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Safety planning intervention with follow-up telephone contact to reduce suicidal behaviour

Submission date
05/05/2017

Recruitment status
No longer recruiting

Registration date
17/05/2017

Overall study status
Completed

Last Edited
28/07/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Although a past suicide attempt is the best predictor of future suicide attempts and suicide, there are no evidence-based treatments for those who are admitted to hospital following emergency admission. The aim of this study is to find out whether an extremely promising new psychosocial intervention (SAFE TEL) developed in the USA may be feasible for use in the UK NHS. The SAFE TEL intervention is comprised of safety planning and telephone support. A safety plan is a prioritised written list – in the patient's own words – of coping strategies and supports that the patient can use during or before suicidal crises. SAFE TEL has been developed to help patients to better identify suicide warning signs and to review their coping strategies and how they respond to triggers to reduce the risk of suicide attempts.

Who can participate?
Patients aged 18 or over admitted to hospital due to a suicide attempt

What does the study involve?
This study is conducted in three phases. In Phase 1, patients and NHS staff are consulted to tailor the existing SAFE TEL intervention for use within the UK NHS. In Phase 2 the intervention is tested with 30 patients after a suicide attempt. In Phase 3, 120 patients are randomly allocated to receive either the SAFE TEL intervention alongside treatment as usual, or treatment as usual only. The acceptability of the intervention to participants and staff, the feasibility of delivery in this setting, and the recruitment and retention of participants are all assessed to confirm whether SAFE TEL is feasible for delivery in the UK and if a large study to test it is justified.

What are the possible benefits and risks of participating?
The researchers cannot guarantee any direct benefit to the participants, but this study may form the basis for a full study which may demonstrate clinical benefit and therefore help people who are suicidal in the future. This study is considered to be low or no risk to participants. There is a slight chance they may become upset or embarrassed by some of the questions. Participants are reminded that participation is entirely voluntary and they can withdraw from the study at any time.

Where is the study run from?
1. Glasgow Royal Infirmary (UK)
2. Queen Elizabeth University Hospital (UK)
3. Royal Alexandra Hospital (UK)
4. Edinburgh Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
May 2017 to April 2019

Who is funding the study?
MQ Research (UK)

Who is the main contact?
Prof. Rory O'Connor
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MQ16PI100009

Study information

Scientific Title
SAFEty planning intervention with follow-up TELephone contact (SAFE TEL) to reduce suicidal behaviour: a development and feasibility study

Acronym
SAFE TEL

Study objectives
To determine whether an innovative and theoretically-driven Safety Planning Intervention with Follow-up Telephone Support (SAFE TEL) developed in the US to reduce suicide attempts is feasible and acceptable in the UK context.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS East of Scotland Research Ethics Service, 23/03/2017, ref: 17/ES/0036

Study design
Three-phase development and exploratory trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Suicidal behaviour

Interventions
Safety Planning Intervention
The core element of the SPI is the collaborative development of the Safety Plan (within the initial session), which is a prioritised written list – in the patient's own words – of coping strategies and supports that individuals can use during or preceding suicidal crises. The SPI incorporates subsequent telephone follow-up in order to conduct periodic risk assessment and mood checks, followed by a review of the Safety Plan, problem-solving obstacles to treatment and assisting with linkage to services. The SPI, which is fully manualised, actively includes evidence-based suicide prevention strategies, including facilitation of problem solving and coping skills, identification and harnessing of social supports and emergency contacts, lethal

means restriction, service linkage and motivational enhancement to promote community treatment engagement.

The Initial Session will take place in person in the hospital and will include a comprehensive clinical suicide risk assessment and development of a Safety Plan, a prioritised list of coping strategies and sources of support that patients can use during or preceding suicidal crises. The Safety Plan is meant to enhance an individual's sense of self-control over suicidal urges and thoughts. During the risk assessment, the researcher will obtain an accurate account of the events that transpired before, during, and after the most recent suicidal crisis. This description may include the activating events as well as the patient's reactions to these events. This discussion helps to facilitate the identification of warning signs to be included in the Safety Plan, as well as the identification of specific strategies or behaviours that may alleviate the crisis. SPI is intended to provide a specific template for rehearsal of safety behaviours, which can be useful for individuals with diminished problem solving capacity during an acute crisis.

Post-Discharge Telephone Sessions
The structured follow-up component consists of weekly phone contacts with the suicidal patient after discharge (over a minimum of 4 weeks). These contacts will include three components:
1. Brief risk assessment/mood check
2. Review/revision of SPI, if needed
3. Facilitation of treatment engagement through motivational enhancement, problem-solving obstacles to care and support
This follow-up outreach is discontinued when the patient begins/resumes outpatient treatment or no longer wishes to be contacted. If patients are determined to be at acute risk, appropriate action will be taken to maintain participant safety, which may include contacting existing providers, referral to the emergency department, or calling the police.

Phase 1 Adaptation
The existing USA intervention will be adapted and tailored to the UK, non-veteran context. This will involve consultation with service users (n=3), NHS staff (n=4 from hospitals identified in Phase 2 (below), Stanley and Brown (authors of the SPI and co-applicants) and representatives from Breathing Space (a service for people experiencing low mood, anxiety or depression). Service users will be recruited via the Scottish Recovery Network and via existing networks and a psychiatrist or psychiatric nurse from each of the four hospitals where recruitment will take place in Phases 2 and 3 will be interviewed. These interviews will identify any problems with the content/implementation of the intervention and the necessary amendments will be made. Once the intervention protocol is finalised, the research staff (research nurse/psychologist/social worker background) delivering the intervention will be trained.

