Patient-oriented research methods to inform and evaluate a digital knowledge translation tool for parents about pediatric acute gastroenteritis: A pragmatic approach to evidence-based, health education

by

Lauren Albrecht

A thesis submitted in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

in

Psychological Studies in Education

Department of Educational Psychology

University of Alberta

Abstract

Pediatric acute gastroenteritis is a common illness with a large burden on children, families, and health care systems. Connecting parents to evidence-based, child health information is essential to minimize this burden. There has been significant research on effective treatments for children with acute gastroenteritis, yet care varies by healthcare provider and across hospitals. This indicates an urgent need for knowledge translation, that is, evidence-based strategies to align what is known from research with what is done in health care practice. Actively involving parents in health care has the potential to optimize knowledge translation; however, the best opportunities and approaches for this engagement are unclear. Prior research indicates that parents look for information about their child's health online, thus digital knowledge translation tools are a promising approach to provide complex, child health information. Rigorous effectiveness evaluation of child health digital tools for parents is a critical next step in the emerging field of knowledge translation for health consumers.

A pragmatic paradigm, patient-oriented research, integrated knowledge translation, and the Knowledge-to-Action Framework guided this research. Four main projects were conducted to inform and evaluate a digital, knowledge translation tool – a whiteboard animation video - for parents about pediatric acute gastroenteritis. A scoping review (project 1) examined existing research on methods used to evaluate the effectiveness of a variety of knowledge translation tools for parents on child health topics. This knowledge synthesis study determined that a diverse set of child-health related knowledge translation tools were available, but effectiveness had not been demonstrated. Specific recommendations to improve methodological rigor and research reporting were detailed. Next, a qualitative study (project 2) described parental experiences of managing pediatric acute gastroenteritis and seeking health care in the emergency department.

Key information needs were identified. The findings of this study illuminated factors reflecting real-life complexity that influenced parents' health care decisions. These findings informed the storyline of the digital knowledge translation tool for parents about this illness. Following this, a pragmatic pilot study protocol was developed to determine the feasibility of methods to evaluate the effectiveness of the digital knowledge translation tool (project 3). Feasibility outcomes were developed in four key domains: 1) process (i.e., What elements are key to study success?); 2) scientific (i.e., Is the intervention effective?); 3) management (i.e., Are the human and data needs optimized?); and, 4) resource (i.e., Are the time and budget allocations reasonable?). Finally, the pragmatic pilot randomized controlled trial, which incorporated qualitative components, was conducted in one pediatric emergency department over a 3-month period (project 4). The goal of this pilot study was to determine the feasibility of pragmatic randomized controlled trial methods to inform a future, full-scale trial. The results confirmed successful study design elements, including a novel electronic data collection platform and data collection efforts in the emergency department waiting room. Areas for improvement were also identified, as well as potential solutions to address these gaps. In future, intermediate mixed methods and/or qualitative research were recommended to improve the functionality of the digital knowledge translation tool to optimize cognitive load and meaningful learning. Future methodological improvements key to the success of a full-scale trial were also described, including the identification of an improved intervention delivery setting, more appropriate scientific outcomes and measures, a comparator condition reflective of standard care, as well as more effective qualitative component recruitment and follow-up data collection methods.

This dissertation addressed current knowledge gaps through the active engagement of parents in the development and pragmatic evaluation of a digital knowledge translation tool on

pediatric acute gastroenteritis. Results of this research have widespread applications in three key areas. First, the state of the science for knowledge translation tools for parents in child health is described, including gaps in the literature and recommendations for future research. Second, this research informed the development of a digital knowledge translation tool, a whiteboard animation video, about pediatric acute gastroenteritis through integrated knowledge translation methods. Third, knowledge translation science was enhanced by developing and piloting methods for pragmatic effectiveness evaluation of digital knowledge translation tools for parents. The findings of this research will advance the pursuit of the best mode of providing and evaluating pragmatic digital health education for parents on acute childhood illnesses.

Preface

This thesis is an original work by Lauren Albrecht. Salary support for this doctoral research was awarded by Alberta Innovates - Health Solutions Graduate Studentship (2015-2020) and Women's & Children's Health Research Institute Graduate Studentship (2015-2017). Graduate student stipends were also provided from a Canadian Institutes of Health Research Knowledge-to-Action Grant (Drs. Shannon D. Scott & Lisa Hartling, Co-Principal Investigators; 2014-2017) and Translating Emergency Knowledge for Kids at the Manitoba Institute for Child Health (2014-2015). Thank you for supporting this work.

Research ethics approvals for the work described in this thesis were received from the University of Alberta Health Research Ethics Board. The following research ethics applications were approved: Knowledge translation tools for parents with children with croup and gastroenteritis, Pro00050107, approved October 8, 2014 to September 7, 2017; Evaluating a knowledge translation tool for parents, Pro00073867, approved July 5, 2017 to May 29, 2019; Evaluating a knowledge translation tool for parents: Secondary Analysis of a pilot randomized trial, Pro00091285, approved on July 12, 2019 to June 15, 2020.

From September 2014 to April 2019, this research was supervised by Drs. Shannon D. Scott and Lisa Hartling. During that time period, Dr. Andrew Dixon and Dr. Joan Robinson were the Supervisory Committee members under the Department of Pediatrics (Medical Sciences Graduate Program). In 2019, LA initiated a transfer of supervisors and Departments through the Faculty of Graduate Studies & Research (FGSR). This transfer request was accepted and completed by FGSR on May 1, 2019. From May 2019 to its conclusion, this research was supervised by Dr. André Grace in the Psychological Studies in Education program in the

Department of Educational Psychology. During that period, Dr. Sharla King and Dr. Phillip Sevigny were the Supervisory Committee members. Thank you all for your academic support.

The research contained in this thesis was conducted in collaboration with other researchers, professionals, and volunteers. Chapters 1, 5, 6 and 7 were written by LA with support and guidance from AG, SK and PS. Chapters 2-4 were written by LA with SDS, LH, AD, and JR. The itemized contributions for all chapters are detailed in the following paragraphs.

Some chapter one components were conducted as part of a Canadian Institutes of Health Research Knowledge-to-Action Grant led by SDS and LH (Co-Principal Investigators). This includes the living systematic review, whiteboard animation video development, and whiteboard animation video usability testing. LA was project coordinator for this grant. For the living systematic review, Robin Featherstone ran the literature search strategies. LA and Sanja Schreiber conducted primary and secondary screening, quality assessment, data extraction. SS conducted data analysis. LA, SS, SDS and LH created a project abstract and poster presentation, which LA presented at the 2016 Cochrane Colloquium. For the video development, LA drafted an initial video script and worked with a script writer and animators at Idea Machine Studio to refine the script into a video prototype and ultimately into the final video. SDS and LH approved each stage of development. LA developed and analyzed feedback surveys for clinicians and parents to inform prototype revisions. SDS and LH approved surveys, results, and revision requests. For the usability testing of the video, LA and SDS developed a survey and focus group guide. LA conducted survey and focus group data collection and analysis. Additional survey data collection was conducted by Nadia Dow, Laura Ebenspanger, Alison Thompson, Sarah Walton, and Amy Zhang. Sarah Walton developed the survey code book. Focus group transcripts were cleaned/verified by AT and SW. LA, SDS and LH created a project abstract and poster

presentation, which LA presented at the 2016 Cochrane Colloquium. LA drafted a manuscript in 2017, which is currently unpublished and held by SDS and LH. Thanks to all for their contributions.

Chapter two was published in 2017 in BMC Health Services Research, volume 17:686 (doi: 10.1186/s12913-017-2632-2), under the title: "Knowledge translation tools for parents on child health topics: a scoping review." This paper was co-authored (in order) by LA, SDS, and LH. All authors designed the scoping review. LA conducted primary and secondary screening, data extraction, data analysis, and manuscript writing. All authors provided substantive feedback and approved the manuscript prior to submission. Thank you to Thane Chambers, University of Alberta research librarian specializing in the field of knowledge translation, for designing and implementing the search strategy. Special thank you to research colleague Xuan Wu for conducting 10% verification of inclusion/exclusion decisions.

Chapter three was published in 2016 in the Canadian Journal of Emergency Medicine volume 19(3), pages 198-206 (doi: 10.1017/cem.2016.363), under the title: "Pediatric acute gastroenteritis: understanding caregivers' experiences and information needs." The copyright in the material on these pages is owned by or licensed to Cambridge University Press and is reprinted with permission. This paper was co-authored (in order) by LA, SDS, and LH. SDS & LH obtained Canadian Institutes of Health Research grant funding, designed, and led the research study as Co-Principal Investigators. LA was project coordinator for this study and conducted data collection, data analysis, and manuscript writing. All authors provided substantive feedback and approved the manuscript prior to submission. Special thanks to Dr. Samina Ali and Nadia Dow for conducting paid contract services to complete initial participant recruitment in the emergency department.

Chapter four was published in 2018 in Pilot & Feasibility Studies, volume 4:131 (doi: 10.1186/s40814-018-0318-0), under the title: "Evaluating a knowledge translation tool for parents about pediatric acute gastroenteritis: a pilot randomized trial." This paper was co-authored (in order) by LA, SDS, and LH. All authors conceptualized the study. The video intervention was previously developed as part of a Canadian Institutes of Health Research Knowledge-to-Action Grant led by SDS & LH; LA was project coordinator for the video development research. LA drafted the manuscript. All authors edited the manuscript and approved the final version.

Chapter five and six were led by LA with support from SDS, LH, AG, and Andrew Wilcox. AW designed the electronic data collection platform, iCare Adventure. LA provided voice recordings, conducted pilot testing, and provided feedback to refine iCare for the specific purposes of this study. Data collection was conducted by LA (Monday to Friday 0900-1500) and volunteers (4 hours x 4 days/week from 1500-2000). Emergency department research staff intermittently collected data for this study (work hours: 1500-2300, 7 days/week). LA trained all data collectors in the study protocol and was available for phone and email support during data collection hours. Thank you to Drs. William Craig and Andrew Dixon for facilitating the conduct of this study within the emergency department and to Manasi Ragigopal and Mithra Sivakumar for coordinating the volunteer shifts and providing office space and computer access in the emergency department. SDS & LH provided financial support for: time spent by MR & MS to organize volunteer shifts; disposable headphones; 2 iPads (provided in kind); and, disinfectant wipes for the iPads. AW provided the iCare Adventure Platform, modified platform interface, and provided ongoing technical support (in kind). LA conducted data analysis, interpretation of study results/findings, and all writing. Thanks to all for your contributions.

Dedication

I crossed this finish line for my little one, Grier.

I encourage you to be curious, think critically, challenge inequity, and be true to yourself.

Know that objectivity is a myth and vulnerability can be a great strength.

Always remember that when you do nothing, you are choosing the status quo.

My greatest wish for you is to find your inspiration and explore it.

I love you as you are.

I will always have your back.

Acknowledgements

My heart is full. Thank you to the myriad folk who helped me to successfully complete this endeavor. This product was six long years in the making and I learned more than I ever imagined. I have experienced some of the best and worst moments of my life in this process and I am grateful to have made it through to the other side with ample wisdom from this experience.

Thank you to my Supervisor, Dr. André Grace. It is difficult to find the words to express my heartfelt gratitude for your warm welcome and ongoing support, guidance, and mentorship. Your outlook on life, academia, and research is hopeful, uplifting, and inspiring. It was exactly the tonic that I needed. Thanks also to my Supervisory Committee members, Drs. Sharla King and Phillip Sevigny. Your kindness, enthusiasm, and willingness to dive in were so appreciated. The three of you helped me to rediscover my confidence and passion for this research. Hearty thank you to my examining committee: Drs. Holly Witteman, Alex Clark, and Cheryl Poth. Thank you for applying rigor and insight to my work and to guide my next steps. It was a pleasure to learn from you all!

Special thank you to Alberta Innovates for providing 1-year of fully-paid parental leave to graduate students. This investment is key to recognizing graduate students as whole people who contribute greatly to the research ecosystem of this Province. I salute you!

I would like acknowledge the positive contributions from Drs. Shannon Scott, Lisa Hartling, Joan Robinson, and Andrew Dixon in this body of work. I would also like to extend my sincere gratitude to those who supported my transition: Dr. Victoria Ruetalo, Associate Dean, Faculty of Graduate Students & Research; Dr. Brooke Milne, Dean, Faculty of Graduate Studies & Research; Dr. Alex Clark, Associate Vice-President Research; Susan Babcock, Director of the

Research Ethics Office; Dr. David Johnson, Special Advisor to the Provost; Fahed Elian, President of the Graduate Students' Association; Drs. Sophie Yohani & George Buck in the Department of Educational Psychology; and, Kathy Morrison, Senior Coordinator, Alberta Innovates. Thank you to Matthew Pietrosanu, Statistical Consultant at the Training and Consulting Centre in the Department of Mathematical & Statistical Sciences for providing statistical guidance and advice. Thanks also to Drs. Lisa Given, Deb Verhoeven, Holly Witteman, and Megan Strickfaden for your thoughtful and sound career advice!

A million thanks to the special people in my life! Dr. Paul Bianchini, thank you for emboldening me to share my voice with strength. Dinuka Gunaratne, thank you for your enthusiasm and the excellent Career Mentoring Program. Thank you to Dr. Christina Stasia & the Dive Graduate Leadership Development Program for creating community and teaching adaptive leadership at a crucial moment. Dr. Cathie Scott & Robyn Blackadar, thank you for your mentorship and for bringing me into the world of evidence-informed policy! Leslie Goldstone, thank you for teaching me about journalism and radio – let's find more stories to tell together! Thank you to Xuan Wu, Dr. Katherine Bannar-Martin, and Dr. Renate Kahlke for stimulating academic friendships. It has been a true pleasure to learn from so many strong, successful women doing interesting and inspiring work! Many, many thanks to my Nerd Nite Edmonton crew, the Epossio, and the Evans Family for sharing adventures together and for having my back. Big, heartfelt thanks to my whole family, especially my in-laws, Kelly & Fred, and my parents, Dean & Diane, for listening, asking important questions, and reminding me that I am tenacious. Last, a very special thank you to my partner, Zack, and my little one, Grier. We experienced every emotion, spoke truth to power, weathered the storm, and grew stronger from it all. I love you and I am excited to build the future together – and I promise, no more degrees!

Table of Contents

List of Tables

List of Figures

Chapter 1 - Introduction

Background, rationale & aims of the research

As a trained educator (B.Ed. 2005), I came to health research incidentally. While working on a master's degree in Adult Education in the Department of Educational Policy Studies (2009-2012), I fortuitously accepted a position as the National Needs Assessment Coordinator (2011-2015) for Translating Emergency Knowledge for Kids (TREKK). At that time, TREKK was a five-year, pan-Canadian knowledge mobilization initiative funded by the Networks of Centres of Excellence (NCE). The mission of TREKK was to connect health providers and consumers with best research evidence on acute pediatric conditions [1].

The first phase of TREKK was the national needs assessment to determine the information needs and preferences of health providers and health consumers (i.e., parents, caregivers) in Canadian general emergency departments (EDs) [2]. My role was to manage and execute this large-scale project. This work included: helping to design two cross-sectional surveys (i.e., one for health professionals and one for health consumers); training and supporting data collectors across the country over a two-year period; helping to design the focus group and observation tools; conducting focus groups and observations in seven hospitals across the country; cleaning, analyzing, and interpreting the qualitative and quantitative data; and, writing reports, manuscripts, abstracts, and presentations to share results/findings.

A key and innovative component of the TREKK initiative was the focus on health consumer needs. To this end, the health consumer needs assessment survey (n=897) demonstrated that 39% of parents had looked for health information prior to bringing their child to an ED [unpublished]. Of that cohort, 62% had looked for that information online, and 77%

had stated a preference to receive future health information via electronic sources, including search engines, websites, smartphone apps, email, social media [unpublished].

To meet this clear health consumer need, the TREKK team conducted a knowledge synthesis phase to determine the best research evidence on a variety of acute childhood conditions. This was followed by a final, knowledge mobilization phase to develop and share novel, knowledge translation tools for health providers and parents to distil, communicate, and interpret the research evidence. For parents, the purpose was to provide guidance about how to manage illnesses at home, when to seek emergency care, and specific recommendations about effective treatments. The end goal was to make these tools freely available to parents online.

The health consumer needs assessment also identified major health reasons that parents brought their child into an ED for medical attention. Of the 897 parents surveyed, 60% had brought a child to the ED with at least one symptom of pediatric acute gastroenteritis (AGE) (i.e., vomiting, diarrhea, fever, etc.) [unpublished]. This was supported by the health professional needs assessment data where pediatric AGE was identified as a clinical information gap, with nearly 20% of clinician respondents selecting AGE as a pediatric condition where more clinical information was required [2]. Therefore, under the umbrella of the TREKK initiative, two of the academic Directors (Drs. Shannon Scott & Lisa Hartling) obtained additional grant funding from the Canadian Institutes of Health Research (CIHR) Knowledge-to-Action grant program and invited me to work with them to target pediatric AGE for further research. This CIHR grant funded the development and usability testing of three digital tools for parents on two acute conditions (i.e., croup and AGE). Within this new project (2014-2017), we worked with parents, artists, and pediatric emergency clinicians to develop and refine two digital tools to synthesize, distil, interpret, and communicate the best research evidence on pediatric AGE - an eBook and a

whiteboard animation video – for parents so that they would have a key resource to guide management of their child's illness and support effective health decision-making [3].

To maximize the benefit of these prior research investments through TREKK and the CIHR grants, leverage the extensive collective experience, and inform future knowledge translation efforts targeting health consumers, rigorous evaluation of the effectiveness of the digital knowledge translation tools was determined to be an important next step. To that end, my doctoral research (2014 – 2020) sought to address this need by answering the following question: How should digital, knowledge translation (KT) tools, developed for parents/caregivers on child health topics, be rigorously evaluated? The question was addressed in four projects, described subsequently, using the test case of one of the previously developed KT tools for pediatric AGE, the whiteboard animation video.

Theoretical framing

Pragmatism as a research paradigm

The philosophy of pragmatism emerged in America in the nineteenth century, through the works of Charles Sanders Peirce, William James, and John Dewey. A core tenet of this philosophical movement saw the truth as 'what works' relative to the current situation [4]. In particular, Dewey articulated the pragmatist philosophy as encompassing both the realities of the past and the possibilities for the future [5]. This relativist positioning challenged the nature of truth as established in earlier philosophical traditions and initiated a separation of epistemology and ontology [4]. However, by understanding that truth is not absolute, but rather a moveable and usable construct for understanding the nature of reality, pragmatism is seen as having the ability to put theory into practice by selecting and applying functional truths [4].

Within pragmatism, knowledge is understood to be socially constructed within a complex reality, with many possibilities. Individual knowledge is contingent on one's real world experience and interests; therefore, multiple and varied perspectives are required to produce an understanding of larger, complex 'truths' [6]. In pragmatism, knowledge is evaluated on its usefulness within a particular set of circumstances or context [6]. Thus, pragmatism philosophically accepts both single or multiple realities to solve real-world problems [7].

The term paradigm describes the philosophical foundation (i.e., generalizations, assumptions, values, beliefs) that defines the worldview, disposition, and actions of the researcher [8]. As a research paradigm, pragmatism encourages researchers to use the philosophical and methodological approaches that work best to address their particular research problem [9]. Pragmatist research is functional, pluralist, critical, and action-oriented [6]. Ultimately, the purpose of pragmatic research is to identify practical and usable solutions to the stated problem [4]. The emphasis on multiplicity and shared meaning making means that pragmatism can be philosophically aligned with multiple health and social science research perspectives and a number of methodologies [10].

A pragmatic process of inquiry applies theories in everyday practice experiences in order to verify what works [5]. A pragmatic research methodology centralizes the 'problem' or research question and the methods are regarded as tools for addressing the problem or answering the research question [11]. Multiple perspectives are required for a robust understanding of the problem and to illuminate the possible solutions [6]. This means that qualitative, quantitative, and mixed methods can be deployed to answer the research question within a pragmatic research methodology [11,12]. It is understood that using multiple methods within a pragmatic research design helps to comprehensively study complex issues within complex environments by

balancing objectivity and subjectivity, engaging multiple voices, and identifying valuable external consequences within a particular context [5,8,14,15].

Applying a pragmatic research paradigm, multi-perspective theorizing was used to interweave collaborative research, patient-oriented research, KT science, pragmatic randomized controlled trial (RCT) methodology, and cognitive science theories to explore a complex, real-world problem and evaluate one potential solution. Together, these theoretical lenses informed the development and evaluation of a multimedia KT tool intended to provide complex child health information to parents about pediatric AGE. The goal of the digital KT tool was to help families better respond to this common acute condition by meeting identified knowledge needs and providing explicit evidence-based guidance on home management strategies, assessing illness severity, and determining appropriate health care seeking. The objectives of this research were to explore: 1) the complexity of evaluating KT interventions for parents on child health topics; 2) pragmatic design and feasibility of effectiveness evaluation methods, and; 3) recommendations for robust future, KT intervention development and rigorous full-scale effectiveness evaluation studies within a complex environment.

Collaborative research

In recent years, the academy has embraced post-modern approaches to science and research as contested; this has legitimized multiple perspectives, leading to an interest in collaborative research [16]. Broadly, collaborative research can be defined as processes to bring together those who study societal issues with those who experience societal issues [16]. Stated plainly, it can be considered research ‘with’ as opposed to research ‘on’ [17]. Through the act of bringing together multiple perspectives to inform practice in order to solve a social problem, collaborative research is aligned with a pragmatic research orientation.

The impetus for collaborative research is prominent across multiple disciplines, including health, education, and social services [18]. Because collaborative research bridges the research-practice divide, it has been supported by a number of research approaches including action research, participatory action research, program evaluation, and integrated KT (iKT) [16,17]. Across these domains, four common themes help to define and understand collaborative research as an academic pursuit: 1) collaborative research requires significant resource investment from all parties to reap significant benefit; 2) trust built informally over time is key to the success of collaborative research; 3) strong leadership is as important to collaborative research as methods or processes; and 4) collaborative research embraces uncertainty and the evolution of learning over time [16]. The main challenge in applying collaborative research is that it can be conducted in the context of many different research methodologies; clear and transparent methods are needed to enhance the development, application, and evaluation of this research approach [19].

Patient/family-centered health care & patient-oriented health research

Alongside the transformation within science and research that brought collaborative research, a similar transformation occurred in health provision, in which patients and families have come to be understood as key partners in health care delivery [20]. This shift has been labeled patient- and family-centered health care. Stewart and colleagues have proposed six interactive components that comprise patient-centered care; these include: 1) exploring patients' feelings, ideas, expectations; 2) understanding patients' social context, life history, and developmental stage; 3) finding common ground between patients and health professionals on problems, priorities, goals, and roles; 4) incorporating prevention and health promotion into health care; 5) enhancing the patient–health professional relationship to include compassion,

healing, self-awareness; and, 6) being realistic about expectations, resources, and time constraints [21].

The delivery of patient- and family-centered health care is seen as particularly challenging in the ED environment. In this context, patients and health providers are dealing with unplanned health issues; illnesses are often acute; stress and anxiety levels are high; action and intervention is time-sensitive, and; overcrowding is a concern [22,23]. It has previously been shown that few EDs have written policies or guidelines to ensure and support patient- and family-centered health care, and few providers are trained in family-centered approaches [24].

Redefining the patient-health professional relationship via this collaborative patient- and family-centered care model has been described as an important counterbalance to the positivist, evidence-based medicine movement [20,25]. It also exposes an ongoing tension between the dominant view of professionalism in health care, in which health professionals hold the authority to judge their work quality, and the more recently introduced viewpoint of consumerism, where quality is determined by customers of health care on the basis of whether health professionals have met their needs [25]. Berwick posits that truly embracing patient- and family-centered care would require radical and uncomfortable changes to long held practices in health care and health professions, including: the elimination of restrictions like hospital visiting hours and clothing and food rules; and establishing new norms like patient owned medical records, patient participation in health care processes and services, and universal use of shared-decision making technologies [25]. This reimagining of health care is often at odds with current health professional training and practice [20].

To explore how best to transform health care delivery within a patient- and family-centered model, new approaches to collaborative health research are required. In 2011, the

Canadian Institutes of Health Research (CIHR), the national health sciences funding body, created a Strategy for Patient-Oriented Research to advance research that engages patients and caregivers as equal partners and focuses on patient-identified priorities to improve patient outcomes [26]. Patient-oriented research (POR) represents a paradigm shift in health research [27] and demonstrates clear linkage to collaborative research and KT science. A 2014 systematic review established that patient engagement in research is feasible at all phases [28]. Previous research has also demonstrated that patient engagement in health research is associated with increased recruitment and retention of participants; the use of patient-centered research methods; and more relevant research questions and outcome measures [29]. Within POR, processes, interventions, and outcomes have been developed and evaluated to facilitate and assess the meaningful involvement of patients and families in health care provision and decision making.

Knowledge translation (KT)

It is well established that the creation of new knowledge through biomedical and health services research does not automatically lead to widespread implementation or health impacts [30]. It has previously been shown that 30-45% of patients do not receive evidence-based care and 20-25% of patients receive unnecessary treatment or care that is potentially harmful [31-34]. Knowledge translation (KT) science holds that closing this research-practice gap by turning knowledge into action will maximize health system resources and improve patient outcomes.

KT is defined by CIHR as a 'dynamic and iterative process that includes the synthesis, dissemination, exchange, and ethically-sound application of knowledge to improve the health of Canadians, provide more effective health services and products, and strengthen health care systems' [30]. KT falls under the implementation science umbrella to address the design and conduct of research studies as well as the dissemination and implementation of research findings

[35]. KT in research is categorized as end-of-grant or integrated KT (iKT). The former refers to research dissemination activities, such as publishing a peer reviewed, journal article, presenting at a conference, media engagements, and/or commercialization of research products [36]. The latter refers to a pragmatic approach to active collaboration between researchers and research users (i.e., health professionals, policy makers, patients and families) throughout the research process [36].

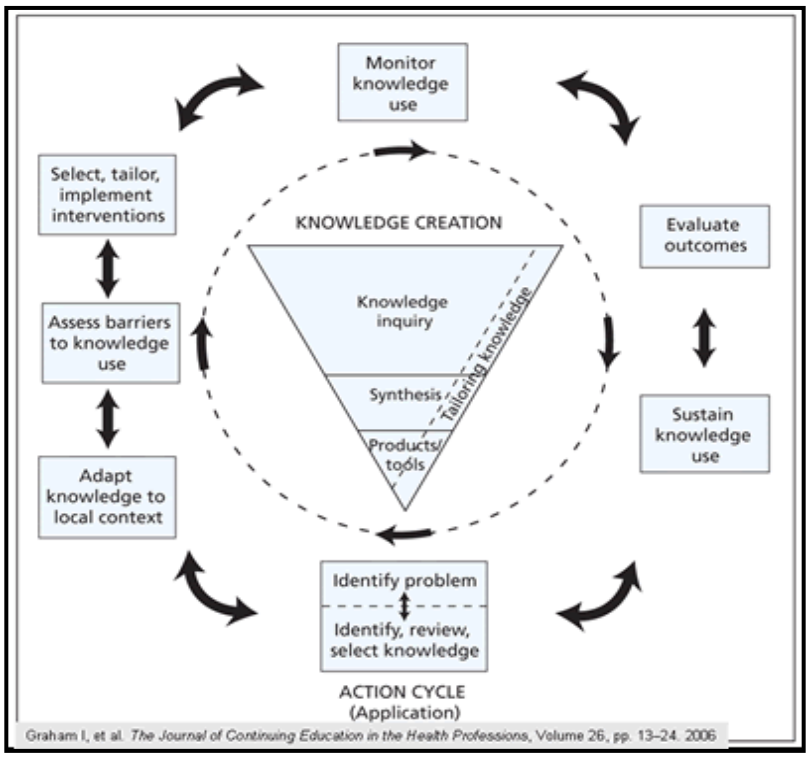
In alignment with a pragmatic research paradigm and intimately connected to collaborative and patient-oriented research, the goal of iKT is to bring together multiple sources of knowledge and find workable solutions to solve individual and social problems within a particular context [5,16,37]. iKT is seen as a method to increase the relevance, applicability, and social impact of research by exploring differences in knowledge from different stakeholders to enhance insight and understanding; thereby closing the research-practice gap [5,38]. This approach is understood as a key method to overcome the conceptual and methodological challenges of KT; however, there is limited evidence to support particular iKT methods or outcomes [39-42]. It has been shown that effective iKT includes early engagement of non-research stakeholders [43]; however, establishing best methods for stakeholder involvement is seen as a priority to advance KT and implementation science [40,41].

To support patient- and family-centered health care, there are increasing calls to facilitate ‘effective consumers’ by creating, implementing, and evaluating KT interventions targeting patients and their families [44,45]. The purpose of these interventions would be to influence their health knowledge, decision-making, and service utilization directly [30,44]. This is particularly salient given the many alternative health information sources available to parents on the internet. Unfortunately, little is known about what interventions work in different contexts [39].

The Knowledge-to-Action Framework (Figure 1), a central iKT approach, offers a conceptual framework to operationalize the key assumptions about context and learning to facilitate sustainable, evidence-based KT interventions [35]. Framed through social constructivism and systems thinking lenses, the learner is defined an active participant in the knowledge creation process based on three key assumptions: 1) learning is a result of an individual's interaction with the environment; 2) cognitive dissonance is the stimulus for learning; and, 3) the social environment plays a key role in the learning process [46]. Systems thinking complements social constructivist theory by foregrounding the complex, adaptive system in which learning and change take place. [47].

The Knowledge-to-Action (KTA) Framework was a result of a review of 31 interdisciplinary planned action theories about the process of change [35]. The Knowledge Creation funnel is at the heart of this Framework, centering knowledge synthesis efforts to create products and/or tools. This highlights the urgent need for pooling of individual study results using rigorous knowledge synthesis methods prior to engaging in KT [48]. In pragmatic philosophy and iKT, the process of knowledge creation is viewed as a never-ending loop, in which multiple stakeholders work to improve past understandings to increase utility of knowledge in their current context [5]. Surrounding knowledge creation is a process to apply knowledge, elucidated in a series of steps called the Action Cycle [35]. Within a pragmatic paradigm, this process can be seen as verifying knowledge by putting it into practice and assessing it for value and refining it to enhance its value [5]. The KTA Framework functions as a dynamic, iterative, non-linear process to develop, design, deliver, and evaluate interventions to implement the knowledge created [35,49,50]. Involvement of stakeholders is seen as critical to the framework [49].

Figure 1.1: Knowledge-to-Action Framework.



Implicit in the KTA Framework are process evaluation components. Previous research identified key process evaluation targets, including determining barriers and facilitators and eliciting opinions about the KT intervention [51,52]. Process evaluation data contextualize outcome effects and identify recommendations for intervention adjustments and future implementations [52]. Integrating process and outcome data maximizes interpretation of study results [51].

Pragmatic randomized controlled trial (PRCT) methodology

Randomized controlled trials (RCTs) are the gold standard in evaluating the efficacy of a health intervention. Traditional efficacy or explanatory trials maximize internal validity to establish a causal relationship between the intervention and desired outcome. However, lack of external validity or generalizability is a significant criticism of traditional RCT methodology and this is seen as a key explanation for the underuse of research evidence in health care practice

(i.e., the research-practice gap) [53]. In response to this critique, pragmatic RCT (PRCTs) methodology has been developed to examine the effectiveness of interventions in real-world conditions to inform real-world practice [54]. PRCT methodology seeks a balance between internal and external validity in order to understand what works, for whom, and in what context. Key aspects of PRCT methodology include: 1) setting of the trial, including geography and clinical environment; 2) selection of participants, including inclusion/exclusion criteria, recruitment, and selection techniques; 3) characteristics of randomized patients, including baseline clinical characteristics, race, gender, severity of disease, comorbidity; 4) differences between trial protocol and routine clinical practice, including experimental and control interventions and timing; 4) outcome measures and follow-up, including use of patient-centered outcomes, frequency, and length of follow-up; and, 5) adverse effects of treatment, including rates of discontinuation and safety procedures [53]. The goal of these methodological decision points is to increase heterogeneity so that study results are relevant and useful to a particular group of patients in a particular clinical setting [53].

Over the last 10 years, there has been substantial methodological development on the addition of qualitative research within or alongside PRCTs within health services research [55-57]. Integrating qualitative methods into PRCT methodology has been promoted as the best approach to evaluate complex interventions, explore the reasons these interventions may or may not work in particular contexts, as well as evaluate and improve RCT processes, including participant recruitment [55,57]. PRCTs are intended to help explain mixed or null effects and to plan for sustainability or scale-up of successful interventions [56]. Challenges remain to develop PRCT methodological and ethical guidance [43,54] and to increase transparency and enhance

reporting of this methodology, particularly in relation to qualitative study components, as well as data integration and analytic techniques [57,58].

The unique environment of the ED positions it as a valuable setting for patient-oriented research efforts, including PRCTs targeting a broad range of patient demographics and health conditions [59]. Using a collaborative research approach, specifically iKT, patient-targeted KT interventions can be examined in this environment. Rigorous, yet pragmatic effectiveness evaluation designs like PRCTs are a valuable approach to refine our understanding of KT interventions. Useful contributions to enhance our understanding of 'what works' can also be made through alternate designs, including process evaluations and feasibility testing of interventions, that evaluate a variety of proximal and intermediate outcomes [40].

Health education

It has been hypothesized that providing evidence-based child health information to parents/caregivers has the power to ensure consistent parental management of child health over time and across settings [60], increase effective health decision-making [61], and reduce health system costs [61]. However, there is presently little guidance on the most effective approach, content, duration, and intensity of health education for this diverse population [62-64]. For example, health education is routine practice in the ED to guide care after discharge [16]. Typically, education is provided at the end of the ED visit; however, previous research has shown that at this juncture parents are tired and anxious to leave, which makes them less likely to ask important questions and retain information [65].

Poor comprehension of health information may be due to many factors. For example, information provided verbally is typically brief [66] and written information is often too complex [67,68]. How content is organized and prioritized, the use of jargon, and a lack of specific

directions can also lead to sub-optimal comprehension [69-71]. Research has estimated that more than 50% of parents who bring their children to EDs have low health literacy, meaning they lack the broad range of skills required to make decisions in health care environments [72-74]. Previous research has established that key health literacy attributes include comprehension, communication, and appropriate health decision-making [75,76]. Unfortunately, a 2011 Cochrane systematic review determined that the evidence evaluating interventions for enhancing health consumers' online health literacy was too weak to draw any conclusions about the design and delivery of specific interventions [77].

Digital health education & knowledge translation

The empowerment of health consumers (i.e., patients and their families) has been greatly accelerated and facilitated by access to the internet [20]. A 2013 systematic review found that online KT strategies have the power to connect researchers, practitioners, policymakers, and consumers and facilitate the timely and relevant communication of health information across geographical boundaries [78]. Barriers to KT have also been identified, including health-related information overload in internet searching, and ability to detect quality information online [78]. Social media has been identified as a digital space that facilitates contact with health consumers in a manner that is both relatable and shareable; however, assessing tools to communication complex health information via these platforms is challenging [79]. A 2014 Cochrane systematic review found that multimedia educational interventions (i.e., education including written words, diagrams and/or pictures combined with audio, animation, or video) for health consumers about medications are superior to no education or usual care for knowledge acquisition, but not superior to interventions provided by a health professional; thus, multimedia interventions should

be added to usual care or provided in contexts where health professionals are not present or able to provide educational support [80,81].

Cognitive load, procedural knowledge & multimedia interventions

Meaningful learning is a result of balancing cognitive processing within a learners' limited capacity; this is termed cognitive load [82]. Concomitantly, cognitive overload is experienced when the cognitive processing required for learning exceeds the learners' given capacity [82]. Thus, instructional methods must be designed to optimize cognitive capacity [83].

Procedural knowledge can be defined as 'how-to' instructions and feedback [84]; in a health context, this can include information like care and discharge instructions. From a cognitive load perspective, this information is best delivered right when learners need it [84]. Previous research has established that procedural information is best communicated through video because desired actions can be demonstrated in sequence [85]. However, factors including literacy level, age, learning motivation, also influence how different populations interact with video versus print [85].

Multimedia instruction uses words and either static or dynamic pictures to facilitate learning [82] via the dual coding theory [83]. The main assumption of this theory is that separate verbal and non-verbal channels additively process information for enhanced learning [83]. However, given the integration of multiple combined elements, cognitive overload has been identified as a significant challenge to multimedia learning [82].

It has been asserted that concise, narrated animation are effective multimedia instructional tools to support meaningful learning and avoid cognitive overload [82,83]. By placing text within graphics alongside simultaneous narration, it is proposed that narrated animation videos leverage integrated and redundant presentation techniques to optimize the

processing of complex information [82]. Stress and uncertainty, which may be present in contexts where complex health information is delivered, may increase cognitive load and negatively influence learning [84]. Thus, multimedia learning, including narrated animation, may be optimized by addressing these factors.

Situating the research

Impact of pediatric acute gastroenteritis

Pediatric acute gastroenteritis (AGE), often referred to as the 'stomach flu,' is a common, acute illness characterized by vomiting, diarrhea, and fever. In developed nations, including Canada, pediatric AGE is most often caused by viruses [86]. However, in developing nations bacteria and parasites can also cause the infection [86].

Pediatric AGE remains an important cause of global pediatric morbidity [86-90]. It is estimated that one in 25 children will be hospitalized for AGE by five years of age [86]. In Canada, there are 5 million annual cases of pediatric AGE, which represent 10% of pediatric ED visits, and result in a yearly healthcare cost of $3.7 billion [91].

In recent years, some of the viruses that cause pediatric AGE have been targeted with vaccines (i.e., rotovirus). In an American retrospective study, pediatric AGE hospitalization rates were examined (n=1,201,458 hospitalizations) following the implementation of a rotavirus vaccine; all-cause acute gastroenteritis hospitalizations were reduced by 55% and rotavirus-coded hospitalizations were reduced by 94% [92]. Another US study, using similar methods and dataset, examined the impact of the rotavirus vaccine on ED visits. They found that ED visits decreased significantly (by 10.3% ±0.3%, $p<0.0001$) in the six post-vaccine years (2008–2013) compared with the pre-vaccine years (2003–2006) [93]. Further, a 2016 Canadian study demonstrated significant decline in rotavirus infection rates after the implementation of a

publicly funded, routine childhood vaccination program; however, this study also documented an increase in the prevalence of norovirus infections – a virus that also causes AGE for which there is presently no available vaccine [94].

In addition to the substantial health and health system impacts, pediatric AGE affects children and families in a multitude of ways. Previous research has demonstrated negative effects on the physical and emotional wellbeing as well as the quality of life of both children and parents [95,96], as well as frequent parental work loss [96-98]. Interestingly, a prospective cohort study confirmed that daycare attendance increased AGE disease burden in the first year; however, this resulted in relative protection from AGE infection up to age 6 years, resulting in an overall similar AGE disease burden between children attending and not attending daycare during the first year of life [90].

Published research on parents/caregivers and pediatric AGE

Few studies have been conducted to understand pediatric AGE through the parent/caregiver lens. A 2002 cross-sectional study evaluated parent/caregiver (n=229) knowledge about AGE and uncovered great variation in knowledge levels [99]. This study further demonstrated that knowledge was positively correlated to accessibility of health information, level of education, ethnicity, and prior experience with dehydration [99]. Recommendations from this research indicated that future education interventions should be designed to improve general knowledge about AGE [99].

A 2011 non-randomized trial targeting parents/caregivers (n=105) of children with AGE in the ED evaluated a one-on-one nursing education session in the ED and an educational home visit versus no intervention control [100]. The study found a small (not statistically significant) increase in knowledge at 1-month, but this change was not sustained at 6-months [100]. A 2012

cluster RCT targeting adults and parents/caregivers (n=400) with children with either tonsillitis or AGE evaluated the effect of patient information sheets [101]. This study found statistically significant, positive effects on behaviour (primary) and knowledge (secondary) outcomes in the information sheet child sub-group compared to the no-information, control child sub-group 10-15 days post-intervention [101]. A 2013 RCT (n=436) investigated the addition of video discharge instructions alongside written instructions to improve parental understanding of pediatric ED visit, plan, and follow-up [102]. The video and written discharge instruction group demonstrated a statistically significantly improvement in knowledge both in the ED and 2 to 5 days after discharge in families overall (p=0.0001) and sub-groups presenting with vomiting and/or diarrhea (n=104; p = 0.0001) and fever (n=178; p=0.0001) [102]. Based on the results of these preceding studies, knowledge has been identified as a key outcome measure, education interventions have shown some promise in improving knowledge and behaviour outcomes, and digital information delivery methods have demonstrated superiority.

Interestingly, a 2016 retrospective cohort study (n=57,921) of pediatric AGE visits to Canadian EDs found that pre-printed discharge sheets for parents/caregivers were associated with increased ED revisits (aOR=1.33, 95% CI 1.08 – 1.65) [103]. This effect was opposite to the study hypothesis. The authors concluded that providing detailed information to parents on when to seek medical care may encourage unnecessary returns to the ED; however, children in this study who returned to the ED tended to be younger (<3 years old) and more unwell [103], which may point to a need for discharge education interventions tailored specifically to this population.

Knowledge translation efforts targeting parents/caregivers

A 2017 American study of caregivers returning to acute care settings for pediatric care (n=500) found that 80.7% reported receiving paper and verbal instructions at initial visit; however, 41.2% did not receive complete information [104]. Specifically, 47.1% did not receive information on expected duration of illness, which may account for unscheduled return visits [104]. Previous research has also demonstrated that parental comprehension of discharge instructions is the only variable significantly related to compliance with these instructions [105]. However, a 2017 systematic review of parental management of discharge instructions found that parents frequently make errors related to knowledge and execution of instructions across multiple domains of care, including medication management and follow-up health care instructions [106]. This body of evidence points to an urgent need for evidence-based development and testing of parental educational tools, including discharge instructions, prior to implementation in health care settings.

Adding to the complexity of health education delivery is the prevalence of low health literacy. Parental low health literacy has been associated with higher levels of nonurgent use of EDs for child health [73,74]. A 2017 qualitative study of parents/caregivers who presented to clinics or EDs for 'sick child' visits found that low health literacy resulted in lack of understanding of illness assessment and treatment, leading to overestimation of illness severity of illness, and thus, increased ED visits [74]. A 2013 systematic review established that prior non-ED interventions to reduce nonurgent ED use have had mixed success, with the greatest magnitude of change found through patient education initiatives [107]. It is critical to determine the optimal content, timing, location, and delivery of evidence-based health information to parents/caregivers to address health literacy barriers. To learn about the variety of KT tools

created for parents/caregivers on child health topics, including the purpose, target condition, and mode of delivery, project 1 was conducted. This project also examined how KT tools were evaluated to inform the final stages (Project 3 and 4) of this PhD research study.

Project 1 (knowledge synthesis): A scoping review of knowledge translation tools for parents/caregivers on child health topics.

Guided by the rigorous, systematic methods outlined by Arksey & O'Malley [108], this scoping review identified and synthesized previously published effectiveness research on child health-related KT tools for parents/caregivers. Secondary analyses were performed to identify and classify the breadth of KT tools that had been developed and evaluated, describe their evaluation methods, and summarize whether the tools and methods were demonstrating the hypothesized effects. A key result of this review was the identification of methodological issues and methodological improvements that could be made in the evaluation and reporting of similar, future studies [109].

Developing a knowledge translation tool for parents/caregivers about pediatric AGE

One strategy to eliminate the research-practice gap in pediatric AGE is to provide parents/caregivers with a reliable, research-based information resource on this common childhood illness. Engaging media, including storybooks, pictograms, and videos, have been demonstrated as promising tools for communicating complex health information to diverse audiences [60,110-115]. Incorporating illustrations and stories into patient education materials has been shown to improve knowledge comprehension, retention, and confidence, as well as compliance with discharge and care instructions [60,110,116].

