

A randomised controlled trial of the effectiveness of a paediatric head injury co-ordinator nurse in reducing subsequent contact with health care professionals

| | | |
|--|--|--|
| Submission date 30/09/2004 | Recruitment status Stopped | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 30/09/2004 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 30/03/2011 | Condition category Other | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Deborah White

Contact details

Box No 7
Paediatric Intensive Care Unit
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 217613
deborah.white@addenbrookes.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0544139664

Study information

Scientific Title

Study objectives

Approximately 15-20% of so called 'mild' head injured children develop morbidities that necessitate further healthcare interventions. 1000 children are seen in Accident and Emergency (A&E) at Addenbrooke's with 'mild head injury' per year. Our study will be conducted in two parts.

On discharge from the accident and emergency department following a minor head injury, the carers of children are given an information card containing information on expected side effects from the accident. This card is standard care and a requirement following NICE (National Institute of Clinical Excellence) guidelines.

Stage 1: A population-based observational study in order to calculate a sample size for stage 2. Following informed consent, we will contact families 2 weeks following their child's A&E attendance and ask a series of questions around their child's recovery to ascertain how long their child had off school and if the family had to seek further help or advice from the GP or A&E department. This stage of the work will be used as a pilot study and the results obtained will allow us to calculate the sample size needed for stage 2, a randomised controlled trial. The information card will be adapted to include the following name and contact number 'Deborah White, Paediatric Research Nurse - 01223 245151 bleep 151-879'.

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Not Applicable: Service delivery

Interventions

Following informed consent, families will be randomised to one of two groups.

The first group will be contacted 1 week following injury to ascertain the progress of the child and offer advice to the family about dealing with the expected symptoms following a head injury.

Both groups 1 and 2 will be contacted 2 weeks following the injury as in stage 1.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The two groups would then be compared to see if the number of visits to A&E or to the GP were any different across the two groups.

Secondary outcome measures

Not provided at time of registration

Overall study start date

04/03/2003

Completion date

03/03/2007

Reason abandoned (if study stopped)

Poor recruitment

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

04/03/2003

Date of final enrolment

03/03/2007

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Box No 7

Cambridge

United Kingdom

CB2 2QQ

Sponsor information**Organisation**

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Cambridge Consortium - Addenbrooke's (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