

Contact and information after self-harm pilot study

Submission date 24/06/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 24/06/2010	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 03/07/2013	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
8434

Study information

Scientific Title
A pilot study of a contact and information based intervention to reduce repeat self-harm

Study objectives

The study is funded by the National Institute of Health Research and will be carried out on patients who have recently attended the emergency departments at two hospitals in Manchester following an episode of self-harm.

We plan to recruit between 50 - 100 people over a three month period who have been discharged from the emergency department following self-harm, into the intervention group or the control group. The intervention group will receive an information leaflet providing details of local and national support agencies, followed by two phone calls, and then letters intermittently up to 12 months after recruitment. Both groups will receive their treatment as usual. The rationale for the intervention is to provide contact and facilitate patient access to appropriate treatment. The phone calls and letters will be from a mental health clinician. The main aim of this study is to inform the implementation of a large multicentre randomised control study. We will also investigate whether the intervention reduces repetition of self-harm.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West 9 Research Ethics Committee - Greater Manchester West approved on the 24th May 2010 (ref: 10/H1014/35)

Primary study design

Interventional

Study design

Single centre randomised interventional treatment trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Suicide and self-harm; Disease: Suicide and self harm

Interventions

Patients in the intervention group will receive two phone calls from a clinical researcher soon after hospital attendance, an information leaflet listing local sources of help, and then letters intermittently up to 12 months after recruitment, as well as treatment as usual.

Patients in the control group will receive treatment as usual.

Follow-up length: 12 months

Study entry: single randomisation only

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

To assess the feasibility of a randomised controlled trial (RCT), in particular, recruitment at 6 and /or 12 months

Key secondary outcome(s)

1. At 12 months we will assess the acceptability of the intervention and help refine it
2. Proportion of patients with at least one repetition of self-harm within 6 and/or 12 months
3. Assess resource use in order to pilot collection of such data

Completion date

30/09/2011

Eligibility

Key inclusion criteria

1. Adults aged over 18 years, either sex
2. Present to the study hospitals with self-harm

Recruitment may take up to three months or we may achieve our target sample size at an earlier stage. "Self-harm" is defined as "an act of intentional self-injury or poisoning irrespective of the apparent purpose of the act". This includes attempts regardless of suicidal intent or medical seriousness and as a definition is in line with that used by NICE guidelines on the short term management of self-harm.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Psychiatric in-patients
2. No fixed abode
3. Do not have telephone access
4. Unable to give informed consent during the first telephone call
5. Have been approached at an earlier stage in the study and had refused consent
6. Not able to understand the English language

Date of first enrolment

01/04/2010

Date of final enrolment

30/09/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Oxford Road

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR)

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	01/07/2013		Yes	No