Given the vast and accessible digital landscape, online media (e.g., podcasts, e-books, animations, infographics) hold promise as superior KT tools for parents and caregivers [117].

Freely available digital tools mean that child health information can be obtained and consumed on-demand when parents and caregivers need it most [118]. Online platforms also allow content to be viewed as frequently as needed, which may improve information retention and compliance [118]. Additionally, a 2017 Canadian study demonstrated that short (approximately three minutes or less), consumer-targeted, evidence-based videos that are created in partnership with consumers and clinical stakeholders can have significant reach [79].

A whiteboard animation video, one form of narrated animated video, was selected as the KT tool modality. In this style of video, an animated hand draws images on a white background simulating a whiteboard as the narration tells the story. Colour is used sparingly to enhance key concepts. Evidence for this type of multimedia learning tool can be drawn from cognitive science and instructional design [82,83]. Thus, a 3-minute whiteboard animation video was developed with and for parents/caregivers to provide the best research evidence on the treatment and management of pediatric AGE and to help parents make the determination about whether and when they need to seek emergency care for their child.

Conducting a living systematic review for up-to-date evidence on the treatment of pediatric AGE

The whiteboard video content was drawn from knowledge synthesis of best research evidence for the treatment and management of pediatric AGE [86]. Systematic reviews are the gold standard methodology of knowledge synthesis; however, given the rigorous methods involved, these reviews require considerable time to complete. It has previously been demonstrated that there can be a time lag of up to eight years from when a primary research study is published to the time it is included in the results of a published systematic review [119].

In the early 2010s, a new systematic review methodology emerged to address the issue of currency. Termed living systematic reviews, this approach focused on continual updating of

systematic reviews by incorporating relevant new evidence as it became available [120]. Living systematic reviews are warranted in fields with rapid publication of new evidence or where current evidence is seen as uncertain or not verified.

Despite rigorous research on treatment for pediatric AGE, substantial variation in care among health providers and hospitals persists [103,121,122]. Thus, living systematic review methodology was employed to monitor the emerging evidence on intervention efficacy to ensure whiteboard animation video content was current and accurate [123]. A research librarian (RF) comprehensively searched four databases at 3-month intervals from September 2014 to March 2016 to locate new studies to update four relevant systematic reviews on interventions for AGE [124-127] contained within an overview of systematic reviews [86]. Using Covidence software [128], two independent reviewers (LA, SS) completed primary and secondary screening using pre-determined criteria, quality assessment using Cochrane Risk of Bias tool [129], and data extraction. Primary and secondary outcomes were meta-analyzed by pooling the new data with previously published meta-analyses (SS).

Over the course of 18-months, 776 studies new were identified and screened. One study (n=123) was included and the data added to a systematic review on the use of probiotics that originally contained 6 studies (n=1170). After including the updated data in the previous meta-analysis, there was no change to the primary outcome or to the three secondary outcomes – all remained not statistically significant. Another study was identified for inclusion regarding the rates and compositions of intravenous rehydration therapy; however, none of the reported outcomes matched those evaluated in the previously published systematic review; therefore, data could not be added to the meta-analysis. Thus, the video content reflected recommendations based on the results of the original four systematic reviews [124-127].

Project 2 (qualitative study): Identifying caregiver information needs for pediatric acute gastroenteritis.

The whiteboard animation video storyline was developed from the results of Project 2, a qualitative study to identify parent/caregiver information needs related to pediatric AGE [130]. This qualitative study of parents/caregivers (n=15) gathered and synthesized first-person stories of the experience of having a child with vomiting and diarrhea and bringing them to an ED for health care [130]. This study highlighted the 'real-life' complexity that influenced health decision-making for pediatric AGE (i.e., past experiences, life circumstances, etc.), as well as AGE-related information needs, including symptom management, understanding the normal course of illness, the cause of illness, information specific to dehydration, where to purchase helpful items, and how to talk to their child about AGE. Based on these analyses, content for the whiteboard animation video for parents about pediatric AGE was developed to explicitly address the identified information needs and provide recommendations for home management strategies and guidelines about when to seek emergency care.

Developing the content for a knowledge translation tool for parents on pediatric AGE.

To develop the whiteboard animation video for parents about pediatric AGE, treatment and management recommendations were drawn from the living systematic review process. The context, sequence of events, and key information was crafted from the qualitative findings on parental experiences and information needs about pediatric AGE after taking their child to an ED for care (Project 2). Multidisciplinary experts, including a script writer, animators, and voice actor were contracted to work with the research team to ensure high quality whiteboard animation video production.

Initial video prototypes were reviewed by pediatric emergency clinicians (n=35) at the annual meeting of Pediatric Emergency Research Canada [131] and parents (n=22) from the Canadian Family Advisory Network annual meeting [132] and TREKK Parent Advisory Committee [133]. A short survey was conducted to obtain specific feedback on video length, aesthetics, character representation, and clinical information presented. This process was very useful to understand how two key stakeholder groups interpreted the video and the prototype was revised based on key stakeholder feedback.

After the initial prototype revisions, the whiteboard animation video underwent a formal process of usability testing. Surveys and focus groups were conducted with parents/caregivers (n=101) in urban, rural, and remote regions of Canada [134]. Usability surveys demonstrated positive results on usefulness, informational, simplicity, ease of use, satisfaction, and future use measures [134]. Focus groups highlighted the authenticity of the video and indicated that the clear, to-the-point, action-oriented video content would be helpful when making healthcare decisions for a child with vomiting and diarrhea [134]. No major revisions were made to the whiteboard animation video based on these usability evaluation results. Full results of usability testing are held by Drs. Scott and Hartling.

At present, the whiteboard animation video is not publicly available. The video copyright holders are Drs. Scott and Hartling. The side-by-side video script is provided in Appendix A.

Evaluating a knowledge translation tool for parents on pediatric AGE

The iterative process of whiteboard animation video development meant that the next logical step would be to determine the effectiveness of the video through a PRCT. However, given calls to reduce research waste in the health sciences as a result of methodological weakness at all stages of the research process [135,136] coupled with the methodological issues

specific to KT tool evaluation that were identified in the scoping review (Project 1), a pilot trial was recognized as an important preliminary step to test the feasibility of effective evaluation methods and provide guidance for full-scale PRCT methods [137-139]. Thus, a pragmatic pilot randomized control trial was designed in Project 3 and the study was conducted in Project 4.

Project 3 (study protocol): A protocol for a pragmatic pilot randomized controlled trial to examine the feasibility of evaluating the effectiveness of a digital knowledge translation tool

Pilot studies as a method are intended to be rigorously designed and executed; however, the focus is on feasibility objectives, not hypothesis testing [137,138]. Thabane and colleagues have outlined four key domains for pilot study objectives and outcomes: scientific, process, management, and resource [137]. Thus, this protocol detailed a pragmatic pilot randomized trial using quantitative and qualitative data to examine methodological feasibility in these four domains in order to optimize future evaluation studies seeking to determine the effectiveness of a multimedia KT tool for parents/caregivers on child health topics [140].

Project 4 (experimental study): The results of a pragmatic pilot randomized controlled trial to examine the feasibility of evaluating the effectiveness of a digital knowledge translation tool

The final project of this dissertation implemented the pilot PRCT that was laid out in Project 3. From November 2017 to February 2018, participants in one pediatric ED were recruited to receive one of two study conditions: 1) the whiteboard animation video about pediatric AGE, and 2) a sham video of similar length about handwashing as infection control. Data was collected via electronic surveys (baseline, post-intervention, and 4-14 day follow up survey) and individual interviews (experimental group only). Methodological feasibility was determined via analyses on scientific, process, management, and resource outcomes and

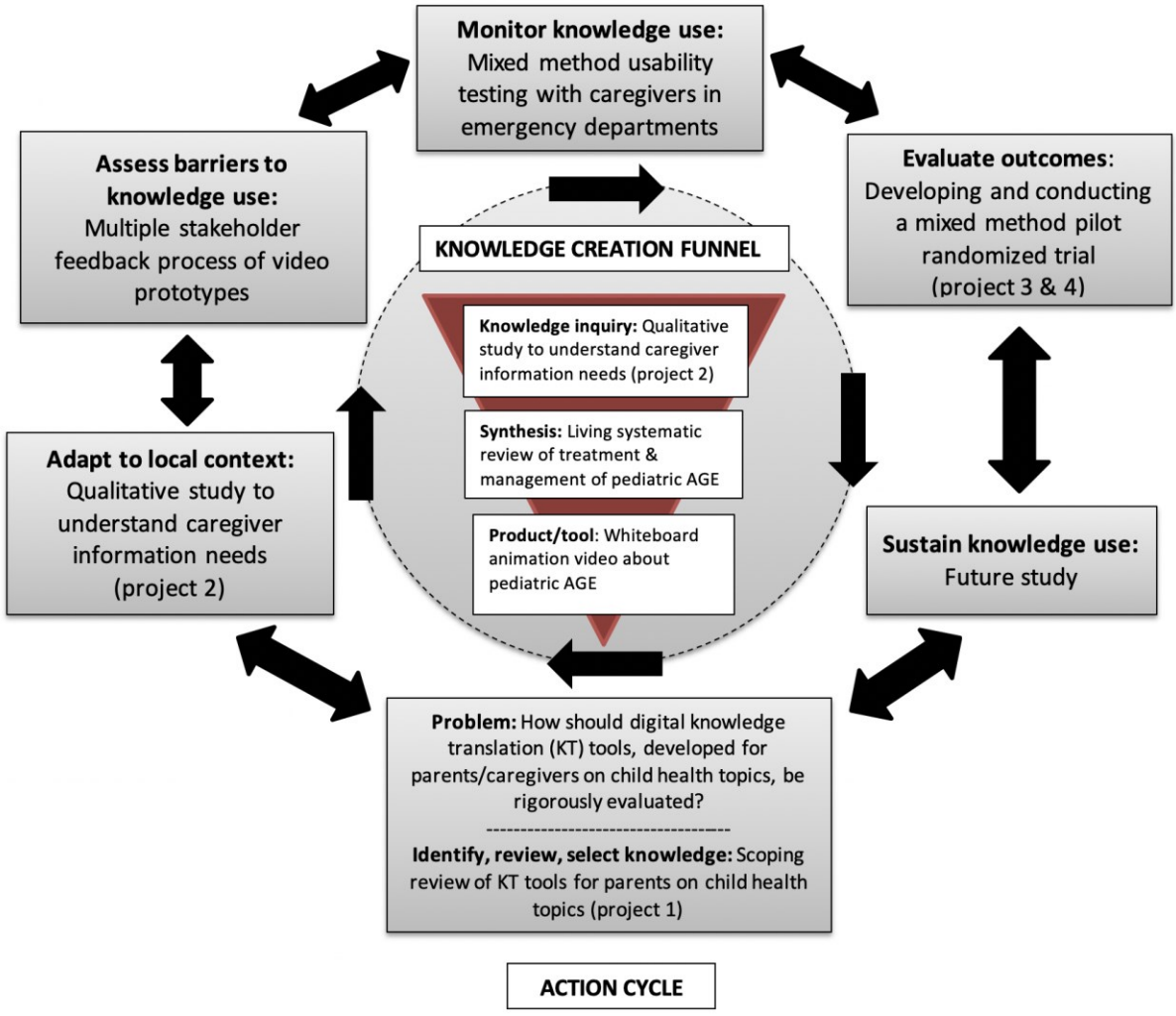
recommendations were made about how to proceed with the design of future, pragmatic effectiveness evaluation studies.

Significance of the research

Pediatric AGE is a common illness with a large burden on children, families, and health care systems. Connecting parents/caregivers to evidence-based information via effective KT tools is essential to minimize this burden and help them manage this common, but potentially serious pediatric illness. Digital KT tools, particularly narrated animated videos, offer a promising approach to provide complex health information and recommendations to a diverse population. Rigorous effectiveness evaluation of these tools is an important development in work to advance the field of KT for health consumers; however, methodological guidance is needed.

My doctoral research filled this knowledge gap by using multiple methods to inform: 1) the development of a whiteboard animation video for pediatric AGE (i.e., living systematic review, qualitative descriptive study); and, 2) the design and selection of pragmatic evaluation methods for multimedia KT tools by piloting processes and methods, and exploring feasibility outcomes (i.e., developing and implementing a pilot PRCT incorporating qualitative methods). Mapping this body of work to the Knowledge-to-Action (KTA) Framework (Figure 1.2), elucidated a theoretically-driven, evidence-based inquiry and addressed calls for determining the feasibility of rigorous evaluation approaches using a pragmatic research design and patient-oriented research methods. The KTA framework illustrates how and where collaborative research and multiple methods were employed throughout this body of research and highlight a fulsome example of an iKT study from knowledge creation through the action cycle.

Figure 1.2: PhD Research and Associated Projects Mapped to Knowledge-to-Action Framework.



Results of this research will have widespread applications in three key areas. First, describing the state of the science for KT tools for parents in child health, including gaps in the literature and recommendations for future research (Project 1). Second, supporting the development of a digital KT tool for pediatric AGE using iKT methods (Project 2). Third, informing KT science by determining and piloting methods for pragmatic effectiveness evaluation of KT tools for parents in child health (Projects 3 & 4). The findings of this research will advance the pursuit of the best mode of evaluating pragmatic health education for parents/caregivers on acute childhood illnesses.

Chapter 1 References

1. Translating Emergency Knowledge for Kids. Our mission and values. TREKK.ca. https://trekk.ca/pages/17-our-mission-and-values. Updated 2019. Accessed February 25, 2015.
2. Translating Emergency Knowledge for Kids. Needs Assessment. Trekk.ca. https://trekk.ca/pages/23-needs-assessment. Updated 2019. Accessed on February 25, 2015.
3. Canadian Institutes of Health Research. Detailed Information. Cihr-irsc.gc.ca. http://webapps.cihr-irsc.gc.ca/decisions/p/project_details.html?applId=302197&lang=en. Updated 2019. Accessed on January 2, 2020.
4. McCaslin ML. Pragmatism. In Given LM, ed. The SAGE Encyclopedia of Qualitative Research Methods. Vol 3. SAGE Publications; 2012.672-675.
5. Nowell L. Pragmatism and integrated knowledge translation: exploring compatibilities and tensions. *Nursing Open*. 2015;2(3):141-148. doi: 10.1002/nop2.30
6. Cornish F, Gillespie A. A pragmatist approach to the problem of knowledge in health psychology. *J Health Psychol*. 2009;14(6):800-809. doi: 10.1177/1359105309338974
7. Feilzer MY. Doing mixed methods research pragmatically: implications for the rediscovery of pragmatism as a research paradigm. *JMMR*. 2010;4(1):6-16.
8. Kaushik V, Walsh CA. Pragmatism as a research paradigm and its implications for social work research. *Soc Sci*. 2019;8(255):1-17. doi: 10.3390/socsci8090255
9. Tashakkori A, Teddlie C. *Mixed methodology: combining qualitative and quantitative approaches.* Volume 46. SAGE Publications; 1998.
10. Shannon-Baker P. Making paradigms meaningful in mixed methods research. *JMMR*. 2016;10(4):319-334. doi: 10.1177/1558689815575861

11. Bryman A. Paradigm peace and the implications for quality. *Int J Soc Res*. 2006;9(2):111-126.
12. Morgan DL. Pragmatism as a paradigm for social research. *Qualitative Inquiry* 2014;20(8):1045-1053.
13. Johnson RB, Onwuegbuzie AJ, Turner LA. Towards a definition of mixed methods research. *JMMR*. 2007;1(2):112-133.
14. Bishop FL. Using mixed methods research designs in health psychology: an illustrated discussion from a pragmatist perspective. *Br J Health Psychol*. 2015;20(1):5-20. doi: 10.1111/bjhp.12122
15. O'Cathain A, Murphy E, Nicholl J. Why, and how, mixed methods research is undertaken in health services research: A mixed methods study. *BMC Health Serv Res*. 2007;7(85). doi: 10.1186/1472-6963-7-85
16. Dennis JL, Lomas J. Convergent evolution: the academic and policy roots of collaborative research. *J Health Serv Res Pol*. 2003;8(S2):1-6. doi: 10.1258/135581903322405108
17. Pushor D. Collaborative research. In Given LM, ed. The SAGE Encyclopedia of Qualitative Research Methods. Vol 2. SAGE Publications; 2008.92:95.
18. Kothari A, Wathen CN. A critical second look at integrated knowledge translation. *Health Policy*. 2013;109:187-191. doi: 10.1016/.healthpol.2012.11.004
19. Jagosh J, Macaulay AC, Pluye P, et al. Uncovering the benefits of participatory research: implications of a realist review for health research and practice. *Milbank Q*. 2012;90(2):311-346. doi: 10.1111/j.1468-0009.2012.00665.x

20. Levesque M, Hovey RB, Christope B. Advancing patient-centered care through transformative educational leadership: a critical review of health care professional preparation for patient-centered care. *J Healthc Leadersh*. 2013;3(5):35-46.
21. Stewart M, Brown JB, Weston WW, et al. *Patient-Centered Medicine, Transforming the Clinical Method*, 2nd ed. Abington, UK: Radcliffe Medical Press Ltd; 2003.
22. Lateef F. Patient expectations and the paradigm shift of care in emergency medicine. *J Emerg Trauma Shock*. 2011;4(2):163-167. doi: 10.4103/0974-2700.82199
23. American Academy of Pediatrics, Committee on Pediatric Emergency Medicine, American College of Emergency Physicians, Pediatric Emergency Medicine Committee. *Pediatrics.* 2006;118(5):2242-2244.
24. Institute of Medicine. *Emergency Care for Children: Growing Pains*. Washington, DC: The National Academies Press; 2007.
25. Berwick DM. What 'patient-centered' should mean: confessions of an extremist. *Health Affairs*. 2009;28(4):w555-556. doi: 10.1377/hlthaff.w55
26. Canadian Institutes of Health Research. Strategy for patient-oriented Research - patient engagement framework. Cihr-irsc.gc.ca. https://cihr-irsc.gc.ca/e/48413.html. Updated May 27, 2019. Accessed Jan. 5, 2020.
27. Mallidou AM, Frisch N, Doyle-Waters MM, et al. Patient-oriented research competencies in health (PORCH) for patients, healthcare providers, decision-makers, and researchers: protocol of a scoping review. *Syst Rev*. 2018;7(101).
28. Domecq JP, Prutsky G, Elraiyah T, et al. Patient engagement in research: a systematic review. *BMC Health Serv Res*. 2014;14:89. doi: 10.1186/1472-6963-14-89

29. Sheridan S, Schrandt S, Forsythe L, Hilliard TS, Paez KA. The PCORI engagement rubric: promising practices for partnering in research. *Ann Fam Med*. 2017;15(2):165–70.

30. Canadian Institutes of Health Research. Knowledge translation. Cihr-irsc.gc.ca. https://cihr-irsc.gc.ca/e/29529.html. Updated Nov 11, 2019. Accessed March 18, 2015.

31. Agency for Health Research and Quality. Reducing errors in health care: translating research into practice. AHRQ.gov. https://archive.ahrq.gov/qual/errors.htm. Accessed February 20, 2015.

32. Schuster M, McGlynn E, Brook RH. How good is the quality of health care in the United States? *Milbank Q*. 1998;76:517–563. doi: 10.1111/j.1468-0009.2005.00403.x

33. Grol R. Successes and failures in the implementation of evidence-based guidelines for clinical practice. *Med Care*. 2001;39(8 Suppl 2):II46–54. doi: 10.1097/00005650-200108002-00003

34. McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. *NEJM*. 2003;348(26):2635–45. doi: 10.1056/NEJMsa022615

35. Graham ID, Logan J, Harrison MB, et al. Lost in translation: time for a map? *J Contin Educ Health Prof. 2006;26*(1):13-24. doi: 10.1002/chp.47

36. Graham ID, Tetroe J. How to translate health research knowledge into effective healthcare action. *Healthc Q*. 2007;10(3):20-22. doi: 10.12927/hcq..18919

37. Johnson RB, Onwuegbuzie AJ. Mixed methods research: a research paradigm whose time has come. *ER*. 2004;33(7):14–26.

38. Rycroft-Malone JO. Evidence-informed practice: from individual to context. *J Nurs Manag*. 2008;16(4):404–408.

39. Bhattacharyya OK, Estey EA, Zwarenstein M. Methodologies to evaluate the effectiveness of knowledge translation interventions: a primer for researchers and health care managers. *J Clin Epi*. 2011;64(1):32-40. doi: 10.1016/j.jclinepi.2010.02.022

40. Wensing M, Grol R. Knowledge translation in health: how implementation science could contribute more. *BMC Med.* 2019;17(88). doi:10.1186/s12916-019-1322-9

41. Gagliardi AR, Berta W, Kothari A, Boyko J, Urquhart R. Integrated knowledge translation (iKT) in health care: a scoping review. *Implem Sci*. 2016;11(38). doi: 10.1186/s13012-016-0399-1

42. Graham ID, Kothari A, McCutcheon C, *et al.* Moving knowledge into action for more effective practice, programmes and policy: protocol for a research programme on integrated knowledge translation. *Implem Sci. 2018;*13(22). doi: 10.1186/s13012-017-0700-y

43. Nicholls SG, Carroll K, Zwarenstein M, et al. The ethical challenges raised in the design and conduct of pragmatic trials: an interview study with key stakeholders. *Trials*. 2019;20(765). doi: 10.1186/s13063-019-3899-x

44. Tugwell PS, Santesso NA, O'Connor AM, Wilson AJ, Effective Consumer Investigation Group. Knowledge translation for effective consumers. *Phys*. 2007;87(12):1728-1738. doi: 10.2522/ptj.20070056

45. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. *Implem Sci*. 2012;7(50). doi: 10.1186/1748-5908-7-50

46. Thomas A, Menon A, Boruff J, Rodriguez AM, Ahmed S. Applications of social constructivist learning theories in knowledge translation for healthcare professionals: a scoping review. *Implem Sci.* 2014;*9*(54). doi: 10.1186/1748-5908-9-54

47. Best A, Holmes B. Systems thinking, knowledge and action: toward better models and methods. *Evidence & Policy. 2010;6*(2):145-159.

48. Ioannidis JPA. Why most published research findings are false. *PLoS Med*. 2005;2(8):e124. doi: 10.1371/journal.pmed.0020124

49. Field B, Booth A, Ilott I, et al. Using the Knowledge to Action Framework in practice: a citation analysis and systematic review. *Implem Sci. 2014;*9(172). doi:10.1186/s13012-014-0172-2

50. Squires JE, Grimshaw JM, Talijaard M, et al. Design, implementation, and evaluation of a knowledge translation intervention to increase organ donation after cardiocirculatory death in Canada: a study protocol. *Implem Sci*. 2014;9(80). doi: 10.1186/1748-5908-9-80

51. Oakley A, Strange V, Bonell C, et al., RIPPLE Study Team. Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 2006;332:413-416.

52. Reelick MF, Faes MC, Esselink RAJ, Kessels RPC, Olde Rikkert MGM. How to perform a preplanned process evaluation for complex interventions in geriatric medicine: exemplified with the process evaluation of a complex falls-prevention program for community-dwelling frail older fallers. *JAMDA*. 2011;12(5):331-336. doi: 10.1016/j.jamda.2011.01.006

53. Rothwell PM. External validity of randomised controlled trials: "To whom do the results of this trial apply?" Lancet 2005;365:82-93.

54. Pawson R. Pragmatic trials and implementation science: grounds for divorce? *BMC Med Res Methodol*. 2019;19(176). doi: 10.1186/s12874-019-0814-9

55. O'Cathain A. Mixed methods research in health sciences: a quiet revolution. *JMMR*. 2009;3(1):1-6. doi: 10.1177/1558689808326272

56. O'Cathain A, Thomas KJ, Drabble SJ, Rudolph A, Hewison J. What can qualitative research do for randomised controlled trials? A systematic mapping review. *BMJ Open*. 2013;3(e002889). doi: 10.1136/bmjopen-2013-002889

57. Richards DA, Bazeley P, Borglin G, et al. Integrating quantitative and qualitative data and findings when undertaking randomized controlled trials. *BMJ Open*. 2019;9(e032081). doi: 10.1136/bmjopen-2019-032081

58. O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services research. *J Health Serv Res Pol*. 2008;13(2):92-98. doi: 10.1258/jhsrp.2007.007074

59. Rising KL, Carr BG, Hess EP, Meisel ZF, Ranney ML, Vogel JA. Patient-centered outcomes research in emergency care: opportunities, challenges, and future directions. *Acad Emerg Res*. 2016;23(4):498-502.

60. Taddio A, Shah V, Leung E, et al. Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain: usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatrics*. 2013;13(23). doi: 10.1186/1471-2431-13-23

61. Morrison AK, Myrvik MP, Brousseau DC, Hoffman RG, Stanley RM. The relationship between parent health literacy and pediatric emergency department utilization: a systematic review. *Acad Pediatr*. 2013;13(5):421-429. doi: 10.1016/j.acap.2013.03.001

62. Wilson EAH, Makoul G, Bojarski EA, et al. Comparative analysis of print and multimedial health materials: a review of the literature. *Patient Educ Couns*. 2012;89(1):7-14. doi: 10.1016/j.pec.2012.06.007

63. Jusko Friedman A, Cosby R, Boyko S, Hatton-Bauer J, Turnbull G. Effective teaching strategies and methods of delivery for patient education: a systematic review and practice

guideline recommendations. *J Cancer Educ*. 2011;26(1):12-21. doi: 10.1007/s13187-010-0183-x

64. Boyd M, Lasserson TJ, McKean MC, Gibson PG, Ducharme FM, Haby M. Interventions for educating children who are at risk of asthma-related emergency department attendance. *Cochrane Database of Syst Rev*. 2009;(2):CD001290. doi: 10.1002/14651858.CD001290.pub2
65. Engel KG, Heisler M, Smith DM, Robinson CH, Forman JH, Ubel PA. Patient comprehension of emergency department care and instructions: are patients aware of when they do not understand? *Ann Emerg Med*. 2009;53(4):454-461. doi: 10.1016/j.annemergmed.2008.05.016
66. Vashi A, Rhodes KV. "Sign right here and you're good to go": a content analysis of audiotaped emergency department discharge instructions. *Ann Emerg Med*. 2011;57(4):315-322. doi: 10.1016/j.annemergmed.2010.08.024
67. Sanders LM, Federico S, Klass P, Abrams MA, Dreyer B. Literacy and child health: a systematic review. *JAMA Pediatrics*. 2009;163(2):131-140. doi: 10.1001/archpediatrics.2008.539
68. Spandorfer JM, Karras DJ, Hughes LA, Caputo C. Comprehension of discharge instructions by patients in an urban emergency department. *Ann Emerg Med*. 1995:25(1):71-74. doi: 10.1016/s0196-0644(95)70358-6
69. Isaacman DJ, Purvis K, Gyuro J. Standardized instructions: do they improve communication of discharge information from the emergency department? *Pediatrics*. 1992;89(6):1204-1208.

70. Samuels-Kalow ME, Stack AM, Porter SC. Effective discharge communication in the emergency department. *Ann Emerg Med*. 2012;60(2):152-159. doi: 10.1016/j.annemergmed.2011.10.023

71. Williams DM, Counselman FL, Caggiano CD. Emergency department discharge instructions and patient literacy: a problem of disparity. *Am J Emerg Med*. 1996;14(1):19-22. doi: 10.1016/S0735-6757(96)90006-6

72. Morrison AK, Schapira MM, Gorelick MH, Hoffman RG, Brousseau DC. Low caregiver health literacy is associated with higher pediatric emergency department use and nonurgent visits. *Acad Pediatr*. 2014;14(3):309-314. doi: 10.1016/j.acap.2014.01.004

73. Morrison AK, Chanmugathas R, Schapira MM, Gorelick MH, Hoffman RG, Brousseau DC. Caregiver low health literacy and nonurgent use of the pediatric emergency department for febrile illness. *Acad Pediatr*. 2014;14(5):505-509. doi: 10.1016/j.acap.2014.05.001

74. May M, Brousseau DC, Nelson DA, et al. Why parents seek care for acute illness in the clinic or the ED: the role of health literacy. *Acad Pediatr*. 2018;18(3):289-296. doi: 10.1016/j.acap.2017.06.010

75. Speros C. Health literacy: concept analysis. *JAN*. 2005;50(6):633-640. doi: 10.1111/j.1365-2648.2005.03448.x

76. Mancusco JM. Health literacy: a concept/dimensional analysis. *Nurs Health Sci*. 2008;10:248-255. doi: 10.1111/j.1442-2018.2008.00394.x

77. Car J, Lang B, Colledge A, Ung C, Majeed A. Interventions for enhancing consumers' online health literacy. *Cochrane Database Syst Rev*. 2011;(6):CD007092. doi: 10.1002/14651858.CD007092.pub2

78. Mairs K, McNeil H, McLeod J, Prorok JC, Stolee P. Online strategies to facilitate health-related knowledge transfer: a systematic search and review. *Health Infor Libr J.* 2013;30(4):261-277. doi: 10.1111/hir.12048

79. Campbell-Yeo M, Dol J, Disher T, et al. The power of a parent's touch: evaluation of reach and impact of a targeted evidence-based YouTube video. *J Perinat Neonat Nur.* 2017:31(4):341-349. doi: 10.1097/JPN.0000000000000263

80. Ritzert B. Multimedia educational interventions for consumers about prescribed and over-the-counter medications. *Public Health Nurs*. 2014;32(2):186-188. doi: 10.1111/phn.12102

81. Coulter A, Ellins J. Effectiveness of strategies for informing, educating, and involving patients. *BMJ*. 2007;335(7609):24-27. doi: 10.1136/bmj.39246.581169.80

82. Mayer RE, Moreno R. Nine ways to reduce cognitive overload in multimedia learning. *Educ Psychol*. 2003;31(1):43-52.

83. Wouters P, Paas F, van Merrienboer JJG. How to optimize learning from animated models: a review of guidelines based on cognitive load. *RER*. 2008;78(3):65-675.

84. Sweller J, van Merrienboer JJG, Paas F. Cognitive architecture and instructional design: 20 years later. *Educ Psychol Rev.* 2019;31:261-292.

85. Wilson EAH, Wolf MS. Working memory and the design of health materials: a cognitive factors perspective. *Patient Educ Couns*. 2009;74(3):318-322. doi: 10.1016/j.pec.2008.11.005

86. Freedman SB, Ali S, Oleszczuk M, Gouin S, Hartling L. Treatment of acute gastroenteritis in children: an overview of systematic reviews of interventions commonly used in developed countries. *EBCH*. 2013;8:1123-1137. doi: 10.1002/ebch.1932

87. Freedman SB, Sivabalasundaram V, Bohn V, Powell EC, Johnson DW, Boutis K. The treatment of pediatrics gastroenteritis: a comparative analysis of pediatric emergency physicians' practice patterns. *Acad Emerg Med*. 2011;18:38-45. doi: 10.1111/j.1553-2712.2010.00960.x

88. Freedman SB, Etorky M, Gorelick M, and the Pediatric Emergency Research Canada Gastroenteritis Study Group. Evaluation of a gastroenteritis severity score for use in outpatient settings. *Pediatrics.* 2010;125:e1278-e1285. doi: 10.1542/peds.2009-3270

89. Kinlin LM, Bahm A, Guttmann A, Freedman SB. A survey of emergency department resources and strategies employed in the treatment of pediatric gastroenteritis. *Acad Emerg Med*. 2013;20(4):361-366. doi: 10.1111/acem.12108

90. Hullegie S, Bruijning-Verhagen, Uiterwaal CSPM, van der Ent CK, Smit HA, de Hoog MLA. First-year daycare and incidence of acute gastroenteritis. *Pediatrics.* 2016;137(5):e20153356. doi: 10.1542/peds.2015-3356

91. Freedman S, Lowerison K. GotGastro.ca. Alberta Provincial Pediatric EnTeric Infection Team (APPETITE) seminar series. GoGastro.ca. http://gotgastro.ca/training/seminar-series-2/. Published 2015. Accessed February 2, 2015.

92. Leshem E, Tate JE, Steiner CA. Acute gastroenteritis hospitalizations among US children following implementation of the rotavirus vaccine. *JAMA*. 2015;313(22):2282-2284. doi:10.1001/jama.2015.5571

93. Shah MP, Tate JE, Steiner CA, Parashar UD. Decline in emergency department visits for acute gastroenteritis among children in 10 US states following implementation of a rotavirus vaccination, 2003-2013. *Pediatr Infect Dis J*. 2016;35(7):782–786. doi:10.1097/INF.0000000000001175

94. Doll MK, Gagneur A, Tapiero B, et al. Temporal changes in pediatric gastroenteritis after rotavirus vaccination in Quebec. *Pediatr Infect Dis J*. 2016;35(5):555–560. doi: 10.1097/INF.0000000000001077

95. Mast TC, DeMuro-Mercon C, Kelly CM, Floyd LE, Walter EB. The impact of rotovirus gastroenteritis on the family. *BMC Pediatr*. 2009;9(11). doi: 10.1186/1471-2431-9-11

96. Marlow R. Finn A, Trotter T. Quality of life impacts from rotavirus gastroenteritis on children and their families in the UK. *Vaccine*. 2015;33(39):5212-5216. doi: 10.1016/j.vaccine.2015.07.012

97. Senecal M, Brisson M, Lebel MH, et al. Measuring the impact of rotavirus acute gastroenteritis episodes (MIRAGE): a prospective community-based study. *Can J Infect Dis Med Microbiol*. 2008;19(6):397-404. doi: 10.1155/2008/451540

98. Edwards CH, Bekkevold T, Flem E. Lost workdays and healthcare use before and after hospital visits due to rotavirus and other gastroenteritis among young children in Norway. *Vaccine*. 2017;35(28):3528-3533. doi: 10.1016/j.vaccine.2017.05.037

99. Anidi I, Bazargan M, James FW. Knowledge and management of diarrhea among underserved minority parents/caregivers. *Ambul Pediatr*. 2002;2:20l-206.

100. Freedman SS, Couto M, Spooner L, Haladyn, K. The implementation of a gastroenteritis education program. *Am J Emerg Med*. 2011;29:271-277. doi: 10.1016/j.ajem.2009.09.032

101. Sustersic M, Jeannet E, Cozon-Rein L, Marechaus F, Genty C, Foote A, David-Tchouda S, Martinez L, Bosson JL. Impact of information leaflets on behavior of patients with gastroenteritis or tonsillitis: A cluster randomized trial in French primary care. *J Gen Int Med*. 2012;28(1):25-31. doi: 10.1007/s11606-012-2164-8

102. Bloch SA, Bloch AJ. Using video discharge instructions as an adjunct to standard written instructions improved caregivers' understanding of their child's emergency department visit, plan, and follow-up: a randomized controlled trial. *Pediatr Emerg Care*. 2013;29(6):699-704. doi: 10.1097/PEC.0b013e3182955480

103. Bahm A, Freedman SB, Guan J, Guttmann A. Evaluating the impact of clinical decision tools in pediatric acute gastroenteritis: a population-based cohort study. *Acad Emerg Med*. 2016;23(5):599-609. doi: 10.1111/acem.12915

104. Navanandan N, Schmidt SK, Cabrera N, DiStefano MC, Mistry RD. The caregiver perspective on unscheduled 72-hour return visits to pediatric acute care sites: a focus on discharge instructions. *Academic Pediatr*. 2017;17(7):755-761. doi: 10.1016/j.acap.2017.02.003

105. Clarke C, Friedman SM, Shi K, Arenovich T, Monzon J, Culligan. Emergency department discharge instructions comprehension and compliance study. *CJEM*. 2005;7(1):5-11. doi: 10.1017/s1481803500012860

106. Glick AF, Farkas JS, Nicholson J, Dreyer BP, Fears M, Bandera C, Stolper T, Gerber N, Yin HS. Parental management of discharge instructions: A systematic review. *Pediatrics*. 2017;140(2):e20164165. doi: 10.1542/peds.2016-4165

107. Rahman Morgan S, Change AM, Alqatari M, Pines JM. Non-emergency department interventions to reduce ED utilization: a systematic review. *Acad Emerg Med*. 2013;20(10):969-985. doi: 10.1111/acem.12219

108. Arksey H, O'Malley L. Scoping studies: Towards a methodological framework. *Int J Social Res Method*. 2005;8:19-31.

109. Albrecht L, Scott SD, Hartling L. Knowledge translation tools for parents on child health topics: A scoping review. Knowledge translation tools for parents on child health topics: A scoping review. *BMC Health Serv Res*. 2017;17(686). doi: 10.1186/s12913-017-2632-2

110. Austin PE, Matlack R, Dunn KA, Kesler C, Brown CK. Discharge instructions: do illustrations help our patients understand them? *Ann Emerg Med*. 1995;25(3):317-320. doi: 10.1016/s0196-0644(95)70286-5

111. Hartling L, Scott SD, Johnson DW, Bishop T, Klassen TP. A randomized controlled trial of storytelling as a communication tool. *PLoS One*. 2013;8(10):e77800. doi: 10.1371/journal.pone.0077800

112. Scott SD, Hartling L, O'Leary KA, Archibald M, Klassen TP. Stories – a novel approach to transfer complex health information to parents: a qualitative study. *Arts & Health*. 2012;4(2):162-173.

113. Yin SH, Dreyer BP, van Schaick L, Foltin GL, Dinglas C, Mendelsohn AL. Randomized controlled trial of a pictogram-based intervention to reduce liquid medication dosing errors and improve adherence among caregivers of young children. *Arch Pediatr Adolesc Med.* 2008;162(9):814-822. doi: 10.1001/archpedi.162.9.814

114. Herman A, Young K, Espitia D, Fu N, Farshidi A. Impact of a health literacy intervention on pediatric emergency department use. *Pediatr Emerg Care*. 2009;25(7):434-438.

115. Armstrong AW, Idriss NZ, Kim RH. Effects of video-based, online education on behavioural and knowledge outcomes in sunscreen use. *Patient Educ Couns*. 2011;83(2):273-277. doi: 10.1016/j.pec.2010.04.033

116. Delp C, Jones J. Communicating information to patients: the use of cartoon illustrations to improve comprehension of instructions. *Acad Emerg Med*. 1996;3(3):264-270. doi: 10.1111/j.1553-2712.1996.tb03431.x

117. Lipstein EA, Brinkman WB, Britto MT. What is known about parents' treatment decisions? A narrative review of pediatric decision making. *Med Decis Making.* 2012;32(2):246-258. doi: 10.1177/0272989X11421528

118. Saidinejad M, Zorc J. Mobile and web-based education: delivering emergency department discharge and aftercare instructions. *Pediatr Emerg Care*. 2014;30:211-216. doi: 10.1097/PEC.0000000000000097

119. Elliott JH, Turner T, Clavisi O, et al. Living Systematic Reviews: An Emerging Opportunity to Narrow the Evidence-Practice Gap. *PLoS Med*. 2014;11(2): e1001603. doi: 10.1371/journal.pmed.1001603

120. Elliot JH, Synnot A, Turner T, et al. Living systematic review: 1. Introduction – the why, what, when, and how. *J Clin Epi*. 2017;91:23-30. doi: 10.1016/j.jclinepi.2017.08.010

121. Freedman SB, Gouin S, Bhaat M, et al. Prospective assessment of practice pattern variations in the treatment of pediatric gastroenteritis. *Pediatrics*. 2011;127(2):e287-e295. doi: 10.1542/peds.2010-2214

122. Tieder JS, Robertson A, Garrison MM. Pediatric hospital adherence to the standard of care for acute gastroenteritis. *Pediatrics*. 2009;124(6):e1081-e1086. doi: 10.1542/peds.2009-0473

123. Cochrane Colloquium Seoul. Abstracts E-Book: P73 Living systematic reviews for up-to-date evidence: case studies on pediatric croup and acute gastroenteritis.

2016.Cochrane.Colloquium.org. http://2016.colloquium.cochrane.org/abstracts-e-book. Published October 2016. Accessed January 2, 2020.

124. Hartling L, Bellemare S, Wiebe N, Russell K, Klassen TP, Craig W. Oral versus intravenous rehydration for treating dehydration due to gastroenteritis in children. *Cochrane Database Syst Rev.* 2006:CD004390.

125. Fedorowicz Z, Jagannath VA, Carter B. Antiemetics for reducing vomiting related to acute gastroenteritis in children and adolescents. *Cochrane Database Syst Rev.* 2011;(9):CD005506. doi: 10.1002/14651858.CD005506.pub5

126. Allen SJ, Martinez EG, Gregorio GV, Dans LF. Pro- biotics for treating acute infectious diarrhoea. *Cochrane Database Syst Rev.* 2010;(11):CD003048. doi: 10.1002/14651858.CD003048.pub3

127. Salari P, Nikfar S, Abdollahi M. A meta-analysis and systematic review on the effect of probiotics in acute diarrhea. *Inflamm Allergy Drug Targets.* 2012;11:3–14.

128. Cochrane Community. Covidence. Community.Cochrane.org. https://community.cochrane.org/help/tools-and-software/covidence. Updated 2020. Accessed Jan. 13, 2020.

129. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ.* 2011;343:d5928. doi: 10.1136/bmj.d5928

130. Albrecht L, Hartling L, Scott SD. Pediatric acute gastroenteritis: understanding caregivers' experiences and information needs. *CJEM*. 2016;1-9. doi: 10.1017/cem.2016.363

131. Pediatric Emergency Research Canada. Who we are. PERC-Canada.ca. https://www.perc-canada.ca/. Updated 2020. Accessed Jan. 13, 2020.

132. Children' Healthcare Canada. Patient and Family Centered Care. ChildrensHealthCanada.ca. https://www.childrenshealthcarecanada.ca/patient-and-family-centred-care. Accessed Jan. 13, 2020.

133. Translating Emergency Knowledge for Kids. TREKK Parent Advisory Group. TREKK.ca https://trekk.ca/pages/43-parent-advisory-group. Updated 2019. Accessed Jan. 13, 2020.

134. Cochrane Colloquium Seoul. Abstracts E-Book: P72 The development of knowledge translation tools for parents in pediatric acute care. 2016.Cochrane.Colloquium.org. http://2016.colloquium.cochrane.org/abstracts-e-book. Published October 2016. Accessed January 2, 2020.

135. Ioannidis JPA. How to make more published research true. *PLoS Med.* 2014;11(10): e1001747. doi: 10.1371/journal.pmed.1001747

136. Bleijenberg N, de Man-van Ginkel JM, Trappenburg JCA, et al. Increasing value and reducing waste by optimizing the development of complex interventions: enriching the development phase of the Medical Research Council (MRC) Framework. *IJNS*. 2018,79:86-93. doi: 10.1016/j.ijnurstu.2017.12.001

137. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. 2010;10(1). doi: 10.1186/1471-2288-10-1

138. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol*. 2010;10(67). doi: 10.1186/1471-2288-10-67

139. Shanyinde M, Pickering RM, Weatherall M. Questions asked and answered in pilot and feasibility randomized controlled trials. *BMC Med Res Methodol*. 2011;11(117). doi: 10.1186/1471-2288-11-117

140. Albrecht L, Scott SD, Hartling L. Evaluating a knowledge translation tool for parents about pediatric acute gastroenteritis: a pilot randomized trial. *BMC Pilot Feasibility Stud*. 2018;4:131. doi: 10.1186/s40814-018-0318-0

Chapter 2 - Knowledge translation tools for parents on child health topics: A scoping review

Background

It is well established that the creation of new knowledge through biomedical and health services research does not automatically lead to widespread implementation or health impacts [1]. To maximize health system resources and improve patient outcomes, it is increasingly important to close the research-practice gap by ensuring that research knowledge translates into action – a process called knowledge translation (KT). KT is defined as the synthesis, exchange, and application of knowledge to improve the health of individuals, provide more effective health services and products, and strengthen health care systems [1]. Current approaches to KT are largely focused on aligning the behaviours of health professionals with best research evidence; however, ever-increasing healthcare complexity and health professional time constraints are barriers to effective research use [2,3]. An emerging approach to KT is directing information to health consumers (i.e., patients, parents, caregivers) to increase their knowledge and participation in health decision-making.

