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

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

# Plain English summary of protocol

Not provided at time of registration

## **Contact information**

## Type(s)

Scientific

#### Contact name

Dr Terry Klassen

#### Contact details

Aberhart Centre One, Room 8213 11402 University Avenue Edmonton Canada T6G 2J3

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

 ${\bf Clinical Trials. gov\ number}$ 

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 11402 University Avenue Edmonton Canada T6G 2J3

## 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