

# 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

**Registration date**

23/01/2004

**Overall study status**

Completed

**Last Edited**

12/01/2010

**Condition category**

Mental and Behavioural Disorders

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ 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

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

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 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?
<a href="#">Results article</a>	results	01/02/2006		Yes	No