In the field of child health, connecting parents and caregivers to research evidence has the power to improve health decision-making and reduce health system costs [4]. Traditional approaches used by health providers to share information with parents and caregivers have been found lacking. For instance, verbal information is often brief [5] and written information is often too complex for most adults to comprehend [6,7]. There is little guidance on the most effective approach, content, duration, and intensity of information provision for the diverse population that parents represent [8-10].

While KT interventions encompass a wide array of strategies to bridge the research-practice gap, including individual, organizational, and structural interventions [11], KT tools are a sub-group of KT interventions that present research-based information in user-friendly language and formats to provide explicit recommendations, and/or meet knowledge/information needs [12]. KT tools are particularly suited for lay audiences, including parents and caregivers. It is hypothesized that KT tools may foster and empower 'effective consumers' with research knowledge to inform their health decision-making [13].

The purpose of this scoping review was to identify previously published effectiveness research on child health-related KT tools for parents/caregivers. We sought to understand the breadth of KT tools that have been developed and evaluated (including their intended purpose), how they are being evaluated (including the outcomes selected), and whether they are demonstrating hypothesized effects. Understanding the evidence-base for KT tools for parents/caregivers in child health and identifying gaps in this emerging field is a critical next step to inform KT science for health consumers.

Methods

This scoping review was guided by the rigorous, systematic methods outlined by Arksey & O'Malley [14].

Search strategy

A comprehensive literature search was designed and implemented by a health research librarian (TC) in eight databases: Medline, Medline In-Process & Other None-Indexed Citations, EBM Reviews, Embase, PsychINFO, CINAHL, SocINDEX, and Web of science. The search included language (English only) and date restrictions (2005 – June 2015) (search strategies and

terms in Appendix B). Date restrictions reflect the advent of KT science [12,15] and the emergence of KT targeting health consumers [16].

Study inclusion criteria

The inclusion criteria are outlined in Table 3.1. In brief, we were interested in any primary research evaluating the effectiveness of a KT tool on a child health topic and targeting parents/lay caregivers. A KT tool was defined as a tangible, on-demand product presenting research-based information in user-friendly language and format(s) to provide explicit recommendations, and/or meet knowledge/information needs.

Table 2.1: Study Inclusion Criteria.

Inclusion Criteria	**Definitions & Notes**
1. Primary research study	Inclusive of all study designs.
2. Evaluated effectiveness of an intervention	Defined as determining efficacy and/or effectiveness (i.e., does it work?). Studies examining functionality, feasibility, and/or acceptability to inform intervention development were excluded.
3. Intervention evaluated was a KT tool	Defined as tangible (i.e., either material or electronic) products presenting research-based information in user-friendly language and format(s) to provide explicit recommendations, and/or meet knowledge/information needs. The KT tool must be available on-demand so that the target audience can mediate its use (i.e., when to use them, how often to use them, etc.).
4. Intervention targeted parents/caregivers	Defined as individuals responsible for the health and wellbeing of child(ren) and are active-participants in child health decision making.
5. Intervention provided research-based information on child health topics	Inclusive of all child health topics.

Study selection

One reviewer (LA) conducted primary and secondary screening using pre-determined criteria (Appendix C). A second, independent reviewer (XW) screened 10% of all studies to verify inclusion/exclusion decisions. Interrater agreement was determined to be 'very good' with a kappa statistic of 0.803 [17].

Data collection

Data were extracted by one reviewer (LA). The following general variables were extracted: authors, year of publication, country, and journal of publication. Methodological elements were also extracted, including: study design, study focus (i.e., purpose), availability of a priori protocol, study population, sample size calculation, recruitment and retention, intervention and comparison groups, data collection methods, primary outcome(s) and measures. We also extracted the results for the primary outcomes, and author conclusions. Additional variables specific to the KT tools were extracted, including: child health topic, purpose of tool, description of tool, tool development approaches (e.g., including end-users, theoretical basis, and preliminary research conducted prior to effectiveness evaluation), type of tool, and number of interacting tool elements.

Methodological quality assessment

Scoping reviews do not typically include critical appraisal of individual studies [14,18]. This has been acknowledged as a limitation of the Arksey & O'Malley method [19]. New methodological recommendations include methodological quality assessment to demonstrate gaps in the evidence-base and demonstrate feasibility of future systematic reviews [19]. However, studies should not to be excluded based on these methodological quality ratings [19], which is how we proceeded in this review.

For randomized controlled trials (RCTs), methodological quality was assessed by one reviewer (LA) using the Cochrane Risk of Bias Tool [20]. This tool has been deemed the most comprehensive for assessing potential for bias in RCTs [21] and has become the standard approach for systematic reviews [22]. A global quality rating of low, high or unclear risk of bias is assigned to each RCT based on seven components: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, 'other' sources of bias.

For all other quantitative study designs, methodological quality was assessed by one reviewer (LA) using the Quality Assessment Tool for Quantitative Studies [23]. Content validity, construct validity, and inter-rater reliability have been established for this tool [24]. A global quality rating of weak, moderate or strong is assigned to each study based on eight components: selection bias, study design, confounders, blinding, data collection methods, withdrawals and dropouts, intervention integrity, and analysis.

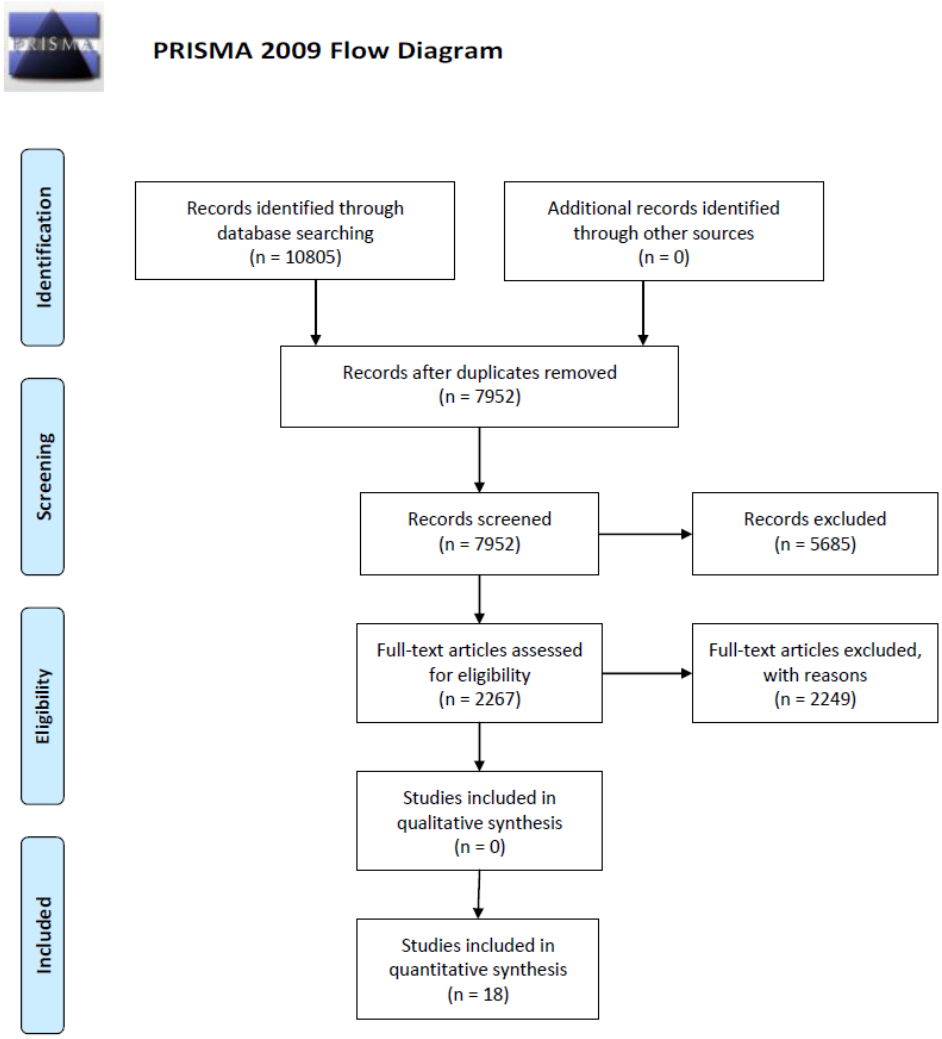
Data analysis

A descriptive analysis of the extracted variables was conducted. The WIDER Recommendations Checklist was applied to describe the reporting quality of the KT tools [25] (Appendix D). Since the studies assessed primary outcomes at different levels, a classification scheme of outcomes for assessing patient-focused interventions was applied [26] (Appendix E). Study results were described as positive effect, mixed effects, no effect, or unclear in relation to the intended impact on the primary outcome(s). A narrative summary of these effects was performed considering the nature of the intervention, topic, and study design features.

Results

After removing duplicates, 7952 titles and abstracts were reviewed in primary screening, 2267 full-text studies were reviewed in secondary screening, and 18 studies met our inclusion criteria (Figure 3.1) [27-44]. The included studies are summarized in Appendix F.

Figure 2.1: PRISMA Flow diagram.



KT tool interventions

The KT tools provided evidence-based information on different acute conditions (n=4; e.g., gastroenteritis, tonsillitis, procedural pain, surgery), chronic conditions (n=5; e.g., inherited metabolic disorders, Type I diabetes, asthma, vision impairment), and public health/health

promotion topics (n=9; e.g., preventive care/minor child health issues, vaccination, antibiotics use, healthy diet & physical activity, infant feeding, smoking prevention) in child health. A variety of KT tool interventions were studied, including pamphlet (n=3), information sheet (n=2), cartoon book (n=1), book (n=1), video (n=1), website (n=2), video + booklet (n=1), 2 videos + 2 booklets (n=2), video + book (n=1), video + pamphlet (n=1), 2 videos + 2 pamphlets (n=1), 5 activity guides + tip sheets + newsletters (n=1), and 6 books (n=1). Additionally, 6 studies had KT tools as comparison/control conditions; these tools included, pamphlet [42], 1 video + 1 pamphlet [34,35], 2 pamphlets [33], 2 information sheets [44] 5 pamphlets [32].

Another approach to classify KT tools is to examine the number of different components (i.e., single or multiple) within the intervention (as shown in the above list) (Table 2.2). In nine studies, KT tools featured one (single) stand-alone component (e.g., information sheet) [27,29,30,36,38-42]; two single-component KT tools were compared and evaluated in one of these studies [42]. In nine studies, KT tools included multiple (more than one) components that worked in tandem (e.g., pamphlet + video) [28,31-35,37,43,44]; two multi-component KT tools were compared and evaluated in five of these studies [32-35,44].

Table 2.2: Effectiveness of KT Tools on Primary Outcome Categories.

Study design	First author (year)	Single/Multiple component KT tool groups (specific KT Tool)	Health category (topic)	Primary Outcome Categories		
				Patient's knowledge	Patient's experience	Health behaviour & health status
Cross-sectional	Dempsey (2006)	Single component (information sheet)	Public health (Vaccination)	-	no effect	-
	Evans (2009)	Multi-component (video + book)	Chronic (Inherited metabolic disorders)	-	-	unclear
	Ranjit (2015)	Single component (book)	Public health (Healthy diet & physical activity)	no effect	mixed effects	no effect

	Sustersic (2013)	Single component (pamphlet)	Acute (Gastroenteritis, tonsillitis)	-	-	mixed effects
Before-after	Skranes (2015)	Single component (website)	Public health (Minor child health conditions)	positive effect	no effect	-
Controlled before-after	Scheinman (2010)	Single component (video)	Public health (Infant feeding)	mixed effects	-	mixed effects
	Taddio (2014)	Single component (pamphlet)	Acute (Procedural pain management)	no effect	-	-
Cohort	Nordfeldt (2002)	Multi-component (2 videos + 2 pamphlets)	Chronic (Type I diabetes)	-	unclear	unclear
		Multi-component (2 pamphlets)				
RCT	Bailey (2015)	Single component (information sheet)	Acute (Surgical pain management)	positive effect	positive effect	mixed effects
	Bauchner (2001)	Multi-component (video + pamphlet)	Public health (Antibiotics use)	no effect	no effect	mixed effects
	Christakis (2006)	Single component (tailored website)	Public health (Preventive care)	-	-	mixed effects
	Jackson (2006)	Multi-component (5 printed activity guides + series of tip sheets for parents + series of newsletters for children)	Public health (Smoking prevention)	-	-	positive effect
		Multi-component (5 information sheets)				
	Nordfeldt (2003)	Multi-component (2 videos + 2 booklets)	Chronic (Type I diabetes)	-	-	mixed effect
		(1 video + 1 booklet)				
	Nordfeldt (2005)	Multi-component (2 videos + 2 booklets)	Chronic (Type I diabetes)	-	-	positive effect
		Multi-component (1 video + 1 booklet)				
	Reich (2010)	Multi-component (6 books)	Public health (Minor child health conditions)	mixed effects	-	-
	Tijam (2013)	Single component (cartoon book)		-	-	mixed effects

	Single component (pamphlet)	Chronic (Vision impairment)			
Wakimizu (2009)	Multi-component (video + booklet)	Acute (Surgery)	mixed effects	mixed effects	-
Wilson (2006)	Multi-component (2 pamphlets)	Public health (Vaccination)	no effect	-	-
	Multi-component (2 information sheets)				

The quality of reporting of the KT tools was described using the WIDER Recommendations Checklist [25] (Table 2.3). Overall reporting quality was low. For the 'Detailed Description of Intervention' recommendation there were 8 components; included studies achieved between 3 and 6 components with a mean of 4 and a mode of 5 components. Generally included studies did not report on characteristics of those delivering the intervention, the intensity of the intervention, and adherence/fidelity to delivery protocols. For the 'Clarification of Assumed Change Process and Design Principles' recommendation there were 3 components. Change techniques used in the intervention were the most reported component (12/18 studies). Causal processes targeted by change techniques and intervention development processes were rarely reported (5/18 studies for both components). Four of 18 studies satisfied the third recommendation, 'Access to Intervention Manuals/Protocols'. For the fourth recommendation, 'Detailed Description of Active Control Conditions', a variety of control conditions were present (i.e., active control, no active control, multiple control groups, no control group).

Table 2.3: WIDER Recommendations Checklist for Intervention Reporting Quality.

Author (Year)	**Detailed Description of Intervention (Y/N)**								**Clarification of Assumed Change Process and Design Principles (Y/N)**			**Access to Intervention Manuals/ Protocols**	**Detailed Description of Active Control Conditions (Y/N)**			
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**1**	**2**	**3**	**Y/N**	**1**	**2**	**3**	**4**

Bailey (2015)	N	Y	Y	Y	Y	N	N	N	N	N	N	N			Y	
Bauchner (2001)	N	Y	Y	Y	N	Y	N	Y	Y	Y	N	N			Y	
Christakis (2006)	N	Y	Y	N	N	N	N	Y	N	Y	N	N	Y		Y	
Dempsey (2006)	N	Y	Y	Y	N	N	Y	Y	N	Y	Y	Y			Y	
Evans (2009)	N	Y	Y	Y	N	Y	N	Y	N	Y	N	N				Y
Jackson (2006)	N	Y	Y	Y	N	N	N	N	N	N	N	N	Y			
	N	Y	Y	Y	N	N	N	N	N	N	N	N	control condition			
Nordfeldt (2002)	N	Y	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y			
	N	Y	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y			
Nordfeldt (2003)	N	Y	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y			
	N	Y	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y			
Nordfeldt (2005)	N	Y	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y			
	N	Y	Y	Y	N	Y	N	Y	Y	Y	Y	N	Y			
Ranjit (2015)	N	Y	Y	Y	N	N	N	Y	N	N	Y	N			Y	
Reich (2010)	N	Y	Y	Y	Y	Y	N	Y	N	N	N	N	Y		Y	
Scheinmann (2009)	N	Y	Y	Y	N	N	N	N	N	N	N	N			Y	
Skranes (2015)	N	Y	Y	Y	N	N	N	N	N	Y	N	Y			Y	
Sustersic (2012)	N	Y	Y	Y	N	Y	N	N	N	Y	N	Y			Y	
Taddio (2014)	N	Y	Y	Y	N	Y	N	Y	N	Y	N	Y			Y	
Tjiam (2012)	N	Y	Y	Y	N	N	N	N	N	N	N	N	Y	Y		
	N	Y	Y	Y	N	N	N	N	N	N	N	N	Y	Y		
Wakimizu (2009)	N	Y	Y	Y	N	Y	N	Y	Y	Y	N	N	Y			
Wilson (2006)	N	Y	Y	Y	N	N	N	N	N	Y	N	N	Y			
	N	Y	Y	Y	N	N	N	N	N	Y	N	N	control condition			

Study designs

Five different quantitative study designs were represented: cross-sectional (n=4) [30,31,36,40], before-after (n=1) [39], controlled before-after (n=2) [38,41], cohort (n=1) [33], and RCT (n=10) [27-29,32,34,35,37,42-44]. No qualitative studies met the inclusion criteria.

Methodological quality

Ten RCTs were assessed for risk of bias (Table 2.4). Five studies were assessed as high risk of bias [27-29,32,44]; the most frequent reason for high risk of bias was lack of blinding of

participants and personnel. Five studies were determined to have unclear risk of bias [34,35,37,42,43]; the most frequent reason for unclear risk of bias was the possibility of selective outcome reporting. None of the included studies were assessed as low risk of bias overall.

Table 2.4: Risk of Bias Assessment of Included RCTs.

Author (year)	Sequence generation	Allocation concealment	Blinding participants & personnel	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reporting	Other sources of bias	Overall score
Bailey (2015)	Low	Low	Unclear	Unclear	Low	High	High	High
Bauchner (2001)	Unclear	Unclear	High	Unclear	Low	Unclear	High	High
Christakis (2006)	Low	Low	High	Low	Unclear	Unclear	Low	High
Jackson (2006)	Unclear	Unclear	High	Low	Low	Unclear	Low	High
Nordfeldt (2003)	Low	Low	Low	Low	Unclear	Unclear	Low	Unclear
Nordfeldt (2005)	Low	Low	Low	Low	Unclear	Unclear	Low	Unclear
Reich (2010)	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Low	Unclear
Tijam (2013)	Unclear	Unclear	Unclear	Low	Low	Unclear	Low	Unclear
Wakimizu (2009)	Low	Unclear	Low	Low	Low	Unclear	Low	Unclear
Wilson (2006)	Unclear	Unclear	Unclear	Unclear	High	Unclear	Unclear	High

All eight of the quantitative, non-RCT studies had a global methodological quality rating of weak [30,31,33,38-41] (Table 2.5). The most problematic domains across studies were ‘study design’ and ‘data collection and methods’; all studies were weak with respect to these domains except one.

Table 2.5: Quality Assessment of Included Non-RCT Studies.

Author (year)	Selection bias	Study design	Confounders	Blinding	Data collection methods	Withdrawals & drop-outs	Global rating
Dempsey (2006)	Weak	Weak	Strong	Moderate	Weak	Moderate	Weak
Evans (2009)	Moderate	Weak	Weak	Moderate	Weak	Strong	Weak

Nordfeldt (2002)	Moderate	Moderate	Weak	Moderate	Weak	Weak	Weak
Ranjit (2015)	Weak	Weak	Weak	Moderate	Weak	Weak	Weak
Scheinman (2010)	Weak	Weak	Strong	Moderate	Weak	Moderate	Weak
Skranes (2015)	Weak	Weak	Weak	Moderate	Weak	Moderate	Weak
Sustersic (2013)	Moderate	Weak	Strong	Moderate	Weak	Strong	Weak
Taddio (2014)	Weak	Weak	Strong	Moderate	Strong	Strong	Weak

Primary outcomes

Primary outcomes were classified into four categories using the Outcomes of Interest for Assessing Patient-Focused Interventions classification scheme [26] (Table 2.2). It was possible for one outcome category to encompass several different outcome measures (e.g., self-efficacy measures and perceived barrier measures are both captured under the Patients' Experience outcome category) (Appendix D). Overall, 11 studies assessed one primary outcome category to determine the effectiveness of KT tools: patients' knowledge (n=3) [37,41,44]; patients' experience (n=1) [30]; health behaviour and health status (n=7) [29,31,3234,35,40,42]. None of the included studies assessed outcomes in the health services utilization and cost category of the outcome classification scheme.

Seven studies assessed KT tool effectiveness with multiple primary outcome categories. Four of these studies identified and assessed primary outcomes in two different outcome categories: patients' knowledge and patients' experience (n=2) [39,43]; patients' knowledge and health behaviour/health status (n=1) [38]; and patients' experience and health behaviour/health status (n=1) [33]. Three studies identified primary outcomes in three different outcome categories: patients' knowledge, patients' experience, and health behaviour/health status categories [27,28,36].

Study results

A summary of study results is presented in Appendix F. Of the 18 included studies, two studies demonstrated significant positive effects on the primary outcome [32,35]. Both studies were RCTs that assessed the effectiveness of multi-component KT tools using the health behaviour/health status primary outcome category. In both studies the primary outcome was assessed using one single measure at two time points (i.e., baseline and follow-up) with a long follow up period (i.e., 2 years, 3 years). Jackson et al. (2006) compared 2 multi-component KT tools, with the more dynamic tool (i.e., 5 printed activity guides with supplementary fact sheets for parents and newsletters for children vs 5 pamphlets) demonstrating effectiveness in delaying initiation of smoking. This study was assessed to have high risk of bias due to lack of blinding of study participants and personnel (Table 2.4). Nordfeldt et al. (2005) compared 2 multi-component KT tools (i.e., 2 videos + 2 booklets vs 1 video + 1 booklet with different information for each study arm) and a usual care control group, with the more dynamic and specific tool (2 videos + 2 booklets on self-control and treatment information vs 1 video + 1 booklet on general diabetes information) demonstrating effectiveness on reducing yearly incidence of severe hypoglycemia needing assistance. This study was assessed to have unclear risk of bias with respect to incomplete outcome data and selective outcome reporting (Table 2.4).

Two additional studies demonstrated significant positive effects on at least one of the identified primary outcome categories [27,39]. Both studies assessed the effectiveness of single-component KT tools. Skranes et al. (2015) utilized a before-after design and determined that a website was effective for improving mothers' knowledge of minor child health conditions, but not mothers' experience (i.e., self-perceived anxiety) over a six to 12-month follow-up period. The methodological quality was assessed as weak (Table 3.5). Bailey et al. (2015) conducted a

RCT and determined that an information sheet was effective for improving knowledge and experience with respect to tonsillectomy surgery pain management, but not health behaviour/status over a 10-day follow-up period. This study was assessed to have a high risk of bias due to selective outcome reporting and other sources of bias (i.e., baseline imbalances in study groups) (Table 2.4).

Nine studies demonstrated a combination of mixed effects and no effect on primary outcome categories (both single and multiple primary outcome categories) [28,29,34,36-38,40,42,43]. These studies were diverse in terms of the KT tool interventions (i.e., a variety of single and multi-component KT tools), study designs, and number of outcomes within and between the three primary outcome categories. Four of nine studies had longer follow-up periods (i.e., from 10 weeks to three years), three had shorter follow-up periods (i.e., less than 8 weeks), and two had undefined follow-up periods (i.e., referred to as post-intervention assessment with no timing provided).

Three studies showed no effect on the primary outcome categories [30,41,44]. These studies were conducted using different designs: cross-sectional [30], controlled before-after [41], and RCT [44]. They represented both single and multi-component KT tools; however, all three KT tools were non-electronic, written materials (i.e., information sheet, pamphlets). The three studies measured single, proximal outcome categories (i.e., knowledge, experience) over a short follow-up period (i.e., 2 weeks, 2 months). The methodological quality of two studies was assessed as weak [30,41] (Table 2.5) and the third study was determined to have high risk of bias [44] (Table 2.4).

Additional key study features

To contextualize the study results and methodological quality ratings, additional data were extracted about key study features with a focus on methodological and intervention development variables (Table 2.6). References to trial registration and a priori protocols were extracted and relevant databases were searched. None of the 18 studies had an a priori protocol publicly available; however, four studies were registered retrospectively [27,29,37,40]. Five of 18 studies provided a sample size calculation [28-30,40,41] and of those studies, three were sufficiently powered to detect the desired change in the primary outcome [28,30,40]. Four of 18 studies described a theoretical basis for the KT tool intervention [30,33,36,43] and five of 18 studies explicitly described end-user involvement in intervention development [28,31,33,38,43]. Finally, nine studies described or referenced preliminary research (i.e., qualitative, feasibility, pilot studies) that informed the current KT tool effectiveness study [28,32-35,38,40,41]. There were no discernable patterns between these variables and the effectiveness of the KT tools.

Table 2.6: Additional Key Study Design & Intervention Development Features.

Study Design	Author (year)	A priori protocol publicly available (Y/N)	Sample size calculation provided (Y/N)	Sufficiently powered for primary outcome (Y/N/?)	Theory-based intervention (Y/N/?)	End-users involved in intervention development (Y/N/?)	Preliminary qualitative/ feasibility/ pilot work referenced (Y/N)
Cross-sectional	Dempsey (2006)	N	Y	Y	Y	?	N
	Evans (2009)	N	N	?	N	Y	N
	Ranjit (2015)	N	N	?	Y	N	N
	Sustersic (2013)	N[1]	Y	Y	?	?	Y
Before-after	Skranes (2015)	N	N	?	N	N	N
Controlled before-after	Scheinman (2010)	N	N	?	N	Y	Y
	Taddio (2014)	N	Y	N	N	?	Y
Cohort	Nordfeldt (2002)	N	N	?	Y	Y	Y
RCT	Bailey (2015)	N[1]	N	?	?	?	N

	Bauchner (2001)	N	Y	Y	N	Y	Y
	Christakis (2006)	N[1]	Y	N	N	?	N
	Jackson (2006)	N	N	?	?	?	Y
	Nordfeldt (2003)	N	N	?	N	?	Y
	Nordfeldt (2005)	N	N	?	N	?	Y
	Reich (2010)	N[1]	N	?	N	?	N
	Tjiam (2013)	N	N	?	N	N	Y
	Wakimizu (2009)	N	N	?	Y	Y	N
	Wilson (2006)	N	N	?	N	?	N

[1]Retrospective protocol registration

Discussion

This scoping review has demonstrated that several different KT tools have been specifically designed for parents/caregivers on diverse child health topics, which include a variety of single- and multi-component strategies. Few KT tools demonstrated positive effects for primary outcomes; the majority of studies showed mixed effects within and between primary outcome categories. Only two studies showed strictly positive effects and both evaluated multi-component KT tools. Three studies showed no effect and these evaluated single-component KT tools, specifically they were all non-electronic, written materials. This suggests that multi-component KT tools may be more effective for health consumers, specifically parents and caregivers. While we did not conduct formal comparisons, these findings contradict previous research indicating the effectiveness of patient-focused interventions decreases as the number of intervention components number increases [45].

This review demonstrated that the most common design was the RCT (n=10), which is recognized as the most rigorous design for evaluating effectiveness [46]. All included RCTs were assessed as unclear or high risk of bias; further, included non-RCT studies all had

substantial methodological weaknesses. Given these methodological weaknesses, it might be expected that interventions would be more likely to demonstrate an effect, particularly for the primary outcomes; however, most studies did not demonstrate significantly positive results on the primary outcomes of interest. This raises three considerations: 1) was the design or certain design features (e.g., sample size, nature of the comparison) inappropriate or inadequate to assess effectiveness; 2) were appropriate outcomes selected and measured to accurately assess intended impact and establish effectiveness; or 3) have the KT tools been appropriately developed and incrementally assessed to establish effectiveness?

There were several design/methodological issues that may have impacted the effectiveness results. None of the included studies was shown to have low risk of bias (i.e., high or unclear risk of bias ratings only). Low methodological quality ratings were due to deficiencies in multiple categories in both tools. Interestingly, no a priori protocols were available and only 4 studies retrospectively registered their protocols. While a priori protocols may not yet be standard for all study designs, it is standard practice to register a priori protocols for RCTs [47,48]. Additionally, only 3 studies (16.7%) demonstrated adequate power to detect statistical significance of the primary outcomes. This information, generally provided in study protocols (if not also in primary publications), is a key aspect of effective comparative studies in health research [49]. With strict journal length restrictions, it is difficult to determine if high risk of bias/weak methodological quality can be attributed to lack of reporting and/or poor study design and execution; however, the publication of study protocols has been proposed as an important approach in the primary prevention of poor medical/health research [50], particularly selective outcome reporting [51].

There is little agreement on the best outcomes and measures to determine effectiveness of patient-focused interventions [26]. Applying the Coulter & Ellins patient-important outcomes framework was useful because it helped to reduce the 'noise' and classify multiple outcome measures within and across four distinct outcome categories. Studies used many different outcome measures across a variety of proximal (i.e., patients' knowledge) and distal (i.e., health services utilization/health behavior) outcome categories. Just under half (44%) of studies skipped proximal outcomes (i.e., knowledge) and instead only measured more distal, behaviour-related outcomes. Two such studies showed statistically significant positive effects of the KT tools, but methodological quality concerns (i.e., high and unclear ratings) and no a priori protocol or sample size estimation limit our confidence in the link between the KT tool and these distal, health behaviour and health status changes. There may be other mitigating factors in the 'black box' between the interventions and outcomes. Additionally, the use of multiple outcome measures within the same primary outcome category and/or measuring multiple primary outcome categories most often resulted in mixed effectiveness (n=9). It is difficult to interpret these results without authors' providing explicit rationale linking primary outcome(s) and measures to the intended effect of the KT tools. It is important to note that only four studies described the theoretical basis for the KT tool; more explicit theoretical underpinnings may help in tool development and linking tools to intended outcomes.

Unfortunately, the overall poor intervention reporting quality in the literature [52-55], including development approaches/methods [46], theoretical basis [56,57], and end-user involvement [58], results in limited understanding of intervention components and relationship/interaction between these components, which are responsible for observed changed and desired effects on outcomes [59]. These issues were exemplified in this review with poor

reporting across all WIDER Recommendation categories. Without detailed understanding of these important elements, KT tool sustainability, replication, scale-up and future development efforts are limited [25].

Effectiveness evaluation is typically resource intensive, yet we need to understand whether KT tools are effective for a lay audience prior to large-scale implementation. Formative research (i.e., qualitative, feasibility, pilot studies) prior to launching into effectiveness evaluation may be essential to attend to intervention development and implementation issues, refine effectiveness evaluation protocols, including most appropriate outcomes and measures, and ensure potential impact [57,60]. However, only half (n=9) of the included studies described or referenced preliminary research that was conducted to inform the current effectiveness evaluation study. Both studies in this review that demonstrated significant positive effects on primary outcomes referenced such preliminary research. Unfortunately, these studies did not provide sufficient detail to guide future KT tool evaluations; however, future research could attend to this need.

There is also a growing body of literature to support the use of qualitative research in the design and implementation of RCTs [61-64]. Qualitative research has been used to add value to trials in the areas of bias, efficiency, ethics, implementation, interpretation, relevance, success, and validity [65]. Novel study designs, beyond RCTs, possibly including mixed methods, may explain why the KT tools worked or not, help explain and interpret effectiveness results, and explore the implementation process [57].

Strengths & limitations

This scoping review provides a detailed summary of the state of the science for the emerging field of KT tools for parents and caregivers on child health topics. By conducting

critical appraisal using two rigorous frameworks for multiple study design types, this review offers important methodological advancement of the Arksey & O'Malley (2005) scoping review method [14,18,19]. One limitation is the lack of a second reviewer to verify data extraction and critical appraisal, as would be expected in a systematic review. Another limitation was the lack of a classification scheme for the KT tools; the Coulter & Ellins patient-focused intervention classification was not used because it had a broader scope than desired [26]. Multiple, overlapping frameworks are a persistent problem in the KT field [66,67]; however, the recently published AIMD meta-framework may be the solution [68] and future research should explore KT tool development, reporting, and classification with this new framework.

Conclusions

KT tools offer a promising approach to communicate complex health information to health consumers. While a breadth of KT tools have been developed to provide research-based information on a wide variety of acute, chronic and public health/health promotion topics in child health, improved reporting is essential to ensure intervention design is appropriate for desired change and that well designed interventions are replicable. Additionally, increased methodological rigor is needed to determine the effectiveness of the KT tools. This includes the publication of a priori protocols, sample size calculations, primary outcome identification, and attending to multiple outcome measures and mixed results. More preliminary research, including KT tool development involving the target end-users and usability testing prior to large-scale trials, may be important to optimize KT tool effectiveness. Further, ensuring all necessary intervention and methodological components are attended to before and during effectiveness evaluation will help provide a more solid scientific base for KT targeting health consumers.

Chapter 2 References

1. Canadian Institutes of Health Research. Knowledge translation. Cihr-irsc.ca. https://cihr-irsc.gc.ca/e/29529.html. Updated Nov 11, 2019. Accessed March 18, 2015.
2. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: The National Academies Press; 2000.
3. Thompson DS, O'Leary K, Jensen E, Scott-Findlay SD, O'Brien-Pallas L, Estabrooks CA. The relationship between busyness and research utilization: it is about time. *J Clin Nurs.* 2008;7(4)539-48. doi: 10.1111/j.1365-2702.2007.01981.x
4. Morrison AK, Myrvik MP, Brousseau DC, Hoffman RG, Stanley RM. The relationship between parent health literacy and pediatric emergency department utilization: a systematic review. *Acad Pediatr*. 2013;13(5):421-29. doi: 10.1016/j.acap.2013.03.001
5. Vashi A, Rhodes KV. "Sign right here and you're good to go": a content analysis of audiotaped emergency department discharge instructions. *Ann Emerg Med*. 2011;57(4):315-22. doi: 10.1016/j.annemergmed.2010.08.024
6. Sanders LM, Federico S, Klass P, Abrams MA, Dreyer B. Literacy and child health: a systematic review. *JAMA Pediatr*. 2009;163(2):131-40. doi: 10.1001/archpediatrics.2008.539
7. Spandorfer JM, Karras DJ, Hughes LA, Caputo C. Comprehension of discharge instructions by patients in an urban emergency department. *Ann Emerg Med*. 1995:25(1):71-4. doi: 10.1016/s0196-0644(95)70358-6
8. Wilson EAH, Makoul G, Bojarski EA, et al. Comparative analysis of print and multimedial health materials: a review of the literature. *Patient Educ Couns*. 2012;89(1):7-14. doi: 10.1016/j.pec.2012.06.007

9. Jusko Friedman A, Cosby R, Boyko S, Hatton-Bauer J, Turnbull G. Effective teaching strategies and methods of delivery for patient education: a systematic review and practice guideline recommendations. *J Cancer Educ*. 2011;26(1):12-21. doi: 10.1007/s13187-010-0183-x
10. Boyd M, Lasserson TJ, McKean MC, Gibson PG, Ducharme FM, Haby M. Interventions for educating children who are at risk of asthma-related emergency department attendance. *Cochrane Database of Syst Rev.* 2009;(2): CD001290. doi: 10.1002/14651858.CD001290.pub2
11. Cochrane Effective Practice and Organisation of Care. EPOC Taxonomy. Epoc.Cochrane.Org. https://epoc.cochrane.org/epoc-taxonomy. Published 2015. Accessed Jan. 8, 2016.
12. Graham ID, Logan J, Harrison MB, et al. Lost in knowledge translation? time for a map. *J Contin Educ in Health Prof*. 2006;26(1):13-24. doi: 10.1002/chp.47
13. Tugwell PS, Santesso NA, O'Connor AM, et al., Effective Consumer Investigative Group. Knowledge translation for effective consumers. *Physical Therapy*. 2007;87(12):1728–38. doi: 10.2522/ptj.20070056
14. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Social Res Method*. 2005;8:19–31.
15. McKibbon KA, Lokker C, Keepanasseril A, Colquhoun H, Haynes RB, Wilczynski NL. WhatisKT wiki: a case study of a platform for knowledge translation terms and definitions – descriptive analysis. *Implem Sci.* 2013;8(13).
16. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. *Implem Sci.* 2012;7(50). doi: 10.1186/1748-5908-7-50

17. Graphpad Software Inc. QuickCalcs: quantify agreement with kappa. GraphPad.com. https://www.graphpad.com/quickcalcs/kappa1/?K=3. Updated 2018. Accessed Nov. 15, 2015.
18. Brien SE, Lorenzetti DL, Lewis S, Kennedy J, Ghali WA. Overview of a formal scoping review on health system report cards. *Implem Sci.* 2010;5(2).
19. Pham MT, Rajic A, Greig, JD, Sargeant JM, Papadopoulos A, McEwen SA. A scoping review of scoping reviews: advancing the approach and enhancing the consistency. *Res Synth Methods*. 2014;5(4):371-85. doi: 10.1002/jrsm
20. Higgins JPT, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions.* Version 5.1.0. The Cochrane Collaboration; 2011.
21. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ.* 2011;343:d5928. doi: 10.1136/bmj.d5928
22. Jorgensen L, Paludan-Muller AS, Laursen DRT, et al. Evaluation of the Cochrane tool for assessing risk of bias in randomized clinical trials: overview of published comments and analysis of user practice in Cochrane and non-Cochrane reviews. *Syst Rev*. 2016;5(80). doi: 10.1186/s13643-016-0259-8
23. Effective Public Healthcare Panacea Project. Quality assessment tool for quantitative studies. Ephpp.ca. https://www.ephpp.ca/quality-assessment-tool-for-quantitative-studies/. Updated 2020. Accessed Jan. 8, 2016.
24. Thomas H, Ciliska D, Dobbins M, Micucci S. A process for systematically reviewing the literature: providing evidence for public health nursing interventions. *Worldviews Evid Based Nurs.* 2004;2:91-9. doi: 10.1111/j.1524-475X.2004.04006.x

25. Albrecht L, Archibald M, Arseneau D, Scott SD. Development of a checklist to assess the quality of reporting of knowledge translation interventions using the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. *Implem Sci*. 2013;8(52). doi: 10.1186/1748-5908-8-52

26. Coulter A, Ellins J. *Patient-focused interventions: A review of the evidence*. London, UK: The Health Foundation; 2006.

27. Bailey L, Sun J, Courtney M, Murphy P. Improving postoperative tonsillectomy pain management in children – a double randomized control trial of a patient analgesia information sheet. *Int J Pediatr Otorhinolaryngol*. 2015;79(5):732-739. doi: 10.1016/j.ijporl.2015.03.003

28. Bauchner H, Osganian S, Smith K, Triant R. Improving parent knowledge about antibiotics: a video intervention. *Pediatrics*. 2001;108(4):845-850. doi: 10.1542/peds.108.4.845

29. Christakis DA, Zimmerman FJ, Rivara FP, Ebel B. Imrproving pediatric prevention via the Internet: a randomized, controlled trial. *Pediatrics*. 2006;118(3):1157-1166. doi: 10.1542/peds.2006-0209

30. Dempsey AF, Zimet GD, Davis RL, Koutsky L. Factors that are associated with parental acceptance of human papillomavirus vaccines: a randomized intervention study of written information about HPV. *Pediatrics*. 2006;117(5):1486-1493. doi: 10.1542/peds.2005-1381

31. Evans S, Daly A, Hopkins V, Davies P, MacDonald A. The impact of visual media to encourage low protein cooking in inherited metabolic disorders. *J Hum Nutr Diet*. 2009;22(5):409-413. doi: 10.1111/j.1365-277X.2009.00953.x

32. Jackson C, Dickinson D. Enabling parents who smoke to prevent their children from initiating smoking: results from a 3-year intervention evaluation. *Arch Pediatr Adolesc Med*. 2006;160(1):36-62. doi: 10.1001/archpedi.160.1.56

33. Nordfeldt S, Ludvigsson J. Self-study material to prevent severe hypoglycaemia in children and adolescents with type 1 diabetes: a prospective intervention study. *Pract Diab Int*. 2002;19(5):131-6.

34. Nordfeldt S, Johansson C, Carlsson E, Hammersjo J-A. Prevention of severe hypoglaecemia in type 1 diabetes: a randomized controlled population study. *Arch Dis Child*. 2003;88:240-5. doi: 10.1136/adc.88.3.240

35. Nordfeldt S, Johansson C, Carlsson E, Hammersjo J-A. Persistent effects of a pedagogical device targeted at prevention of severe hypoglycaemia: a randomized, controlled study. *Acta Paediatr*. 2005;94:1395-401. doi: 10.1111/j.1651-2227.2005.tb01810.x

36. Ranjit N, Menendez T, Creamer M, Hussaini A, Potratz CR, Hoelscher DM. Narrative communication as a strategy to improve diet and activity in low-income families: the use of role model stories. *Am J Health Educ*. 2015;46:99-108.

37. Reich SM, Bickman L, Saville BR, Alvarez J. The effectiveness of baby books for providing pediatric anticipatory guidance to new mothers. *Pediatrics*. 2010;125(5):997-1002. doi: 10.1542/peds.2009-2728

38. Scheinmann R, Chiasson AM, Hartel D, Rosenberg TJ. Evaluating a bilingual video to improve infant feeding knowledge and behaviour among immigrant Latina mothers. *J Community Health*. 2010;35:464-70. doi: 10.1007/s10900-009-9202-4

39. Skranes LP, Lohaugen GCC, Skranes J. A child health information website developed by physicians: the impact of use on perceived parental anxiety and competence of Norwegian mothers. *J Public Health*. 2015;23:77-85.

40. Sustersic M, Jeannet E, Cozon-Rein L, et al. Impact of information leaflets on behavior of patients with gastroenteritis or tonsillitis: a cluster randomized trial in French primary care. *J Gen Intern Med*. 2012;28(1):25-31. doi: 10.1007/s11606-012-2164-8

41. Taddio A, MacDonald NE, Smart S, Parikh C, Allen V, Halperin B, Shah V. Impact of a parent-directed pamphlet about pain management during infant vaccinations on maternal knowledge and behaviour. *Neonatal Netw*. 2014;33(2):74-82. doi: 10.1891/0730-0832.33.2.74

42. Tijam AM, Holtslag G, Van Minderhout HM, et al. Randomised comparison of three tools for improving compliance with occlusion therapy: an educational cartoon story, a reward calendar, and an information leaflet for parents. *Graefes Arch Clin Exp Ophthalmol*. 2013;251(1):321-9. doi: 10.1007/s00417-012-2107-4

43. Wakimizu R, Kamagata S, Kuwabara T, Kamibeppy K. A randomized controlled trial of an at-home preparation programme for Japanese preschool children: effects on children's and caregiver's anxiety associated with surgery. *J Eval Clin Pract*. 2009;15(2):393-401. doi: 10.1111/j.1365-2753.2008.01082.x

44. Wilson FL, Brown DL, Stephens-Ferris M. Can easy-to-read immunization information increase knowledge in urban low-income mothers? *J Pediatr Nurs*. 2006;21(1):4-12. doi: 10.1016/j.pedn.2005.06.003

45. Silagy C, Lancaster T, Gray S, Fowler G. Effectiveness of training health professionals to provide smoking cessation interventions: systematic review of randomized controlled trials. *Qual Health Care*. 1994;3(4):193-8. doi: 10.1136/qshc.3.4.193

46. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council Guidance. *BMJ.* 2008;337. doi: 10.1136/bmj.a1655

47. Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-207. doi: 10.7326/0003-4819-158-3-201302050-00583

48. Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586. doi: 10.1136/bmj.e7586

49. Jones SR, Carley S, Harrison M. An introduction to power and sample size estimation. *Emerg Med*. 2003;20(5):453-8. doi: 10.1136/emj.20.5.453

50. Chalmers I, Altman DG. How can medical journals help prevent poor medical research? Some opportunities presented by electronic publishing. *The Lancet*. 1999;353(9151):490-493. doi: 10.1016/S0140-6736(98)07618-1

51. Chan AW, Hrobjartsson A, Haahr MT, Gotzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles. *JAMA*. 2004;291(20):2457-65. doi: 10.1001/jama.291.20.2457

52. Dane AV, Schneider BH. Program integrity in primary and early secondary prevention: are implementation effects out of control?. *Clin Psychol Rev*. 1998;18(1):23-45. doi: 10.1016/s0272-7358(97)00043-3

53. Gresham FM, Gansle KA, Noell GH. Treatment integrity in applied behavior analysis with children. *J Appl Behav Anal*. 1993;26(2):257-263. doi: 10.1901/jaba.1993.26-257

54. Moncher FJ, Prinz RJ. Treatment fidelity in outcome studies. *Clin Psychol Rev.* 1991;11(3):247-266.

55. Odom SI, Brown WH, Frey T, Karasu N, Smith-Canter LL, Strain PS. Evidence-based practices for young children with autism: contributions for single-subject design research. *Focus Autism Other Dev Disabil*. 2003;18:166-175.