Phase 2 Piloting
The intervention will be piloted with up to 30 participants recruited from three hospitals in NHS Greater Glasgow & Clyde (Glasgow Royal Infirmary (GRI), Queen Elizabeth University Hospital (QEUH), Royal Alexandra Hospital (RAH) and the Edinburgh Royal Infirmary (ERI) in NHS Lothian. All interviews will take place at a hospital site or University of Glasgow premises.

In addition to delivering the SAFE TEL intervention (i.e., SPI and follow up phone calls), the pilot phase will include a 1-2 months follow-up to test the intervention feasibility of collecting the suicide attempt data for Phase 3. Interviews will also be conducted to assess the feasibility and barriers with NHS clinical staff at each site (n=6) and there will be up to 10 participant interviews and a focus group with intervention providers (actual number dependent on data saturation) as well as a focus group with intervention providers. Data will be analysed using thematic analysis to identify key themes. Phase 3 progression criteria will then be developed in collaboration with

the independent Trial Steering Committee. The intervention will be modified as necessary for Phase 3.

In Phase 3 120 hospitalised patients will be randomised 2:1 across four hospitals to either:
1. The SPI with Follow-up Telephone Support + TAU with 6-month follow-up (n=80)
2. TAU only with 6-month follow-up (n=40)
Web-based randomisation with stratification for sex and self-reported self-harm history

Process Evaluation:
A mixed methods process evaluation will be completed to explore feasibility and acceptability (Phases 1-3) as well as context, reach, exposure fidelity, recruitment, retention and contamination (Phases 2-3). In the exploratory trial, after the 6 month follow-up period, up to 10 NHS clinical staff at the sites and 30 patients (numbers dependent on data saturation) will be interviewed and another focus group will be conducted with intervention staff. The interviews and focus groups will explore views of the intervention including the acceptability and the feasibility of delivering the intervention in practice. Barriers and facilitators to implementation as well as suggestions for improvements will also be explored.

Participants for the interviews and focus groups will be sampled to allow for a range of views. Key sampling characteristics will include gender and age. For phases 2 and 3, the trialists will additionally seek to sample according to engagement with the intervention as well as whether or not individuals have attempted further suicide attempts.

Twenty percent of the sample of sessions will be randomly selected and audio-recorded to check for fidelity against a standardized measure of fidelity for the SPI (Safety Planning Intervention Rating Scale) and a checklist for the follow-up calls. Potential mediators of the intervention effect will also be explored and the logic model will be tested using both qualitative and quantitative data.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcomes including:
1. The acceptability of the intervention to participants and intervention staff
2. The feasibility of delivery in this setting
3. Recruitment
4. Retention
5. Intervention adherence
6. The feasibility of collecting the suicide attempt outcome data (which would be the primary outcome in a full trial)

In Phase 3, the feasibility/acceptability information will be collected after participants have completed their participation in the study. The actual timeline will be informed by feedback from Phases 1 and 2, however, these data will be collected no earlier than 4 weeks post intervention. Staff and intervention staff will also be interviewed.

Secondary outcome measures
In Phase 3, hospital-treated suicidal behaviour (self-harm and suicide attempts) in the 6 months post-randomisation, determined by hospital medical records linked by hospital CHI numbers, will be used to estimate the primary outcome event rates to inform a full trial

Overall study start date
15/05/2017

Completion date
30/04/2019

Eligibility

Key inclusion criteria
Phase 1:
1. Past history of a suicide attempt, or
2. Experience of contact with those who have attempted suicide (in a clinical or research role)

Phases 2 and 3:
1. Admission to hospital, presenting with a self-harm episode where there was evidence of suicidal intent (i.e., a suicide attempt)
2. Age 18 years or over
These inclusion criteria for may change following feedback during Phases 1 and 2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 in Phase 2 and 120 in Phase 3

Key exclusion criteria
Phase 1:
1. Imminent risk of suicide

Phases 2 and 3:
1. Participants with no suicidal intent
2. Participants who are unfit for interview
3. Those from whom we cannot gain informed consent
4. Those patients whose understanding of English is not sufficient to complete the SPI
5. Those patients who are participating in another psychological intervention in the hospitals
6. Those patients who do not have access to a telephone

Date of first enrolment
01/06/2017

Date of final enrolment

14/09/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Glasgow Royal Infirmary
Glasgow
United Kingdom
G4 0SF

Study participating centre
Queen Elizabeth University Hospital
Glasgow
United Kingdom
G51 4TF

Study participating centre
Royal Alexandra Hospital
Paisley
United Kingdom
PA2 9PN

Study participating centre
Edinburgh Royal Infirmary
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
NHS Greater Glasgow & Clyde

Sponsor details

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
MQ Research

Results and Publications

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

Intention to publish date
30/04/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Rory O'Connor (rory.oconnor@glasgow.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/02/2019	23/03/2020	Yes	No
Results article		27/07/2022	28/07/2022	Yes	No
HRA research summary			28/06/2023	No	No