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A brief intervention for patients in emergency departments who self-harm

Submission date
16/11/2021

Recruitment status
No longer recruiting

Registration date
18/11/2021

Overall study status
Ongoing

Last Edited
01/05/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] 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 lives each year, causing suffering to those they leave behind. The risk of suicide is hundreds 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 that 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, an intervention called the ASsuRED approach has been developed to provide support for patients presenting to EDs in the NHS context. This trial will test the clinical and cost-effectiveness of the ASsuRED approach. This trial forms part of a National Institute for Health Research (NIHR) funded research programme. In this trial, the ASsuRED approach will be compared to treatment as usual in approximately 10 EDs and 620 patients.

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 asked for consent to take part in the study. Participants allocated to the ASsuRED arm will be offered a therapeutic assessment and enhanced safety planning and three follow-up appointments with the same practitioner

over 8 weeks, in addition to an optional ‘bank’ session to be taken over the following 9 months and three personalised letters sent over 9 months. Participants in the treatment as usual arm will receive a standard psychosocial assessment. All participants will be asked to complete a research interview at baseline, and then at 3, 9, and 18 months.

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. People also report that talking to researchers can be beneficial.

Where is the study run from?
Devon Partnership NHS Trust (UK) and City, University of London (UK)

When is the study starting and how long is it expected to run for?
November 2021 to April 2026

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

Who is the main contact?
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Study website
https://www.assuredstudy.co.uk

Contact information

Type(s)
Public, Scientific

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
279991

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 279991, CPMS 50572

Study information

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

Acronym
ASsuRED RCT

Study objectives
Current study hypothesis as of 07/02/2024:
The ASSURED brief intervention for people attending the emergency department with self-harm will reduce subsequent reattendance to the emergency department for self-harm over 18 months compared with treatment as usual.

Previous study hypothesis:
A brief intervention compared with treatment as usual for people attending the emergency department with self-harm will reduce subsequent reattendance to the emergency department for self-harm over 18 months.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/11/2021, London - City & East Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0)20 7972 2545; cityandeast.rec@hra.nhs.uk), ref: 21/LO/0683

Study design
Individual randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Self-harm

Interventions
Current interventions as of 07/02/2024:
Participants allocated to the ASsuRED arm will be offered a therapeutic assessment, enhanced safety planning and three follow-up appointments with the same practitioner over 8 weeks. In addition, there is an optional fifth bank session that can be taken within 9 months of randomisation and three personalised letters over 9 months. All participants will be asked to complete a research interview at baseline, and then at 3-, 9- and 18-months.

The intervention consists of:
1. A narrative interview
2. A safety plan focusing on warning signs of an impending crisis, internal coping strategies, how to change the environment to stay safe, who to contact to resolve a crisis and professional agencies to contact if required
3. Rapid follow-up support: consisting of three follow-up sessions over 8-weeks based on a solution-focused model.

The ASsuRED pilot study is registered at https://www.isrctn.com/ISRCTN16003313

Previous interventions:
Allocation to the ASsuRED approach or treatment as usual, will depend on the practitioner that patients are allocated to. Participants allocated to the ASsuRED arm will be offered a 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 an 8-week period. Participants in the treatment as usual arm will receive a standard psychosocial assessment.
All participants will be asked to complete a research interview after their ED assessment, and then at 3- and 18-months.

The intervention consists of:
1. A therapeutic psychosocial assessment using narrative interviewing. The assessment will take approximately 60-minutes, which is the typical duration of assessment delivered in usual care
2. A safety plan focusing on warning signs of an impending crisis, internal coping strategies, how to change the environment to stay safe, who to contact to resolve a crisis and professional agencies to contact if required
3. Rapid follow up support: consisting of a 72-hour phone call and three follow-up sessions over 8-weeks based on a solution focused model.

The ASsuRED pilot study is registered at https://www.isrctn.com/ISRCTN16003313

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 07/02/2024:
1. Self-reported self-harm using online surveys at 1, 2, 3, 9, and 18 months
2. Suicidal ideation measured with the Beck Scale for Suicide Ideation (Beck & Steer, 1993) at baseline, 3, 9 and 18 months
3. Psychological wellbeing measured with CORE-OM (Barkham et al., 2001; Mavranezouli et al., 2011) at baseline, 3, 9 and 18 months
4. Social outcomes measured with the Social Outcomes Index (SIX) (Priebe et al., 2008) at baseline, 3, 9 and 18 months
5. Quality of life measured with the EQ-5D-5L (Herdman et al. 2011) at baseline and 3-, 9-, and 18-months.
6. Psychological wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS, short version) (Tennant et al., 2007) at baseline, 3, 9 and 18 months
7. Experiences of care in Accidents & Emergency Questionnaire, devised for this study, and measured at baseline
8. All cause mortality (including suicide) derived from NHS/local authority/coroner records at 18 months
9. All patient attendances to the Emergency Department at 18 months following the index episode extracted from Trust records
10. Total healthcare use measured using the Client Service Resource Inventory at baseline, 3-, 9, and 18-months and NHS Digital data