56. Davies P, Walker AE, Grimshaw JM. A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. *Implem Sci*. 2010;5(114). doi: 10.1186/1748-5908-5-14

57. McCormack L, Sheridan S, Lewis M, et al. Communication and dissemination strategies to facilitate the use of health-related evidence. Ahrq.gov. https://www.ahrq.gov/research/findings/evidence-based-reports/commstrattp.html. Updated Nov. 2013. Accessed Jan. 8, 2016.

58. Gagliardi AR, Berta W, Kothari A, Boyko J, Urquhart R. Integrated knowledge translation (IKT) in health care: a scoping review. *Implem Sci*. 2016;11(38). doi: 10.1186/s13012-016-0399-1

59. Michie S, Fixsen D, Grimshaw JM, Eccles MP. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implem Sci*. 2009;4(40).

60. Green LW, Ottoson JM, Garcia C, Hiatt RA. Diffusion theory and knowledge dissemination, utilization, and integration in public health. *Annu Rev Public Health*. 2009;30:151-74. doi: 10.1146/annurev.publhealth.031308.100049

61. Snowdon C. Qualitative and mixed methods research in trials. *Trials*. 2015;16(558).

62. Woolfall K, Young B, Frith L, et al. Doing challenging research studies in a patient-centred way: a qualitative study to inform a randomised controlled trial in the pediatric emergency care setting. *BMJ Open*. 2014;4(e005045).

63. Murtagh MJ, Thomson RG, May CR, et al. Qualitative methods in a randomised controlled trial: the role of an integrated qualitative process evaluation in providing evidence to discontinue the intervention in one arm of a trial of a decision support tool. *Qual Saf Health Care*. 2007;16:224-229.

64. O'Cathain A, Goode J, Drabble SJ, Thomas KJ, Rudolph A, Hewison J. Getting added value from using qualitative research with randomized controlled trials: a qualitative interview study. *Trials*. 2014;15(215). doi: 10.1186/1745-6215-15-215

65. O'Cathain A, Thomas KJ, Drabble SJ, Rudolph A, Hewison J. What can qualitative research do for randomised controlled trials? A systematic mapping review. *BMJ Open*. 2013;3(e002889). doi:10.1136/ bmjopen-2013-002889

66. Colquhoun H, Leeman J, Michie S, et al. Towards a common terminology: a simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies. *Implem Sci*. 2014;9(51). doi: 10.1186/1748-5908-9-51

67. Walshe K. Pseudoinnovation: The development and spread of healthcare quality improvement methodologies. *Int J Qual Health Care*. 2009;21(3):153–159. doi: 10.1093/intqhc/mzp012

68. Bragge P, Grimshaw JM, Lokker C, Colquhoun H, The AIMD Writing/Working Group. AIMD - A validated, simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies. *BMC Med Res Methodol*. 2017;17(38).

Chapter 3 - Pediatric acute gastroenteritis: A qualitative study to understand caregivers' experiences and information needs

Introduction

Pediatric acute gastroenteritis (AGE) is an acute illness characterized by vomiting and diarrhea. Pediatric AGE is a common presentation in emergency departments (EDs) and remains a leading cause of global pediatric morbidity [1–4]. In Canada, there are 5 million cases of pediatric AGE every year with an annual health care costs of 3.7 billion dollars [5]. It is estimated that 1 in 25 children will be hospitalized for AGE by 5 years of age [1]. Exacerbating the substantial health system impacts is persistent practice variation in the treatment and management of pediatric AGE [1,6,7]. Additionally, pediatric AGE affects families in a multitude of ways, including negative impacts on physical and emotional well-being of children and parents [8] and frequent parental work loss [9].

One proposed solution towards resolving these multifaceted issues linked to current approaches to care for pediatric AGE is to explore caregivers' perspectives of this common, acute, childhood illness. Understanding the patient/caregiver perspective may highlight misconceptions, knowledge gaps, or systemic issues contributing to the high burden of this common, acute illness. The purpose of this qualitative study was to describe caregivers' experiences of a child with pediatric AGE and to identify their information needs, preferences, and priorities.

Methods

Research ethics approval for this study was obtained from the University of Alberta Health Research Ethics Board. Participants were recruited at the Stollery Children's Hospital

ED, a specialized pediatric ED in a major Canadian urban center (Edmonton, Alberta). The inclusion criteria for study participation were 1) caregiver of a child 16 years old or younger; 2) child presenting to the Stollery Children's Hospital ED with vomiting and diarrhea; 3) caregiver fluent in English; and 4) caregiver willing to be contacted for follow-up data collection. Study exclusion criteria included 1) child with significant chronic gastrointestinal problem or inflammatory bowel disease; 2) child taking immunosuppressive therapy or known history of immunodeficiency; 3) oral or gastrointestinal surgery within the preceding 7 days; and 4) child with prior visit to ED for vomiting and diarrhea during the illness episode. Consecutive caregivers meeting the selection criteria from December 1, 2014 to January 17, 2015 during recruitment team hours (i.e., 1500–2300, 7 days a week) were approached about the study in the ED waiting room, and the project coordinator (LA) followed up with interested caregivers by telephone to schedule an interview.

Data were collected through semi-structured, qualitative interviews (Appendix G). Interviews were conducted in-person or by telephone, digitally recorded, and transcribed verbatim. This data collection strategy was used to obtain all information required, to probe participants' responses, and to give participants' freedom to respond and illustrate concepts in an open-ended fashion [10]. Qualitative methods do not allow prospective determination of a sample size; however, 12–15 interviews with participants were anticipated to see patterns in experiences [10]. Interview questions moved from the general to the specific with interviews later in the data collection period becoming increasingly more focused [11].

Analysis was completed in NVivo 1012 and was reviewed by the research team throughout the analytic process. Thematic analysis was guided by the hybrid approach of inductive and deductive coding and theme development described by Fereday & Muir-Cochrane

(2006) [13]. Data saturation is not a proxy for sample adequacy or rigour in this analytic approach; the hybrid thematic analytic approached used is underpinned by Schutz's social phenomenology in which people are able to ascribe meaning to an experience or situation and then make judgments [14]. To ensue rigour, this hybrid thematic analysis determined logical consistency through the initial process of deductive coding of interview transcripts using the semi-structured interview guide as a framework. This step ensured transparency in the method of formulating overarching themes [13,14]. Then, smaller units of data emerged inductively and were coded for increased granularity and specificity. This step demonstrated subjective interpretation as participants' words were used to demonstrate interpretations through quotations [13,14].

Results

Demographics

Fifteen interviews were completed. Interviews took place ranging from 3–25 days post-ED visit with the average interview occurring 12 days post-ED visit. Interviews ranged in length from 10–23 minutes with an average interview length of 15 minutes. Demographic variables for the 15 participants are presented in Table 3.1. Thematic analysis of the interviews revealed five major themes: 1) caregiver management strategies; 2) reason for going to the ED; 3) treatment and management of AGE in the ED; 4) caregiver information needs; and 5) additional factors influencing caregivers' experiences and decision-making. Each of these broad themes contained a number of subthemes described below. Participant quotations supporting each theme are displayed in Table 3.2.

Table 3.1: Participant Demographics (n=15).

Variable	**Category**	**n (%) [total N=15]**
Caregiver role	Parent	14 (93)

	Grandparent	1 (7)
Gender	Female	12 (80)
	Male	3 (20)
Caregiver relationship status	Married	13 (87)
	Single	2 (13)
Age of caregiver	21-30 years	3 (20)
	31-40 years	11 (73)
	41-50 years	1 (7)
Age of child	Under 1 year old	4 (27)
	1-2 years old	8 (53)
	3-5 years old	2 (13)
	Over 5 years old	1 (7)
Total number of children in the house	1 child	6 (40)
	2 children	6 (40)
	3 children	2 (13)
	4 children	1 (7)
Caregiver highest level of education	Less than high school	2 (14)
	High school diploma	2 (14)
	Post-secondary certificate/diploma	3 (20)
	Post-secondary degree	3 (20)
	Graduate degree	5 (33)
Average household income	Under $25,000	3 (20)
	$25,000-$49,000	2 (20)
	$50,000-$74,999	2 (13)
	$75,000-$99,999	4 (27)
	$100,000-$149,999	4 (27)

Table 3.2: Participant Quotes to Support Thematic Analyses.

Thematic Analysis	**Participant Quotes**
Theme 1: Caregiver Management Strategies	
Sub-theme: Medication administration	"Yeah. I mean, we tried Tylenol, but because he was barfing so much, he wasn't really keeping anything down, and then we tried a warm bath, and - but yeah, nothing really seemed to help." (Interview 10, child aged 1 year 4 months)
Sub-theme: Contacting health providers	"I phoned the [telephone health advice] number because I wanted to know, and so did the wife actually, how long - like she couldn't do kind of - she can't keep the fluids in her, so she will get dehydrated, so we phoned, we phoned the [telephone health advice] number and got to ask about her, and that the nurse on the phone, after she went through question, she just told us since our daughter didn't - can't hold the milk for so many amount of hours now and didn't have a wet diaper and all that type of stuff to take her to the [children's hospital] to make sure she doesn't get

	dehydrated, so that's why we went over right to the [emergency department]." (Interview 7, child aged 6 months)
Sub-theme: Feeling scared/worried and uncertain/confused	"[I felt] scared, confused, and powerless." (Interview 2, child aged 2 years)
Theme 2: Reason for Going to the ED	
Sub-theme: Child's symptom's not improving	"So we kept on doing overnight, but, like, with time he started vomiting every hour, hour and a half, but it didn't stop, so by 5o'clock in the morning - 4:30 or 5 - then we decided, like, he's not stopping vomiting with anything so we should go to the hospital, like, it's going too much now. It was almost 12, 13 times he vomited overnight, right? So then we thought we should go, yeah." (Interview 6, child aged 2 years 6 months)
Theme 3: Treatment and Management of AGE in the ED	
Sub-theme: Oral rehydration	"We had to wait 20 minutes for the medication to settle and take effect, and then after the 20-minute mark, we were told that they gave us Pedialyte in a syringe, and I believe it was 10 mls. We were supposed to give it to her every 15 minutes after the 20-minute mark once that medication kicked in, so when - we were to keep hydrated to see if she was going to vomit anymore, so we gave it to her every 15 minutes, and she never vomited. She was actually taking it, and she was actually - she was gradually getting better, actually, while we were waiting in the waiting room." (Interview 7, child aged 6 months)
Theme 4: Caregiver Information Needs	
Sub-theme: Caregiver questions about AGE	"But yah, like when something starts first time in home, there are so many questions in your mind, right? Why this happening, right? So what we should give him to eat, what is safe, right? So I learned a lot about that, like, some sites, like, some people say don't give milk, right? So then some say it's okay, don't give dairy products, anything like that. There was so many things, like, confusing things, but I will say just go with the simple things like Pedialyte, water." (Interview 6, child aged 2 years 6 months)
Sub-theme: Learning about effective treatments for AGE	"The Pedialyte popsicles are the lifesaver because they want something cold for the fever, and it's something to keep in them. Yeah. So that was - that's the biggest motherly advice I can say. If your kid is sick, make sure you have these." (Interview 2, child aged 2 years)
Sub-theme: Conflicting information learned about the role of water for managing AGE	"Yeah. Like I used to know, like, when having diarrhea, just give them fluids -- I discovered later that not every kind of fluid, do not give them juice even if it is unsweetened. Just give them water." (Interview 9, child aged 1 year 9 months)

	"So that was a big one that I never would've known by myself. I thought sipping water was the best thing for her, and in the end when we cut the water, that's what helped - that's what, like, gave her rest overnight, and I think she would've been throwing up all night had I kept going." (Interview 5, child aged 5 years)
Sub-theme: Acting sooner in future cases of AGE	"Like I think I should've taken her [to the emergency department] a day before and maybe and maybe I should have because her - she already had symptoms of dehydration. They might have admitted her instead of me trying to keep her home as long as possible, like - I usually try to delay going to the hospitals, like, or to the doctor. Try to take care at home, so that's just me." (Interview 4, child aged 9 years)
Sub-theme: Waiting longer to act in future cases of AGE	"So in other words, I learned I probably won't go back unless I deem it to be more serious and probably wait. Unfortunately, I'd probably wait for symptoms to get more severe to go back." (Interview 14, child aged 5 months)
Sub-theme: Use information sheet provided by hospital in future cases of AGE	"I think I would go through the steps they had in the pamphlet and just make sure to keep her isolated - I mean if it comes down - like keep an eye for the signs of, you know, it getting worse and severe dehydration and things like that. If it did, I would still probably take her to the hospital." (Interview 12, child aged 1 year 9 months)
Sub-theme: Advice for other caregivers dealing with a child with AGE	"Trust your gut." (Interviews 4, 11, 13, children aged 9 years, 2 years, and 7 months)
Theme 5: Additional Factors Influencing Caregivers' Experiences and Decision Making	
Sub-theme: Negative prior experience	"They [telephone health advice service] can't give medical advice for liability reasons, so all they ever say when you call [telephone health advice service] is take your kid in [to the emergency department]." (Interview 14, child aged 5 months)
Sub-theme: Additional 'life' stressors	"You knew it was bad when he stopped filling his diaper, so that's when I called the doctor to see if I could get him in there, but she was completely booked up, so we ended up taking him to the emergency [department]." (Interview 2, child aged 2 years)

Theme 1: Caregiver management strategies

As AGE signs and symptoms emerged, caregivers reported feeling scared and worried about their child with AGE and uncertain or confused about how to proceed to help their child to be well again (see Table 3.2). In spite of this, they engaged in a number of management

strategies prior to taking the child to the ED. These strategies included putting the child to bed, giving the child a bath, changing the child's routine or environment (i.e., not going to school, sleeping on the couch), and spending time together while providing reassurance through words and touch. Caregivers also provided particular fluids, such as Pedialyte, milk, breast milk, juice, and water; some also provided specific foods, including ice cream and potatoes. Additionally, caregivers administered medication, including Gravol, Tylenol, and Advil (see Table 3.2).

Prior to going into the ED, caregivers contacted health providers with questions and for advice. These providers included provincial telephone health advice service, family physicians, pediatricians, a walk-in clinic physician, and a pharmacist (see Table 3.2). In some cases, caregivers contacted more than one health professional. A few caregivers also sought additional advice from health providers after the ED visit, which included following up with their regular physician and in two instances, returning to the ED.

Theme 2: Reason for going to the ED

Caregivers decided to bring their child into the ED for differing reasons. Most commonly, the caregiver felt that the child's symptoms were not improving fast enough (see Table 3.2). Other reasons included worsening symptoms, previous experience with a similar illness requiring emergency care, regular physician (i.e., family doctor or pediatrician) unavailable for consult, recommendation from another health provider (i.e., telephone health advice service, walk-in clinic doctor). Additionally, one caregiver was concerned that the child's behaviour had changed and another wanted to use the latest technology in the ED for the best diagnosis, management, and treatment.

Theme 3: Treatment and management of pediatric acute gastroenteritis in the ED

Generally, ill children in this study were treated with oral rehydration once in the ED (see Table 3.2). Additionally, antiemetics (i.e., ondansetron) and/or analgesics were administered to the majority of children. A few were given extra tests, including stool samples, blood tests, and urine tests. One child was administered IV rehydration. It is important to note that one child was provided with antibiotics for AGE on a follow-up visit with his or her regular physician post-ED discharge. During the ED visit, approximately half of caregivers indicated that they did not receive education about AGE, and of the participants who did receive education, two received verbal education only, and four received written information sheets that they could refer to after leaving the ED.

Theme 4: Caregiver information needs

Caregivers identified and described the following information needs about pediatric AGE: 1) how to alleviate AGE symptoms; 2) what to expect from a normal course of AGE; 3) how AGE is caused; 4) signs and symptoms of dehydration; 5) where to purchase helpful items (i.e., vomit bags, Pedialyte popsicles); and 4) what to tell their child about AGE. Caregivers expressed many questions as they reflected on and came to understand their information needs for this illness (see Table 3.2).

Caregivers also shared what they learned by experiencing pediatric AGE and by seeking care in the ED. They described learning about effective treatments, including over-the-counter options (i.e., Pedialyte, Pediasure, Gravol) and prescription medication (i.e., antiemetic such as ondansetron) (see Table 3.2). They also highlighted a better understanding of the symptoms of AGE, as well as how to recognize and deal with dehydration symptoms. There was some conflicting information learned about providing water; one caregiver learned that this was an

appropriate fluid to give their child, and another reported learning that water should not be provided to children with AGE (see Table 3.2). One caregiver indicated that he or she had more knowledge about viruses and the seasonal nature of AGE, and another had a better understanding of non- ED health providers available to consult about AGE.

Caregivers also described how new knowledge gained from this experience would impact their future actions and decisions. This largely focused on taking action sooner (i.e., go to ED earlier, provide fluids sooner, take medication earlier); however, a few noted that they would wait longer to bring their child to the ED because they felt more able to handle less severe symptoms because of this experience (see Table 3.2). Two caregivers stated that they would take the same course of action in the future, and another two caregivers would review the written information sheet provided by the ED to determine future actions. One caregiver indicated he or she would rather go to the ED than see the family physician because of the severity of the child's AGE in this instance, and another stated that he or she would rather see their pediatrician than visit the ED because of the wait time and lack of treatment for AGE during this experience. When asked what advice they had for other caregivers, recommendations included checking with a health provider if there was concern or doubt about the child's health and to "trust your instincts" as a parent (see Table 3.2) when it comes to your child's health and well-being.

Theme 5: Additional factors influencing caregivers' experiences and decision-making

In addition, caregivers described a number of factors that influenced their experience of pediatric AGE, decision-making, and actions. This included relevant past experiences, such as previously having a child with AGE, dissatisfaction with prior visits to the ED, and dissatisfaction with prior experiences of using the provincial telephone health advice service (see Table 3.2). Additional stressors at the time that their child was sick included multiple sick family

members in the home at the same time; repeated illnesses with the same child; and the regular physician (i.e., family doctor, pediatrician) being unavailable for appointments (see Table 3.2). Other caregiver burdens included being the primary caregiver for the sick child and for multiple children.

Discussion

The findings of this study show that caregivers employ a number of management strategies at home before seeking emergency care for pediatric AGE; however, these may be informed by popular cultural misconceptions that are not supported by best research evidence. Similarly, this study highlights inconsistencies in ED care, adding further evidence to previous research on practice variation in pediatric AGE [6,7]. This study demonstrates that caregivers want to know basic information about pediatric AGE (e.g., What does AGE normally look like? What can I do to help my child get better? What causes AGE? What should I tell my child?). However, it is clear that reasons for bringing a child to the ED and other health decisions are heavily influenced by factors reflecting "real-life" complexity, making it impossible to use one single approach to meet the needs of all caregivers and families dealing with pediatric AGE.

In this study, caregiver at home management of pediatric AGE was underpinned by common misconceptions. Caregivers reported providing their children with juice (i.e., orange juice, lemonade), milk, and ice cream, typically because it was a favourite food and they were trying to encourage their child to eat or drink. However, previous research has demonstrated that high sugar foods and fluids (e.g., juice, ice cream) may exacerbate AGE symptoms and should be avoided [15]. There was also some misunderstanding regarding the role of water to combat dehydration. Oral rehydration solutions containing water and electrolytes are preferable to water alone and high sugar fluids that were provided by some caregivers in this study;

however, the main consideration in determining appropriate foods and fluids to administer at home or whether to seek medical attention is the extent of dehydration. In cases of minimal or no dehydration, a regular diet and adequate fluids are sufficient, but these recommendations change as the severity of dehydration increases [16]. Lack of understanding of appropriate fluids aligns with AGE research dating back up to 20 years [17,18]. This complexity supports the need to provide specific information about what to do at home and when to seek health care to reduce non-urgent ED visits, improve patient outcomes, and reduce caregiver burden.

Inconsistencies in approaches to care were also present in ED treatment and management of pediatric AGE in this study. Approximately half of the participants (n = 7) indicated they did not receive education from a health care provider while in the ED. At present, it is standard practice to provide health education to parents seeking care for their children in EDs [19]; relevant information should be provided to all patients/ caregivers, even in cases of common, short-duration illnesses like AGE. Previous research has established that spoken medical advice is accurately remembered only 14% of the time [20-22]; whereas, written information is better remembered and leads to improved treatment adherence [20,23]. With no formal, written information provided to the majority of participants in this study (n = 11), the burden is put upon caregivers to accurately remember discharge/care instructions and effectively manage their child's present and future AGE episodes.

Additionally, one health provider provided antibiotics to a child with AGE during a follow-up visit after the ED visit. Evidence has demonstrated that antibiotics are largely ineffective for AGE, because 75% to 90% of cases are viral [24]; however, in another study, 24% of pediatric emergency care and urgent care visits for AGE resulted in antibiotic prescriptions [25]. This research-practice gap is consistent with qualitative evidence highlighting

pressure felt by physicians to provide antibiotics for pediatric acute infections (i.e., sore throat), even when it is known that this treatment is ineffective and inconsistent with best research evidence due to fear of endangering the doctor-patient relationship and a lack of understanding of patient expectations of care [26].

Based on the findings of this study, it is clear that past experiences and current life circumstances affect caregiver health decision-making. For example, if caregivers are unable to consult with their regular physician, they may feel compelled to go to the ED even if they could manage their child's AGE at home. Alternately, parents with previous negative experiences with a health service (i.e., telephone health advice service or previous ED visit) may wait longer to seek care. These nuances make it difficult to determine a "one-size-fits-all" solution for patient/caregiver information provision. Understanding patients'/caregivers' experiences and connecting families to research evidence have the power to alleviate feelings of fear and uncertainty [9], ensure consistent management of child health over time and across settings [19], increase effective health decision-making [27], and reduce health system costs [27]. Future research should examine the best opportunities (i.e., timing, location, mode of delivery) to provide caregivers with evidence-based information on AGE.

Caution should be used when generalizing the results of this study to other regions, populations, and child health conditions. Study participants were recruited in the ED of a tertiary care facility in an urban area in a developed country; thus, findings cannot be extrapolated to caregivers that manage AGE at home without seeking emergency care, or caregivers in other types of care centres or geographic regions. Additionally, this study does not reflect the health provider perspective on the illness trajectory, the treatment and management of AGE in the ED, and patient information provision.

Conclusions

This study provides important information around caregivers' experiences of pediatric AGE. Qualitative approaches illuminated five major themes, including 1) caregiver management strategies; 2) reason for going to the ED; 3) treatment and management of AGE in the ED; 4) caregiver information needs; and 5) additional factors influencing caregivers' experiences and decision- making. Providing timely, appropriate, and engaging research-based information to caregivers about AGE may enhance their ability to communicate with health providers about their questions, concerns, and expectations for care and may also create the necessary conditions for health providers to align treatment and management with best research evidence. The challenge is to provide consistent information to caregivers that accounts for variation in the clinical presentation of AGE, potential complications of AGE and dehydration, and the experiences and needs of a diverse population of caregivers of children with AGE.

Chapter 3 References

1. Freedman SB, Ali S, Oleszczuk M, et al. Treatment of acute gastroenteritis in children: an overview of systematic reviews of interventions commonly used in developed countries. *EBCH*. 2013;8:1123-1137. doi: 10.1002/ebch.1932
2. Freedman SB, Sivabalasundaram V, Bohn V, et al. The treatment of pediatrics gastroenteritis: a comparative analysis of pediatric emergency physicians' practice patterns. *Acad Emerg Med*. 2011;18:38-45. doi: 10.1111/j.1553-2712.2010.00960.x
3. Freedman SB, Etorky M, Gorelick M, et al. Evaluation of a gastroenteritis severity score for use in outpatient settings. *Pediatrics*. 2010;125:e1278-e1285. doi: 10.1542/peds.2009-3270
4. Kinlin LM, Bahm A, Guttmann A, et al. A survey of emergency department resources and strategies employed in the treatment of pediatric gastroenteritis. *Acad Emerg Med*. 2013;20(4):361-366. doi: 10.1111/acem.12108
5. Freedman S, Lowerison K. GotGastro.ca. Alberta Provincial Pediatric EnTeric Infection Team (APPETITE) seminar series. GotGastro.ca. http://gotgastro.ca/training/seminar-series-2/. Published 2015. Accessed February 2, 2015.
6. Freedman SB, Gouin S, Bhaat M, et al. Prospective assessment of practice pattern variations in the treatment of pediatric gastroenteritis. *Pediatrics.* 2011;127(2):e287-e295. doi: 10.1542/peds.2010-2214
7. Tieder JS, Robertson A, Garrison MM. Pediatric hospital adherence to the standard of care for acute gastroenteritis. *Pediatrics*. 2009;124(6):e1081-e1086. doi: 10.1542/peds.2009-0473
8. Mast TC, DeMuro-Mercon C, Kelly CM, et al. The impact of rotovirus gastroenteritis on the family. *BMC Pediatr*. 2009;9(11). doi: 10.1186/1471-2431-9-11

9. Senecal M, Brisson M, Lebel MH, et al. Measuring the impact of rotavirus acute gastroenteritis episodes (MIRAGE): a prospective community-based study. *Can J Infect Dis Med Microbiol*. 2008;19(6):397-404. doi: 10.1155/2008/451540
10. Morse J, Field P. *Qualitative research methods for health professionals*. 2nd ed. Thousand Oaks. CA: SAGE; 1995.
11. Yin, R. *Qualitative research from start to finish*. New York, NY: The Guilford Press; 2011.
12. NVivo (for Windows) [qualitative data analysis software]. Version 10. QSR International Pty Ltd.; 2012.
13. Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. *IJQM.* 2006;5(1):80-92.
14. Schutz A. Collected papers I: the problem of social reality. The Hague: Martinus Nijhoff; 1973.
15. Elliot EJ. Acute gastroenteritis in children. *BMJ*. 2007;334(7583):35-40.
16. Churgay CA, Aftab Z. Gastroenteritis in children: part II. treatment and management. *Am Fam Physician*. 2012;85(11):1066-1070.
17. Li ST, Klein EJ, Tarr PI, et al. Parental management of childhood diarrhea. *Clin Pediatr*. 2009;48(3):295-303. doi: 10.1177/0009922808327057
18. O'Laughlin EV, Notaras E, McCullough C, et al. Home-based management of children hospitalized with acute gastroenteritis. *J Paediatr Child Health*. 1995;31(3):189-191.
19. Taddio A, Shah V, Leung E, et al. Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain: usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatr*. 2013;13(23). doi: 10.1186/1471-2431-13-23

20. Kessels R. Patients' memory for medical information. *J R Soc Med*. 2003;96(5):219-222. doi: 10.1258/jrsm.96.5.219

21. Houts PS, Bachrach R, Witmer JT, et al. Using pictographs to enhance recall of spoken medical instructions. *Patient Educ Couns*. 1998;85(2):83-88.

22. Thomson AM, Cunningham SJ, Hunt NP. A comparison of information retention at an initial orthodontic consultation. *Eur J Orthod*. 2001;23:169-78.

23. Blinder D, Rotenberg L, Peleg M, et al. Patient compliance to instructions after oral surgical procedures. *Int J Oral Maxillofac Surg*. 2001;30(3):216-219.

24. Churgay CA, Aftab Z. Gastroenteritis in children: part I. diagnosis. *Am Fam Physician*. 2012;85(11):1059-1062.

25. Beatty ME, Griffin PM, Tulu A, et al. Culturing practices and antibiotic use in children with diarrhea. *Pediatrics*. 2004;113(3):628-629. doi: https://doi.org/10.1542/peds.113.3.628

26. Butler CC, Rollnick S, Pill R, et al. Understanding the culture of prescribing: qualitative study of general practitioners' and patients' perceptions of antibiotics for sore throats. *BMJ*. 1998;317(7159):637-642. doi: 10.1136/bmj.317.7159.637

27. Morrison AK, Myrvik MP, Brousseau DC, et al. The relationship between parent health literacy and pediatric emergency department utilization: a systematic review. *Acad Pediatr*. 2013;13(5):421-429. doi: 10.1016/j.acap.2013.03.001

Chapter 4 – An a priori protocol for a pragmatic pilot randomized trial to evaluate a knowledge translation tool for parents about pediatric acute gastroenteritis

Background

Pediatric acute gastroenteritis (AGE), characterized by vomiting and diarrhea, is a common presentation in emergency departments (ED) and remains a leading cause of global pediatric morbidity [1-4]. In Canada and other developed countries, AGE is most often caused by viruses [1]. Annually, there are 5 million cases of pediatric AGE in Canada and it represents 10% of Canadian pediatric ED visits, resulting in a yearly healthcare cost of $3.7 billion [5]. In addition to substantial health system impacts, pediatric AGE affects families in a multitude of ways, including negative effects on physical and emotional wellbeing of children and parents [6] and frequent parental work loss [7].

A recent Canadian, qualitative study of parents/caregivers (n=15) highlighted the 'real-life' complexity that influences health decision-making for pediatric AGE (i.e., past experiences, life circumstances, etc.) as well as AGE-related information needs, which included symptom management, understanding the normal course of illness, the cause of illness, information specific to dehydration, where to purchase helpful items, and how to talk to their child about AGE [8]. An American, cross-sectional study that evaluated parent/caregiver (n=229) knowledge about AGE indicated a wide variation in knowledge levels and demonstrated that knowledge was positively correlated to accessibility of health information, level of education, ethnicity, and experience with dehydration. This study recommended that future education interventions should be designed to improve general knowledge [9]. A Canadian, non-randomized trial targeting

parents/caregiver (n=105) of children with AGE in the ED evaluated one-on-one nursing education session in the ED and an educational home visit versus no intervention control. The study found a small (not statistically significant) increase in knowledge at 1-month, but this change was not sustained at 6-months [10]. A French cluster randomized trial targeting adults and parents/caregivers (n=400) with children with either tonsillitis or AGE evaluated the effect of patient information sheets. This study found statistically significant, positive effects on behaviour (primary) and knowledge (secondary) outcomes in the information sheet child sub-group compared to the no-information, control child sub-group 10-15 days post-intervention [11].

Knowledge translation (KT) is defined as the synthesis, exchange, and application of knowledge to improve the health of individuals, provide more effective health services and products, and strengthen health care systems [12]. Current approaches to KT research are largely focused on aligning the behaviours of health professionals with best research evidence; however, there are increasing calls for KT interventions for health consumers to influence health knowledge, decision making, and service utilization [13], especially given the many alternative health options open to parents through the internet. At present, there is little guidance on the most effective approach, content, duration, and intensity of education for this diverse population [14-16]; however, it is hypothesized that providing evidence-based child health information to parents and families has the power to ensure consistent parental management of child health over time and across settings [17], increase effective health decision-making [18], and reduce health system costs [18]. It is critical to generate empiric evidence to help determine the optimal modes for delivering evidence-based information to parents and families.

At present, it is routine practice to provide health education to parents seeking care for their children in EDs to guide care after discharge [17]. Typically, education is provided at the end of the emergency department visit when parents are tired and anxious to leave, making them less likely to ask important questions and retain information [19]. Additionally, information provided verbally is often brief [20] and written information is often too complex for most adults to comprehend [21,22].

Since online tools (e.g., podcasts, e-books, animations, infographics, etc.) are low or no-cost, easily accessible, and can be consumed on-demand, they hold promise as an effective approach to KT for parents and caregivers seeking research-based information related to child health [23,24]. Additionally, online platforms allow content to be viewed as frequently as needed, which may improve information retention and compliance [24].

To address the research-practice gap in pediatric AGE and provide parents with a reliable, research-based information resource, our research team developed a 3-minute whiteboard animation video using patient-oriented research methods to provide key information on home management strategies and guidance on when AGE requires emergency care [25]. Whiteboard animation videos are short, hand-drawn and narrated videos optimized for online streaming. Video content was drawn from knowledge synthesis results of treatment and management strategies for pediatric AGE [1]. The video storyline was developed from a qualitative study (n=15) that gathered and synthesized stories from parents/caregivers of children with vomiting and diarrhea who visited an ED for healthcare [8]. Video prototypes were reviewed, and a final version approved by pediatric emergency clinicians, research nurses, and parents. The video depicts a family with a sick child trying to determine whether medical attention is required. The family recalls an information sheet given to them at a hospital when

their child was ill with the same symptoms at an earlier time. The family assesses their child using the information sheet and determines to monitor and manage the child's illness at home until symptoms resolve. The family describes worsening symptoms that would require them to take their child to the emergency department. Artists, including a script writer, animators, and voice actor were contracted to work with the research team to ensure high quality video production.

Rigorous evaluation of the effectiveness of the whiteboard animation video is a critical next step. Given some uncertainty regarding the most appropriate methods for evaluating the effectiveness of KT tools for parents [26], including best outcome measures and parameters for sample size calculations, we have chosen to first undertake a pilot trial [27-29]. We are also interested in exploring the feasibility of using an electronic platform to assist with recruitment, intervention delivery, and data collection. The study objectives are listed in Table 4.1 according to four key pilot trial domains [27].

Table 4.1: Study Objectives.

Pilot Trial Domains	**Study Objectives**
Scientific domain	• To determine the potential effectiveness of a digital knowledge translation tool for parents/caregivers about pediatric AGE.
	• To understand the perceived benefit and value of KT tools for this population, including important components that enhance knowledge and decision making.
Process domain	• To examine the feasibility of using an electronic, web-based platform for intervention delivery and data collection with this population.
Management domain	• To assess this population's willingness to participate in future, similar research (i.e., full-scale trial).
Resource domain	• To determine time required for participants to complete data collection forms.
	• To examine the feasibility of using iPads to collect data with this population.

Methods

This is a parallel-arm, randomized, pilot trial. Convenience sampling will be used to recruit parents/caregivers seeking care for a child with vomiting and diarrhea in the ED and randomize them to receive the intervention of interest (i.e., whiteboard animation video) or a sham control condition (i.e., standard video of similar length). Data will be collected using quantitative and qualitative methods over a 6-month period. This protocol has been registered on clinicaltrails.gov (NCT03234777) and has obtained ethics approval from the University of Alberta Health Research Ethics Board and operational approval from the provincial health authority.

Study location & population

The study will be conducted at one Canadian, tertiary care, pediatric hospital. Parents meeting the eligibility criteria in Table 4.2 will be invited to participate.

Table 4.2: Study Eligibility Criteria.

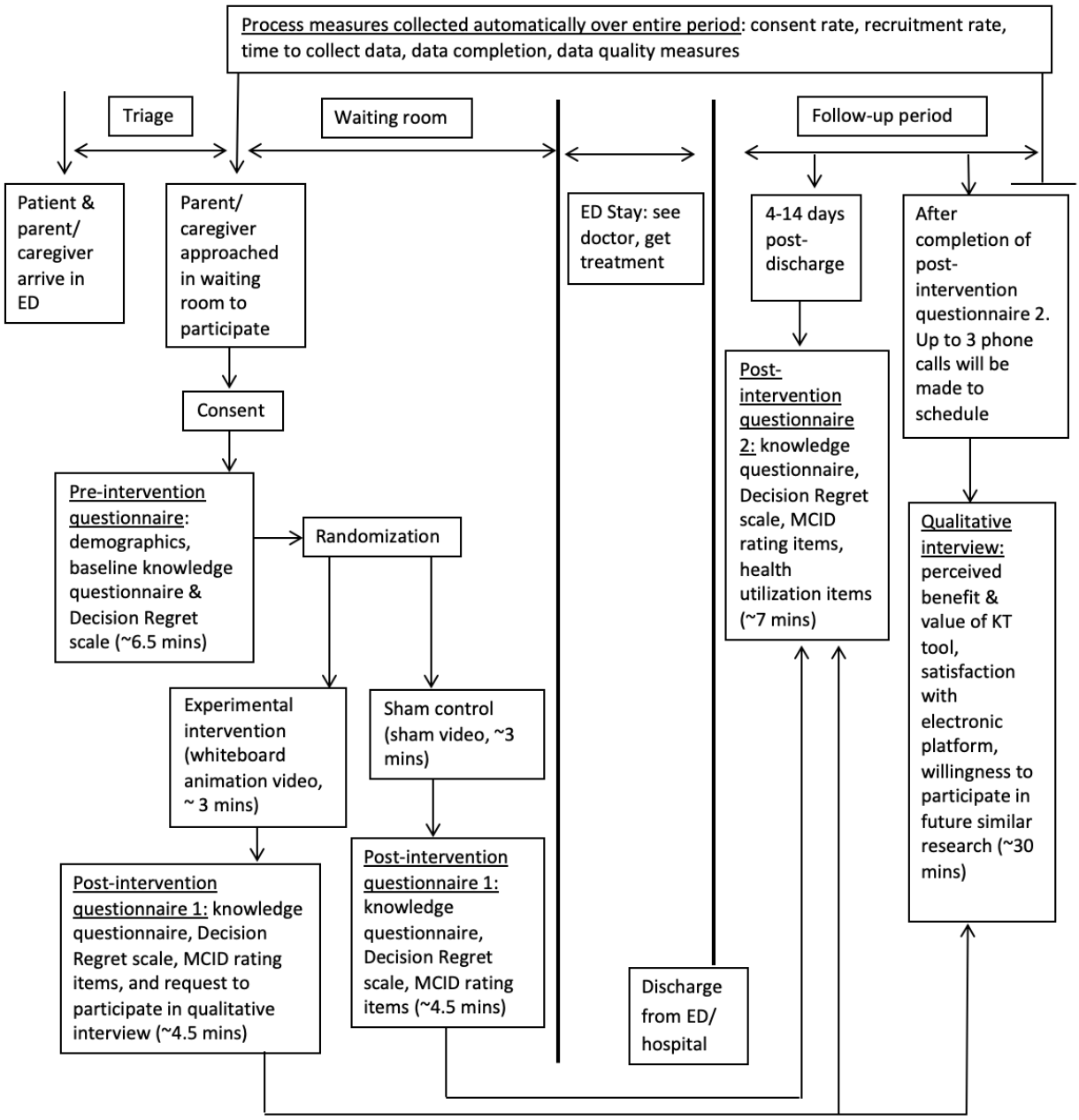
Inclusion criteria	• Parent or caregiver of a child 16 years old or younger • Child is presenting to the ED with vomiting and diarrhea • Parent is fluent in English • Parent is willing to be contacted for follow-up data collection
Exclusion criteria	1. Child has significant chronic gastrointestinal problem or inflammatory bowel disease (i.e., Crohn's Disease, Inflammatory Bowel Disease, Ulcerative Colitis, chronic constipation) 2. Child is taking immunosuppressive therapy or 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 ED for vomiting and diarrhea within the preceding 14 days

Recruitment

ED triage records will be screened in real-time to identify potential study participants. The parent/caregiver of consecutive individuals with primary complaint of vomiting and diarrhea

will be approached in the ED waiting room post-triage assessment (Figure 4.1) during data collection recruitment hours (0900-2300 Monday to Friday, 1500-2300 Saturday and Sunday). A member of the study team will assess inclusion/exclusion criteria and review the study information letter. Informed consent will be indicated on iPads as part of the electronic data collection platform.

Figure 4.1: Trial Flow & Timing of Data Collection



Interventions

The interventions take place in the ED waiting room post-triage assessment and prior to consultation with a physician. Post-intervention, all participants will receive standard medical care from healthcare providers. The study hospital has an information sheet about AGE,

however, education about AGE including whether the information sheet is given to parents/patients is at the discretion of the attending physician.

For this study, the experimental intervention is a three-minute, whiteboard animation video about a family's experience with pediatric AGE The sham control condition is a three-minute standard video developed by the Centres for Disease Control and Prevention about hand washing for infection control (URL: https://www.cdc.gov/cdctv/healthyliving/hygiene/fight-germs-wash-hands.html) [30]. Parents will view either the experimental or sham control intervention once on an iPad in the ED waiting room post-triage assessment. Disposable headphones will be provided with the iPads to maintain blinding. At the end of data collection in the ED (post-intervention questionnaire 1), parents can opt to receive a link to their assigned video via email to view as often as they wish from their own device(s). Parents from the experimental intervention group that are participating in the qualitative interview will view the whiteboard animation video again at the start of the interview.

Randomization

Blocked randomization with randomly chosen block sizes will be used to ensure equal distribution of participants to the experimental and sham intervention study arms [31]. The blocked randomization sequence will be computer generated. Following sequence generation, the randomization sequence will be entered into a confidential module on the electronic platform. Once the sequence is entered, the randomization module will only be accessible using a confidential password. The randomization sequence will be kept confidential. It will be inaccessible to data collectors/outcome assessors and to the study participants.

After completing the pre-intervention questionnaire, including demographic information and baseline outcome data, on the electronic data collection platform, individual

parents/caregivers will automatically be randomized to one of the study conditions (i.e., experimental intervention or sham control) based on the randomization sequence. This process will be seamless to participants. After viewing the study condition materials, participants will be automatically directed to post-intervention questionnaire 1. At study completion, all participants will receive a thank you email with links to both videos shown in the study.

Blinding

Using an electronic platform for data collection, study group allocation, and intervention viewing will allow participants to access the interventions and provide data independent of the research team. Participants and study staff will be blind to how the content on the iPads differs between groups during data collection.

Outcomes

A detailed description of study outcomes and outcome measures is presented in Table 4.3. KT tools are intended to impact end-user experience, including increasing knowledge, influencing healthcare decision making, and use of healthcare resources/services. Comprehension and retention of health information is a key component of the patient experience, a determinant of care instruction follow-through, and the cornerstone of health literacy; therefore, parental knowledge of childhood AGE (e.g., cause of AGE, signs of dehydration, management of dehydration) over time will be assessed. In addition to comprehension, educational materials may also influence health decision making; therefore, parental decision regret over time will be assessed to examine this impact considering the decision to bring their child to the ED for care. Additionally, minimum clinically important differences (MCIDs) will be identified for both knowledge and decision regret outcome measures. Finally, healthcare utilization post-ED visit will be explored as a potential future outcome.

Table 4.3: Study Outcomes, Outcome Measures, and Data Analysis Methods by Domain.

Study Domain	Outcomes & Outcome Measures	Data Analysis Methods
Scientific Domain	**Quantitative:** Parental knowledge will be evaluated using an 8-item knowledge questionnaire developed by the research team. This questionnaire was informed by the abridged Caregiver Gastroenteritis Knowledge Questionnaire (CGKQ) [19] and tailored to key content in the experimental intervention video. It has been piloted with the target population (n=15) and revised for clarity. It takes approximately 2.5 minutes to complete.	Correct responses will be given a score of one and are summed for a final score (0-8).
	Quantitative: Decision regret will be measured by the Decision Regret Scale comprised of 5, 5-point Likert items. Internal consistency and validity have been demonstrated and it is a useful tool for measuring regret after health care treatment decisions, is easy to administer, takes less than one minute to complete, and results in very few missing responses [20].	Items are scored individually and converted to a 0-100 scale following instructions in the user manual [21]. Items are summed and averaged for a final score, with regret increasing with a higher score.
	Quantitative: Post-ED healthcare utilization will be assessed by 3 items developed by the research team.	Descriptive statistics will be calculated.
	Quantitative: The perceived benefit and value of the KT intervention for pediatric AGE will be evaluated using 4 items developed by the research team and by examining the number of participants that request a video link after questionnaire 1.	Descriptive statistics will be calculated.
	Qualitative: The perceived benefit and value of the KT intervention for pediatric AGE will be also evaluated via a qualitative interview with a convenience sample of volunteer parents from the experimental intervention group.	Thematic analysis of interview data will be conducted.
Process Domain	**Quantitative:** Consent rate will be measured by: 1) percentage of people approached who consent to participate; 2) timing (date, time of day) of refusals.	Descriptive statistics will be calculated.
	Quantitative: Recruitment rate will be measured by: 1) percentage of people who consented to participate and complete pre-intervention questionnaire, post-intervention questionnaire 1, post intervention questionnaire 2, and qualitative interview; 2) timing (date, time of day) of recruitment.	Descriptive statistics will be calculated.

	Quantitative: Data completion will be measured by: 1) percentage of missing/blank survey items; 2) percentage of drop-outs at post-intervention questionnaire 2.	Descriptive statistics will be calculated.
	Qualitative: Satisfaction with electronic platform will be evaluated in the qualitative semi-structured interview with a convenience sample of volunteer parents from the experimental intervention group.	Thematic analysis of interview data will be conducted.
Management Domain	**Quantitative:** Data quality will be measured by number, type, and duration of technical problems (i.e., error messages, problems with internet connectivity, lost data, etc.) with online platform throughout study period.	Descriptive statistics will be calculated.
	Qualitative: Parents' willingness to participate in future, similar research will be assessed using qualitative approaches. This will be evaluated by a qualitative interview with a convenience sample of volunteer parents from the experimental intervention group.	Thematic analysis of interview data will be conducted.
Resource Domain	**Quantitative:** Time to collect data will be measured by: 1) average length of time to complete study questionnaires; 2) average length of time (days) to complete post-intervention questionnaire 2 post-discharge.	Descriptive statistics will be calculated.
	Quantitative: The feasibility of using iPads to collect data in the ED with parents/caregivers will be measured by tracking the number of broken, lost or stolen iPads, iPad chargers (including cord and plug), iPad cases, and Wi-Fi hubs.	Descriptive statistics will be calculated.

Sample size estimate

Sample size calculations are not required for pilot/feasibility studies as hypothesis testing is not the focus of this research design [36,37]. Rather, recruitment will take place over a 6-month period and will be evaluated as part of the identified process outcome measures. This 6-month period is intended to reflect the seasonal nature of viral gastroenteritis, the most common cause of infection, in temperate climates [38]. Recruitment will take place over the peak infection time of late winter [38]. The study site has approximately 500 patients presenting with symptoms of AGE over a 6-month period.

Philosophically, qualitative methods do not conduct prospective determinations of a sample size; instead, an adequate sample permits a deep, case-oriented analysis that results in a new understanding of experience [39]. In this study, convenience sampling will be used to recruit participants. It is anticipated that 12-20 interviews will be sufficient to see patterns in experiences [40].

Data collection

Participants will be provided with disposable headphones and an iPad containing the iCare Adventure electronic platform. iCare Adventure is a client-server-based e-therapeutics platform designed to expedite and improve the management of patients' care within pediatric ED facilities. iPads, which are locked to the iCare Adventure app, are given to parents participating in research in the ED. All content within the app, including screen flow, textual content, images, videos, protocols, and questionnaires, is controlled on a centralized server. When the application restarts, it calls to the server, the iPads report all user interactions back to the server in real-time, and the server can dynamically create real-time reports of the aggregated data. Data collection processes and forms will be piloted with the research team prior to the start of data collection.

The informed consent process and quantitative data collection will be completed on iCare Adventure and participants will be automatically given the questionnaires and appropriate intervention (i.e., whiteboard video or sham video) based on the randomization sequence. A unique study identifier will be generated for each participant within the iCare Adventure platform. All data collection points will be electronically time-stamped.

As part of the post-intervention questionnaire 1, participants receiving the experimental intervention will be asked about their willingness to be contacted later for an individual, in-depth, semi-structured, qualitative interview. If interested, they will provide contact information

(i.e., name, phone number, and best time to contact) and a member of the research team will follow-up via telephone.

Using a qualitative descriptive approach [41,42], a semi-structured interview guide will be used. This data collection strategy will be used to obtain all information required, probe participants' responses, and give participants freedom to respond and illustrate concepts in an open-ended fashion [40]. Interview questions will move from the general to the specific, with interviews later in the data collection period becoming increasingly more focused [43]. Interviews will be conducted in-person or over the telephone and will be audio recorded. Audio recordings will be anonymized, de-identified, and transcribed verbatim by a third-party contractor. Transcriptionists will sign a confidentiality agreement.

The following data will be collected over the course of this study:

1. Pre-intervention questionnaire (baseline, see Appendix H): Participants will complete a pre-intervention questionnaire that includes demographics, knowledge questionnaire, and Decision Regret Scale within the iCare Adventure platform on the iPad.

   **Participants will then be randomized to view the study intervention or the standard care intervention within the iCare Adventure platform on the iPad. This process will be seamless for the participants.

2. Post-intervention questionnaire 1 (immediate, see Appendix I): After viewing the intervention, participants will complete the knowledge questionnaire and Decision Regret Scale a second time. In addition, participants will complete 2 items assessing their own performance on the knowledge questionnaire and Decision Regret Scale and 1 item regarding the perceived value and benefit of the KT tool. They will also be

asked if they would like a video link emailed to them. At the end of this questionnaire, parents will be informed that the post-intervention questionnaire 2 will be emailed to them 4 days after this ED visit for completion at their earliest convenience. Experimental intervention group parents will be asked about participation in a qualitative focus group at this time.

3. Post-intervention questionnaire 2 (4-14 days post-ED, see Appendix J): Participants will be emailed a secure link on day 4 post-ED discharge to complete the knowledge questionnaire and Decision Regret Scale a third time, 2 items assessing their own performance on the knowledge questionnaire and Decision Regret Scale, 3 items related to healthcare utilization, and 3 items related to the perceived value and benefit of the KT tool (if applicable). Reminders to complete post-intervention questionnaire 2 will be sent to those who have not completed the survey every third day (day 7, 10, 13) to complete the survey by day 14 post ED-discharge (Appendix K). Previous research has demonstrated that 82% of AGE cases are resolved in three days or less and 14 days [44] represents the outer limit for pediatric AGE resolution [45].
4. Post-intervention semi-structured interview (sub-sample of experimental group, see Appendix L): Participants in the experimental group indicating willingness to participate in an in-depth, semi-structured, qualitative interview will be contacted via telephone after completion of post-intervention questionnaire 2. Up to three phone calls will be made to establish interview date/time. Qualitative interviews will focus on satisfaction with iCare Adventure platform, perceived benefit and value of the KT intervention, and willingness to participate in future, similar research.

Data analysis

All data will be aggregated and analyzed. Quantitative data will be downloaded from a secure Canadian server to SPSS for data cleaning and analysis [46]. Data cleaning measures may include recoding into categorical variables and comparing and recoding free text responses where appropriate. Descriptive statistics and estimation are the recommended focus of pilot/feasibility trials [47,48]. Descriptive statistics (e.g., frequencies, measures of variation and spread, etc.) will be calculated to describe the study groups. Analyses by outcome measure are presented in Table 3. Analyses will be conducted based on intention-to-treat.

Initial data will be collected to perform a sample size calculation for a full-scale trial [47]. Estimation for knowledge and decision regret outcomes will focus on calculating confidence intervals of different widths to illustrate strength of preliminary evidence [47,48]. Confidence intervals for the difference of means (paired) will be presented for both potential effectiveness outcome measures to account for repeated measures [49]. The confidence interval for the difference of means from time 1 to time 2 for both groups will be calculated to examine initial change scores and the difference of means from time 2 to time 3 for both groups will be calculated to examine sustained change score. Confidence interval widths for both initial and sustained change measures will be set at: 99%, 95%, 90%, 85%, 80%, and 75% and presented together alongside a minimum clinically important difference (MCID) in a graph [50]. If each confidence interval crosses both 0 and the MCID, this is inconclusive evidence of effect; however, if each confidence interval both excludes 0 and crosses the MCID, there is evidence of a potentially clinically important difference. A confidence interval that is above or equal to the MCID indicates that at this level that there is a clinically meaningful difference between the groups.

Qualitative data will be de-identified during verbatim transcription. Prior to analysis, transcripts will be checked with the audio files for accuracy. Qualitative data will be managed and analyzed using NVivo data management software [51]. Qualitative outcomes will be analyzed using thematic analysis by breaking interview text into small units for a detailed, nuanced account of the data [52-54]. This iterative process will be concurrent to data collection [41]. Thematic analysis will be guided by the hybrid approach of inductive and deductive coding and theme development described by Fereday & Muir-Cochrane (2006) [55]. Deductive coding of the interview transcripts will be done first using the semi-structured interview guide as a framework; smaller units of data that emerge inductively will be coded for increased granularity and specificity. To ensure analytic rigor, field notes will be collected during the data collection and analysis process and coded alongside interview data [52,56,57].

Data storage & security

All data will be stored on secure Canadian servers that are compliant with data privacy and security regulations to safeguard medical information as per the Health Insurance Portability and Accountability Act of 1996 [58]. The server is protected by a firewall and is backed up daily. All data stored in the server database is anonymous. Once data collection is complete, all data will be transferred to the researchers for analysis and long term, secure storage, and deleted from the iCare Adventure servers. The questionnaires have been made to be anonymous. Participants will not be identified by name or be identifiable by their responses.

Interview data will be transferred between the research team and the third-party, transcription contractor via a secure, online portal or by courier. Transcripts will be de-identified. All data will be transferred to the researchers for analysis and long term, secure storage, and

deleted by the third-party contractor once transcription is complete. Master lists will be stored on a secure Canadian server only accessible to the research team.

Conclusions

Pediatric AGE is a common childhood illness representing a large burden on our healthcare system. Connecting parents and families to effective, evidence-based patient education is key to effective decision-making and therapeutic management of pediatric AGE. Digital KT tools offer a promising approach to communicate complex health information to parents and families. The evidence-based whiteboard animation video being evaluated in this pilot trial has been tailored to the needs of parents and families seeking care for pediatric AGE in EDs. This study will inform the design and conduct of a full-scale, effectiveness trial by gathering key data in four domains: 1) scientific, 2) process, 3) management, and 4) resource. These results will impact the emerging field of knowledge translation efforts targeting health consumers and advance the science on the best mode of patient education for acute childhood illnesses.

Chapter 4 References

1. Freedman SB, Ali S, Oleszczuk M, Gouin S, Hartling L. Treatment of acute gastroenteritis in children: an overview of systematic reviews of interventions commonly used in developed countries. *EBCH*. 2013;8:1123-1137. doi: 10.1002/ebch.1932
2. Freedman SB, Sivabalasundaram V, Bohn V, Powell EC, Johnson DW, Boutis K. The treatment of pediatrics gastroenteritis: a comparative analysis of pediatric emergency physicians' practice patterns. *Acad Emerg Med*. 2011;18:38-45. doi: 10.1111/j.1553-2712.2010.00960.x
3. Freedman SB, Etorky M, Gorelick M, Pediatric Emergency Research Canada Gastroenteritis Study Group. Evaluation of a gastroenteritis severity score for use in outpatient settings. *Pediatrics*. 2010;125:e1278-e1285. doi: 10.1542/peds.2009-3270
4. Kinlin LM, Bahm A, Guttmann A, Freedman SB. A survey of emergency department resources and strategies employed in the treatment of pediatric gastroenteritis. *Acad Emerg Med*. 2013;20(4):361-366. doi: 10.1111/acem.12108
5. Freedman S, Lowerison K. GotGastro.ca. Alberta Provincial Pediatric EnTeric Infection Team (APPETITE) seminar series. GotGastro.ca. http://gotgastro.ca/training/seminar-series-2/. Published 2015. Accessed February 2, 2015.
6. Mast TC, DeMuro-Mercon C, Kelly CM, Floyd LE, Walter EB. The impact of rotovirus gastroenteritis on the family. *BMC Pediatr*. 2009;9(11). doi: 10.1186/1471-2431-9-11
7. Senecal M, Brisson M, Lebel MH, et al. Measuring the impact of rotavirus acute gastroenteritis episodes (MIRAGE): a prospective community-based study. *Can J Infect Dis Med Microbiol*. 2008;19(6):397-404. doi: 10.1155/2008/451540

8. Albrecht L, Hartling L, Scott SD. Pediatric acute gastroenteritis: understanding caregivers' experiences and information needs. *CJEM*. 2016;1-9. doi: 10.1017/cem.2016.363
9. Anidi I, Bazargan M, James FW. Knowledge and management of diarrhea among underserved minority parents/caregivers. *Ambul Pediatr*. 2002;2:20l-206.
10. Freedman SS, Couto M, Spooner L, Haladyn, K. The implementation of a gastroenteritis education program. *Am J Emerg Med*. 2011;29:271-277. doi: 10.1016/j.ajem.2009.09.032
11. Sustersic M, Jeannet E, Cozon-Rein L, et al. Impact of information leaflets on behavior of patients with gastroenteritis or tonsillitis: a cluster randomized trial in French primary care. *J Gen Intern Med*. 2012;28(1):25-31. doi: 10.1007/s11606-012-2164-8
12. Canadian Institutes of Health Research. Knowledge translation. Cihr-irsc.gc.ca. https://cihr-irsc.gc.ca/e/29529.html. Updated Nov 11, 2019. Accessed March 18, 2015.
13. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. *Implem Sci*. 2012;7(50). doi: 10.1186/1748-5908-7-50
14. Wilson EAH, Makoul G, Bojarski EA, et al. Comparative analysis of print and multimedial health materials: a review of the literature. *Patient Educ Couns*. 2012;89:7-14. doi: 10.1016/j.pec.2012.06.007
15. Jusko Friedman A, Cosby R, Boyko S, Hatton-Bauer J, Turnbull G. Effective teaching strategies and methods of delivery for patient education: a systematic review and practice guideline recommendations. *J Cancer Educ*. 2011;26:12-21. doi: 10.1007/s13187-010-0183-x
16. Boyd M, Lasserson TJ, McKean MC, Gibson PG, Ducharme FM, Haby M. Interventions for educating children who are at risk of asthma-related emergency department attendance.

Cochrane Database of Syst Rev. 2009;(2):CD001290. doi: 10.1002/14651858.CD001290.pub2

17. Taddio A, Shah V, Leung E, et al. Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain: usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatr*. 2013;13(23). doi: 10.1186/1471-2431-13-23
18. Morrison AK, Myrvik MP, Brousseau DC, Hoffman RG, Stanley RM. The relationship between parent health literacy and pediatric emergency department utilization: a systematic review. *Acad Pediatr*. 2013;13(5):421-429. doi: 10.1016/j.acap.2013.03.001
19. Engel KG, Heisler M, Smith DM, Robinson CH, Forman JH, Ubel PA. Patient comprehension of emergency department care and instructions: are patients aware of when they do not understand? *Ann Emerg Med*. 2009;53(4):454-461. doi: 10.1016/j.annemergmed.2008.05.016
20. Vashi A, Rhodes KV. "Sign right here and you're good to go": a content analysis of audiotaped emergency department discharge instructions. *Ann Emerg Med*. 2011;57(4):315-322. doi: 10.1016/j.annemergmed.2010.08.024
21. Sanders LM, Federico S, Klass P, Abrams MA, Dreyer B. Literacy and child health: a systematic review. *JAMA Pediatr*. 2009;163(2):131-140. doi: 10.1001/archpediatrics.2008.539
22. Spandorfer JM, Karras DJ, Hughes LA, Caputo C. Comprehension of discharge instructions by patients in an urban emergency department. *Ann Emerg Med*. 1995:25(1):71-74. doi: 10.1016/s0196-0644(95)70358-6

23. Lipstein EA, Brinkman WB, Britto MT. What is known about parents' treatment decisions? A narrative review of pediatric decision making. *Med Decis Making*. 2012;32(2):246-258. doi: 10.1177/0272989X11421528

24. Saidinejad M, Zorc J. Mobile and web-based education: delivering emergency department discharge and aftercare instructions. *Pediatr Emerg Care*. 2014;30:211-216. doi: 10.1097/PEC.0000000000000097

25. Sacristan JA. Patient-centred medicine and patient-oriented research: improving health outcomes for individual patients. *BMC Med Inform Decis Making*. 2013;13(6). doi: 10.1186/1472-6947-13-6

26. Albrecht L, Scott SD, Hartling L. Knowledge translation tools for parents on child health topics: A scoping review. *BMC Health Serv Res*. 2017;17(686). doi: 10.1186/s12913-017-2632-2

27. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. 2010;10(1). doi: 10.1186/1471-2288-10-1

28. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol*. 2010;10(67). doi: 10.1186/1471-2288-10-67

29. Shanyinde M, Pickering RM, Weatherall M. Questions asked and answered in pilot and feasibility randomized controlled trials. *BMC Med Res Methodol*. 2011;11(117). doi: 10.1186/1471-2288-11-117

30. Centres for Disease Control and Prevention. Fight Germs: Wash Your Hands (3:00). CDC.gov. https://www.cdc.gov/cdctv/healthyliving/hygiene/fight-germs-wash-hands.html. Updated Oct. 13, 2016. Accessed Jan. 15, 2017.

31. Efird J. Blocked randomization with randomly selected block sizes. *IJERPH*. 2011;8(1):15-20. doi: 10.3390/ijerph8010015

32. Freedman SB, Deiratany S, Goldman RD, Benseler S. Development of a caregiver gastroenteritis knowledge questionnaire. *Ambulatory Pediatrics*. 2008;8:261-265. doi: 10.1016/j.ambp.2008.02.003

33. Brehaut JC, O'Connor AM, Wood TJ, et al. Validation of a decision regret scale. *Med Decis Making*. 2003;23(4):281-292. doi 10.1177/0272989X03256005

34. O'Connor AM. User Manual – Decision Regret Scale. Ohri.ca. www.ohri.ca/decisionaid. Updated 2003. Accessed Feb 2, 2015.

35. Wells G, Beaton D, Shea B, et al. Minimal clinically important differences: review of methods. *J Rheumatol*. 2001;28(2):406-412.

36. Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. *Trials*. 2014;15(264). doi: 10.1186/1745-6215-15-264

37. Billingham SAM, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network Database. *BMC Med Res Methodol*. 2013;13(104). doi: 10.1186/1471-2288-13-104

38. Elliott EJ. Acute gastroenteritis in children. *BMJ.* 2007;334(7583):35-40.

39. Sandelowski M. Sample size in qualitative research. *Res Nurs Health*. 1995;18:179-183.

40. Morse J, Field P. Qualitative research methods for health professionals. 2nd edition. Thousand Oaks, CA: SAGE; 1995.

41. Sandelowski M. Whatever happened to qualitative description? *Res Nurs Health*. 2000;23:334-40.

42. Sandelowski M. What's in a name? Qualitative description revisited. *Res Nurs Health*. 2010;33:77-84.

43. Yin, R. Qualitative research from start to finish. New York, NY: The Guilford Press; 2011.

44. Jones TF, McMillian MB, Scallan E, Frenzen PS, Cronquist AB, Thomas S, Angulo FJ. A population-based estimate of the substantial burden of diarrhoeal disease in the United States; FoodNet, 1996-2003. *Epidemiol Infect*. 2007;135:293-301. doi: 10.1017/S0950268806006765

45. King CK, Glass R, Brese JS, Duggan C. Managing acute gastroenteritis among children: oral rehydration, maintenance, and nutritional therapy. *MMWR Recommendations & Reports*. 2003;52(RR16):1-16.

46. IBM SPSS Statistics for Windows [quantitative data analysis software]. Version 22. IBM Corp; 2013.

47. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: Recommendations for good practice. *J Eval Clin Pract*. 2004;10(2):307-312. doi: 10.1111/j..2002.384.doc.x

48. Lee EC, Whitehead AL, Jacques RM, Julious SA. The statistical interpretation of pilot trials: should significance thresholds be reconsidered? *BMC Med Res Methodol*. 2014;14(41).

49. Gardner MJ, Altman DG. Confidence intervals rather than P values: estimation rather than hypothesis testing. *BMJ*. 1986;292:746-750.

50. Cohen J. The earth is round ($p < .05$) *American Psychologist*. 1994;49(12):997-1003.

51. NVivo (for Windows) [qualitative data analysis software]. Version 11. QSR International Pty Ltd.; 2015.

52. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing & Health Sciences*. 2013;15:398-405. doi: 10.1111/nhs.12048

53. Sparker A. Narrative analysis: exploring the what's and how's of personal stories. In: Holloway I, ed. *Qualitative Research in Health Care*. 1st edition. Berkshire, UK: Open University Press; 2005:191-208.

54. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006; 3:77–101.

55. Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. *IJQM*. 2006;5(1):80-92.

56. Ballinger C, Yardley L, Payne S. Observation and action research. In: Marks DF, Yardley L, eds. *Research Methods for Clinical and Health Psychology*. 1st ed. London, UK: Sage Publications Ltd; 2004: 102–121.

57. Rolfe G. Validity, trustworthiness and rigour: quality and the idea of qualitative research. *J Adv Nurs*. 2006;53:304–310. doi: 10.1111/j.1365-2648.2006.03727.x

58. SoftLayer. HIPPA & SoftLayer: Protecting Patient Privacy. Softlayer.com. http://www.softlayer.com/info/hipaa. Accessed Mar. 1, 2017.

Chapter 5 – The process of implementing a pragmatic pilot randomized trial to evaluate a knowledge translation tool for parents about pediatric acute gastroenteritis in a real-world setting

Background

A single-site, parallel-arm, pragmatic pilot randomized controlled trial (PRCT) was implemented following the study protocol outlined in Chapter 4 [1]. This pilot trial was conceived and conducted as a pragmatic design to assess the feasibility of methods to evaluate a whiteboard video intervention for parents about pediatric acute gastroenteritis (AGE) in a real-world setting with the goal of maximizing applicability [2]. This is in contrast to the traditional-style of explanatory trial design, which is focused on efficacy in highly controlled settings, thus producing limited generalizability [2]. In PRCTs, the intervention of interest is evaluated against other interventions (i.e., sham, best practice) and a wide spectrum of outcomes, including patient-centered outcomes, are evaluated [2]. Assessing the feasibility of PRCTs has been identified as a priority to advance this emergent methodology [3].

The whiteboard animation video was developed to provide parents with evidence-based information on the treatment and management of pediatric AGE, a common childhood illness, and includes specific guidance on when to seek emergency care. The video development process was described in Chapter 1. Chapter 3 reviews a qualitative study that was conducted to understand parental knowledge needs about pediatric AGE [4] and the whiteboard animation video was designed to meet these needs.

Methods overview

The purpose of this pilot study was to answer the following research question: what is the feasibility of an RCT to evaluate a knowledge translation (KT) tool, specifically a whiteboard animation video, for parents/caregivers about pediatric acute gastroenteritis (AGE)? To robustly address this question, pilot trial outcomes were evaluated in four key domains: 1) scientific (i.e., is the intervention effective?), 2) process (i.e., what elements are key to study success?) 3) management (i.e., are the human and data needs optimized?), and 4) resource (i.e., are the time and budget allocations reasonable?) [5]. These feasibility outcomes cover four key patient-important outcomes categories: patients' knowledge; patients' experience; service utilization and cost; and, health behavior and health status [6].

The target population recruited to participate in this study were parents or caregivers of children presenting to one emergency department (ED) with symptoms of AGE over a three-month period. Participants were randomized in blocks to one of two study conditions: the experimental intervention, a narrated, animation video about AGE, or a sham control intervention, a video of the same length about infection control. Participants were blind to their study condition and to the allocation of other participants. To ensure intervention reporting meets accepted standards [7-9], Table 5.1 describes the study conditions in detail using the WIDER Recommendations to Improve Reporting of the Content of Behaviour Change Interventions framework [10].

Table 5.1: Applying WIDER Recommendations to Improve Reporting of the Content of Behaviour Change Interventions to Study Conditions.

WIDER Recommendations	Supplementary Recommendations	Study Characteristics
Detailed description of	1) characteristics of those delivering the intervention	Intervention video was delivered 1 time to randomly selected parents of children

interventions in published papers	2) characteristics of the recipients 3) the setting 4) the mode of delivery 5) the intensity 6) the duration 7) adherence/fidelity to delivery protocols 8) detailed description of the intervention content provided for each study group	visiting the ED for symptoms of AGE. Intervention video was automatically delivered via iPad after the baseline questionnaire and before the post-intervention questionnaire. The intervention video was approximately 3 minutes in length. It was programmed to play through and participants could not stop video or change the screen until it was over. The intervention video was about a family's experience with a child with AGE. Appendix A contains the side-by-side video script.
Clarification of assumed change process and design principles	1) the intervention development 2) the change techniques used in the intervention 3) the causal processes targeted by these change techniques	The Knowledge-to-Action Framework was used to describe the iterative process of intervention development and evaluation in Chapter 1. Detailed description of cognitive science and instructional design theoretical underpinnings of the intervention are in Chapter 1.
Access to intervention manuals/protocols,	Submit protocols or manuals for publication to make these supplementary materials easily accessible (i.e., online).	Video script is in Appendix A.
Detailed description of active control conditions	1) characteristics of those delivering the control 2) characteristics of the recipients 3) the setting 4) the mode of delivery 5) the intensity 6) the duration 7) adherence/fidelity to delivery protocols 8) detailed description of the control content provided	Sham control video was delivered 1 time to randomly selected parents of children visiting the ED for symptoms of AGE. Control video was automatically delivered via iPad after the baseline questionnaire and before the post-intervention questionnaire. The control video was approximately 3 minutes in length. It was programmed to play through and participants could not stop video or change the screen until it was over. The control video was developed by the Centres for Disease Control, a reputable government health agency. The content focused on infection control, a beneficial topic for parents of children with contagious AGE. It can be viewed here: https://www.cdc.gov/cdctv/healthyliving/hygiene/fight-germs-wash-hands.html

The pre-intervention questionnaire, intervention delivery, and immediate post-intervention questionnaire were administered via an electronic data collection platform on an iPad in the ED waiting room before the ill child was seen by a physician. A second, follow-up, post-intervention questionnaire was emailed to the participant for completion at home after the ED visit was complete. Experimental intervention participants were also invited to take part in a qualitative interview.

An a priori study protocol was designed and published; this was detailed in Chapter 4. The protocol was also registered on Clinicaltrials.gov and regularly updated with study progress (NCT03234777). A priori protocols are standard practice for RCTs as a key strategy for the prevention of poor medical and health research [11-13]; the lack of such protocols was identified as a noteworthy weakness in the results of the scoping review of studies evaluating KT tools for parents on child health topics (detailed in Chapter 2). The purpose of this Chapter is to explain in detail the implementation of the study protocol in a real-world setting and specifically highlight any changes or deviations that occurred due to study context. This adheres to best pilot and feasibility trial reporting practices in the CONSORT extension for randomized pilot and feasibility trials [14,15].

Study location & population

This study was implemented in the Stollery Children's Hospital ED. The Stollery Children's Hospital is a full-service pediatric hospital covering a geographical area of over 500,000 kilometers [16]. It is the only pediatric hospital servicing central and northern Alberta, as well as sections of the far north.

The Stollery ED treats approximately 27,000 children per year, which translates to around 70 patients per day [17]. Study data collection took place from November 2017 to February 2018. During that time, the wait time to see a physician in the ED ranged from a median wait time of 1.1 to 2.1 hours for both non-urgent and urgent cases [18].

As of October 2018, there were 14 ongoing research studies taking place in the Stollery ED [19]. Given the hospital's immediate proximity to the University of Alberta, there is a great capacity and high demand for research. To address this, the Department of Pediatrics within the Faculty of Medicine and Dentistry at the University of Alberta established a team to coordinate research efforts in the pediatric ED and alleviate the research burden on clinical staff. This team is led by physician-researchers and comprised of student volunteers, research assistants, research nurses, and research coordinators to conduct a variety of paid and unpaid services related to participant recruitment and data collection in this environment. The team also has an office and computer equipment within the ED. They meet monthly to review ongoing studies and to discuss challenges and successes.

This research study was planned in consultation with the Department of Pediatrics ED research team. The agreement was to provide support in two ways: 1) access to the office and computer equipment from 0900-1500 Monday to Friday for the researcher to conduct participant recruitment and data collection, and 2) including this study in their research recruitment/data collection roster during their regularly scheduled shifts (1500-2300, 7 days/week). Student volunteers would be allocated to recruit participants in the evenings 4 days/week and the research assistants and research nurses would be tasked with study recruitment on the evenings without volunteers if/when time allowed between duties from other research studies. The

researcher provided training and ongoing support to all potential data collectors, as well as attended the regular monthly team meetings.

At the time of this study, there was another ongoing research study recruiting families and children with AGE in the Stollery ED [20]. That study was a multi-site initiative with a data collection period of five-years. To minimize negative impacts to both studies, the researcher liaised with the Principal Investigator of the other study to ensure both studies could be conducted simultaneously in the Stollery ED for a 3-month period of time. Regular updates were shared between the two studies at the monthly team meetings.

Preparations for study implementation

Research approval and registration processes

This study was approved by the University of Alberta Health Research Ethics Board (Pro00073867, Pro00091285). Operational approval was provided by the health authority, Alberta Health Services (AHS), to conduct research in the Stollery Children's Hospital ED waiting room. An AHS Data Disclosure Agreement was signed to provide view-only access to an electronic hospital database for participant screening purposes.

Tailoring the iCare Adventure electronic platform

iCare Adventure was the electronic questionnaire platform used to collect questionnaire data and to deliver the interventions in this study [21]. iCare Adventure was developed by Andrew Wilcox as a client-server-based e-therapeutics platform designed for use on iPads. Prior to study launch, the researcher and Mr. Wilcox worked collaboratively to tailor the iCare Adventure platform to the needs of this study.

Given the busy nature of the pediatric ED environment, significant time was spent designing the platform interface to ensure data collection was user-friendly and efficient with the

goal of maximizing questionnaire engagement and completion. First, the background imagery was changed to a neutral orange color with a cartoon-style heart. This was done to appeal to the adult target population of the study. However, since the bulk of data collection occurred in a pediatric ED setting, the interface remained child-friendly and approachable, with the understanding that children may watch their parent/caregiver complete the questionnaire as a distraction while waiting in the ED.

Next, an animated female face with voice over narration was added to the interface. The researcher provided the voicing and the animation was created in her likeness. This feature was added to enhance engagement with the questionnaire and to assist participants with hearing impairments, English as a Second Language learners, and/or those with low written literacy skills. To ensure this feature didn't become a hinderance to fast readers, it could be disabled on demand by using the touch screen and the questionnaire screen could be advanced before the narration was complete.

Third, the platform was programmed so that the study information sheet and the intervention videos could not be skipped or advanced before completion. Backwards navigation was also disabled. This was done to ensure proper informed consent, intervention fidelity, and to minimize missing data. To mitigate any related concerns, instructions were added to the beginning of the questionnaire to indicate that participants cannot go back to re-read questions or change responses. A progress bar was added along the bottom of the screen to indicate the length remaining to complete the questionnaire. This was added to encourage questionnaire completion and reduce incomplete questionnaire or study dropouts.

Fourth, decision rules were added where possible to eliminate incorrect questionnaire responses. These included decision rules for: valid email address format; year of birth limited to

numbers 1900-2018; child age limited to numbers 0-16; for number of children, 0 could not be entered nor more than 20; and, questions requiring a number as an answer were restricted from entering letters in the response.

There were features in the iCare Adventure platform that could not be altered. These may be important considerations when developing other similar platforms. First, on the iPad in the ED, the survey and intervention could only be viewed in landscape-mode. While this maximizes font size, the iPad keyboard could obscure the question and responses depending on the amount of text. Participants could scroll to view complete information; however, this was an added step that had the potential to be missed. If portrait-mode could have been enabled, the participant could view the entire question and response options on the screen without scrolling, which may increase speed of survey completion and reduce missing data. Second, the questionnaire was optimized for an iPad; this means that if the post-intervention questionnaire 2 conducted at home was completed on a different electronic device (i.e., smartphone, laptop, desktop computer) there may be awkward spacing or visibility issues. Third, there were limited options for differentiating text within the platform. For example, it was not possible to use spacing, bolding, highlighting, or underlining to differentiate instructional text from the questions themselves. This functionality could possibly enhance the usability or speed of questionnaire completion. Finally, because of how the platform was programmed to email the post-intervention questionnaire 2, all participants received it regardless of whether they completed post-intervention questionnaire 1. Only 1 follow-up survey had to be removed in analyses because the prior survey was not completed.

Pilot testing

Prior to data collection, the researcher led pilot testing of the electronic platform, forms, and automatically generated emails from October 16, 2017 to November 29, 2017. Multiple iPad

devices were tested by researchers and non-researchers (n=18). Pilot testing took place in the ED and at home to mimic study conditions, ensure functionality in situ, and to identify any process issues. A number of issues were identified and resolved by the researcher and Mr. Wilcox. The electronic platform, forms, and study processes were updated to reflect revisions. The database was wiped, and email settings changed on November 29, 2017 in preparation for data collection.

Data collector training

After pilot testing was completed, the researcher provided hands-on training for all potential ED data collectors (n=10). This included two, one hour, in-person education sessions to review the study purpose, practice approaching potential participants, and use the electronic data collection platform to assess study eligibility and informed consent. Data collectors also familiarized themselves with the content of the questionnaire. In addition, the researcher reviewed all study processes and answered questions. These sessions took place on November 21 and 22, 2017.

A trial manual (Appendix M) was developed and made available to all data collectors and a copy was posted in the ED office to reinforce training and provide trouble-shooting support over the data collection period. Data collectors contacted the researcher with questions or concerns via email or telephone during the data collection period when support was required. All contact information was provided.

Data collection

Data collection took place over 3-months from November 30, 2017 to February 27, 2018 (79 days). This time period reflected the seasonal nature of viral gastroenteritis in temperate climates, which peaks in late winter [22]. Data collection was suspended from December 23, 2017 to January 2, 2018 due to statutory holidays; no research staff were present in the ED at

that time. The study duration was reduced from the protocol timeline of 6-months for four key reasons: 1) the seasonal nature of viral gastroenteritis; 2) to align with the recommended best practice for pilot trials [23-25], 3) significant planned recruitment time of 46 hours per week, and; 4) the researcher began an extended parental leave on February 28. 2018.

Data collector scheduling

Participants were recruited by the researcher and ED research volunteers and staff in the ED waiting room. The researcher allocated dedicated recruitment and data collection time Monday to Friday from 0900-1500 for the duration of the study. The potential available time for recruitment and data collection by ED research team volunteers and staff was 7 days/week from 1500-2300 (i.e., the team's regular hours of operation); however, actual time spent on this study was variable depending on the needs of other ongoing studies. For November and December 2017, one volunteer was present to collect data in the evenings for four hours between 1500-2000, four days per week. In January and February 2018, there were availability issues and only 12 volunteer shifts were completed out of an anticipated 32 shifts (i.e., 4 shifts per week over 8 weeks). ED research staff (i.e., research assistants and nurses) occasionally conducted recruitment and data collection for this study. In November and December 2017, paid staff did not perform these duties; however, in January and February 2018, they did enroll study participants due to lack of available volunteers.

Study enrollment strategies

The main enrollment strategy for this study was to conduct in-person screening and recruitment. Participant recruitment took place in the ED, a setting with little to do and a potentially long wait time. The questionnaire was also optimized to serve as a distraction for the

ill child. Initial participant recruitment numbers were very good, however, recruitment proved more challenging over time.

To encourage more enrollment in 2018, study reminder emails were sent to the data collectors on January 19 and February 6, 2018. These emails provided reminders about study population, recruitment process, and charts on recruitment to date. In the last month of participant recruitment, the researcher sent out weekly recruitment reports to all data collectors.

The researcher also explored implementing small incentives for data collectors based on recruitment numbers to boost evening and weekend study enrollment. The initiative was ultimately abandoned because it was not a strategy incorporated into other research studies on the ED roster. There was concern about creating an incentive-based culture among data collectors that would create negative competition between research studies.

Incentives for participants were also explored. The researcher consulted the University of Alberta Research Ethics Office guidelines to determine a suitable process [26]. A core guideline is that compensation should reflect time spent on the research and estimated time to complete the study components was minimal (i.e., 15-20 minutes in ED, 7-10 minutes at home, up to 30 minutes for interview). Since data collectors were present in the ED for the pre-intervention, and post-intervention questionnaire 1, incentives would be best deployed to encourage post-intervention questionnaire 2 and interview completion outside of the ED; however, the electronic platform was not designed to deliver a gift card link to participants upon successful completion of all data collection components. These platform alterations would take considerable effort to design and implement and it was determined not to attempt this during active data collection. Finally, the research ethics application and study information would need to be amended and

approved to implement these changes. After weighing the pros and cons, it was determined not to proceed with participant incentives.

Participant screening & recruitment

Data collectors monitored the Emergency Department Information System (EDIS) [27], an electronic triage program, to identify children 16 years and younger presenting to the ED with vomiting and diarrhea, the main symptoms of pediatric AGE. Once a potential child with AGE was identified, data collectors then approached their parent/caregiver in the ED waiting room to introduce the study. The approach took place post-triage assessment, but prior to seeing a physician. If the parent/caregiver was interested in participating, data collectors reviewed the study eligibility criteria.

At the time of study recruitment, another study targeting the same population and condition was ongoing in the ED. In order to facilitate the conduct of both studies at the same time, the study teams met to discuss options. It was determined that recruitment for this study would differ by time of day: 1) from 0900-1500 recruitment followed the original inclusion/exclusion criteria detailed in the study protocol, and 2) from 1500-2300 recruitment followed modified inclusion criteria described in Table 5.2 (i.e., changes in bold text). This was because the researcher was the only data collector conducting research recruitment in the ED during the daytime hours. All recruitment for other ongoing studies took place in the evening during the Department of Pediatrics ED research team regular hours.

Table 5.2: Study Eligibility Criteria Depending on Time of Day.

Recruitment period	**Inclusion criteria**	**Exclusion criteria**
Recruitment from 0900-1500	• Parent or caregiver of a child 16 years old or younger • Child is presenting to the ED with vomiting and diarrhea • Parent is fluent in English	• Child has significant chronic gastrointestinal problem or inflammatory bowel disease (i.e., Crohn's Disease, Inflammatory Bowel

	• Parent is willing to be contacted for follow-up data collection	Disease, Ulcerative Colitis, chronic constipation) • Child is taking immunosuppressive therapy or known history of immunodeficiency • Child has undergone oral or gastrointestinal surgery within the preceding 7 days • Child has had a prior visit to the ED for vomiting and diarrhea within the preceding 14 days
Recruitment from 1500-2300	• Parent or caregiver of a child 16 years old or younger • Child is presenting to the ED with **less than 3 episodes** of vomiting and diarrhea **in the last 24 hours AND/OR has had vomiting and diarrhea for 7 or more days** • Parent is fluent in English • Parent is willing to be contacted for follow-up data collection	• Child has significant chronic gastrointestinal problem or inflammatory bowel disease (i.e., Crohn's Disease, Inflammatory Bowel Disease, Ulcerative Colitis, chronic constipation) • Child is taking immunosuppressive therapy or known history of immunodeficiency • Child has undergone oral or gastrointestinal surgery within the preceding 7 days • Child has had a prior visit to the ED for vomiting and diarrhea within the preceding 14 days

Both sets of study inclusion/exclusion criteria were integrated into the electronic data collection platform. Depending on time of day, the appropriate eligibility criteria were presented as a checklist on the iPad for the data collector to assess with the potential participant. The number of eligible and non-eligible participants approached were recorded within the data collection platform.

If the participant met the inclusion/exclusion criteria, the data collector then provided them with the iPad to review the study information letter. The information letter was also

provided in hard copy for participants' records. The data collector was available nearby in the ED waiting room to answer questions or assist with technology. Once the information letter was read, the iPad screen advanced and the potential participant could select either a "consent" or "do not consent" button. If the potential participant did not consent, a thank-you screen was automatically generated, which indicated to return the iPad to the data collector, and the system re-set. If consent was provided, the screen automatically advanced to the pre-intervention questionnaire and the participant could proceed with the study.

Experimental group participants were also invited to participate in an individual interview. The interview request was embedded in post-intervention questionnaire 1 based on the randomization sequence. If interested, participants provided their contact information for the researcher to arrange an interview date/time after the survey follow-up period. Three attempts were made by the researcher to schedule an interview. Voicemail messages were left for participants where possible. When an interview date and time was set, the researcher sent a reminder 24 hours prior via email or text based on participant preference.

Questionnaire data collection in the ED

The pre-intervention questionnaire (Appendix H), intervention or sham video, and post-intervention questionnaire 1 (Appendix I) were delivered seamlessly via the electronic platform on the iPad in the ED waiting room. During this process, the data collector was available nearby to answer questions or assist with technology. Disposable headphones were provided to participants to maintain blinding and reduce noise in the busy clinical environment.

Two issues were encountered in the study period that affected ED data collection. First, the final survey question (i.e., 15-point scale to assess decision regret) did not appear in four questionnaires as of January 10, 2018 (i.e., 31 days into data collection period). To trouble-shoot

this issue, the iPad settings were changed so that closing the cover did not automatically put the iPad to sleep because the iCare Adventure app is programmed to delete data immediately after upload and the iPad cover and/or Wi-Fi connectivity could potentially interfere with this process (completed on Jan. 15, 2018). Mr. Wilcox also added an extra screen to end of the questionnaire (i.e., a reminder to return iPad to data collector) to increase the time lag so that the data could be uploaded to the remote server and deleted without interfering with questionnaire content (completed on Jan. 16, 2018). Second, on the evening of February 22, 2018, the app expired and was not usable for data collection. On the same evening, Mr. Wilcox renewed the platform and restored the app. Data collectors updated the app on the iPads the next day and functionality resumed.

Post-intervention questionnaire 2 data collection at home

Post-intervention questionnaire 2 (Appendix J) was conducted via email 4–10 days post-ED visit on participants own electronic devices (i.e., smartphone, tablet, laptop, desktop). Electronic reminders (Appendix K) to complete post-intervention questionnaire 2 were sent via email on day 6, day 8, and day 10 post-ED visit or until the survey was completed. The pre-intervention, post-intervention 1, and post-intervention 2 questionnaires were linked in the database via individual identifiers.

Three issues were encountered during the study period that affected follow-up questionnaire data collection. First, post-intervention questionnaire 2 was emailed at the incorrect time from November 30 to December 5, 2017. The error was due to a flaw in the platform logic. Emails were sent to participants immediately after completing the post-intervention questionnaire 1 and not four days post-ED visit as planned. The error affected seven participants. It was corrected as of December 6, 2017. The second error related to post-

intervention questionnaire 2 email reminders. The reminders were not initially programmed and, therefore, not sent from November 30 to December 14, 2017. This error affected 13 participants. On December 14, prior participants received 1 email reminder to complete post-intervention questionnaire 2 (i.e., 15 days into the data collection period) and future participants received the planned three email reminders (i.e., day 6, 8, and 10 post-ED visit). Finally, one question in post-intervention questionnaire 2 did not register any data in one survey on January 15, 2018. Mr. Wilcox could not locate source of error, but continuously monitored issue during data collection period.

Interview data collection

Semi-structured, individual interviews (Appendix L) were conducted with experimental group participants only. Participants were offered the option of meeting in-person for the interview or completing them over the telephone. All participants selected a telephone interview.

