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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Richard Mayou

#### Contact details

University of Oxford Department of Psychiatry Warneford Hospital Oxford United Kingdom OX3 7JX

# Additional identifiers

# **Protocol serial number** 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

## Study type(s)

**Not Specified** 

# 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(s)

- 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

## Key secondary outcome(s))

Not provided at time of registration

## 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

# Healthy volunteers allowed

No

## Age group

Not Specified

#### Sex

**Not Specified** 

# 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

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)

# Funder(s)

# Funder type

Government

## Funder Name

NHS Executive South East (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 | 01/06/2000   |            | Yes            | No              |