arrangements for follow-up sessions to the patient.

Intervention delivery:
The intervention will be implemented with up to 40 patients. Following the patient's first presentation to ED, treatment will be comprised of weekly telephone sessions, delivered by LP staff. The first follow-up session will take place between 24-72 hours after the patient's ED attendance. Subsequent follow-up calls will be delivered by LP staff approximately once a week for up to 1 month, with each session usually lasting up to 30 minutes.

Collection of quantitative outcome data:
In order to assess the acceptability and feasibility of the intervention, the research team will determine its uptake, retention and delivery. The research team will record details about the number of sessions offered to patients, the number of sessions attended, and staff adherence to the treatment protocol. LP staff delivering the intervention will also record quantitative data

on patient outcomes. This data will be collected at baseline and then upon completion of the final telephone follow-up session. Staff will collect the following brief, pragmatic outcome measures, and will record these using the REDCap (Research Electronic Data Capture) system, which has been approved for use by the University of Bristol Medical School:
1. Suicidal ideation (COLUMBIA questionnaire)
2. Self-harm frequency (Self-report questions based on the CASE study (Madge et al. 2008)
3. Depression (PHQ-9)
4. Anxiety (GAD-7)
5. Substance use (DUDIT)
6. Quality of life (EQ-5D 5L)

Collection of qualitative data:
The research team will conduct qualitative interviews with a purposive sample of up to 15 patients, about their experiences of receiving intervention treatment and of participating in the study. Each patient will take part in one interview. Interviews will take place following the completion of treatment and will be conducted by the study manager, by telephone. The research team will invite all staff involved in the delivery of the intervention to take part in an interview. Each staff member will take part in one interview. Interviews will take place when the delivery of intervention treatment is complete and will be conducted by the study manager, by telephone or online.

Intervention Type
Other

Primary outcome(s)
Recruitment rate is recorded as the number of eligible participants who consent to participate in the study by 12 months

Key secondary outcome(s))
1. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline and at the final session of intervention delivery
2. Anxiety is measured using the Generalised Anxiety Disorders Assessment (GAD-7) at baseline and at the final session of intervention delivery
3. Quality of life is measured using the EQ-5D-5L at baseline and at the final session of intervention delivery

Completion date
29/06/2022

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Presenting to hospital emergency department following a suicide attempt or act of self-harm
3. Harmful use of alcohol and /or regular illicit unprescribed psychoactive substance use

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Unable to give informed consent
2. Unable to speak English fluently enough to participate in procedures

Date of first enrolment
03/05/2021

Date of final enrolment
30/05/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital Bristol
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Bristol and Weston Hospitals Charity

Results and Publications

Individual participant data (IPD) sharing plan
The quantitative dataset generated and analysed during the current study are not expected to be made available because we did not seek consent from participants to share their data outside the research team. A copy of the final report will be made available on reasonable request to the Chief Investigator and with the agreement of the funder.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No