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A help sheet to reduce self-harm among people admitted to hospital for self-harm

Submission date
27/04/2012

Recruitment status
No longer recruiting

Registration date
03/05/2012

Overall study status
Completed

Last Edited
25/04/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Suicide is a national priority and a history of self-harm is its best predictor. Much research effort has been directed at reducing self-harm (SH) and by implication the risk of suicide. Psychosocial interventions (treatment) targeted at those who self-harm have been shown to offer promise in terms of reducing SH repetition. However, one of the major issues with delivering such interventions is that it is very difficult to maintain patients who self-harm in treatment. As a result, it is desirable to intervene more while the patient is in hospital to reduce risk. This study will investigate whether a new, low intensity psychosocial intervention, the volitional help sheet (VHS), has utility in reducing SH. This study will address three research questions:
1. Does VHS reduce the number of people who re-present to hospital with SH in the six months following an index episode of SH?
2. Does a VHS reduce the number of SH episodes per person in the six months following an index episode of SH? and
3. What is the incremental cost of the VHS per SH event averted?

Who can participate?
All male and female patients over the age of 16 years, with a history of self-harm, who have been admitted to the Combined Assessment Area 6 (Royal Infirmary of Edinburgh), with suicidal self-harm can participate.

What does the study involve?
Participants who have presented to hospital following suicidal self-harm will be randomised into either the intervention (treatment as usual + VHS) or control (treatment as usual) arms of the study. At Time 2, six months later, we will determine whether the intervention had an effect on re-presentation to hospital for self-harm. The study involves answering questions about psychological well-being, current and previous self-harm episodes and depending on the arm of the study, some participants will be asked to complete the help sheet.

What are the possible benefits and risks of participating?
There are no risks associated with taking part in the study but participants may find it beneficial to take part as it may help them to stop self-harming again in the future.

Where is the study run from?
Royal Infirmary of Edinburgh (UK)

When is study starting and how long is it expected to run for?
April 2012 to April 2015

Who is funding the study?
Chief Scientist Office of the Scottish Executive Health Department (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZH/4/704

Study information

Scientific Title
A volitional help sheet to reduce self-harm among people admitted to hospital for self-harm: a randomised controlled trial

Study objectives
1. Does a Volitional Help Sheet reduce the number of people who re-present to hospital with self-harm in the six months following an index episode of self-harm?
2. Does a Volitional Help Sheet reduce the number of self-harm episodes per person in the six months following an index episode of self-harm?
3. What is the incremental cost per self-harm event averted?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian NHS Board, South East Scotland Research Ethics Committee, 07/02/2012, ref: 12/SS /0012

Study design
Single-centre randomised controlled study

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
Hospital treated self-harm

Interventions
At baseline, participants in both the intervention and control group will receive treatment as usual and will complete standard demographic measures as well as a number of clinical /psychological measures.

In addition to this, participants in the Intervention group will complete the Volitional Help Sheet with the assistance of the research assistant. The Volitional Help Sheet will be produced such that a carbon copy will be available. Upon completion of the help sheet, participants will be asked to take a copy home with them and encouraged to refer to it at home. The research assistant will keep the other copy.

Approximately 2 months post baseline, all those in the intervention group will be sent a single booster help sheet. The booster will involve re-sending a copy of the completed help sheet and in the covering letter a summary of the solutions and associated critical situations that the participant thought might be helpful at baseline.

Six months following baseline, data will be extracted by the Information Services Division (ISD) if the NHS National Services Scotland. ISD maintains a national database of hospital records and mortality data. This nationally linked database will allow us to determine whether a patient has been re-admitted to hospital anywhere in Scotland with selfharm at any time since their index episode. This information will be extracted for each participant.

As copies of the self-help sheets will be kept, fidelity checks can be conducted on the administration of the intervention. In addition to this, during the data collection phase, a member of the research team will sit in on a random selection of participant assessments to monitor adherence to trial protocol.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Whether a participant re-presented to any hospital in Scotland with self-harm during the follow up period of six months
2. How many times a participant re-presented at hospital with self-harm during the six month follow up period. All of this information will be gathered from data from the nationally linked database held by the Information Services Division (ISD) of the NHS National Services Scotland.
3. Cost effectiveness of the self-help sheet, as measured by estimated incremental cost per self-harm event/suicide averted

Secondary outcome measures
Time to representation at hospital with self-harm within the six month follow up period. This will be measured in weeks/months and this information will be gathered from data from the nationally linked database held by the Information Services Division (ISD) of the NHS National Services Scotland.

Overall study start date
19/04/2012

Completion date
19/04/2015

Eligibility

Key inclusion criteria
1. Male and female patients admitted to the Combined Assessment Area 6 of Royal Infirmary of Edinburgh with self-harm
2. Those with a past history of self-harm
3. Those with suicidal intent (associated with the present episode)
4. Age 16 + years no upper age range

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
518 people (259 in each arm)

Key exclusion criteria
1. Those below 16 years old
2. Those with no reported suicidal intent (associated with the present episode)
3. Those with no past history of self-harm prior to the index episode
4. Patients who are unfit for interview
5. Those from who informed consent cannot be gained
6. Those patients for whom English is not their first language
7. Those who are participating in other research at the Royal Infirmary of Edinburgh
8. Those that present at the emergency department but are subsequently discharged without hospital admission

Date of first enrolment
19/04/2012

Date of final enrolment
19/04/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Glasgow
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Sponsor information

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ROR
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Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (ref: CZH/4/704)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2017		Yes	No