

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 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/01/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2000

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

Age group

Child

Lower age limit

7 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

276

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

England

United Kingdom

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)

Sponsor details

The Department of Health

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SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

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