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Efficacy of an information booklet in reducing post-traumatic symptoms after road traffic accidents

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 05/07/2018	**Condition category** Other	

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
SPGS765/AO

Study information

Scientific Title
Efficacy of an information booklet in reducing post-traumatic symptoms after road traffic accidents

Study objectives
1. To test whether a trauma booklet given out during a single session of cognitive behavioural advice is more effective in reducing PTSD symptoms after a road traffic accident than no intervention (wait list) in the short-term (immediately afterwards) and in the long-term (up to one year after the accident).
2. To compare the therapeutic effect of the booklet with that of specialist cognitive behavioural treatment CBT). What proportion of the CBT effect can be achieved by giving the booklet on its own?
3. To determine the effectiveness of postal follow-up of trauma service attenders and publicity to general practitioners in identifying road accident victims with distressing and disabling PTSD at 2 to 3 months.
4. Cost-effective delivery of simple self-help and specialist treatment for the large numbers of trauma victims who suffer distressing and disabling post-traumatic symptoms.

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
Not applicable

Interventions
1. Trauma booklet
2. Cognitive behavioural treatment (CBT) including the trauma booklet.
3. Wait list

The booklet and CBT will be given at 3 months after the accident.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Structured interviews and self-reports for the assessment of PTSD symptoms developed by Foa and colleagues
2. Beck depression Inventory
3. Beck anxiety Inventory
4. Measures of travel anxiety and avoidance developed in previous Oxford research
5. We will also report medical consultation and effects on quality of everyday activities

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/1998

Completion date
01/05/2002

Eligibility

Key inclusion criteria
Possible subjects will be identified at the John Radcliffe Hospital, Oxford and the Northampton General Hospital.
Patients will be contacted within 2 months of their road traffic accident and asked to fill out the post-traumatic stress disorder (PTSD) Diagnostic Scale (PTSD, Foa 1996) to assess PTSD. Subjects will be eligible if they suffer from PTSD at 2 months after the accident and have a minimum severity of symptoms of 20 on the post-traumatic stress diagnostic scale (PDS). This cut-off was chosen based on RM's prospective study. Patients meeting this criterion have a low probability of spontaneous remission (<30%). Approximately 14% of the patients contacted will meet this criterion.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Include brain damage, spinal cord injuries, chronic major psychiatric disorder (schizophrenia, manic-depressive disorder, alcohol or drug dependence) or severe current psychiatric problems which are thought to require immediate intervention

Date of first enrolment
01/05/1998

Date of final enrolment
01/05/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
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.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (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	01/06/2000		Yes	No