

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	<input type="checkbox"/> Prospectively registered
Registration date 03/05/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/04/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre

University of Glasgow

Glasgow

United Kingdom

G12 0XH

Sponsor information

Organisation

University of Stirling (UK)

ROR

<https://ror.org/045wgfr59>

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

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