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A randomised controlled trial to determine whether mental health problems and significant psychological distress in children involved in everyday road traffic accidents can be prevented

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/01/2010	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
C/INJ/12/05.99/Stallard

Study information

Scientific Title

Study objectives
A significant number of children develop mental health problems (PTSD, depression, anxiety) and suffer major psychological changes (mood, relationships, behaviour, social life, school attendance) as a result of road traffic accidents. This study aims to evaluate whether a brief intervention designed to encourage discussion about the accident is effective in preventing mental health problems whilst facilitating post-accident psychological functioning.

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)
Prevention

Health condition(s) or problem(s) studied
Post-traumatic stress disorder (PTSD); depression; anxiety

Interventions
1. Trauma discussion (intervention)
2. Standard care

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Pre and post measures will allow between & within group comparisons in order to determine whether the intervention was effective in preventing the development of mental health problems and facilitating post-accident psychological functioning. Standard psychometric questionnaires and semi-structured interview will be used.

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/2003

Eligibility

Key inclusion criteria
A total of 276 children aged 7-18 attending a hospital A&E Department following involvement in a road traffic accident will be recruited.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Avon & Western Wiltshire Mental Health Care NHS Trust
Bath
United Kingdom
BA1 3NG

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive South West (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	01/02/2006		Yes	No