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A brief psychological intervention for self-harm in Emergency Departments

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
04/02/2020

Overall study status
Ongoing

Last Edited
18/09/2023

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
In the UK, around 6000 people take their own life each year, causing suffering to those they leave behind. The risk of suicide is 100s of times greater among people who self-harm than among the general population, with 15-43% of people attending the Emergency Department (ED) with self-harm in the year before death. For this reason, the Government's Suicide Prevention Strategy has identified those presenting with self-harm as a priority group. Each year, around 220,000 episodes of self-harm by 150,000 people are managed by EDs in England. Most EDs have a psychiatric liaison team of specialist mental health practitioners who conduct psychosocial assessments to engage patients, assess their current and future health and social care needs and make onward referrals. However, assessments are often inadequate due to limited capacity in these services and patients often not attending or dropping out, emphasising the need for effective intervention. An appropriate brief intervention which changes routine meetings with patients in the ED could reach around 220,000 patient contacts each year in England. Evidence from recent international trials indicates that such interventions delivered by specialist mental health practitioners in EDs are effective in reducing self-harm and suicide. Training existing mental health teams to deliver the intervention would be relatively cheap, making wider rollout in the NHS attractive. Based on existing international evidence and feedback from all stakeholders, this study aims to pilot the intervention across four Emergency Departments in England. This pilot study forms part of a National Institute for Health Research (NIHR) funded research programme. In this pilot study, the intervention will be tested at four EDs around London, with 16 practitioners and 96 patients. Feedback will be collected on the intervention from patients, carers and practitioners, so that we can learn about potential barriers to implementation and this will lead to further development of the intervention. Assuming the pilot study is successful and acceptable to participants, the next phase will be a large scale cluster randomized controlled trial across 26 Emergency Departments in England.

Who can participate?
Patients aged 16 and over who present to the recruiting Emergency Departments having self-harmed.

What does the study involve?
Participants who are identified as eligible for the study will be offered an adapted therapeutic

assessment and enhanced safety planning with the practitioner they see in the Emergency Department. They will then be offered three follow up appointments with the same practitioner over a three-month period. A six-month outcome assessment will then be carried out. Interviews will be carried out with patients, carers and practitioners, to inform the ongoing development of the intervention, in preparation for a future cluster randomized controlled trial.

What are the possible benefits and risks of participating?
Participating in a study whilst people are in distress may present a risk of further distress to people who are emotionally vulnerable. If the practitioners or the researchers feel that the research is too overwhelming, they will stop the process immediately. Our Lived Experience Advisory Panel (LEAP), confirmed that while there is the possibility of causing additional distress, participating in the study may also be beneficial to patients as it may help people feel that they are contributing and are able to help improve services. There are also benefits in terms of being able to talk and being listened to.

Where is the study run from?
1. Newham University Hospital (UK)
2. St Helier Hospital (UK)
3. East Surrey Hospital (UK)
4. Royal London Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2020 to July 2025

Who is funding the study?
Programme Grants for Applied Research, National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Sally O'Keeffe (public)
Sally.OKeeffe@city.ac.uk
Prof Rose McCabe (scientific)
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Study website
https://www.assuredstudy.co.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
257373

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3.0, IRAS 257373

Study information

Scientific Title
ASsuRED pilot: Improving outcomes in patients who self-harm - Adapting and evaluating a brief pSychological inteRvention in Emergency Departments

Acronym
ASsuRED pilot

Study objectives
This study aims to address four research questions:
1. Can practitioners implement a brief psychological intervention to patients presenting in the Emergency Department to improve care in routine practice in the NHS?
2. What barriers and facilitators to implementing the intervention are experienced by practitioners, patients and carers?
3. Is it feasible for patients to rate outcome measures in the Emergency Department setting for

a randomized controlled trial?
4. What are the main resources involved in implementing the intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2019, London - Surrey Borders Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8134; NRESCommittee.London-SurreyBorders@nhs.net), ref: 19/LO/0778