Interviews were audio recorded using an app called Call Recorder [28]. This app has the functionality to obtain high quality recordings of both sides of a telephone call. Audio recordings were transcribed verbatim by the researcher into text files for analysis.

Survey data management

Study data collected within the electronic platform were uploaded automatically to a remote Canadian server at four time points: 1) after study eligibility criteria were reviewed, 2) after the informed consent process, 3) at the end of the post-intervention questionnaire 1, and 4) at the end of post-intervention questionnaire 2. If a participant did not meet the eligibility criteria or provide consent, data were uploaded and the survey automatically re-started. If a participant did not fully complete the questionnaires, there were two means of initiating a data upload. In the ED, the iCare Adventure app on the iPad had to be force quit in order to trigger a data upload.

The app then needed to be re-started for a new user. At home, the data upload was initiated when the participant closed their browser window.

All content within iCare Adventure were controlled on a centralized, secure, Canadian server. When the application restarted, it called to the server and the iPads reported encrypted user interactions back to the server in real-time. The server then dynamically created real-time reports of the aggregated data.

Questionnaire data were securely downloaded via a password protected portal weekly. Data snapshot reports were generated by the researcher. The purpose was to monitor data quality and identify any technical or data issues. Data were stored on a secure server at the University of Alberta.

Data analysis

Questionnaire data were downloaded as a CSV file. CSV files were converted into MS Excel files for data cleaning by the researcher. Variables were recoded into categorical variables, free-text responses were grouped and re-coded, knowledge and decision regret items were scored. A data cleaning log was maintained by the researcher.

Quantitative data analysis was performed by the researcher using SPPS version 26 [29]. Data analyses proposed in the study protocol and performed at study completion are compared and described in Table 5.3. Changes to the analytic plan, including rationale and supporting data, are described in the following paragraphs. Results of these analyses are presented in Chapter 6.

Table 5.3: Proposed and Performed Data Analysis Methods by Domain.

Study Domain	**Outcomes & Outcome Measures**	**Proposed Data Analysis Methods**	**Data Analysis Methods Performed**
Process Domain	**Quantitative:** Consent rate will be measured by: 1) percentage of people approached who	Descriptive statistics	Descriptive statistics

	consent to participate; 2) timing (date, time of day) of refusals.		
	Quantitative: Recruitment rate will be measured by: 1) percentage of people who consented to participate and complete baseline, post-intervention, and follow-up surveys and qualitative interview; 2) timing (date, time of day) of recruitment.	Descriptive statistics	Descriptive statistics
	Quantitative: Data completion will be measured by: 1) percentage of missing/blank survey items; 2) percentage of drop-outs at follow-up survey.	Descriptive statistics	Descriptive statistics
	Qualitative: Satisfaction with electronic platform will be evaluated via a qualitative interview.	Thematic analysis	Data summarized and quotes presented
	Quantitative: Consent rate will be measured by: 1) percentage of people approached who consent to participate; 2) timing (date, time of day) of refusals.	Descriptive statistics	Descriptive statistics
Scientific Domain	**Quantitative:** Parental knowledge will be evaluated using an 8-item knowledge questionnaire.	Confidence intervals (CI) for the difference of means (paired) for time 1 to time 2 and time 2 to time 3	• Shapiro-Wilk test of normality • Wilcoxon signed rank test for time 1 to time 2 • Related-samples Hodges-Lehmann median difference confidence intervals for time 1 to time 2 • Chi-square test of homogeneity & Fisher's exact test • Descriptive statistics for time 3
	Quantitative: Decision regret will be measured by the Decision Regret Scale comprised of 5, 5-point Likert items.	Confidence intervals (CI) for the difference of means (paired) for time 1 to	• Shapiro-Wilk test of normality • Wilcoxon signed rank test for time 1 to time 2

		time 2 and time 2 to time 3	• Related-samples Hodges-Lehmann median difference confidence intervals for time 1 to time 2 • Descriptive statistics for time 3
	Quantitative: Minimum clinically important difference (MCID) estimates	• Anchor-based method using 15-point global rating scale at time 2 and time 3 • Distribution-based method using SEM as proxy at time 2 and time 3	• Anchor-based method using 15-point global rating scale at time 2 • Distribution-based method using SEM as proxy at time 2 and time 3
	Quantitative: Self-rated improvement in knowledge and decision regret score	N/A	• Shapiro-Wilk test of normality • Mann-Whitney U test for time 2 • Descriptive statistics for time 3
	Quantitative: Sample size estimate for full-trial	Not specified	Calculation performed for comparing paired differences using MCID as effect size.
	Quantitative: Post-ED healthcare utilization will be assessed by 3 items developed by the research team.	Descriptive statistics	Descriptive statistics
	Quantitative: The perceived benefit and value of the KT intervention for pediatric AGE will be evaluated using 4 items developed by the research team and by examining the number of participants that request a video link after questionnaire 1.	Descriptive statistics	Descriptive statistics
	Qualitative: The perceived benefit and value of the KT intervention for pediatric AGE	Thematic analysis of interview data	Data summarized and quotes presented

	will be also evaluated via a qualitative interview.	will be conducted.	
Management Domain	**Quantitative:** Data quality will be measured by number, type, and duration of technical problems with online platform throughout study period.	Descriptive statistics	Descriptive statistics
	Qualitative: Parents' willingness to participate in future, similar research will be evaluated via a qualitative interview.	Thematic analysis	Data summarized and quotes presented
Resource Domain	**Quantitative:** Time to collect data will be measured by: 1) average length of time to complete study questionnaires; 2) average length of time (days) to complete post-intervention questionnaire 2 post-discharge.	Descriptive statistics	Descriptive statistics
	Quantitative: The feasibility of using iPads to collect data in the ED with parents/caregivers will be measured by tracking the number of broken, lost or stolen iPads and peripheral equipment.	Descriptive statistics	Descriptive statistics

Quantitative analyses were intended to be intention-to-treat; however, for the pre-intervention and post-intervention 1 questionnaires, the amount of missing data was under the 5% threshold for performing imputation and thus complete case analysis was performed [30]. At post-intervention questionnaire 2, there was significant loss-to-follow-up and missing data was too numerous to conduct any imputation method [30]. Instead, descriptive analysis was performed.

Descriptive statistics were calculated to describe study groups. Descriptive statistics were also calculated to describe the following measures: health care utilization, perceived benefit and value of the intervention measures, consent rate, recruitment rate, data completion rate, data quality, time to collect data, and feasibility of using iPads to collect data. The chi-square test of

homogeneity was used to assess differences between the two study groups on multinomial and binomial dependent variables. Where the sample size was inadequate, a Fisher's exact test was performed.

To understand the distribution of the data collected in this pilot study and determine the most suitable analytic approach, a Shapiro-Wilk test of normality was performed for knowledge and decision regret scores and improvement ratings. A significance value less than 0.05 indicated that the data significantly deviated from a normal distribution (see Table 5.4); thus, non-parametric tests were performed. The analytic plan detailed in Chapter 4 did not account for non-normal data distribution; therefore, the following two paragraphs detail the revised analytic plan, including analytic tests, suitable for non-normal data.

Table 5.4: Shapiro Wilk Test of Normality for Knowledge and Decision Regret Scores.

Outcome measure	**Intervention group**	**Shapiro Wilk Test of Normality**		
		Statistic	Df	Sig.
Knowledge Score Time 1	Control group	0.856	20	**0.007**
	Intervention group	0.860	22	**0.005**
Knowledge Score Time 2	Control group	0.882	20	**0.019**
	Intervention group	0.947	22	0.280
Knowledge Improvement Rating	Control group	0.725	19	**0.000**
	Intervention group	0.893	19	**0.037**
Decision Regret Score Time 1	Control group	0.931	20	0.159
	Intervention group	0.924	22	0.091
Decision Regret Score Time 2	Control group	0.878	20	**0.016**
	Intervention group	0.910	22	**0.047**
Decision Regret Improvement Rating	Control group	0.766	19	**0.000**
	Intervention group	0.744	19	**0.000**

The Wilcoxon signed rank test, a non-parametric equivalent to the paired-samples t-test, was performed to evaluate parental knowledge and decision regret scores from pre-intervention to post-intervention 1 questionnaires. Related-samples Hodges-Lehmann median difference confidence intervals (i.e., 99%, 95%, 90%, 85%, 80%, 75%) were generated for the median

difference between pre-intervention to post-intervention 1 questionnaires for both outcome measures. The chi-square test of homogeneity and Fisher's exact test were performed to examine individual knowledge items at pre-intervention and post-intervention questionnaires 1. A Mann-Whitney U test was performed to determine if there were differences between the study groups on self-rated improvement on knowledge and decision regret scores at post-intervention questionnaire 1. This test is a non-parametric equivalent to the independent-samples t-test. Given the large and differential loss-to-follow-up at Time 3, comparisons for knowledge and decision regret outcome measures between the study groups at post-intervention questionnaire 2 could not be calculated. Instead, descriptive statistics were calculated.

Two methods were used to generate minimum clinically important difference (MCID) estimates for the knowledge and decision regret outcome measures at post-intervention questionnaire 1. The first approach was an anchor-based method that defined the MCID as the change in patient-reported outcome scores of a group of participants according to their answers to a global assessment scale. In the survey, participants self-rated their change on a 15-point global scale and the MCID for this study was defined as the mean change in score of the "slightly improved" group (Table 5.5) [31,32].

The second approach was a distribution-based method that defined the MCID as the change in patient-reported outcomes scores to a measure of variability, in the case the standard error of measurement (SEM). The SEM is the variation in scores due to the unreliability of the measure. The MCID was defined as the value of 1 SEM where SEM is defined as baseline SD × the square root of one minus Cronbach's alpha [31,32]. Due to small sample size, MCIDs could not be generated for post-intervention questionnaire 2 using either method.

Table 5.5: Global Rating Scale for MCID Estimation.

15-point global rating scale	Participant categories
-7 to -5	Much worse
-4 to -2	Slightly worse
-1 to +1	No change
+2 to +4	**Slightly improved**
+5 to +7	Much improved

A sample size estimation for future, full-scale trial was conducted for comparing paired differences. The MCID for parental knowledge score was set as the effect size estimate. Alpha was set at 0.05 and power was set at 80%. A second calculation was performed with the power set at 90% and all other parameters the same.

Interview data were transcribed verbatim by LA into MS Word. Due to a dearth of data (n=2), formal qualitative data analyses were not performed. Interview data were summarized and illustrative quotes presented.

Discussion

The experience of conducting a pilot PRCT has reinforced the critical importance of this investment prior to a full-scale, PRCT. Previous research has established that pilot studies play an important role in justifying the need for a full-scale PRCT [33,34]. Furthermore, pilot trials are an important preliminary step to ensure PRCT methods and resources are appropriate and achievable before significant resources are invested [33]. It has been demonstrated that publishing the results of well conducted pilot and/or feasibility studies is important to advance science, irrespective of study outcome [35]. Unfortunately, pilot studies are often conducted in place of full-scale RCTs due to lack of resources and a short timeline [5]; this practice is not methodologically sound. Current best practice for pilot studies are to: assess feasibility, be rigorously designed, be thoroughly reported, and to draw connections to the justification and/or planning of a future study [5]; however, formal methodological guidance on the conduct and

reporting of pilot studies is emergent [5,33, 35, 36]. Detailing the process of pilot trial implementation has revealed the complexity of a methodologically rigorous pilot pragmatic randomized trial, highlighted the ways in which real-world implementation can deviate from planned protocols, demonstrated the significant time invested before and during the study period to ensure appropriate implementation, and underscored critical areas for detailed planning of a full-scale trial to avoid the same unanticipated issues that arose in this study.

A number of successful study components were confirmed during pilot trial implementation. Participant screening using the EDIS system and recruitment using the electronic iCare Adventure platform on the iPads within the ED resulted in identifying the appropriate study population. Approaching participants in the ED waiting room after their triage assessment and before the physician consultation was an appropriate time to conduct research recruitment and data collection. Data collection and intervention delivery using iCare Adventure on the iPads within the ED resulted in effective block randomization sequences, maintained blinding, established intervention fidelity, and resulted in high quality data. The iCare Adventure platform also allowed for effective data management. All of these elements could be successfully deployed in a full-scale trial.

As with any pilot study, a number of issues were also identified. Remedying these aspects would improve the implementation of a full-scale, effectiveness trial and optimize study results. Unsurprisingly, the issues identified centered on participant recruitment and retention. Prior research has demonstrated that approximately 50% of trials do not meet recruitment targets, even with an extension [37,38]. Additionally, high quality evidence on recruitment interventions is lacking [38-41]. It is likely that a multi-faceted approach is required, as some of the unsuccessful pilot trial elements could be addressed with a simple change (i.e., different study time frame) and

other elements may require a substantive methodological re-design to facilitate the implementation of a successful full-scale trial (i.e., revised follow-up data collection strategy). Considerations for improvement in future studies are detailed in the following five paragraphs.

The first substantive methodological issue was the different inclusion/exclusion criteria implemented before and after 3pm to accommodate the other ongoing study recruiting from the same population. This added complexity to participant recruitment had the potential to introduce recruiter error and result in less than optimal study enrollment. Confusion between the two criteria was mitigated in a few ways. First, by implementing different screening checklists in the iCare Adventure platform based on time of day. Second, by having data collectors only work one of the two time periods for the duration of the study period. Third, through data collector training sessions. However, having two studies drawing from the same population was not ideal and it is likely that the modified screening criteria used after 3pm, which is typically the busiest time in an ED, reduced the pool of potential participants at that time of day and slowed recruitment efforts.

In reality, studies 'competing' for the same population is a difficult conflict to overcome. Advance planning and coordination are required to reserve the necessary time to conduct the research in the ED environment and to ensure there is no overlap with other study populations, but this is not always feasible. In this instance, the other ongoing study was scheduled to collect data over the course of five years; this was too long to wait. Additionally, in some hospitals, there is no central coordinating department for research studies, which could make identifying the target populations of other ongoing studies difficult or impossible. Futures suggestions could be for hospitals to make a list of current studies, their topics, and their time frames available to interested researchers and/or the public. Additionally, a mechanism within existing research

ethics and/or administrative approval submission processes could identify and share this information with relevant parties.

Second, despite the best efforts of the ED research team, this study experienced inconsistent availability and scheduling of volunteer data collectors in the evenings. This was exacerbated by communication gaps between the ED research team and the study team, which meant that the availability issues were only identified and discussed retrospectively. Monthly meetings were not sufficient to anticipate and resolve this issue; more frequent meetings and/or access to the scheduling system may have helped. A sufficient research budget to support paid data collection services could be the best approach to establish clear time commitments from data collectors.

Third, there was significant loss-to-follow up at post-intervention questionnaire 2 and the individual interview. This impacted data quality and restricted data analysis options. In the implementation of a full-scale trial, it would be important to-re-think this aspect of the study design. For example, the follow-up data collection reminders and/or the post-intervention questionnaire 2 could be administered by telephone; however, this may not be effective as it proved difficult to contact potential interview participants and there was a relatively high no-show rate after study telephone calls. Another option could be to expand functionality of the iCare Adventure platform to disperse incentives upon completion of these study components. This would need to be vetted in the research ethics approval process and integrated into the study information letter and informed consent process. It would require a sufficient budget and appropriate incentives that are meaningful rewards for study participants in exchange for their time. Future research could explore the allocation and value of such incentives at various stages of the trial process.

A stand-alone or embedded qualitative or mixed methods research study focused on the recruitment process of a full-scale trial could be an additional solution to address study enrollment and follow-up data collection gaps identified in this pilot study. Prior qualitative research has demonstrated that parents are willing and able to consult on RCT design and that this contribution is valuable to a trial's success [42]. However, it is important to note that continuous engagement of health consumers in the research process is a key aspect of patient- and family-oriented research to avoid tokenism [43]. As one example of how this could be achieved, The Prioritising Recruitment in randomized Trials study (PRioRiTy) successfully employed a James Lind Alliance priority setting partnership to examine trial recruitment methods and identified the following key criteria to optimize recruitment: normalize trials as part of clinical care; enhance communication; address barriers, enablers and motivators around participation, and; explore greater public involvement in the research process [44]. A similar priority setting process could be used, with the learnings applied from the PRioRiTy study, to guide a potential qualitative study and improve recruitment in the implementation of a future, full-scale trial [44,45].

It is important to note that the technical errors that occurred over the course of this study were valuable learning opportunities and demonstrated the vital importance of real-world pilot testing and pilot studies. The errors that had the most impact on data quality (i.e., immediate emailing of post-intervention questionnaire 2, lack of follow-up questionnaire reminders) occurred in the first two weeks of data collection. This may point to the need for more robust pilot testing methods before study implementation with a minimum two-week time frame. Pilot testing rigor could be enhanced in a couple of ways: 1) conduct pilot testing in the same ED environment with simulated patients, or; 2) use the first two weeks of the study period as a 'pilot

testing' phase with real participants. It would be important to determine the research team's capacity to address issues quickly and make necessary changes before deciding which approach is best.

Finally, a more robust and detailed analytical plan would be beneficial in the development of an apriori protocol. To reduce the potential for bias, it is important to specify procedures to evaluate the distribution of the data ultimately collected and detail how analyses would proceed with in the case of either normally distributed or non-normally distributed datasets. Methods for preventing and addressing missing data are critical and best handled at the planning and design stage of a trial [46,47]. This would ensure that the prospective analytic plan could account for important factors that will impact analyses and thus interpretation of results; create the opportunity for rigorous evaluation prior to the initiation of a full-scale trial, and; robust analyses can be performed as intended at the end of a resource intensive pragmatic randomized control trial study.

Conclusions

The pilot trial achieved its purpose of testing the feasibility of methods for evaluating a knowledge translation intervention for parents/caregivers about AGE in a real-world setting before undergoing the significant investment of a full-scale trial. In addition to confirming successful study design elements, areas for improvement were identified, as well as potential solutions to address these gaps in future. The iCare Adventure platform has now been well tested for research purposes in the ED; overall, it was an integral aspect of this study design and the experience of implementing this platform for research purposes will only strengthen its utility for future health services research applications. Exploring the factors that influenced the implementation of the pragmatic pilot randomized trial, including the protocol deviations and

real-world challenges of research in a hospital setting, contextualize the study results that are detailed in Chapter 6.

Chapter 5 References

1. Albrecht L, Scott SD, Hartling L. Evaluating a knowledge translation tool for parents about pediatric acute gastroenteritis: a pilot randomized trial. *BMC Pilot & Feasibility Studies*. 2018:4(131). doi: 10.1186/s40814-018-0318-0
2. Patsopoulos NA. A pragmatic view on pragmatic trials. *Dialogues Clin Neuro*. 2011;13(2): 217-224.
3. Thabane L, Lancaster G. Improving the efficiency of trials using innovative pilot designs: the next phase in the conduct and reporting of pilot and feasibility studies. *Pilot and Feasibility Studies*. 2017;4(14). doi: 10.1186/s40814-017-0159-2
4. Albrecht L, Hartling L, Scott SD. Pediatric acute gastroenteritis: understanding caregivers' experiences and information needs. *CJEM*. 2016;1-9. doi: 10.1017/cem.2016.363
5. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. 2010;10(1). doi: 10.1186/1471-2288-10-1
6. Coulter C, Ellins J. Effectiveness of strategies for informing, educating, and involving patients. *BMJ.* 2007;335(7609):24-27. doi: 10.1136/bmj.39246.581169.80
7. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council Guidance. *BMJ*. 2008;337:a1655. doi: 10.1136/bmj.a1655
8. Davies P, Walker AE, Grimshaw JM. A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. *Implem Sci*. 2010;5(114). doi: 10.1186/1748-5908-5-14
9. Michie S, Fixsen D, Grimshaw JM, Eccles MP. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implem Sci*. 2009;4(40).

10. Albrecht L, Archibald M, Arseneau D, Scott SD. Development of a checklist to assess the quality of reporting of knowledge translation interventions using the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. *Implem Sci*. 2013;8(52). doi: 10.1186/1748-5908-8-52
11. Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-207. doi: 10.7326/0003-4819-158-3-201302050-00583
12. Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ.* 2013;346:e7586. doi: 10.1136/bmj.e7586
13. Chalmers I, Altman DG. How can medical journals help prevent poor medical research? Some opportunities presented by electronic publishing. *The Lancet*. 1999;353(9151):490-493. doi: 10.1016/S0140-6736(98)07618-1
14. Eldridge SM, Chan CL, Campbell MJ, et al., PAFS consensus group. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot and Feasibility Studies*. 2016;2(64). doi 10.1186/s40814-016-0105-8
15. Thabane L, Hopewell S, Lancaster GA, et al. Methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials. *Pilot Feasibility Stud*. 2016;2(25). doi: 10.1186/s40814-016-0065-z
16. Alberta Health Services. Stollery Children's Hospital. AlbertaHealthServices.ca. https://www.albertahealthservices.ca/stollery/Page14264.aspx. Accessed on Nov. 19, 2019.
17. University of Alberta. Faculty of Medicine & Dentistry: Pediatrics. Ualberta.ca. https://www.ualberta.ca/pediatrics/divisions/emergency-medicine. Updated 2020. Accessed on Nov. 19, 2019.

18. Health Quality Council of Alberta Focus on Healthcare: Patient time to see an emergency doctor. Focus.HQCA.ca. https://focus.hqca.ca/emergencydepartments/patients-time-to-see-an-emergency-doctor/. Updated 2020. Accessed on Nov. 19, 2019.
19. Alberta Health Services. Stollery Children's Hospital: Current child health research studies. AlbertaHealthServices.ca. https://www.albertahealthservices.ca/assets/hospitals/stollery/stollery-research-studies.pdf. Updated Oct. 19, 2018. Accessed Nov. 19, 2019.
20. Freedman SB, Lee BE, Louie M, et al. Alberta Provincial Pediatric EnTeric Infection Team (APPETITE): epidemiology, emerging organisms, and economics. *BMC Pediatr*. 2015:15:89.
21. EverAge Consulting. iCare Adventure. EverageConsulting.com. https://www.everageconsulting.com/icare-adventure/. Accessed Dec. 1, 2019.
22. Elliott EJ. Acute gastroenteritis in children. *BMJ*. 2007;334(7583):35-40.
23. Cocks K, Torgerson DJ. Sample size calculations for pilot randomized trials: a confidence interval approach. *J Clin Epidemiol*. 2013;66(2):197–201. doi: 10.1016/j.jclinepi.2012.09.002
24. Whitehead A, Julious S, Cooper C, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res*. 2016;25(3):1057–1073. doi: 10.1177/0962280215588241
25. Bell ML, Whitehead AL, Julious SA. Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. *Clin Epidemiol*. 2018;10:153-157. doi: 10.2147/CLEP.S146397

26. University of Alberta. The use of incentives in research. Ualberta.ca. https://www.ualberta.ca/research/support/ethics-office/human-research-ethics/use-of-incentives-in-research. Updated 2020. Accessed December 2, 2019.
27. Logibec Canada. Clinical solutions: Emergency Department Information System (EDIS). Logibec.com. https://www.logibec.com/en/products/emergency-department-information-system-edis/. Published 2016. Accessed December 4, 2019.
28. Tellstar. Call Recorder – IntCall. Tellstarint.net. https://www.telestarint.net/call-recorder. Accessed on Dec. 11, 2019.
29. IBM SPSS Statistics for Windows [quantitative data analysis software]. Version 26. IBM Corp; 2019.
30. Jakobsen JC, Gluud C, Wetterslev J, Winkel P. When and how should multiple imputation be used for handling missing data in randomised clinical trials – a practical guide with flowcharts. *BMC Med Res Methodol. 2017;*17(1):162. doi: 10.1186/s12874-017-0442-1
31. Copay AG, Subach BR, Glassman SD, Polly DW, Schuler TC. Understanding the minimum clinically important difference: a review of concepts and methods. *Spine J*. 2007;7:541-546. doi: 10.1016/j.spinee.2007.01.008
32. Wells G, Beaton D, Shea B, Boers M, Simon L, Strand V, Brooks P, Tugwell P. *J Rheumatol*. 2001;28(2):406-412.
33. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: Recommendations for good practice. *J Eval Clin Pract*. 2004;10(2):307-312. doi: 10.1111/j..2002.384.doc.x

34. Medical Research Council. Developing and evaluating complex interventions. MRC.ukri.org. https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/. Accessed December 8, 2019.
35. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol*. 2010;10(67). doi: 10.1186/1471-2288-10-67
36. Shanyinde M, Pickering RM, Weatherall M. Questions asked and answered in pilot and feasibility randomized controlled trials. *BMC Med Res Methodol*. 2011;11(117). doi: 10.1186/1471-2288-11-117
37. McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials*. 2006;7(9).
38. Gardner H, Fraser C, MacLennan G, Treweek S. A protocol for a systematic review of non-randomised evaluations of strategies to improve participant recruitment to randomised controlled trials. *Syst Rev*. 2016;5(131). doi: 10.1186/s13643-016-0308-3
39. Bower P, Brueton V, Gamble C, Treweek S, Tudur Smith C, Young B, Williamson P. Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. *Trials*. 2014;15(399). doi: 10.1186/1745-6215-15-399
40. Treweek S, Mitchell E, Pitkethly M, et al. Strategies to improve recruitment to randomised controlled trials. *Cochrane Database Syst Rev*. 2010;2:MR000013. doi: 10.1002/14651858.MR000013.pub6

41. Treweek S, Lockhart P, Pitkethly M, et al. Methods to improve recruitment to randomized controlled trials: Cochrane systematic review and meta-analysis. *BMJ Open*. 2013;3:e002360.

42. Edwards V, Wyatt K, Logan S, Britten N. Consulting parents about the design of a randomized controlled trial of osteopathy for children with cerebral palsy. *Health Expectations*. 2011;14(4):429-438. doi: 10.1111/j.1369-7625.2010.00652.x

43. Domecq JP, Prutsky G, Elraiyah T et al. Patient engagement in research: a systematic review. *BMC Health Serv Res*. 2014;14(89). doi: 10.1186/1472-6963-14-89

44. Healy P, Galvin S, Williamson PR, et al. Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership – the PRioRiTy (Prioritising Recruitment in Randomised Trials) study. *Trials*. 2018;19(1):147. doi: 10.1186/s13063-018-2544-4.

45. Hennessy M, Hunter A, Healy P, Galvin S, Houghton C. Improving trial recruitment processes: how qualitative methodologies can be used to address the top 10 research priorities identified within the PRioRiTy study. *Trials.* 2018;19(1): 584. doi: 10.1186/s13063-018-2964-1

46. Bell ML, Fiero M, Horton NJ, Hsu CH. Handling missing data in RCTs: a review of the top medical journals. *BMC Med Res Methodol*. 2014;14**(**118). doi:10.1186/1471-2288-14-118

47. Jakobsen JC, Gluud C, Wetterslev J, Winkel P. When and how should multiple imputation be used for handling missing data in randomised clinical trials – a practical guide with flowcharts. *BMC Med Res Methodol*. 2017*;*17(162). doi:10.1186/s12874-017-0442-1

Chapter 6 - Results of a pragmatic pilot randomized trial to evaluate a knowledge translation tool for parents about pediatric acute gastroenteritis

Methods overview

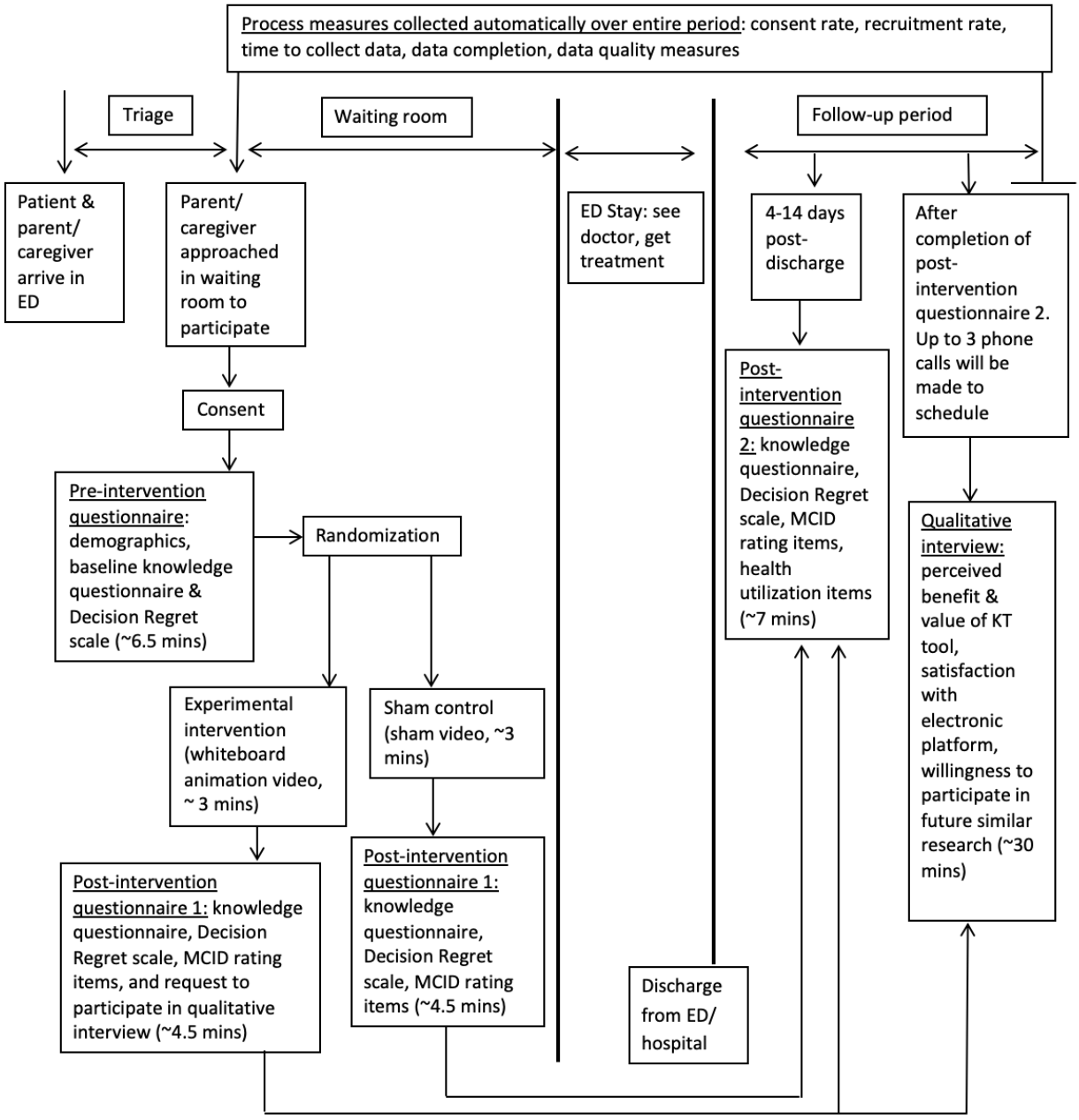
The purpose of this study was to determine the feasibility of pragmatic randomized controlled trial (PRCT) methods to evaluate a multimedia knowledge translation (KT) tool for parents about pediatric acute gastroenteritis (AGE). The development of the multimedia KT tool was described in Chapters 1 and 3; it was designed to meet identified knowledge needs and to provide explicit recommendations on home management, assessing illness severity, and health care seeking. The study protocol is outlined in Chapter 4. Study implementation processes, including changes to the study protocol, are described in Chapter 5. This chapter presents the results of pragmatic pilot trial data analyses.

Parents/caregivers seeking medical care for a child with AGE in one pediatric emergency department (ED) were randomized to receive a 3-minute, whiteboard animation video about the treatment and management of AGE, or a sham control video on handwashing as infection control of approximately the same length. The pilot trial employed quantitative and qualitative methods to evaluate the feasibility objectives in four key domains at three time periods. These outcome domains were: 1) process; 2) scientific; 3) management; and, 4) resource [1].

Multiple outcomes and measures were evaluated via questionnaires at pre-intervention, post-intervention 1, and post-intervention 2, and also via an individual interview with experimental group participants only. The pre-intervention questionnaire, intervention delivery, and post-intervention questionnaire 1 took place within the ED waiting room. Post-intervention questionnaire 2 and the individual interview took place at home. Quantitative study data

collection was facilitated by an electronic data collection platform called iCare Adventure both in the ED and afterwards. Figure 6.1 illustrates the study flow and timing of data collection.

Figure 6.1: Trial Flow & Timing of Data Collection.



Results

Over the course of approximately three months (November 30, 2017 to February 27, 2018), 42 individuals participated in the pilot PRCT. These 42 participants were randomly allocated in variable blocks to either the control or intervention conditions; 20 participants were assigned to the control group and 22 to the intervention group. Consent, recruitment, and completion/drop-out rates are detailed under the Process domain outcomes section.

Participant demographics at baseline are described in Table 6.1. Demographic variables were compared between the two study conditions using the chi-square test of homogeneity or, where sample sizes were inadequate, a Fisher's exact test. There were no statistically significant differences between groups on demographic variables.

Table 6.1: Participant Demographics at Baseline by Group Assignment (n=42).

Demographic variables		**Control group (n=20) n (%)**	**Intervention group (n=22) n (%)**	**p-value**
Gender	Female	17 (85.0)	19 (86.4)	1.00
	Male	3 (15.0)	3 (13.6)	
	Other	0 (0.0)	0 (0.0)	
	Prefer not to answer	0 (0.0)	0 (0.0)	
Birth Year	1970-1974	1 (5.0)	0 (0.0)	0.93
	1975-1979	4 (20.0)	3 (13.6)	
	1980-1984	7 (35.0)	8 (36.4)	
	1985-1989	7 (35.0)	9 (40.9	
	1990-1994	1 (5.0)	2 (9.1)	
Ethnicity	White	7 (35.0)	12 (54.5)	0.32
	Aboriginal	0 (0.0)	0 (0.0)	
	South Asian	2 (10.0)	3 (13.6)	
	Chinese	2 (10.0)	0 (0.0)	
	Black	1 (5.0)	3 (13.6)	
	Filipino	2 (10.0)	0 (0.0)	
	Latin American	2 (10.0)	1 (4.5)	
	Arab	1 (5.0)	0 (0)	
	Southeast Asian	1 (5.0)	0 (0)	
	West Asian	0 (0)	0 (0)	
	Korean	0 (0)	0 (0)	

	Japanese	0 (0)	0 (0)	
	Other	0 (0)	2 (9.1)	
	Prefer not to answer	2 (10.0)	1 (4.5)	
Citizenship status	Canadian by birth	8 (40.0)	11 (50)	0.08
	Canadian by naturalization	9 (45.0)	3 (13.6)	
	Citizen of another country	2 (10.0)	7 (31.8)	
	Prefer not to answer	1 (5.0)	1 (4.5)	
Relationship status	Single	4 (20.0)	4 (18.2)	0.92
	Partnered	14 (70.0)	17 (77.3)	
	Other	1 (5.0)	1 (4.5)	
	Prefer not to answer	1 (5.0)	0 (0.0)	
Highest level of education completed	High school diploma/equivalency	5 (25.0)	7 (31.8)	0.36
	Certificate of apprenticeship/certificate of qualification as journeyperson	0 (0)	0 (0)	
	College, CEGEP or other non-university certificate/diploma	2 (10.0)	4 (18.2)	
	University certificate/diploma	1 (5.0)	4 (18.2)	
	Bachelor degree	7 (35.0)	5 (22.7)	
	Graduate degree	3 (15.0)	0 (0.0)	
	Prefer not to answer	2 (10.0)	2 (9.1)	
Parental role	Mother	17 (85.0)	19 (86.4)	1.00
	Father	3 (15.0)	3 (15.0)	
	Other	0 (0.0)	0 (0.0	
	Prefer not to answer	0 (0.0)	0 (0.0)	
Number of children	1	8 (40.0)	6 (27.3)	0.31
	2	11 (55.0)	10 (45.5)	
	3	1 (5.0	5 (22.7)	
	4	0 (0.0)	1 (4.5)	
Ill child's age	Under 1 year old	4 (20.0)	3 (13.6)	0.19
	1-2 years old	6 (30.0)	11 (50.0)	
	3-5 years old	9 (45.0)	4 (18.2)	
	6-10 years old	1 (5.0)	4 (18.2)	
Ill child's gender	Female	9 (45.0)	10 (45.5)	1.00
	Male	12 (54.5)	11 (55.0)	
	Other	0 (0.0)	0 (0.0)	
Ill child experience vomiting & diarrhea in the past	Yes	14 (70.0)	16 (72.7)	1.00
	No	6 (30.0)	6 (27.3)	
	Unsure	0 (0.0)	0 (0.0)	

Current symptom start time	today	3 (15.0)	2 (9.1)	0.82
	1-2 days ago	7 (35.0)	8 (36.4)	
	3-5 days ago	6 (30.0)	6 (27.3)	
	6 or more days ago	3 (15.0)	6 (27.3)	
	Other	1 (5.0)	0 (0.0)	
Number of vomits in last 24 hours	None	1 (5.0)	0 (0.0)	0.18
	1 –5	16 (80.0)	15 (68.2)	
	6 –10	1 (5.0)	6 (27.3)	
	More than 10	2 (10.0)	1 (4.5)	
Number of episodes of diarrhea in last 24 hours	None	5 (25.0)	4 (18.2)	0.45
	1 –5	12 (60.0)	12 (54.5)	
	6 –10	1 (5.0)	5 (22.7)	
	More than 10	2 (10.0)	1 (4.5)	
Other members of household with vomiting and diarrhea in last month	Yes	4 (20.0)	9 (40.9)	0.42
	No	14 (70.0)	12 (54.4)	
	Unsure	2 (10.0	1 (4.5)	
Contact health professional before coming to ED today	Yes	12 (60.0)	13 (59.1)	0.95
	No	8 (40.0)	9 (40.9)	
Look up information before coming to ED today	Yes	9 (45.0)	14 (63.6)	0.23
	No	11 (55.0)	8 (36.4)	

The last two demographic questions in Table 6.1 (i.e., contacting a health professional and looking up information) were accompanied by open text fields to allow participants to describe the health professionals they contacted and where they looked for information. See Table 6.2 for responses by group assignment. Parents specifically identified a number of online resources, including: Alberta ED wait times, The Mayo Clinic, and BabyCentre.ca.

Table 6.2: Resources for Parental Information before Coming to the ED.

Intervention group	**Who did you contact for advice before coming to the ED? (n=26)**	**Where did you look for information before coming to ED? (n=24)**
Control group participant responses	Family physician/pediatrician	Internet/Google
	Physician at a walk-in clinic	Talked to a family member or friend
	HealthLink (811)	
Intervention group participant responses	Physician at a walk-in clinic	Internet/Google
	HealthLink (811)	Talked to a family member

	Pharmacist	Child's daycare provider and other parents from daycare

The post-intervention questionnaire 2 group was comprised of nine participants with unequal distribution between study conditions. Six participants that completed post-intervention questionnaire 2 were from the intervention group and three were from the control group. All post-intervention questionnaire 2 respondents were female, identified as mothers, and were born between 1982 and 1992. Eight respondents identified their ethnicity as White and one respondent self-identified as mixed ethnicity. Seven were Canadian citizens by birth, one was a Canadian citizen by naturalization, and one self-identified as holding multiple citizenships. Seven respondents were partnered and two were single. Highest level of education ranged from: high-school diploma (n=3), college, CEGEP or other non-university certificate/diploma (n=3), Bachelor's degree (n=2), and graduate degree (n=1). Two respondents had 1 child, 5 respondents had 2 children, one respondent had 3 children, and one respondent had 4 children. The ill child's age ranged from less than one year old (n=2), 1-2 years old (n=6), and 3-5 years old (n=1). Five of the ill children were male and four were female. All respondents except one indicated that their child had experienced vomiting and diarrhea in the past with current symptoms starting today (n=1), 1-2 days ago (n=3), 3-5 days ago (n=2), 6 or more days ago (n=2), and one participant indicated symptoms began 2 months ago. The number of vomits in the last 24 hours ranged from 1 to 15 and the mean number of vomit was 5.8. The number of diarrheal episodes in the last 24 hours ranged from 0 to 10 and the mean number of diarrheal episodes was 4.2. Three respondents indicated that other members of the household experienced symptoms of AGE in the past month. Seven of the nine respondents contacted a health professional for advice prior to coming to the ED and five looked for information prior to coming to the ED. See Table 6.3 for

details on the health professionals contacted and information source that respondents used before coming to the ED.

Table 6.3: Post-intervention Questionnaire 2 Parental Information Sources before Coming to the ED.

Intervention group	**Who did you contact for advice before coming to the ED? (n=7)**	**Where did you look for information before coming to ED? (n=5)**
Control group	Family physician/pediatrician	Internet/Google
	Physician at a walk-in clinic	
	HealthLink (811)	
Intervention group	Physician at a walk-in clinic	Internet/Google
	HealthLink (811)	Talked to a family member

Process domain outcomes

Consent rate

Sixty-three individuals were approached in the ED waiting room and screened for the study. Fifty-two individuals consented to participate in the study (82.5%). Eleven individuals did not consent to participate (17.5%). Figure 6.2 details the time of day of study refusals and Figure 6.3 details the day of week of study refusals.

Figure 6.2: Number of Study Refusals by Time of Day.

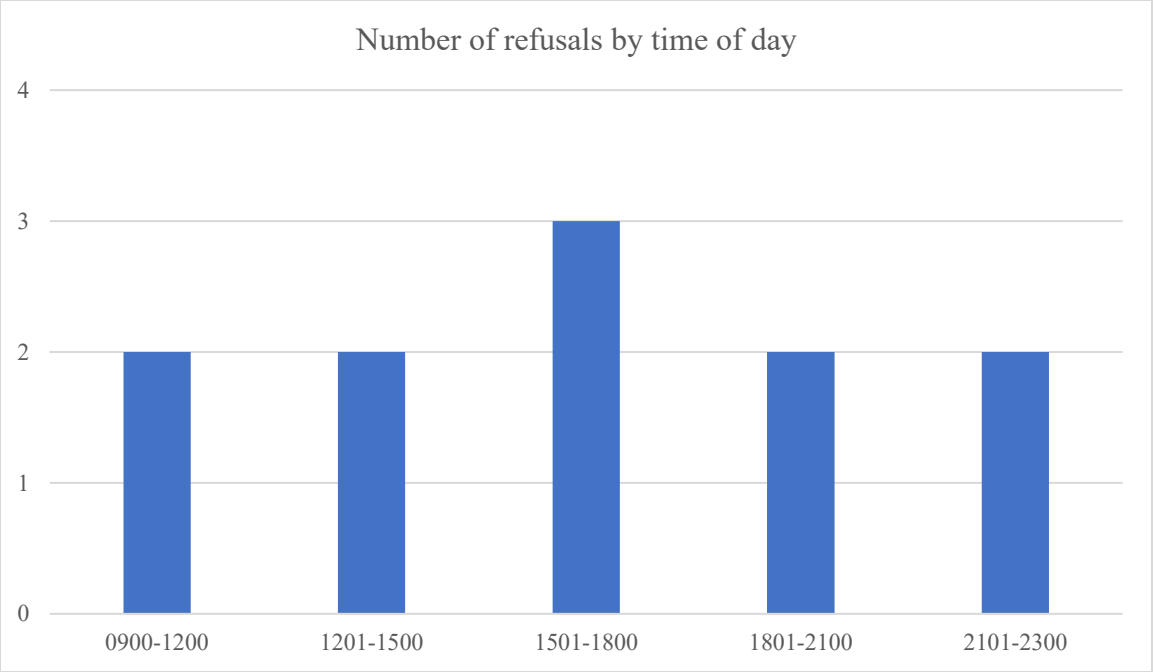
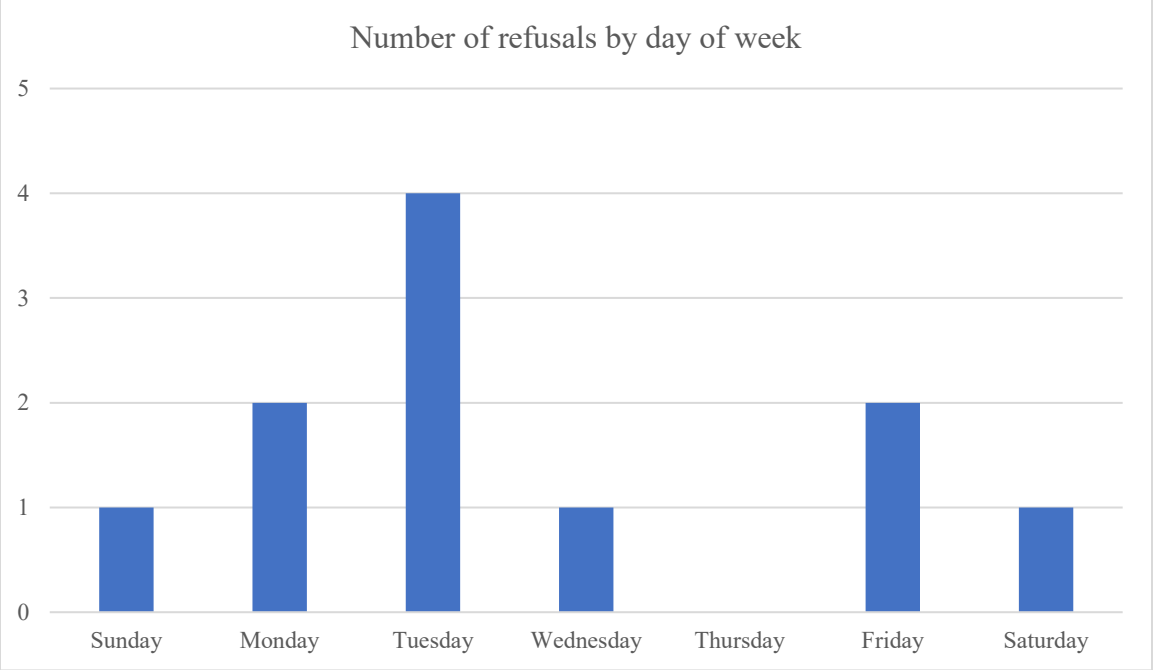


Figure 6.3: Number of Study Refusals by Day of Week.