Previous secondary outcome measures as of 01/02/2022 to 07/02/2024:
1. Self-reported self-harm using online surveys at 1, 2, 3, and 18 months
2. Suicidal ideation measured with Beck's Scale for Suicide Ideation (Beck & Steer, 1993) at baseline, 3, 9 and 18 months
3. Psychological wellbeing measured with CORE-OM (Barkham et al., 2001; Mavranezouli et al., 2011) at baseline, 3, 9 and 18 months
4. Social outcomes measured with the Social Outcomes Index (SIX) (S. Priebe et al., 2008) post-baseline and at 3, 9 and 18 months
5. Quality of life measured with the Warwick-Edinburgh Mental Wellbeing Scales (short version) post-baseline and at 3, 9 and 18 months
6. Experiences of attending the Emergency Department Questionnaire, devised for this study post-baseline
7. Death by suicide, i.e., cause of death is intentional self-harm or undetermined intent derived from NHS/local authority/coroner records at 18 months

Previous secondary outcome measures:
1. Self-reported self-harm, using online surveys at 1-, 2-, 3-, and 18-months.
2. Suicide severity, administered by researchers on the Columbia–Suicide Severity Rating scale (Posner et al., 2011) post-baseline and 18-months.
3. Psychological wellbeing measured with CORE-OM (Barkham et al., 2001; Mavranezouli et al., 2011) at baseline, 3- and 18-months.
4. Social outcomes, measured with the Social Outcomes Index (SIX) (S. Priebe et al., 2008) post-baseline and at 3- and 18-months.
5. Quality of Life, measured with the Warwick-Edinburgh Mental Wellbeing Scales (short version) post-baseline and at 3- and 18-months.
6. Experiences of attending the Emergency Department Questionnaire, devised for this study post-baseline.
7. Death by suicide, i.e., cause of death is intentional self-harm or undetermined intent derived from NHS/ local authority/coroner records at 18-months.

Overall study start date
12/11/2021

Completion date
30/04/2026

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 07/02/2024:
1. 16 years of age or older
2. Presenting to 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 and/or presenting with suicidal ideation, i.e., thoughts of not wanting to live
4. On presenting to the ED, can be admitted for a brief admission to the acute hospital

Previous participant 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
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
620

Key exclusion criteria
Current previous participant exclusion criteria as of 07/02/2024:
1. Patients admitted to a psychiatric hospital
2. Patients with 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
7. Receiving intensive psychological input e.g. DBT
8. Out of the hospital borough and Trust
9. Concerns about safety to practitioner or researcher
10. Not registered with a GP

Previous participant exclusion criteria:
1. Patients admitted to a psychiatric hospital
2. Patients with 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
7. Receiving intensive psychological input e.g. DBT
8. Out of the hospital borough and Trust

Date of first enrolment
21/03/2022

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Homerton University Hospital
United Kingdom
E9 6SR

Study participating centre
Whipps Cross Hospital
United Kingdom
E11 1NR

Study participating centre
East Surrey Hospital
United Kingdom
RH1 5RH

Study participating centre
Royal London Hospital
United Kingdom
E1 1FR

Study participating centre
Coventry Hospital
United Kingdom
CV2 2DX

Study participating centre
Warwick Hospital
United Kingdom
CV34 5BW

Study participating centre
George Eliot Hospital
United Kingdom
CV10 7DJ

Study participating centre
Royal Devon & Exeter Hospital
United Kingdom
EX2 5DW

Study participating centre
Torbay Hospital
United Kingdom
TQ2 7AA

Study participating centre
North Devon District Hospital
United Kingdom
EX31 4JB

Sponsor information

Organisation
Devon Partnership NHS Trust

Sponsor details
Wonford House Hospital
Dryden Road
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United Kingdom
EX2 5AF
+44 (0)1392 674114
tobit.emmens@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.dpt.nhs.uk/

ROR
https://ror.org/04fkxrb51

Organisation
City, University of London

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Myddelton Street Building, 1 Myddelton Street
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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
01/01/2026

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?
HRA research summary			28/06/2023	No	No