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

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
Self-harm

Interventions
The ASsuRED pilot study is a single-arm trial taking place across four sites. Participants who present to Emergency Departments having self-harmed will be recruited and will be offered a brief psychological intervention. The intervention will be delivered by practitioners in liaison psychiatry teams, who currently offer a risk assessment to patients. The practitioners will be trained to deliver a therapeutic risk assessment with enhanced safety planning, with follow up care after the patient leaves the Emergency Department. The patient will receive a phone call within 72-hours of leaving the Emergency Department, and three follow-up meetings at 1, 4 and 8 weeks, which will be based on a solution-focused approach to supporting the patient. Follow up contact will be offered by the same practitioner that the patient met in the Emergency Department. Longer-term contact over 9-months will be offered through regular letters from the practitioner.

Sixteen practitioners will implement the intervention with up to 6 patients each providing 96 practitioner-patient dyads. Practitioners will be trained in delivering the intervention. Identified barriers to implementation and feedback on outcomes will be collected and synthesised to guide refinement of the intervention, and this data will be collected using interviews with patients, carers and practitioners.

Updated 28/05/2021:
Sixteen practitioners will implement the intervention with patients and we will recruit 60 practitioner-patient dyads. Practitioners will be trained in delivering the intervention. Identified barriers to implementation and feedback on outcomes will be collected and synthesised to guide refinement of the intervention, and this data will be collected using interviews with patients, carers and practitioners.

Intervention Type
Behavioural

Primary outcome measure
Repeat self-harm identified by searching Emergency Department electronic records at the end of the study

Secondary outcome measures
Current secondary outcome measures as of 28/05/2021:
At baseline and 6 months follow up:
1. Therapeutic relationship, self-rated by patients on the Helping Alliance Scale
2. Self-reported self-harm
3. Suicide severity from the Columbia–Suicide Severity Rating scale
4. Social outcomes from the Social Outcomes Index (SIX)
5. Quality of Life measured with the Manchester Short Assessment of Quality of Life (MANSA)
6. Psychological distress measured with Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM)
7. Experiences of attending accident & emergency measured using the experiences of attending accident & emergency questionnaire
8. Death by suicide, i.e. cause of death is intentional self-harm or undetermined intent, derived from NHS/local authority/coroner records

Previous secondary outcome measures:
At baseline and 6 months follow up:
1. Therapeutic relationship, self-rated by patients on the Helping Alliance Scale
2. Self-reported self-harm
3. Suicide severity from the Columbia–Suicide Severity Rating scale
4. Beck Depression Inventory
5. Beck Hopelessness Scale
6. Quality of life measured with CORE-OM
7. Death by suicide, i.e., cause of death is intentional self-harm or undetermined intent derived from NHS/ local authority/coroner records

Overall study start date
01/05/2019

Completion date
31/07/2025

Eligibility

Key inclusion criteria

1. >16 years of age
2. Presenting in the ED
3. Presenting with self-harm, i.e., an intentional act of self-poisoning or self-injury, irrespective of the motivation or apparent purpose of the act
4. On presenting to the ED, can be admitted for a brief admission to the acute hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
60

Total final enrolment
62

Key exclusion criteria
1. Admitted to a psychiatric hospital
2. Cognitive (e.g. dementia) or other psychiatric difficulties interfering with ability to participate
3. Experiencing a psychotic episode
4. No capacity to provide written informed consent
5. Needing an interpreter
6. Ministry of Justice patients subject to a restriction order

Date of first enrolment
04/02/2020

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newham University Hospital
Glen Road

Plaistow
London
United Kingdom
E13 8SL

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
Royal London Hospital
Tower Hamlets Mental Health Liaison and Psychological Medicine
David Hughes Building
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E1 1FR

Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04fkxrb51

Organisation
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Sponsor type
University/education

Website
http://www.city.ac.uk

ROR
https://ror.org/04489at23

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

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
31/07/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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 8.0	13/08/2021	16/09/2022	No	No
HRA research summary			28/06/2023	No	No