

# Evaluation of a knowledge translation tool for parents of children with diarrhea and vomiting

<b>Submission date</b> 09/03/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/03/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/06/2023	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Diarrhea and vomiting in children is a common reason for parents to take their child to the emergency department. There has been a lot of research on how to treat children with diarrhea and vomiting in the emergency department. There are also things parents can do at home to help their children when they have diarrhea and vomiting. Some of these things could help avoid a trip to the emergency department. It is important that parents are aware of this information so they can make the best decisions for their children's health. The researchers have made a short video with parent input to tell them about how to manage a child with diarrhea and vomiting. It is important to test this video to make sure that it helps parents before we make the video widely available. In this project, parents will help us test the video.

### Who can participate?

Parent or caregiver of a child 16 years or younger presenting to the emergency department with vomiting and diarrhea.

### What does the study involve?

Parents who come to the emergency department with a child who has diarrhea and vomiting will be invited to participate in the study. They will be randomized to view the video or a sham video. Then they will answer some questions. Parents who watch the video will also be invited to participate in an interview. The questionnaires and interview will help us understand if the video works and if parents find the video helpful. The researchers will also ask parents about how they found the study process, including the use of an electronic, web-based platform to collect data. This will help to understand whether parents are willing to participate in similar research in the future.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

Stollery Children's Hospital (Canada)

When is the study starting and how long is it expected to run for?  
April 2020 to August 2021 (updated 13/07/2021, previously: July 2021 (updated 09/03/2021, previously: March 2021))

Who is funding the study?  
Canadian Institutes of Health Research

Who is the main contact?  
Dr Lisa Hartling  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
NCT03234777

**Secondary identifying numbers**  
Pro00091675

## Study information

**Scientific Title**  
A pilot and feasibility randomized trial of a knowledge translation tool for parents

**Study objectives**

The primary objective is to evaluate the potential effectiveness of a digital knowledge translation tool for parents about acute gastroenteritis. Another key objective is to examine the feasibility of using an electronic, web-based platform for intervention delivery and data collection.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 16/08/2019, University of Alberta Health Research Ethics Board (Research Ethics Office, 308 Campus Tower, 8625 – 112 Street, Edmonton, AB T6G 1K8, Canada; +1 780 492 0459; reoffice@ualberta.ca), ref: Pro00091675

### **Study design**

Single-centre pilot and feasibility randomized trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Other

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

### **Health condition(s) or problem(s) studied**

Acute gastroenteritis

### **Interventions**

Participants will be randomly allocated to intervention or control groups.

The intervention is a 3-minute whiteboard animation video about acute gastroenteritis. The sham control is a 3-minute video about handwashing produced by the US Centres for Disease Control. The participants (i.e., parents or caregivers of children with gastroenteritis) will watch the video to which they are randomized once while waiting in the emergency department; they will have an option to be sent a link to the video by email after having watched it. At the end of the study, all participants will be sent a link to both videos that were used in the study.

The intervention/control is 3 minutes in duration. Participants are asked to complete three questionnaires. The first questionnaire is completed before the intervention. The second questionnaire is completed immediately after the intervention. The third questionnaire is sent to participants by email 4 days after entering the study. They will have up to 14 days following entry into the study to complete the third questionnaire. Participants in the intervention group

are also invited to participate in a qualitative interview about the perceived benefit and value of the video, and study processes (e.g., the use of the electronic, web-based platform for intervention delivery and data collection).

The randomization sequence will be computer generated and will be kept confidential. Participants, research staff, and study investigators will not know the randomization sequence. Randomization, based on the computer generated sequence, will be deployed within the web-based platform. The video to which participants are randomized will automatically begin to play after they complete the first questionnaire. Participants will be blinded to the interventions being compared. Study investigators and the statistician will be blinded to group allocation.

## **Intervention Type**

Other

## **Primary outcome measure**

Potential effectiveness will be assessed based on parent knowledge, decision regret, healthcare utilization, perceived benefit and utility of the intervention. All outcomes will be based on participant self-reports and collected through questionnaires completed by the participants.

1. Parent knowledge is based on 8 questions about acute gastroenteritis (informed by the Caregiver Gastroenteritis Knowledge Questionnaire); these questions will be asked at baseline, immediately after the intervention, and at follow-up (4-14 days post-intervention)
  2. Parent decision regret is based on the Decision Regret Scale which consists of 5 items; these questions will be asked at baseline, immediately after the intervention, and at follow-up (4-14 days post-intervention)
  3. Healthcare utilization includes two items about whether the participant returned to the emergency department or visited another healthcare provider because of their child's gastroenteritis; these questions will be asked at follow-up (4-14 days post-intervention)
  4. For perceived benefit and utility of the intervention, participants will answer 2 questions immediately after the intervention, and 5 questions at follow-up (4-14 days post-intervention).
- Participants who were randomized to the whiteboard animation video will be invited for a qualitative interview which will follow a semi-structured guide with 15 questions about their perceptions of the intervention and study processes. The interview will be conducted after the participant completes the follow-up questionnaire.

## **Secondary outcome measures**

Feasibility of using an electronic, web-based platform for intervention delivery and data collection measured using data completion from the above measures and participant experience measured using qualitative interviews as above.

## **Overall study start date**

21/05/2019

## **Completion date**

31/08/2021

# **Eligibility**

## **Key inclusion criteria**

1. Parent or caregiver of a child 16 years or younger
2. Child is presenting to the emergency department with vomiting and diarrhea
3. Parent is fluent in English
4. Parent is willing to be contacted for follow-up data collection

**Participant type(s)**

Carer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Total final enrolment**

103

**Key exclusion criteria**

1. Child has significant chronic gastrointestinal problem or inflammatory bowel disease (i.e., Crohn's Disease, Inflammatory Bowel Disease, Ulcerative Colitis, chronic constipation)
2. Child is taking immunosuppressive therapy or has known history of immunodeficiency
3. Child has undergone oral or gastrointestinal surgery within the preceding 7 days
4. Child has had a prior visit to the emergency department for vomiting and diarrhea within the preceding 14 days

**Date of first enrolment**

01/04/2020

**Date of final enrolment**

31/08/2021

**Locations****Countries of recruitment**

Canada

**Study participating centre**

Stollery Children's Hospital

8440 112 St NW

Edmonton

Canada

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# Sponsor information

## Organisation

University of Alberta

## Sponsor details

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## Sponsor type

University/education

## Website

<https://www.ualberta.ca>

## ROR

<https://ror.org/0160cpw27>

# Funder(s)

## Funder type

Government

## Funder Name

Canadian Institutes of Health Research

## Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Canada

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

30/06/2023

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	02/08/2018	11/03/2020	Yes	No
<a href="#">Results article</a>		25/05/2023	09/06/2023	Yes	No