ISRCTN25835525 https://doi.org/10.1186/ISRCTN25835525

A randomised controlled trial to assess the effectiveness of giving self-help information to people with symptoms of acute stress disorder following a traumatic injury.

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
15/07/2009

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Catherine Scholes

Contact details
Clinical Psychology
114 St Anthony Road
Sheffield
United Kingdom
S10 1SG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0071137440

Study information

Scientific Title

Study objectives
The aims of the study are:
1. To assess the relationship between giving self-help information to traumatic injury patients with symptoms of Acute Stress Disorder (with or without acute dissociation) and subsequent symptom severity.
2. To identify potential predictors of those patients who will benefit from self-help information.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Acute stress disorders

Interventions
The study will employ a between-groups repeated measures design to assess psychological sequelae and quality of life for individuals experiencing symptoms of Acute Stress Disorder (ASD) following attendance at Accident and Emergency after a traumatic event.
There will be three different groups:
Group 1- the Information group - will consist of patients with symptoms of Acute Stress Disorder who receive the self-help booklet within one month of their traumatic injury;
Group 2 - the Waiting List Control group - will consist of patients with symptoms of Acute Stress Disorder who receive the self-help booklet at the end of the study period;
Group 3 - the non-ASD Control Group- will consist of patients without symptoms of Acute Stress

Disorder who receive the self-help booklet at the end of the study period.
These groups will be assessed at three points in time (within one month of the trauma, three months posttrauma and six months posttrauma).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2003

Completion date
30/09/2004

Eligibility

Key inclusion criteria
1. Two Acute Stress Disorder groups
1.1 Accident and Emergency patients involved in road traffic accidents, assaults and occupational injuries of at least moderate severity between the months of July 2003 and January 2004.
1.2 meet the cut-off criteria for Acute Stress Disorder symptomatology (with or without dissociation)
1.3 consent to participate in the study
1.4 between the ages of 18 and 65.
2. Non-Acute Stress Disorder control group
2.1 patients who have had an accident of at least moderate severity
2.2 do not meet the cut-off criteria for Acute Stress Disorder symptomatology

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria

1. suffering from a psychotic illness
2. learning disability
3. head injury
4. illiterate or do not speak English

Date of first enrolment
01/08/2003

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Psychology
Sheffield
United Kingdom
S10 1SG

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Research council

Funder Name
Sheffield Health and Social Research Consortium (UK)

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	01/11/2007		Yes	No