

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	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 15/07/2009	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre
Clinical Psychology
Sheffield
United Kingdom
S10 1SG

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Research council

Funder Name
Sheffield Health and Social Research Consortium (UK)

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	01/11/2007		Yes	No