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

Submission date
09/03/2020

Recruitment status
No longer recruiting

Registration date
11/03/2020

Overall study status
Completed

Last Edited
09/06/2023

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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

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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?
Protocol article	protocol	02/08/2018	11/03/2020	Yes	No
Results article		25/05/2023	09/06/2023	Yes	No