A pilot study to evaluate a Guided Self-Help Programme for people who have self harmed and a follow up study of patients who have participated in Exeter GUS 1.1

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	☐ Individual participant data
16/04/2015	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0079153958

Study information

Scientific Title

A pilot study to evaluate a Guided Self-Help Programme for people who have self harmed and a follow up study of patients who have participated in Exeter GUS 1.1

Study objectives

To assess whether guided self help (GSH) in addition to standard care, has the potential to improve mood systems, hopelessness and social function compared to standard care alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Self harm

Interventions

Guided self help (GSH) in addition to standard care compared to standard care alone.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Assess the potential effect size of intervention on mood and suicide risk and social function. Measures: HAD anxiety and depression scale, Beck Hopelessness Scale, Beck suicidal intent scale. Social function questionnaire - all at 0 weeks, 2-4 weeks, and 6 weeks.

Secondary outcome measures

Patient satisfaction questionnaire at end of study and coping strategy questionnaire at beginning and end of study.

Overall study start date

02/03/2004

Completion date

02/07/2005

Eligibility

Key inclusion criteria

Consecutive attendances at R&D of patients aged 16-65 years who have self harmed and are not thought to require immediate medical attention or have severe mental illness affecting their ability to consent to research or of imminent and serious suicide risk.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

25 patients - 2 groups

Key exclusion criteria

- 1. Children under the age of 16
- 2. Patients of no fixed abode, not resident in Devon, not contactable by telephone
- 3. Serious mental health problem or suicide risk requiring urgent admission

Date of first enrolment

02/03/2004

Date of final enrolment

02/07/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Exeter Exeter United Kingdom

EX2 5AF

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Devon Partnership NHS Trust (UK), NHS R&D Support Funding

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 summaryNot provided at time of registration