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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

Registration date
30/09/2004

Overall study status
Stopped

Last Edited
30/03/2011

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
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

Study type(s)
Treatment

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(s)
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.

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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Box No 7
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration