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

Study design

Randomised controlled trial

Primary study design

Interventional

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