Recruitment rate

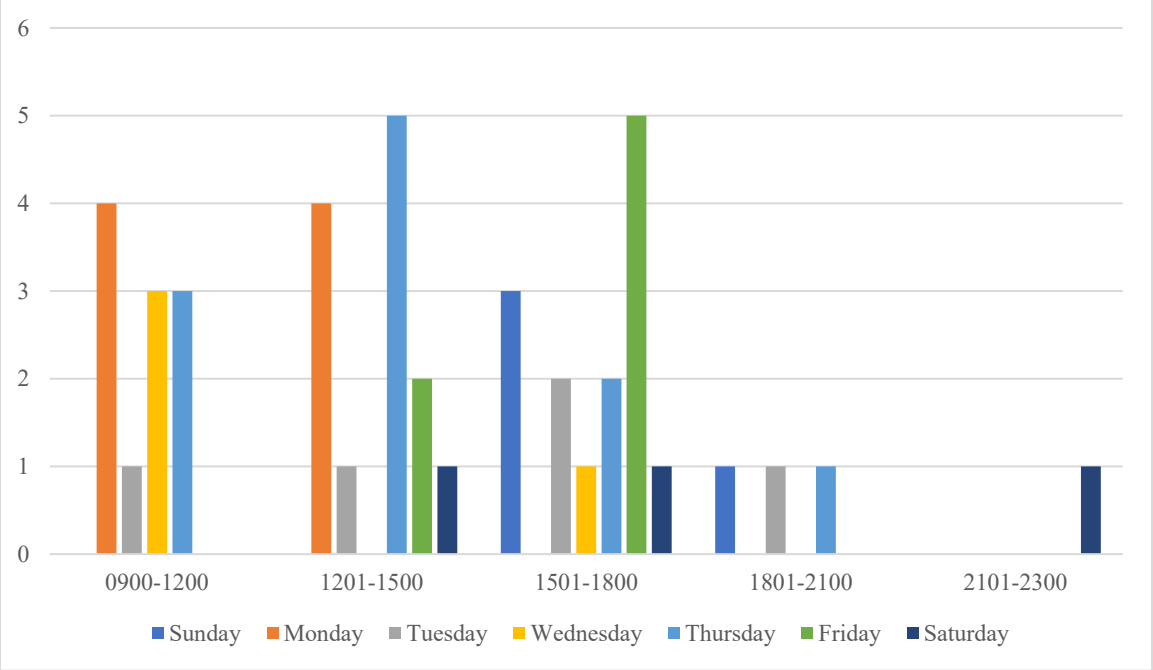
Of the 52 participants that consented to participate in the study, 45 completed the pre-intervention questionnaire and were randomized to one of the study conditions (86.5%) in the

ED. Seven of 52 participants did not complete the pre-intervention questionnaire and were not randomized to a study condition (13.5%). Table 6.4 details the screening, consent, and recruitment rate by data collector. Figure 6.4 details the number of participants recruited by time of day and day of week.

Table 6.4: Consent and Recruitment Rate by Data Collector.

Data collection phase	**Data collectors**		**Total Participants**
	LA (full eligibility criteria)	ED research volunteers & staff (modified eligibility criteria)	
Total Screened	34 (54%)	29 (46%)	63
Total Consented	30 (58%)	22 (42%)	52
Total Randomized	25 (56%)	20 (44%)	45

Figure 6.4: Number of Participants Recruited by Time of Day and Day of Week.



For the qualitative interview, 24 of 45 participants were randomized to the experimental condition (53%). Of these 24 individuals, nine agreed to be contacted about the qualitative

interview (38%) and six participants scheduled an interview. This represents 67% of those who agreed to participate in the interview (n=9) and 25% of possible participants (n=24).

Data completion and drop-out rate

For the ED data collection, 45 participants were randomized to a study condition, meaning they completed the pre-intervention questionnaire. This represents an 83% pre-intervention questionnaire completion rate (n=52). The pre-intervention drop-out rate was 13.5%

Of the 45 participants that were randomized, 42 completed post-intervention questionnaire 1. This represents a 93% post-intervention questionnaire 1 completion rate. The post-intervention questionnaire 1 drop-out rate was 6.7%.

For post-intervention questionnaire 2, 13 of 45 individuals opened the emailed link (28.9%). Of those 13 individuals, only 10 initiated post-intervention questionnaire 2, which represents 76.9% of individuals that opened the emailed link and 22.2% of possible participants (n=45). Of those 10, eight participants completed post-intervention questionnaire 2 (80%); however, 1 questionnaire had to be deleted in analysis because the participant did not complete the initial ED survey data collection. The post-intervention questionnaire 2 completion rate was 15.6%. The drop-out rate was 71.1% upon receiving the survey link (32/45) and 84.4% (38/45) at study completion.

For the qualitative interview, two of the six individuals who scheduled an interview completed the interview (33%). Three individuals did not show up for the interview at the agreed time and place and could not be reached. There was 1 cancellation due to a family emergency.

Missing/blank questionnaire items

Of the 45 individuals that were randomized, there were no missing values (0.0%) in the pre-intervention questionnaire. In the post-intervention questionnaire 1, there were 49 missing

values (2.4%) representing 16 variables (34.8%) and eight participants (17.8%). Of these missing values, 44 (89.8%) were from the same three participants who dropped out immediately after receiving their allocated intervention. An additional four values (8.1%) were attributed to a technical error on the final survey question (i.e., decision regret improvement scale). There was one missing value unaccounted for (4.1%). Given the low proportion of missing values overall (under 5%) imputation and intention-to-treat analyses were not performed. Instead, the three individuals that accounted for most of the missing values were removed from the dataset and the remaining missing values (n=5) were trimmed.

In post-intervention questionnaire 2, overall there were 718 missing values (82.2%) representing 19 variables (100%) and 39 participants (84.8%). Given the high proportion of missing values in the majority of participants, imputation could not be performed. Intention-to-treat analyses could not be performed. However, for the 9 participants that initiated the questionnaire, there were 31 missing values (19.4%) representing 16 variables (88.9%) and 2 participants (i.e., they dropped-out mid survey).

Satisfaction with electronic platform

Both participants that were interviewed expressed satisfaction with the electronic platform and experienced no technical issues. Participant 1 indicated: “I found it really good.” Participant 2 indicated: “Yeah. It was streamlined. Like it was good. I didn’t have to go to another room [in the ED] or anything like that so that was good for sure.”

Scientific domain outcomes

Parental knowledge score

The Wilcoxon signed rank test demonstrated that in the control group (n=20), the sham intervention elicited a statistically significant median decrease in knowledge score, z= -2.060, p

< 0.05 (-0.50, 0.00). While the intervention group (n=22) demonstrated a statistically significant median increase in knowledge score, z = 3.245, p=0.001 (0.50, 2.00). Varying confidence intervals are presented in Table 6.5.

Table 6.5: Wilcoxon Signed Ranks Test for Knowledge Score.

Test statistics	**Control group (n=20)**	**Intervention group (n=22)**
Z	-2.060	3.245
Asymp. Sign. (2-tailed)	**0.039**	**0.001**
99% CI	-1.00, 0.00	0.50, 2.00
95% CI	-0.50, 0.00	0.50, 2.00
90% CI	-0.50, 0.00	0.50, 2.00
85% CI	-0.50, 0.00	1.00, 1.50
80% CI	-0.50, 0.00	1.00, 1.50
75% CI	-0.50, 0.00	1.00, 1.50

Given the statistically significant change in knowledge score in both groups, individual knowledge items were examined at all three time points. Chi-square test of homogeneity and Fisher's exact test were performed to compare the control group and the intervention group on the binomial dependent variables. See Table 6.6. for pre-intervention questionnaire results and Table 6.7 for post-intervention questionnaire 1 results.

Table 6.6: Knowledge Test Items by Intervention Group at Baseline.

Knowledge item	**Item response**	**Control group (n=20) n (%)**	**Intervention group (n=22) n (%)**	**p-value**
Gastroenteritis is often caused by: [fill in the blank].	Correct	9 (45.0)	14 (63.6)	0.23
	Incorrect	11 (55.0)	8 (36.4)	
Dehydration is when: [choose the best option].	Correct	17 (85.0)	17 (77.3)	0.70*
	Incorrect	3 (15.0)	5 (22.7)	
A child is likely dehydrated if he/she: [check all that apply].	Correct	0 (0.0)	4 (18.2)	0.11*
	Incorrect	20 (100.0)	18 (81.8)	
You should take your child to the	Correct	3 (15.0)	8 (37.)	0.12
	Incorrect	17 (85.0)	14 (63.6)	

emergency department if he/she has vomiting and/or diarrhea and has: [check all that apply].				
What types of fluids are encouraged to prevent/help dehydration [choose the best option]?	Correct	13 (65.0)	11 (50.0)	0.33
	Incorrect	7 (35.0)	11 (50.0)	
Which medications are helpful for a child with gastroenteritis [check all that apply]?	Correct	5 (25.0)	3 (13.6)	0.45*
	Incorrect	15 (75.0)	19 (86.4)	
[Fill in the blank] is an example of a good oral rehydration solution to prevent and/or help dehydration.	Correct	4 (20.0)	13 (54.2)	**0.02**
	Incorrect	16 (80.0)	11 (45.8)	
If child is not dehydrated, but is vomiting and/or having diarrhea over a few days, you should take him/her to see a doctor [true or false].	Correct	18 (90.0)	16 (72.7)	0.24
	Incorrect	2 (10.0)	6 (27.3)	

*Fisher's exact test

Table 6.7: Knowledge Test Items by Intervention Group at Post-intervention Questionnaire 1.

Knowledge item	**Item response**	**Control group (n=20) n (%)**	**Intervention group (n=22) n (%)**	**p-value**
Gastroenteritis is often caused by: [fill in the blank].	Correct	4 (20.0)	15 (68.2)	**0.002**
	Incorrect	16 (80.0)	7 (31.8)	

Dehydration is when: [choose the best option].	Correct	17 (85.0)	19 (86.4)	1.00*
	Incorrect	3 (15.0)	3 (13.6)	
A child is likely dehydrated if he/she: [check all that apply].	Correct	0 (0.0)	9 (40.9)	**0.001***
	Incorrect	20 (100.0)	13 (59.1)	
You should take your child to the emergency department if he/she has vomiting and/or diarrhea and has: [check all that apply].	Correct	2 (10.0)	9 (40.9)	**0.02**
	Incorrect	18 (90.0)	13 (59.1)	
What types of fluids are encouraged to prevent/help dehydration [choose the best option]?	Correct	15 (75.0)	15 (71.4)	1.00
	Incorrect	5 (25.0)	6 (28.6)	
Which medications are helpful for a child with gastroenteritis [check all that apply]?	Correct	3 (15.0)	16 (72.7)	**0.000**
	Incorrect	17 (85.0)	6 (27.3)	
[Fill in the blank] is an example of a good oral rehydration solution to prevent and/or help dehydration.	Correct	4 (20.0)	16 (72.7)	**0.001**
	Incorrect	16 (80.0)	6 (27.3)	
If child is not dehydrated, but is vomiting and/or having diarrhea over a few days, you should take him/her to see a doctor [true or false].	Correct	17 (85.0)	17 (77.3)	0.70*
	Incorrect	3 (15.0)	5 (22.7)	

*Fisher's exact test

At post-intervention questionnaire 2 there were seven valid responses for the knowledge test. The mean parental knowledge score was 4.86 (out of a total of 8), the median was 4.0, and the mode was 3.0. The range was 3.0 to 7.0 with a variance of 3.14. Whole group proportions for each knowledge item are presented in Table 6.8.

Table 6.8: Knowledge Test Items at Post-intervention Questionnaire 2 (n=7).

Knowledge item	**Correct n (%)**	**Incorrect n (%)**
Gastroenteritis is often caused by: [fill in the blank].	6 (85.7)	1 (14.3)
Dehydration is when: [choose the best option].	7 (100.0)	0 (0.0)
A child is likely dehydrated if he/she: [check all that apply].	1 (14.3)	6 (85.7)
You should take your child to the emergency department if he/she has vomiting and/or diarrhea and has: [check all that apply].	4 (57.1)	3 (42.9)
What types of fluids are encouraged to prevent/help dehydration [choose the best option]?	4 (57.1)	3 (42.9)
Which medications are helpful for a child with gastroenteritis [check all that apply]?	3 (42.9)	4 (57.1)
[Fill in the blank] is an example of a good oral rehydration solution to prevent and/or help dehydration.	6 (85.7)	1 (14.3)
If child is not dehydrated, but is vomiting and/or having diarrhea over a few days, you should take him/her to see a doctor [true or false].	3 (42.9)	4 (57.1)

Self-rated improvement in knowledge score was also assessed. A Mann-Whitney U test was run to determine if there were differences in knowledge improvement score between groups at post-intervention questionnaire 1. Distributions of the knowledge improvement scores for intervention and control groups were not similar, as assessed by visual inspection. Knowledge improvement scores for the intervention group (mean rank = 27.57) were statistically

significantly higher than for the control group (mean rank = 14.83), U = 352.5, z = 3.428, p = 0.001.

At post-intervention questionnaire 2 there were seven valid responses. The mean self-rated improvement in knowledge score was 1.29, the. median was 0.0, and the mode was 0.0. The range was -1 to 4 and the variance was 4.24.

Parental decision regret score

The Wilcoxon signed rank test demonstrated that neither study group demonstrated a statistically significant effect on decision regret scores. The control group (n=20) demonstrated slight decrease in decision regret score from pre-intervention to post-intervention questionnaire 1. The intervention group (n=22) demonstrated a small increase in decision regret score from pre-intervention to post-intervention questionnaire 1. Varying confidence intervals are presented in Table 6.9.

Table 6.9: Wilcoxon Signed Ranks Test for Decision Regret.

Test statistics	**Control group (n=20)**	**Intervention group (n=22)**
Z	-0.579	0.770
Asymp. Sign. (2-tailed)	0.563	0.441
99% CI	-7.50, 5.00	-2.50, 7.50
95% CI	-5.00, 2.50	-2.50, 5.00
90% CI	-5.00, 2.50	0.00, 5.00
85% CI	-5.00, 2.50	0.00, 2.50
80% CI	-5.00, 2.50	0.00, 2.50
75% CI	-2.50, 0.00	0.00, 2.50

At post-intervention questionnaire 2 there were seven valid responses. The mean decision regret score was 22.1, the median was 25.0, and the mode was 25. The range was 0.0 to 45.0 and the variance was 207.1.

Self-rated improvement in decision regret score was also assessed. A Mann-Whitney U test was run to determine if there were differences in decision regret improvement score between

groups at post-intervention 1. Distributions of the decision regret improvement scores for intervention and control groups were similar, as assessed by visual inspection. Median decision regret score was not statistically significantly different between the intervention group (1.00) and control group (0.00), U = 211.5, z = 0.97 p = 0.37, using an exact sampling distribution for *U*.

At post-intervention questionnaire 2 there were seven valid responses. The mean self-rated improvement in decision regret score was 0.29, the median was 0.0, and the mode was 0.0. The range was -1 to 4 and the variance was 2.9.

Minimum clinically important differences (MCIDs)

Parental knowledge score. For the anchor-based approach, the mean change in knowledge score from pre-intervention to post-intervention 1 was calculated for the "slightly improved" group resulting in an MCID of 0.31 (n=13). There were not enough responses to calculate this estimate at post-intervention 2.

For the distribution-based approach, the standard error of measurement (SEM) was established as the proxy for the MCID. Using the following calculation, baseline SD (1.17) × the square root of one minus Cronbach's alpha (0.577), the SEM or MCID was 0.758 at post-intervention questionnaire 1. At post-intervention questionnaire 2, baseline SD (1.17) × the square root of one minus Cronbach's alpha (0.58), the SEM or MCID was 0.75.

Parental decision regret score. For the anchor-based approach, the mean change in decision regret score was calculated for the "slightly improved" group resulting in an MCID of 3.33 (n=6). There were not enough responses to calculate this estimate at post-intervention 2.

For the distribution-based approach, the standard error of measurement (SEM) was established as the proxy for the MCID. Using the following calculation, baseline SD (72.08) × the square root of one minus Cronbach's alpha (0.780), the SEM or MCID was 33.807 at post-

intervention questionnaire 1. At post-intervention questionnaire 2, baseline SD (72.08) × the square root of one minus Cronbach's alpha (0.73), the SEM or MCID was 37.24.

Sample size estimation for a future, full-scale trial

The study would require a sample size of 84 pairs to achieve a power of 80% and a level of significance of 5% (two sided), for detecting an effect size of 0.31 between pairs [2]. In other words, if you select a random sample of 84 pairs and determine that the effect size is 0.31, you would have 80% power to declare that the mean of the paired differences is significantly different from zero, i.e. a two-sided p-value is less than 0.05. If all other factors remain the same, but the power is increased to 90%, a sample size of 112 pairs would be required [2].

Given the rate of recruitment (i.e., 42 participants in a 3-month period), in this pilot study, a future, full-scale trial should be planned to run for six to eight months to recruit 84-112 participants. However, if the retention/drop-out rate (i.e., 7 participants completed post-intervention questionnaire 2 in a 3-month period) experienced in this pilot trial is factored into the planning of a full-scale trial, then 36 to 48 months would be needed to retain 84-112 participants at post-intervention questionnaire 2.

Post-ED healthcare utilization

Nine participants responded to the healthcare utilization questions at post-intervention questionnaire 2; three from the control group and six from the intervention group. None of the respondents returned to the ED for additional care. Four of the nine respondents did seek additional care elsewhere. Two respondents took their child to a walk-in clinic to be seen again by a physician; both of these respondents were in the intervention group. Two respondents visited their family physician; both of these respondents were in the control group.

Perceived value & benefit of intervention

Eight of 41 participants (19.5%) requested a link to the videos in post-intervention questionnaire 1. Four experimental intervention group participants requested a link (9.8%) and four sham control group participants requested a link (9.8%). One individual did not respond to this question (i.e., unaccounted for missing value).

Only one of these eight participants completed a follow-up survey, which represents 12.5% of participants requesting a video link. This respondent was part of the intervention group; however, they did not watch the video again after survey completion; therefore, no data was obtained regarding the number of times the video was watched and the reason(s) for watching the video again.

The two interview participants described the video intervention as useful. Interview Participant 1 learned new information about effective home management strategies for pediatric AGE and gained decision making confidence about when to see a doctor and when to bring a child to the ED for AGE. Interview Participant 2 indicated that the video intervention recommendations and the advice from a nurse via a tele-care line (e.g., HealthLink) were not in sync. Participant 2 aired on the side of caution and came into the ED because of the nurse recommendation and because the video intervention recommendations weren't tailored to infants. However, the video intervention did help Participant 2 to understand how to handle pediatric AGE the next time around and provided reassurance about managing symptoms at home prior to coming into the ED. See Table 6.7.

Table 6.10: Participant Interview Quotes about the Value and Benefit of Intervention.

Interview participant	**Participant interview quote**
Participant 1	"Yeah. It did yeah, for sure. I guess when my child is sick and if they don't have a fever per se, I don't think to given them

	Tylenol like for vomiting or diarrhea. It just didn't occur to me. But anything you can give them to kind of feel better, I am on board for. So that was helpful. And also the Pedialyte. I always looked at Pedialyte as being a last resort type thing, so it was good that it would be okay to give her a bit of that if necessary. And it helped to assure me that I did the right thing by not taking her in immediately too. You never know exactly what to do, but I didn't want to go, so I didn't know if it was me not wanting to go or her not needing to do. So it was helpful for sure."
	"I know that I would feel more confident in my decision about when to take her and when not to. That's probably the biggest thing I took from that video."
	"But definitely to go see a doctor, now I'm more aware that it's okay after the 3 day mark, so that was helpful."
Participant 2	"Um yeah, so then I watched the video when I was there and it said to kind of give clear fluids and wait a few days, but I was just concerned because she was so young – like she was only just turned, well let's see yeah just under 4 months old. And I wanted to air on the side of caution and I guess they did too at Health Link."
	"Oh yeah, for sure. It was good. It just kind of talked about what to do in a bit of an older child which is going to be [child's name] soon right, so that was helpful."
	"Yeah, um, just to kind of wait a bit before coming in. It also kind of reassured me that I might have been okay not coming in and just kind of monitoring her. So that was good. I thought it was definitely helpful to know not to rush in."
	"I probably wouldn't have come sooner. I guess based on the video, I kind of came to soon anyway. But I guess, she was breastfeeding, so I couldn't have given clear fluids anyway. Maybe I would have seen if she had vomited a third time. Yeah, maybe I would have come in a bit later. I might have just like tried to find the wait time before I came in and just to see how, that might have given me time to see how she was doing too."

Both interview participants felt that the intervention delivery timing and location were not ideal. See Table 6.11. For Interview Participant 1, the ideal timing would have been prior to the ED visit, when pediatric AGE symptoms began. In hindsight, receiving the video information earlier in the illness trajectory would have meant bringing the child to see a doctor sooner based

on the recommended 3-day time frame in the video. It also would have meant potentially avoiding or dealing more immediately with symptoms of dehydration. For Interview Participant 1, the ideal setting for intervention delivery would still be in a healthcare setting, but delivered at a time when the child wasn't ill. The suggestions provided by Participant 1 were to show the video in a medical lab and/or doctor office waiting rooms.

For Interview Participant 2, seeing the video before coming to the ED likely wouldn't have impacted decision making because the video content wasn't tailored to infants. However, this participant felt that the ideal timing would have been to receive the information after the ED visit to help with future bouts of pediatric AGE when the child was older. For Participant 2, the ideal place to see the video would be online via a trusted source, like a government website or a website that the hospital directed parents to for viewing.

Table 6.11: Participant Interview Quotes about Ideal Timing and Location of Video Intervention.

Interview participant	**Participant interview quotes**
Participant 1	"Well, it was helpful at that time too, but had I seen it at the beginning of the week or something it would have helped me kind of gauge a little better. And maybe I would have actually brought her in sooner because I believe the video says after three days or something. So, and then take her to the doctor actually. So, I probably maybe would have taken her in sooner to the doctor."
	"But the Pedialyte stuff for sure is good information. Because my daughter was dehydrated actually when we were there, so that would have been good to have known, to have done earlier on."
	"I think where it would be helpful to see it is like the DynaLife places. Because I know I have gone there myself and I would have caught the video and would have retained information I think in those types of environments. Like the Doctors office. Places where parents are kind of sitting waiting for their own appointments and would come across it. Once you're in the hospital, you're already there, so your

	chance of reading it and leaving are probably slim because you're here anyways so might as well stay and double check. I would say beforehand would be probably the most helpful."
Participant 2	"Um yeah, it would have been helpful after we left the hospital because like I said she'll be older soon. Um yeah. It would have been helpful."
	"I have a ton of email, so probably just a website. Like if, like the government has lots of websites and stuff and if one of them just kind of included the video that would probably be good. Yeah and you know even people at the Stollery could mention, here is a video on gastritis and then they just go and look at it you know?"

Management domain outcomes

Data quality

Five technical errors occurred during study period. These were described in Chapter 5 and included: 1) the final post-intervention survey question (i.e., 15-point scale to assess decision regret) did not appear in four surveys as of January 10, 2018; 2) the app expired and was not usable for data collection on the evening of February 22; 3) the follow-up survey was emailed at the incorrect time from November 30 to December 5, 2017 (n=7); 4) follow-up survey email reminders not sent from November 30 to December 14, 2017 (n=13); 5) one question in the follow-up survey did not register any data on January 15, 2018 (n=1).

Willingness to participate in future research

Both interview participants were happy to participate in a research study while in the ED waiting room. Both participants did not experience any issues with ED and/or home surveys. Both participants also indicated that they would be willing to participate in future, similar research.

Resource domain outcomes

Time to collect data

For ED data collection, the mean time to complete the pre-intervention questionnaire, view the intervention or sham videos, and complete the post-intervention questionnaire 1 was 19 minutes 39 seconds. The median time to complete the ED surveys was 18 minutes and 38 seconds. The minimum time to complete was 11 minutes and 49 seconds and the maximum time to complete was 41 minutes and 55 seconds.

For post-intervention questionnaire 2, the mean time in minutes to complete the survey was 6 minutes, 52 seconds. The median time to complete was 6 minutes 21 seconds. The minimum time to complete was 1 minute 39 seconds and the maximum time to complete was 20 minutes 48 seconds.

For the post-intervention questionnaire 2, the mean time to complete in days was 4.9 days post-ED visit. The median days to complete was 5. The mode days to complete was 4. The minimum days to complete was 0 due to a technical error affecting 7 participants. The maximum days to complete was 8, with the study maximum for survey completion set at 10 days post-ED visit.

Feasibility of using iPads to collect data

There were no lost, broken, or stolen iPads, chargers, or Wi-Fi hubs. iPads were returned to data collectors immediately after survey completion. Chargers and Wi-Fi hubs were not located in public view.

Discussion

To address current literature gaps and ensure optimal reporting and conduct, this pilot PRCT has been reported using the Consolidated Standards of Reporting Trials (CONSORT) extension for pilot and feasibility trials [3,4]. The checklist is provided in Appendix N.

Like other PRCTs before, this pilot trial confirmed that the ED waiting room is a good setting to locate and approach parents/caregivers of children with acute illnesses like AGE to participate in research [5]. The study consent and recruitment rates for the ED questionnaire portion were high (>80%) and qualitative responses indicating willingness to participate in future research in the ED waiting room. Recruitment was higher during the daytime hours, which was unexpected. The daytime is typically described as non-optimal for research because medical rounds are conducted in the morning and there are fewer patients than in the evening; however, the higher daytime recruitment rate in this study may be a result of consistent, dedicated resources approaching patients at that time and also the number of studies being conducted simultaneously in the evenings (n=14), including the one ongoing study that was drawing from the same target population as this pilot trial. Further research should examine whether daytime hours are more effective for research recruitment as well as the optimal number of simultaneous research studies engaging in participant recruitment in the ED to maximize recruitment and ED research resources.

Study consent and recruitment rates for the qualitative interview, as well as the data completion rate, drop-out rate, and amount of missing/blank questionnaire items for post-intervention questionnaire 2 were insufficient for the planned analyses. This may point to a methodological failing. Parent participants were willing to engage in research while in the ED environment, but not willing to continue their research involvement afterwards from home. This may be due to busyness of life as parents of young children. Prior research has demonstrated that

telephone is superior to email as a mode of follow-up with families of children who visit a pediatric ED [6]; however, in this study telephone outreach to recruit for the qualitative portion of this study was unsuccessful, as was email follow-up with regular email reminders for the post-intervention questionnaire 2. Emerging research has also found that SMS/text message reminders did not improve questionnaire response rates, time to response, or affect the need for additional reminders in the context of an RCT study [7]. Future research should investigate the feasibility of different research follow-up or reminder techniques, including combinations of approaches, for this population.

Five technical errors did occur during the study period, which affected at least 18 participants (i.e., 43%); this represents a large proportion of participants of this study. This is likely because this pilot study was the first research application for the iCare Adventure electronic data collection platform. Fortunately, there were no issues with lost or broken technology or components. The iCare Adventure platform worked well in the ED environment and should be considered for future research applications in this setting, particularly with the significant investment in tailoring the platform and identifying, then resolving technical issues in the course of this pilot study.

The limited qualitative responses demonstrated parent satisfaction with the electronic data collection platform. There were no technical issues from the parent perspective while in the ED or at home; however, the sample of parents interviewed were small (n=2) and we do know that there was significant drop-out at the follow-up data collection stage. Two of the main technological errors that occurred in this study were related to how and when the post-intervention questionnaire 2 and reminders were deployed and future research could address these failings. However, further research may be needed to determine how best to use to this

platform for follow-up data collection once parents have left the ED environment. For example, rather than using email for follow-up data collection, the iCare Adventure platform could be deployed differently to function as a smartphone app with pop-up reminders.

While the KT intervention demonstrated positive effects on parental knowledge scores, the sham intervention elicited a statistically significant negative impact on parental knowledge scores at post-intervention questionnaire 1. This points to a methodological issue with the sham control condition itself and/or the knowledge test used to evaluate this outcome. To better align with pragmatic trial practices, a tool already used in the practice setting should be the control arm of the study, rather than a sham control, to best assess comparative effectiveness [8,9]. For example, using the vomiting and diarrhea page of the Alberta Health Services Health Education and Learning (HEAL) website or the vomiting and diarrhea information sheet [10].

Additionally, the KT intervention demonstrated no effect on parental decision regret scores and it is likely that this outcome measure was not well suited to this study. The reasons for this may be: 1) parents are not making the decision to come to ED for themselves, so as a proxy decision maker for a child, parents are likely to be more conservative in care seeking choices; 2) it is likely that parents weighed the pros and cons of coming to ED before traveling and waiting for care prior to being recruited into this study; and 3) parents coming to the pediatric ED may have higher anxiety, may feel seeking care is a form of good parenting, or may not have access to primary care, compared to those that did not come to the ED and thus were not represented in this study. The video was not designed to address such complexity and at 3 minutes in length, it was unlikely to impact this considered and nuanced parental decision making. An additional factor to consider is that decision regret should be dependent on illness severity; it is important that decision regret increase for those who did not need ED care; however, in the case of AGE,

dehydration can be a serious complication warranting an ED visit and those parents should feel reassured (i.e., less decision regret) in making the most appropriate healthcare choice. Future studies using this outcome measure must take this into consideration.

Only four study participants requested a link to the intervention video and the same number of participants requested a link to the sham control video. This does not support positive perceived value and benefit of the KT intervention. There may be a multitude of reasons for this. For example, parents may feel the video content was common sense or intuitive and did not see a need for repeat viewing. As suggested in the qualitative findings, it may be that the video was not specific enough to their child's age to be seen as useful at this time or, the timing and location of the intervention delivery was not ideal. The qualitative findings demonstrated that participants would have found this information more useful outside of the ED setting at a time when their child wasn't ill. Suggestions for consideration were a government or hospital website or the waiting room of a primary care or lab clinic. This reflects current recommendations for effectiveness or pragmatic trials stating that the study setting should reflect the initial care facilities available to a diverse population with the condition of interest [11]. Daycare attendance has also been associated with increased AGE incidence, particularly in the first 12 months [12]; this could also be an excellent location for recruiting parents and families to assess KT interventions for pediatric AGE before they are sick, with a good likelihood they will experience AGE within a short period of time.

The main thrust of this study was to understand whether the whiteboard animation video was an effective approach for providing parents with evidence-based information on pediatric acute gastroenteritis (AGE). It is clear that more work is needed to establish how best to deliver educational, knowledge translation interventions to parents on child health topics. A recent

comparative usability analysis found that parents preferred Blogshot over a plain language summary or Wikipedia page for the delivery of information on childhood acute otitis media [13]; however, further investigation is needed to compare different multimedia approaches, including animated videos, to these and other modes of electronic print information.

The equivocal findings match the current state of the field on animation instructional materials [14]. However, three techniques have been proposed to enhance the effectiveness of instructional animation: 1) reducing extraneous cognitive load via user control (i.e., video functions can be executed by viewer at will; 2) reducing extraneous cognitive load via load-cuing and segmenting (i.e., tools incorporated to direct viewer attention to key information); and, 3) promoting germane cognitive load (i.e., having viewers respond to key video frames) [14]. This could involve start/stop capacity (this would be available in real world implementation, but not in this research study), creating segments within the video to separate key concepts, adding specific cues for core video content including coloured or bolded text or audio phrases, incorporating an animated character to act as a guide and direct viewer attention to key information, presenting precise solutions steps to the problem in the video, and/or highlighting key video frames at the end with an activity [14]. Incorporating some or all of these suggestions into a revised version of the whiteboard animation video could strengthen the video's design to ensure optimal cognitive load conditions, and result in meaningful learning [15].

Synthesized scoping review findings detailed in Chapter 2 posed three key questions for evaluating the success of KT tools aimed at parents/caregivers on child health topics and it is important to consider these in the context of this pilot study [16]. First, was the design or certain design features (e.g., sample size, nature of the comparison) inappropriate or inadequate to assess effectiveness? Second, were appropriate outcomes selected and measured to accurately assess

intended impact and establish effectiveness? Finally, have the KT tools been appropriately developed and incrementally assessed to establish effectiveness? These questions pose important considerations for reflecting on the results of this pilot study and determining how to move forward in future evaluations of KT tools for parents; responses to these queries are explored in the following three paragraphs.

This pilot randomized trial demonstrated feasibility of some design features (i.e., iCare Adventure platform, ED data collection methods) and identified issues to be addressed to improve other design aspects (i.e., control condition, study outcomes, follow-up data collection methods). Further research should follow-up on the intriguing qualitative findings that point to a need to receive this type of intervention differently and, as suggested in Chapter 5, examine these options using qualitative or mixed methods prior to a full-scale randomized controlled trial. Methods to address follow-up data collection could also be explored as part of this future descriptive/exploratory work.

Second, feasibility outcomes ensured a robust understanding of a variety of process, scientific, management and resource outcomes in this pilot trial. However, multiple issues were noted with the selected scientific outcomes assessing potential effectiveness. Calculating MCIDs have provided estimated target effect sizes for a future, full-scale trial and the results for the parental knowledge score are in line with recommended standard effect sizes [17]. Appropriate patient important outcomes could also be explored in future descriptive/exploratory research.

Third, using an iKT approach and the Knowledge-to-Action Framework [18] ensured appropriate, patient- and family-oriented research through the development of the KT intervention and usability testing showed promise. However, the end goal of a pilot trial is to provide justification for whether or not a full-scale trial is warranted. The results of this study

have demonstrated key scientific gaps that need to be addressed before an effectiveness trial of this whiteboard animation video should proceed. Intermediate research to revise the video using current cognitive science and instructional design principles and/or to identify more appropriate timing and location of intervention delivery, a better comparator, appropriate patient-oriented outcomes, and different methods of follow-up data collection, should be performed before the investment of a full-scale, randomized controlled trial.

In the time since this study was conceived and conducted, significant methodological guidance for pilot feasibility studies has emerged. Future work should tap into this guidance, specifically feasibility studies incorporating qualitative research [19]. Of particular note, as of 2019, experts in the field have created a website to provide up-to-date guidance on methods for performing well-designed randomized and non-randomized pilot and feasibility studies [20].

Conclusions

The purpose of this pilot study was to determine the feasibility of PRCT methods to evaluate a KT tool for parents about pediatric acute gastroenteritis (AGE). Feasibility outcomes were evaluated in four key domains: 1) process (i.e., what elements are key to study success?); 2) scientific (i.e., is the intervention effective?); 3) management (i.e., are the human and data needs optimized?); and, 4) resource (i.e., are the time and budget allocations reasonable?). Some aspects of the pilot trial were appropriate and feasible methods to implement in a future, full-scale trial; however, a number of key aspects did not function as planned and require revision and/or new approaches all-together before the investment of a full-scale, PRCT. Intermediate mixed-methods and/or qualitative research is recommended to improve the whiteboard animation video intervention and/or identify more appropriate intervention delivery setting, scientific outcomes and measures, comparator condition, and follow-up data collection methods.

Chapter 6 References

1. Thabane L, Ma J, Chu R, Cheng J, Rios LP, Robson R, Thabane M, Giangregoria L, Goldsmith CH. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. 2010;10(1). doi: 10.1186/1471-2288-10-1
2. Dhand N K, Khatkar MS. Sample size calculator for comparing two paired means. Statulator.com. http://statulator.com/SampleSize/ss2PM.html. Published 2014. Accessed Dec. 13, 2019.
3. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot and Feasibility Studies, 2*(64). doi 10.1186/s40814-016-0105-8
4. Abbade LPF, Abbade JF, Thabane L. Introducing the CONSORT extension to pilot trials: enhancing the design, conduct and reporting of pilot or feasibility trials. *J Venom Anim Toxins Incl Trop Dis.* 2018;24(4). doi: 10.1186/s40409-018-0142-2
5. Hartling L, Scott SD, Johnson DW, Bishop T, Klassen TP. A randomized controlled trial of storytelling as a communication tool. *PLOS One*. 2013;8(10):e77800. doi: 10.1371/journal.pone.0077800
6. Goldman RD, Mehrotra S, Pinto TR, Mounstephen W. Follow-up after a pediatric emergency department visit: telephone vs email? *Pediatrics*. 2004;114(4):988–991**.** doi: 10.1542/peds.2004-0015
7. Partha Sarathy P, Kottan L, Parker A, et al. Timing of electronic reminders did not improve trial participant questionnaire response: A randomized trial and meta-analyses. *J Clin Epi.* 2020;S0895-4356(19)30953-30959.

8. Patsopoulos NA. A pragmatic view on pragmatic trials. *Dialogues Clin Neuro*. 2011;13(2): 217-224.
9. Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical health policy. *JAMA*. 2003; 290(12):1624-1632. doi: 10.2522/ptj.20070056
10. Alberta Health Service. Vomiting and diarrhea. AlbertaHealthServices.ca. https://www.albertahealthservices.ca/info/page12429.aspx. Accessed Dec. 20, 2019.
11. Gartlehner G, Hansen RA, Nissman D, Lohr KN, Carey TS. A simple and valid tool distribuished efficacy from effectiveness studies. *J Clin Epidemiol*. 2006;59:1040-1048. doi: 10.1016/j.jclinepi.2006.01.011
12. Hullegie S, Bruijning-Verhagen P, Uiterwaal CSPM, van der Ent C, Smit HA, de Hoog MLA. First-year daycare incidence of acute gastroenteritis. *Pediatrics*. 2016;137(5):e20153356. doi: 10.1542/peds.2015-3356
13. Anzinger H, Elliott SA, Hartling L. Comparative usability analysis and parental preference of three web-based knowledge translation tools: Multimethod study. JMIR. 2020;22(3):e14562.
14. Ayers P, Paas F. Making instructional animations more effective: a cognitive load approach. *Appl Cognit Psychol*. 2007;21(6):695-700.
15. Mayer RE, Moreno R. Nine ways to reduce cognitive overload in multimedia learning. *Educ Psychol*. 2003;31(1):43-52.
16. Albrecht L, Scott SD, Hartling L. Knowledge translation tools for parents on child health topics: A scoping review. *BMC Health Services Research*. 2017;*17*(686). doi: 10.1186/s12913-017-2632-2

17. Bell ML, Whitehead AL, Julious SA. Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. *Clin Epidemiol*. 2018;10:153-157.
18. Field, B., Booth, A., Ilott, I. et al. Using the Knowledge to Action Framework in practice: a citation analysis and systematic review. *Implem Sci.* 2014*;*9(172). doi:10.1186/s13012-014-0172-2
19. O'Cathain A, Hoddinott P, Lewin S. et al. Maximising the impact of qualitative research in feasibility studies for randomized controlled trials: guidance for researchers. *Pilot and Feasibility Studies*. 2015;1(32).
20. Chan CL. A website for pilot and feasibility studies: Giving your research the best chance of success. *Pilot and Feasibility Studies*. 2019;5:122.

Chapter 7 – Reflections on the research process and research results, and potential future research directions

Conclusions of this research

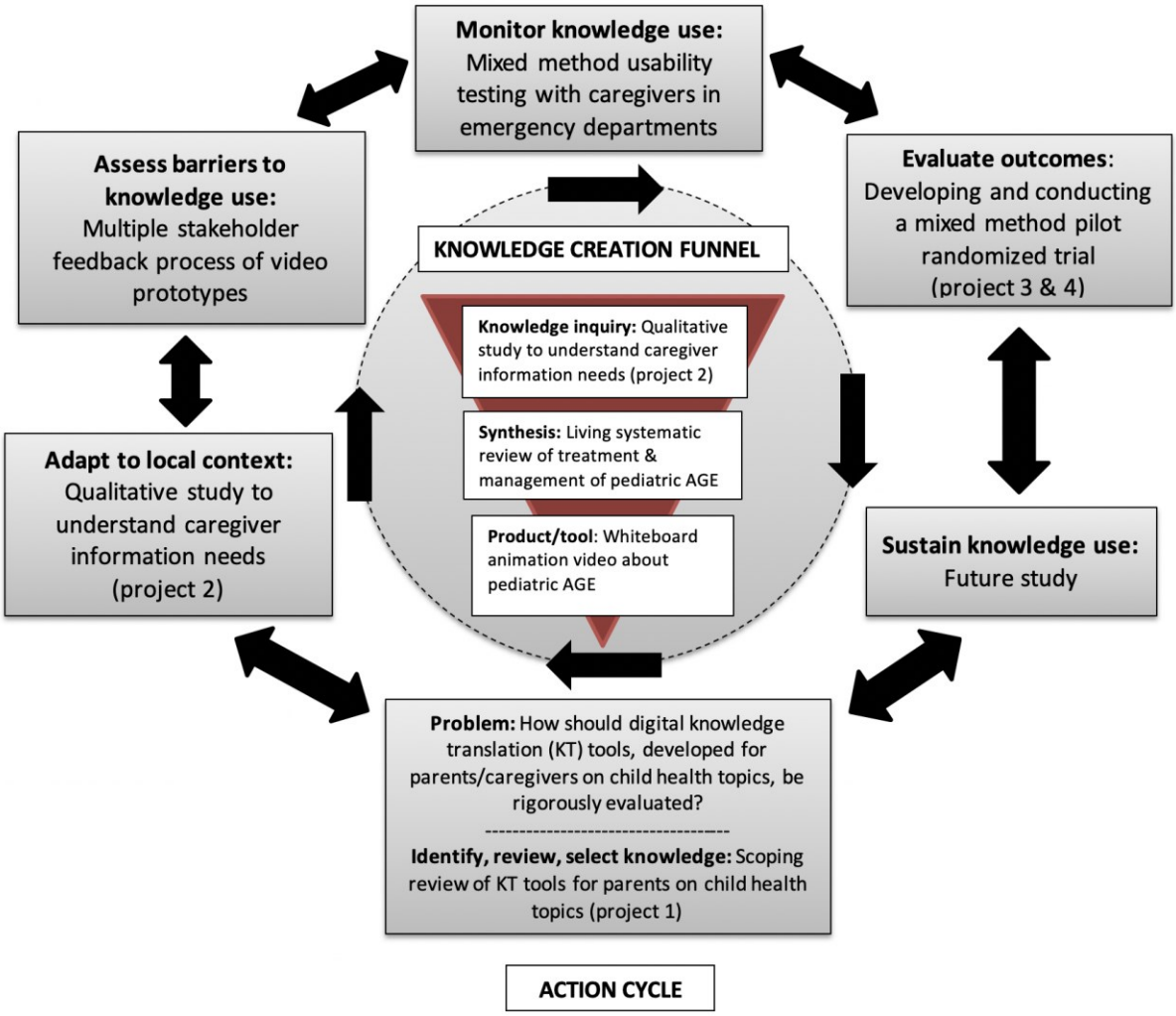
This research was conducted within a pragmatic research paradigm that situated pediatric acute gastroenteritis (AGE) as a common, acute health condition experienced by Canadian families and exacting a considerable toll on children, parents, and our healthcare system. Connecting parents to evidence-based information about AGE was deemed as one solution to address this real-world problem with the goal of minimizing the burden of AGE. Through collaborative, patient-oriented research lenses, integrated knowledge translation (iKT) that actively involved parents was conducted using the Knowledge-to-Action (KTA) Framework [1]. The knowledge funnel process identified and refined relevant knowledge into a useful tool - a multimedia video intervention designed to help parents manage pediatric AGE and determine if and when to seek emergency care. Engaging in the KTA action cycle, the video was refined, implemented, and evaluated in order to enhance the utility of the video and determine the best approaches to pragmatic effectiveness evaluation with the goal of creating a sustainable KT tool for parents about AGE.

