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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
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
16/04/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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SW1A 2NL
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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 summary
Not provided at time of registration