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Communication tools for parents of children presenting to the Emergency Department with croup

Submission date 04/10/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/10/2007	**Overall study status** Completed	
Last Edited 11/11/2013	**Condition category** Respiratory	

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
N/A

Study information

Scientific Title

Acronym
CCT (Croup Communication Tools) Study

Study objectives
Stories, delivered through printed and illustrated story booklets, versus standard information sheets distributed in the Emergency Department (ED), will produce different results in terms of:
1. Parental anxiety, knowledge, satisfaction, and decisional regret
2. Healthcare utilisation patterns, and
3. Costs

Please note that as of 05/09/2008, the anticipated end date of this trial was extended to 31st March 2009 to create more time to recruit the full sample size. The previous anticipated end date was 31st March 2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by University of Alberta Health Research Ethics Board on the 14th September 2007 (ref: B-110607).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Acute obstructive laryngitis (croup)

Interventions
Patients are randomly assigned to one of the following:
1. Experimental intervention is three booklets that integrate stories, as told by parents of children with croup attending the ED, with evidence regarding the epidemiology and treatment

of the condition. These will be given when they are recruited and randomised at the beginning of their ED visit. They will be able to take the information home and refer to it at their convenience. Parents will be interviewed when they are recruited to the study (baseline), on discharge from the ED, one day post-ED discharge and three days post-ED discharge. For patients who still have symptoms at day three, the parents will be interviewed every two days until the symptoms resolve or until 9 days post-discharge. A convenience sample of 30 parents randomised to the story group will be asked to participate in an in-depth qualitative interview approximately 2 weeks after the ED visit. All parents will be interviewed at 1 year post-ED visit
2. Control intervention is a standard patient information sheet on croup

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Parental anxiety measured using the State-Trait Anxiety Inventory (STAI-S, Form Y). Anxiety will be measured at baseline, discharge from ED, one day post-discharge, and when child is symptom free.

Secondary outcome measures
1. Event impact
2. Parental knowledge, measured at day 3 post-discharge, 1 year post-discharge
3. Parental satisfaction with ED visit, measured at day 1 post-discharge
4. Decisional regret, measured at day 1 post-discharge
5. Incidence of return for medical care, measured at day 1, day 3 and every two days thereafter until child is symptom-free or until day 9 post-discharge
6. Healthcare utilisation patterns, measured at day 1, day 3 and every two days thereafter until child is symptom-free or until day 9 post-discharge, 1 year post-discharge
7. Costs, measured at day 1, day 3 and every two days thereafter until child is symptom-free or until day 9 post-discharge, 1 year post-discharge

Overall study start date
15/10/2007

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Parents of children with a clinical diagnosis of croup
2. Parents must also meet the following criteria:
2.1. Have a telephone and be willing to be contacted for follow-up interviews
2.2. Fluent in English
2.3. Provide informed consent
2.4. No prior visit to an ED during this episode of the disease
2.5. No prior visit to an ED for another episode of croup during the study period

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
420

Key exclusion criteria
Parents will be excluded if:
1. Stridor is due to another cause (e.g., bacterial tracheitis, presence of a supraglottic foreign body)
2. Parent has previously been included in the study

Date of first enrolment
15/10/2007

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Canada

Study participating centre
Aberhart Centre One, Room 8213
Edmonton
Canada
T6G 2J3

Sponsor information

Organisation
University of Alberta (Canada) - Department of Paediatrics

Sponsor details
Aberhart Centre One
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Sponsor type
University/education

Website
http://www.ualberta.ca/

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
University/education

Funder Name
University of Alberta (Canada) - Department of Paediatrics

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	25/10/2013		Yes	No