Four main projects were conducted and mapped to the KTA Framework (Figure 7.1). Project one was a scoping review to synthesize existing research on methods for evaluating KT tools for parents on child health topics (Chapter 2) [2]. The contribution of this review was a list of previously developed KT tools in child health and the evaluation methods used to determine their effectiveness. Additionally, specific recommendations were detailed to improve research reporting and methodological rigor and guide future studies evaluating KT tools in child health

[2]. Project two was a qualitative study to describe parental experiences of managing pediatric AGE and the process of seeking health care in the emergency department (ED) (Chapter 3) [3]. The contribution of this study was the identification of key parental information needs about pediatric AGE along with an explication of factors that create 'real-life' complexity when it comes to home management of AGE and health care seeking. These findings informed the storyline of the multimedia video intervention designed to meet these knowledge needs and provide explicit recommendations on evaluating illness severity, including identifying signs and symptoms of dehydration, providing evidence-based treatments at home, and determining when to seek emergency care [3]. The third project was the development of a pilot PRCT protocol to determine rigorous, pragmatic, effectiveness evaluation methods. The contribution of this protocol was an exploration of four key feasibility domains (i.e., process, scientific, management, and resource) and a detailed example of how these domains could be applied in a pragmatic pilot trial design (Chapter 4) [4]. In project four, the pilot PRCT was conducted with parents of children with AGE symptoms presenting to one pediatric ED over a 3-month period (Chapters 5 and 6). The contributions of this study composed a detailed accounting of how real-world pilot PRCT implementation differed from planned implementation; the confirmation of a number of successful study design elements, including a novel electronic data collection platform and data collection methods in the ED waiting room; as well as clearly defined areas for improvement to enhance future pragmatic evaluation studies, an important goal of pilot trials. Collectively this body of work illuminated a detailed example of the process of conducting an iKT study, from knowledge creation through the action cycle, within a pragmatic research paradigm. Collaborative research and patient-centered research provided important theoretical lenses to enhance engagement with parents using the Knowledge-to-Action (KTA) Framework

and create and implement a pragmatic pilot trial design to investigate patient-oriented research methods for evaluating pragmatic health education.

Figure 7.1: PhD Research and Associated Projects Mapped to Knowledge-to-Action Framework.



The central research question posed by this body of research was "how should digital, knowledge translation (KT) tools, developed for parents/caregivers on child health topics, be rigorously evaluated?" Pilot study results demonstrated that feasibility is an important parameter to explore prior to the investment of a full-scale study and that in this case, methodological

improvements are necessary to design a successful, future PRCT. Rather than proceeding to a PRCT at this time, results from this body of work support additional, intermediate research to: 1) improve the video intervention design and delivery; and 2) optimize key evaluation design parameters, including more suitable scientific outcomes and measures, a different comparator condition that reflects the current standard care, and improved approaches to effective follow-up and qualitative data collection.

The whiteboard animation video that was the subject of this research was designed to meet identified parental knowledge needs on pediatric AGE and to provide explicit recommendations about evaluating disease severity, including assessing for dehydration; providing home management strategies where appropriate; and, seeking emergency care where appropriate. The results of the pilot PRCT demonstrated that the video significantly improved parental knowledge and that the difference between the intervention and control group was clinically meaningful. Additional, qualitative findings supported that parents found the video appealing, informative, and useful. However, the intervention did not impact the decision regret outcome in a meaningful way; only two participants requested a video link for potential future viewing; and qualitative findings also supported that the parents felt the video would have been more useful if presented at a different time and place. Optimizing the video design and delivery is a key and necessary improvement towards rigorous effectiveness evaluation designs to assess KT tools for parents on child health topics. This could be achieved by incorporating and testing recommendations from multimedia learning theory (e.g., segmenting, cueing, etc.) in order to optimize cognitive load and generate meaningful learning. Intermediate research could also be conducted to identify settings to access parents before they made the pivotal decision to bring their child to an ED for health care. Prospectively identifying parents whose children are likely to

contract AGE would be an ideal aspect of pragmatic design so that families could be followed over time in order to observe whether they actually use the video when their child is ill with AGE and how they respond in real-time to the recommendations presented.

While the knowledge outcomes measure demonstrated promise, there was a statistically significant decrease in knowledge in the control group. This points to a concern with the measurement of this outcome and/or the comparison condition that was used in this study. Additional research is needed to determine the most appropriate patient-important outcomes and measures for AGE educational tools for parents and a real-world comparator condition, both of which are key tenets of pragmatic trial design. Finally, a major gap in the rigorous evaluation of KT tools for parents is the challenge of retaining busy participants with complex lives for the duration of follow-up and qualitative data collection. Innovative retention and/or data collection approaches are needed to successfully implement a future PRCT in order to evaluate the effectiveness of a digital KT tool over time and ensure sustainability.

Implications for future practice

Future health education & knowledge translation efforts

Current best evidence indicates that multimedia- or print-based patient education may improve patient knowledge, anxiety, and behavior outcomes; however, neither multimedia nor print interventions can presently be identified as the clearly superior mode of information delivery [5]. To maximize impact, it is important that multimedia interventions, including animated videos, are available online for parents and caregivers as they search for child health information. However, online positioning of such interventions is critical. It is not enough to passively post an online intervention to a researcher webpage or social media account, like YouTube®. Research has shown that YouTube® videos created for informal caregivers (i.e..,

family) have low overall viewership, thus simply having videos available on popular social media platforms is of little utility [6]. To maximize research resources spent on the development and evaluation of multimedia interventions, it is necessary to ensure that: 1) parents and caregivers are able to search for and locate them online; 2) interventions can be consumed with ease on any electronic device; and, 3) intervention content is easy to understand, credible, and relevant. Explicit connection to already trusted sources of health information and health care delivery could provide a robust platform for active and targeted distribution to patients and families in need. For example, distributing a new multimedia tool through the social media platforms of health authorities (i.e., Alberta Health Services, Alberta Health, primary care networks), hosting a multimedia tool within existing patient resource collections, and/or frontline health professionals actively distributing video links to their patients. The qualitative findings from the pilot trial point to a few examples of organizations to be explored for such partnerships, including Alberta ED wait times website, HealthLink (811), walk-in clinics, pharmacies, and daycares. Researcher investment in community partnerships with a variety of stakeholders is a key feature of patient- and family-oriented research [7,8] and may be vital to ensure the long-term success of KT in child health for parents and caregivers.

Interestingly, previous research has established that caregivers of very young children (i.e., under 2 years old) seek healthcare equally, regardless of health literacy status [9]. Additionally, pediatric AGE disproportionately affects younger children who present with greater illness acuity [10]. This knowledge provides a compelling rationale to move away from a one-size-fits-all approach for parents of all children and focus on sub-populations, like parents of very young children, who are already looking for information. Tailoring tools to the unique needs and care seeking patterns of parents of infants and toddlers may require specialized skills

in order to be effective; for example, engaging experts in early childhood development, creative, and communications fields to ensure the health research evidence is distilled and packaged into an attractive, usable, accessible, and engaging form. There are also additional, exciting opportunities to integrate tailored tools about the health and wellbeing of very young children into existing opportunities for parental education, including pre-natal and post-natal care professionals, classes, and settings; maternity hospital or birth center discharge information; and, public health clinics, among others. These additional stakeholders should be incorporated into the research plan from its early stages to ensure comprehensive understanding of the current parent education landscape from all perspectives, including existing strengths, known gaps, and key points of information and resource coordination and integration.

Implications for future research

Future collaborative research & patient-oriented research

Applying an explicit patient-oriented research model in the development of full-scale PRCT methods could help to address the challenges identified in this pilot trial. KT is a fundamental aspect of the Canadian Institutes of Health Research (CIHR) mandate; a core element of KT is the exchange of knowledge between researchers and knowledge users, which can include decision makers and health consumers. To facilitate this exchange with patients and families, CIHR has established the SPOR Patient Engagement Framework. This framework identifies 'co-building' as a guiding principal of Canadian health research, with patient-informed and/or directed research identified as a key metric of future success [7]. This means that patients, families, and researchers must work together from the identification of a research idea to engage in collaborative methods of research. A future PRCT could be co-designed with parents to attend to diversity, including hard-to-reach patients and the spectrum of racial/cultural and educational

backgrounds [11]; address the methodological and practical issues that arose from this pilot study; and, optimize the research methods and processes to enhance patient and family engagement in the design, implementation, and analysis of a full-scale PRCT.

Additionally, to ensure future interventions, like the multimedia video featured in this body of research, are optimized to the needs of patients and families, integrated knowledge translation (iKT) is necessary at all stages of intervention design and development. While patients and families were engaged throughout this body of research, there were some gaps that resulted in missed opportunities. These gaps and opportunities are described in the following paragraphs.

One example of a misstep in the process of patient/family engagement was the inconsistent integration of diverse parents in the video development process. In the qualitative study (Chapter 3), parents were recruited from an urban, pediatric ED and the interview findings formed the video storyline. By limiting recruitment to one care setting that represented urban families and/or more acute presentation of AGE in the ED setting, opportunities were missed to understand and incorporate the rural context and parental engagement at different health system access points where illness presentation may have been different. Both of these elements are likely to influence parent information needs and preferences. Video usability testing (Chapter 1) was conducted in urban, rural, and remote care settings from a diverse cohort (i.e., ethnic/cultural background, educational background, etc.), which provided important data to support the functionality and accessibility of the video; however, the video prototype had already been produced and given the positive usability ratings, thus no major changes were made to content or design of the prototype before it was finalized. Reflecting back, assumptions were infused into the video prototype, specifically the representation of a nuclear family structure (i.e.

mother/father/child), the character names (i.e., Mom, Dad, Chris), and fluid/food representation, which didn't robustly address diversity, cultural contexts, or intersectional perspectives to ensure the video resonated with broad audiences. An explicit patient-oriented research model would have ensured consistent representation and engagement from the early stages of development and may have better attended to these unconscious biases.

A second consideration reflected in the results of the pilot study was the gendered/feminized nature of this research space. Mothers were the vast majority of respondents (36/42 participants or 86%). A more encompassing gender-based design to this body of research may have helped to anticipate this result and develop strategies to pro-actively address it in recruitment, data collection, and data analysis methods in order to identify the unique needs of mothers in child rearing and accessing the health system, and optimize both the video and the research process to meet those needs. Additionally, to enhance design and analysis, methods could have been examined to address and support the participation of fathers in this body of research. Additional data from fathers would have allowed for robust analysis by gender to gain important insight as to whether mothers and fathers have different information needs and preferences to support the health and wellbeing of their children. Finally, it is also important to attend to the representation of gender and sexual diversity in families to reflect our contemporary society.

To ensure patient- and family-centered tools are designed to achieve the intended impact with the target audience, a rigorous process is needed. Incorporating the UCD-11, a validated measure of the user-centeredness of the design and development processes of tools to be used by health consumers, offers a systematic approach to creating tools with and for patients and parents/caregivers by quantifying user involvement [12]. Preliminary research has demonstrated

that higher UCD-11 scores are associated with sustained availability of the tools [13]. Gathering this data is an important step to support increased methodological rigor of individual studies and facilitate cross-study comparisons to elucidate best practices and advance the field.

In order to move forward with robust patient and family engagement in health services research, patient and family compensation must be included [14]. Often researchers reimburse participant expenses (i.e., parking, child care costs) to negate costs of participation, with the assumption that this will improve study recruitment and retention. Reimbursement, however, is not the same as compensation; rather monetary or non-monetary compensation honors the time, skills, effort, and expertise that patients and families provide to enhance the research. Offering compensation for health consumer research partners honors five key principles of: equity (i.e., addressing power imbalance), different motivations (i.e., participation not related to career advancement), respect for vulnerability (i.e., sharing lived experience), commitment (i.e., setting aside time in their day to be present), and barrier removal (i.e., create opportunity for diverse representation) [14]. In addition to having a research budget to support patient/family compensation, experienced patient partners recommend beginning the payment discussion at the outset of a project, and including in that discussion the rate of pay, frequency of pay, process of payment, tax implications, and non-monetary options (i.e., gift cards, donations, bill payment, training/professional development, etc.) [14]. Further, a written compensation agreement should be drafted to outline the terms, responsibilities, and timing of participation and compensation in easy to understand language [14]. There are a number of organizations that have developed guidance for determining if and how a research study should determine patient compensation [15-17]; future patient- and family-oriented research should utilize this guidance and describe

this aspect of the research processes so that approaches to patient engagement can be assessed and evaluated as part of the overall methodology.

Future pragmatic research methodologies

RCTs have long been promoted as the ideal methodology for causal inference in the health and social sciences [18]. However, RCTs assessing the effectiveness of education and KT interventions designed to implement evidence-based practices are plagued by null or mixed effects [19]. Even within the sub-genre of PRCTs, a number of ethical issues have been identified [20]. These include justice and equity concerns within risk, consent, selection of study participants procedures; roles and responsibilities of different stakeholders; publication and reporting transparency, and; governance of research activities [20]. This begs the question, are there other approaches better suited to effectiveness evaluation in complex settings? Fortunately, methodologists have proposed a number of innovative ways forward.

Deaton and Cartwright have described a cross-disciplinary approach to understanding the 'power and pitfalls' of RCT studies [18]. By integrating various disciplinary methodological literatures, they hypothesize that researchers can come to a greater understanding of how best to apply the RCT to minimize research waste, maximize high quality data, and ensure robust analyses and interpretation of results [18]. They argue that researchers must embrace theory and heterogeneity to move beyond the question of whether an intervention 'works' and explore why an intervention may or may not work in different contexts in order to create real-world improvements [18].

Connolly and colleagues have proposed the integration of logic model frameworks in the educational or behavioural intervention design process to better identify underlying theories of change and describe required study investments, activities, outcomes, and outputs [19]. These

components could then be robustly considered in the RCT design and evaluation via rigorous process evaluations [19]. Such an approach would address the dual challenges of articulating theoretical underpinnings of RCTs and attending to contextual nuance [19].

Long and colleagues advocate a pragmatic complexity theory approach to implementation and evaluation in health services research [21]. This method focuses on the research context, rather than on short-term outcomes of individual interventions, which have been the traditional focus of RCT studies [21]. This can be achieved through designs that focus on continual learning, including simulation, network analysis methods, time-series analysis, ethnography, or social surveys, among other methods [21].

Another approach for consideration is described by Pawson as a pragmatic, multi-method, case study method for implementation science [22]. This methodology closely aligns with Popper's Theory of the Growth of Scientific Knowledge [22]. Pawson recommends beginning an inquiry with a broad programme theory and then using results of RCTs as case studies to test and refine this theory. The goal becomes the identification of recurring patterns across case studies to understand the conditions for the success of each programme theory [22].

The field of PRCTs and pilot and feasibility study design is rapidly expanding and new methods emerging. The ultimate goal of pragmatic methods is to better address context, complexity, and heterogeneity in the development, implementation, and evaluation of educational and behavioural interventions in real-world settings to increase their utility to solve a particular problem. This can be achieved in many ways, including engaging with multiple stakeholders to ensure a fulsome understanding of a problem and the potential solutions, attending to external validity or generalizability within the selected research methodology, and including multiple methods of data collection to ensure rich, nuanced data to inform analyses.

This dissertation demonstrated that enhanced reporting of the process of conducting research can be more illuminating than the presentation of results alone, particularly when presenting the results of a pilot or feasibility study intended to guide future, full-scale pragmatic evaluation studies. Current health services research guidance encourages the publication of study protocols to reduce research waste by declaring an area of study in advance and ensuring detailed description of research methods; however, prospective accounts of methods and processes represents the best laid plans. It's critical that results publications provide a detailed roadmap to what actually happened in a given research study and, more importantly, provide the reasons why events occurred and certain choices were made, so that future researchers and research studies can benefit from collective learning. Methodological advancements may hinge on exposing these decision points and their underlying context in order to better delineate real-life scenarios from ideal research plans and further, to understand what is both lost and gained when researchers grapple with real life complexity in service of understanding what works, for whom, and in what circumstances.

The future of evidence-based practice in health services research

Reflecting on the process and findings of this research, as well as the bigger picture of methodological development and refinement that occurred within this work, it is clear that traditional approaches to health services research are not fully aligned with patient, caregiver, and family needs. Various methodological frameworks, methods, and tools help to bring a patient- and family-oriented perspective to the health services research process, including iKT; however, it may be worth considering whether a fundamental incongruity exists. There may be a need for a radical overhaul of the philosophy that underpins health services research in order to ensure that future research is done 'with' rather than 'on' patients and families.

One transformative idea gaining traction is to reframe the concept of evidence-based practice to explicitly account for intersectionality. Coined 'practice-based evidence,' this new perspective for health services research emerged from the understanding that the dominant scientific paradigm, specifically evidence-based practice in the form of the RCT, emphasizes structured uniformity rather than identifying and embracing variation [23]. Foundational to evidence-based practice are Western/white cultural assumptions, including urban environments with ideal settings and resources for implementation [24]. The result is a failure to account for differences in both culture and need, which alienates the evidence-based practice process from a patient-centered orientation [24].

Through an extensive process of engagement and collaboration, the Indigenous Evidence-Based Effective Model was developed to articulate practice-based evidence by augmenting evidence-based practice with methods compatible with Indigenous cultures and values [24]. The three levels of this model are: 1) level I client/patient-based evidence: three sources of data must be collected, analyzed, and reported on (e.g., satisfaction surveys, comment cards, interviews, focus groups, case studies, etc.); 2) level II practice-based evidence: four data sources must be collected, analyzed, and reported on (e.g., Indigenous expert opinion, articles, awards, Elder interviews, ceremonies etc.); and, 3) level III research-driven evidence: a research study must be conducted (e.g., participatory/action research, before-after study, etc.), plus two additional data sources must be collected (e.g., journal articles, review panels, etc.) [24]. This model offers a compelling example of a new, rigorous approach to patient- and family-oriented research that addresses current shortcomings to health services research by transforming our understanding of knowledge and evidence-generation. There is great opportunity to bring an exciting new methodological approach like this one into the evolving fields of

collaborative/patient-oriented and mixed methods research to address shared challenges by foregrounding real-world complexity and the context, culture, and perspectives of the people affected, in the hopes of identifying innovative and effective solutions.

Reflecting on this body of work from the context of a global pandemic

At the end of this PhD journey, we have collectively been confronted with a global pandemic of an infectious disease, COVID-19. Locally, we are in a state of public health emergency requiring rigorous social distancing measures. Schools of all levels and daycares are indefinitely closed; citizens, where possible, are working from home and limiting time in public spaces; key services, like libraries, public transit, and community leagues, are closed or restricted; and, our health care system is extremely stressed. These unprecedented events provide a unique opportunity to reflect on this body of work from the vantage point of an extreme circumstance. As the pandemic has rapidly evolved and various levels of government have attempted to respond in different ways, it has become clear that the general public has great difficulty sorting through the cacophony of health information and identifying reliable health evidence in order to understand and apply: 1) hygiene and social distancing practices to slow or eliminate the spread of infection; 2) symptoms of the infectious illness and immediate steps that should be taken if they suspect they have been exposed and/or are showing signs of illness; and, 3) how to manage the numerous, significant, and evolving social changes for an uncertain period of time, whether they are ill or not. To address this, health organizations, like Alberta Health Services, have rapidly developed tools targeting health consumers. For example, the COVID-19 self-assessment test [25] has been accessed by millions in a short period of time and because of this it's been used to strategically communicate critical public health and health service information to the wider population. Mechanisms to get best research evidence into the hands of

the public are critical, but in order to cut through the noise and contribute unified key messages, the real-world implementation of such tools must be thoughtful and coordinated in order to maintain public trust.

Key leaders have emerged from this crisis, including elected officials like Rachel Notley (i.e., MP for Edmonton-Strathcona and Leader of the Alberta Official Opposition) and Justin Trudeau (i.e., the Prime Minister of Canada); the Alberta Chief Medical Officer of Health, Dr. Deena Hinshaw; alberta.ca/covid19 website; HealthLink (811); and, the Public Health Agency of Canada. Researchers must collaborate with multidisciplinary experts to ensure health evidence is presented in meaningful and usable ways and to channel these messages, products, and tools to the sources that have the attention and trust of the public. This circumstance has clarified the importance of collaboration to achieve mutual goals. Working with patients and families, all levels of government, and local health authorities, is critical to ensure clear and usable recommendations are presented in ways that can be easily understood and actioned within our systems and social norms. The alternative is confusion, disarray, spread of infection, and a rising death toll.

There will be much to learn from the public health responses to this pandemic in the coming days, weeks, and months. Much will be gleaned about the health information needs and preferences of the public; the types of interventions that can facilitate successful communication and implementation of best health and social practices; and, the best mechanisms to combat the spread of misinformation and anti-science bias. This information will come at great cost; however, future socially responsible research should collate, analyze, and synthesize this knowledge with guidance and participation from patients, families, health providers, and decision-makers, to contribute to our collective knowledge about managing infectious conditions

like AGE and COVID-19 at all levels of society (i.e., individual-, community-, system-level) and maximize future health services interventions, health care delivery, and health policies in Alberta and worldwide.

Chapter 7 References

1. Field, B., Booth, A., Ilott, I. et al. Using the Knowledge to Action Framework in practice: a citation analysis and systematic review. *Implem Sci.* 2014;9(172). doi:10.1186/s13012-014-0172-2
2. Albrecht L, Scott SD, Hartling L. Knowledge translation tools for parents on child health topics: A scoping review. *BMC Health Services Research*. 2017;17(686). doi: 10.1186/s12913-017-2632-2
3. Albrecht L, Hartling L, Scott SD. Pediatric acute gastroenteritis: understanding caregivers' experiences and information needs. *CJEM*. 2016;1-9. doi: 10.1017/cem.2016.363
4. Albrecht L, Scott SD, Hartling L. Evaluating a knowledge translation tool for parents about pediatric acute gastroenteritis: a pilot randomized trial. *BMC Pilot & Feasibility Studies*. 2018:4(131). doi: 10.1186/s40814-018-0318-0
5. Chapman E, Haby MM, Setsuko Toma T, et al. Knowledge translation strategies for dissemination with a focus on healthcare recipients: An overview of systematic reviews. *Implement Sci.* 2020;15(14).
6. Wittenberg-Lyles E, Parker Oliver D, Demiris G, et al. YouTube as a tool for pain management with informal caregivers of cancer patients: A systematic review. *J Pain Symptom Manage*. 2014;48(6):1200-1210. doi: 10.1016/j.jpainsymman.2014.02.015
7. Canadian Institutes of Health Research. Strategy for patient-oriented Research - patient engagement framework. Cihr-irsc.gc.ca. https://cihr-irsc.gc.ca/e/48413.html. Updated May 27, 2019. Accessed Jan. 5, 2020.

8. Mallidou AM, Frisch N, Doyle-Waters MM, MacLeod MLP, Ward J, Atherton P. Patient-oriented research competencies in health (PORCH) for patients, healthcare providers, decision-makers, and researchers: protocol of a scoping review. *Syst Rev*. 2018;7(101).
9. Morrison AK, Chanmugathas R, Schapira MM, et al. Caregiver low health literacy and nonurgent use of the pediatric emergency department for febrile illness. *Acad Pediatr*. 2014;14(5):505-509. doi: 10.1016/j.acap.2014.05.001
10. Bahm A, Freedman SB, Guan J, et al. Evaluating the impact of clinical decision tools in pediatric acute gastroenteritis: a population-based cohort study. *Acad Emerg Med*. 2016;23(5):599-609. doi: 10.1111/acem.12915
11. Basch E, Abernethy AP, Reeve BB. Assuring the patient centeredness of patient-reported outcomes: Content validity in medical product development and comparative effectiveness research. Value in Health. 2011;14:965-966. doi: 10.1016/j.jval.2011.10.002
12. Witteman HO, Vaisson G, Provencher T, et al. Development and validation of UCD-11: An 11-item measure of user-centered design for patient-centered tools. *Manuscript pre-print.* doi:10.31219/osf.io/w5vnk
13. Higgins KS, Tutelman P, Chambers CT, et al. Availability of eHealth tools for pediatric pain Assessment and management: Barriers, facilitators, costs, and design. Pain Rep. 2018;3(Supp 1):e686. doi: 10.1097/PR9.0000000000000686
14. Richards DA, Bazeley P, Borglin G, et al. Integrating quantitative and qualitative data and findings when undertaking randomized controlled trials. *BMJ Open*. 2019;9:e032081. doi: 10.1136/bmjopen-2019-032081
15. Patient-Centered Outcomes Research Institute. Compensation framework. PCORI.org. https://www.pcori.org/document/compensation-framework. Accessed Mar. 19, 2020.

16. Canadian Institutes of Health Research Strategy for Patient Oriented Research. Considerations when paying patient partners in research. Cihr.gc.ca. https://cihr-irsc.gc.ca/e/51466.html. Updated May 27, 2019. Accessed Mar. 19, 2020.
17. The Change Foundation. Should money come into it? A tool for deciding whether to pay patient-engagement participants. Changefoundation.ca. https://changefoundation.ca/patient-compensation-report/. Accessed Mar. 19, 2020.
18. Deaton A, Cartwright N. Understanding and misunderstanding randomized controlled trials. Soc Sci Med. 2018;210:2-21. doi: 10.1016/j.socscimed.2017.12.005
19. Connolly P, Keenan C, Urbanska K. The trials of evidence-based practice in education: a systematic review of randomised controlled trials in education research 1980–2016. *Educational Research*. 2018;60(3):276-291.
20. Nicholls SG, Carroll K, Zwarenstein M, et al. The ethical challenges raised in the design and conduct of pragmatic trials: an interview study with key stakeholders. *Trials*. 2019;20(765). doi: 10.1186/s13063-019-3899-x
21. Long KM, McDermott F, Meadows GN. Being pragmatic about healthcare complexity: our experiences applying complexity theory and pragmatism to health services research. *BMC Medicine*. 2018;16(94).
22. Pawson R. Pragmatic trials and implementation science: grounds for divorce? *BMC Med Res Methodol*. 2019;19(176). doi: 10.1186/s12874-019-0814-9
23. Alberta Government. Well-being and resiliency: The miyo resource kâ-nâkatohkêhk miyo-ohpikinawâwasowin. Open.Alberta.ca. https://open.alberta.ca/publications/9781460143384. Published Mar. 2019. Accessed Mar. 5, 2020.

24. Naquin V, Manson SM, Curie C, et al. Indigenous evidence-based effective practice model: Indigenous leadership in action. IJPL. 2008;4(1):14-24.

25. Alberta Health Services. COVID-19 self-assessment. MyHealth.Alberta.ca. https://myhealth.alberta.ca/Journey/COVID-19/Pages/COVID-Self-Assessment.aspx. Accessed Mar. 19, 2020.

Reference list

Abbade, L.P.F., Abbade, J.F. & Thabane, L. (2018). Introducing the CONSORT extension to pilot trials: Enhancing the design, conduct and reporting of pilot or feasibility trials. *Journal of Venomous Animals and Toxins including Tropical Diseases, 24*(4). doi: 10.1186/s40409-018-0142-2

Agency for Health Research and Quality. (2000). *Reducing errors in health care: Translating research into practice.* AHRQ.gov. https://archive.ahrq.gov/qual/errors.htm

Alberta Government (2020, March 5). Well-being and resiliency: The miyo resource kâ-nâkatohkêhk miyo-ohpikinawâwasowin. Open.Alberta.ca. https://open.alberta.ca/publications/9781460143384.

Alberta Health Services. (2019, November 19). *Stollery Children's Hospital*. AlbertaHealthServices.ca. https://www.albertahealthservices.ca/stollery/Page14264.aspx.

Alberta Health Services. (2019, November 19). *Stollery Children's Hospital: Current child health research studies*. AlbertaHealthServices.ca. https://www.albertahealthservices.ca/assets/hospitals/stollery/stollery-research-studies.pdf.

Alberta Health Services. (2019, December 20). *Vomiting and diarrhea*. AlbertaHealthServices.ca. https://www.albertahealthservices.ca/info/page12429.aspx.

Alberta Health Services (2020, March 19). *COVID-19 self-assessment*. MyHealth.Alberta.ca. https://myhealth.alberta.ca/Journey/COVID-19/Pages/COVID-Self-Assessment.aspx.

Albrecht, L., Archibald, M., Arseneau, D. & Scott, S.D. (2013). Development of a checklist to assess the quality of reporting of knowledge translation interventions using the

Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. *Implementation Science, 8*(52). doi: 10.1186/1748-5908-8-52

Albrecht, L., Hartling, L. & Scott, S.D. (2016). Pediatric acute gastroenteritis: Understanding caregivers' experiences and information needs. *Canadian Journal of Emergency Medicine*, 1-9. doi: 10.1017/cem.2016.363

Albrecht, L., Scott, S.D. & Hartling, L. (2017). Knowledge translation tools for parents on child health topics: A scoping review. *BMC Health Services Research*, *17*(686). doi: 10.1186/s12913-017-2632-2

Albrecht, L., Scott, S.D. & Hartling, L. (2018). Evaluating a knowledge translation tool for parents about pediatric acute gastroenteritis: A pilot randomized trial. *BMC Pilot & Feasibility Studies, 4*(131). doi: 10.1186/s40814-018-0318-0

Allen, S.J., Martinez, E.G., Gregorio, G.V. & Dans, L.F. (2010). Probiotics for treating acute infectious diarrhoea. *Cochrane Database of Systematic Reviews*, (11), CD003048. doi: 10.1002/14651858.CD003048.pub3

American Academy of Pediatrics (2006). Committee on Pediatric Emergency Medicine, American College of Emergency Physicians, Pediatric Emergency Medicine Committee. *Pediatrics*, *118*(5), 2242-2244.

Anidi, I., Bazargan, M. & James, F.W. (2002). Knowledge and management of diarrhea among Underserved minority parents/caregivers. *Ambulatory Pediatrics, 2*, 201-206.

Anzinger, H., Elliott, S.A. & Hartling, L. (2020). Comparative usability analysis and parental preference of three web-based knowledge translation tools: Multimethod study. *Journal of Medical Internet Research, 22*(3), e14562.

Arain, M., Campbell, M.J., Cooper, C.L. & Lancaster, G.A. (2010). What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology, 10*(67). doi: 10.1186/1471-2288-10-67

Arksey. H. & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology, 8*(1), 19-31.

Armstrong, A.W., Idriss, N.Z. & Kim, R.H. (2011). Effects of video-based, online education on behavioural and knowledge outcomes in sunscreen use. *Patient Education and Counseling, 83*(2), 273-277. doi: 10.1016/j.pec.2010.04.033

Austin, P.E., Matlack, R., Dunn, K.A., Kesler, C. & Brown, C.K. (1995) Discharge instructions: Do illustrations help our patients understand them? *Annals of Emergency Medicin*e, *25*(3), 317-320. doi: 10.1016/s0196-0644(95)70286-5

Ayers, P. & Paas, F. (2007). Making instructional animations more effective: A cognitive load approach. *Applied Cognitive Psychology, 21*(6), 695-700.

Bahm, A., Freedman, S.B., Guan, J. & Guttmann, A. (2016). Evaluating the impact of clinical decision tools in pediatric acute gastroenteritis: A population-based cohort study. *Academic Emergency Medicine, 23*(5), 599-609. doi: 10.1111/acem.12915

Bailey, L., Sun, J., Courtney, M. & Murphy, P. (2015). Improving postoperative tonsillectomy pain management in children – A double randomized control trial of a patient analgesia information sheet. *International Journal of Pediatric Otorhinolaryngology, 79*(5), 732-739. doi: 10.1016/j.ijporl.2015.03.003

Ballinger, C., Yardley, L. & Payne, S. (2004). Observation and action research. In D.F. Marks & L. Yardley (Eds.). Research methods for clinical and health psychology 1st ed. (102-121). Sage Publications.

Basch, E., Abernethy, A.P. & Reeve, B.B. (2011). Assuring the patient centeredness of patient-reported outcomes: Content validity in medical product development and comparative effectiveness research. *Value in* Health, *14*, 965-966. doi: 10.1016/j.jval.2011.10.002

Bauchner, H., Osganian, S., Smith, K. & Triant, R. (2001). Improving parent knowledge about antibiotics: A video intervention. *Pediatrics*, *108*(4), 845-850. doi: 10.1542/peds.108.4.845

Beatty, M.E., Griffin, P.M., Tulu, A. & Olson, S.J. (2004). Culturing practices and antibiotic use in children with diarrhea. *Pediatrics, 113*(3), 628-629. doi: https://doi.org/10.1542/peds.113.3.628

Bell, M.L., Fiero, M., Horton, N.J. & Hsu, C.H. (2014). Handling missing data in RCTs: A review of the top medical journals. *BMC Medical Research Methodology, 14*(118). doi:10.1186/1471-2288-14-118

Bell, M.L., Whitehead, A.L. & Julious, S.A. (2018). Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. *Clinical Epidemiology, 10*, 153-157. doi: 10.2147/CLEP.S146397

Berwick, D.M. (2009). What 'patient-centered' should mean: Confessions of an extremist. *Health Affairs, 28*(4), w555-556. doi: 10.1377/hlthaff.28.4.w555

Best, A. & Holmes, B. (2010). Systems thinking, knowledge and action: Toward better models and methods. *Evidence & Policy, 6*(2), 145-159.

Bhattacharyya, O.K., Estey, E.A. & Zwarenstein, M. (2011). Methodologies to evaluate the effectiveness of knowledge translation interventions: A primer for researchers and health care managers. *Journal of Clinical Epidemiology, 64*(1), 32-40. doi: 10.1016/j.jclinepi.2010.02.022

Billingham, S.A.M., Whitehead, A.L. & Julious, S.A. (2013). An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network Database. *BMC Medical Research Methodol*ogy, *13*(104). doi: 10.1186/1471-2288-13-104

Bishop, F.L. (2015). Using mixed methods research designs in health psychology: An illustrated discussion from a pragmatist perspective. *British Journal of Health Psychology, 20*(1), 5-20. doi: 10.1111/bjhp.12122

Bleijenberg, N., de Man-van Ginkel, J.M., Trappenburg, J.C.A., Ettema, R.G.A., Sino, C.G., Heim, N., … Schuurmans, M.J. (2018). Increasing value and reducing waste by optimizing the development of complex interventions: Enriching the development phase of the Medical Research Council (MRC) Framework. *International Journal of Nursing Studies, 79*, 86-93. doi: 10.1016/j.ijnurstu.2017.12.001

Blinder, D., Rotenberg, L., Peleg, M. & Taicher, S. (2001). Patient compliance to instructions after oral surgical procedures. *International Journal of Oral Maxillofacial Surgery, 30*(3), 216-219.

Bloch, S.A. & Bloch, A.J. (2013). Using video discharge instructions as an adjunct to standard written instructions improved caregivers' understanding of their child's emergency department visit, plan, and follow-up: A randomized controlled trial. *Pediatric Emergency Care, 29*(6), 699-704. doi: 10.1097/PEC.0b013e3182955480

Bower, P., Brueton, V., Gamble, C., Treweek, S., Tudur Smith, C., …Williamson, P. (2014). Interventions to improve recruitment and retention in clinical trials: A survey and workshop to assess current practice and future priorities. *Trials, 15*(399). doi: 10.1186/1745-6215-15-399

Boyd, M., Lasserson, T.J., McKean, M.C., Gibson, P.G., Ducharme, F.M. & Haby, M. (2009) Interventions for educating children who are at risk of asthma-related emergency department attendance. *Cochrane Database of Systematic Reviews,* (2), CD001290. doi: 10.1002/14651858.CD001290.pub2

Bragge, P., Grimshaw, J.M., Lokker, C., Colquhoun, H. & The AIMD Writing/Working Group. (2017). AIMD - A validated, simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies. *BMC Medical Research Methodology, 17*(38).

Braun, V. & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*(2), 77–101.

Brehaut, J.C., O'Connor, A.M., Wood, T.J., Hack, T.F., Siminoff, L, Gordon, E. & Feldman-Stewart, D. (2003). Validation of a decision regret scale. *Medical Decision Making, 23*(4), 281-92. doi 10.1177/0272989X03256005

Brien, S.E., Lorenzetti, D.L., Lewis, S., Kennedy, J. & Ghali, W.A. (2010). Overview of a formal scoping review on health system report cards. *Implementation Science, 5*(2).

Bryman, A. (2006). Paradigm peace and the implications for quality. *International Journal of Social Research Methodology, 9*(2), 111-126.

Butler, C.C., Rollnick, S., Pill, R., Maggs-Rapport, F. & Stott, N. (1998). Understanding the culture of prescribing: Qualitative study of general practitioners' and patients' perceptions of antibiotics for sore throats. *BMJ, 317*(7159), 637-642. doi: 10.1136/bmj.317.7159.637

Campbell-Yeo, M., Dol, J., Disher, T., Benoit, B., Chambers, C.T., Sheffield, K., …Caddell, K. (2017). The power of a parent's touch: Evaluation of reach and impact of a targeted

evidence-based YouTube video. *Journal of Perinatal & Neonatal Nursing, 31*(4), 341-349. doi: 10.1097/JPN.0000000000000263

Canadian Institutes of Health Research. (2014). *Strategy for patient-oriented research: Patient engagement*. Cihr-irsc.gc.ca. http://www.cihr-irsc.gc.ca/e/48413.html

Canadian Institutes of Health Research. (2015*). Knowledge translation definition*. Cihr-irsc.gc.ca. http://www.cihr-irsc.gc.ca/e/39033.html.

Canadian Institutes of Health Research. (2019). *Detailed Information*. http://webapps.cihr-irsc.gc.ca/decisions/p/project_details.html?applId=302197&lang=en.

Canadian Institutes of Health Research. (2020, March 19). *Strategy for patient-oriented research: Considerations when paying patient partners in research*. Cihr.gc.ca. https://cihr-irsc.gc.ca/e/51466.html.

Car, J., Lang, B., Colledge, A., Ung, C. & Majeed, A. (2011). Interventions for enhancing consumers' online health literacy. *Cochrane Database of Systematic Reviews,* (6), CD007092. doi: 10.1002/14651858.CD007092.pub2

Centres for Disease Control and Prevention. (2016). *Fight germs. Wash your hands*. CDC.gov. https://www.cdc.gov/cdctv/healthyliving/hygiene/fight-germs-wash-hands.html

Chalmers, I. & Altman, D.G. (1999). How can medical journals help prevent poor medical research? Some opportunities presented by electronic publishing. *The Lancet, 353*(9151), 490-493. doi: 10.1016/S0140-6736(98)07618-1

Chan, A.W., Hrobjartsson, A., Haahr, M.T., Gotzsche, P.C. & Altman, D.G. (2004). Empirical evidence for selective reporting of outcomes in randomized trials: Comparison of protocols to published articles. *JAMA, 291*(20), 2457-2465. doi: 10.1001/jama.291.20.2457

Chan, A.W., Tetzlaff, J.M., Altman, D.G., Laupacis, A., Gøtzsche, P.C., Krleža-Jerić, K., …Moher, D. (2013). SPIRIT 2013 statement: Defining standard protocol items for clinical trials. *Annals of Internal Medicine, 158(3)*, 200-207. doi: 10.7326/0003-4819-158-3-201302050-00583

Chan, A.W., Tetzlaff, J.M., Gøtzsche, P.C., Altman, D.G., Mann, H., Berlin, J., …Moher, D. (2013). SPIRIT 2013 explanation and elaboration: Guidance for protocols of clinical trials. *BMJ, 346*, e7586. doi: 10.1136/bmj.e7586

Chan, C.L. (2019). A website for pilot and feasibility studies: Giving your research the best chance of success. *Pilot and Feasibility Studies, 5*(122).

Chapman, E., Haby, M.M., Setsuko Toma, T., de Bortoli, M.C., Illanes, E., Oliveros, J. & Barreto, J.O.M. (2020). Knowledge translation strategies for dissemination with a focus on healthcare recipients: An overview of systematic reviews. *Implementation Science, 15*(14).

Children' Healthcare Canada. (2020, January 13). *Patient and family centered care*. ChildrensHealthCanada.ca. https://www.childrenshealthcarecanada.ca/patient-and-family-centred-care.

Christakis, D.A., Zimmerman, F.J., Rivara, F.P. & Ebel, B. (2006). Improving pediatric prevention via the Internet: A randomized, controlled trial. *Pediatrics, 118*(3), 1157-1166. doi: 10.1542/peds.2006-0209

Clarke, C., Friedman, S.M., Shi, K., Arenovich, T., Monzon, J. & Culligan, C. (2005). Emergency department discharge instructions comprehension and compliance study. *Canadian Journal of Emergency Medicine, 7*(1), 5-11. doi: 10.1017/s1481803500012860

Churgay, C.A. & Aftab, Z. (2012). Gastroenteritis in children: Part I diagnosis. *American Family Physician, 85*(11), 1059-1062.

Churgay, C.A. & Aftab, Z. (2012). Gastroenteritis in children: Part II treatment and management. *American Family Physician, 85*(11), 1066-1070.

Cochrane Colloquium Seoul Abstracts E-Book. (2016). *P72 The development of knowledge translation tools for parents in pediatric acute care*. http://2016.colloquium.cochrane.org/abstracts-e-book.

Cochrane Colloquium Seoul Abstracts E-Book. (2016). *P73: Living systematic reviews for up-to-date evidence: case studies on pediatric croup and acute gastroenteritis*. http://2016.colloquium.cochrane.org/abstracts-e-book

Cochrane Community. (2020, January 13). *Covidence*. Community.Cochrane.org. https://community.cochrane.org/help/tools-and-software/covidence.

Cocks, K. & Torgerson, D.J. (2013). Sample size calculations for pilot randomized trials: A confidence interval approach. *Journal of Clinical Epidemiology, 66*(2), 197–201. doi: 10.1016/j.jclinepi.2012.09.002

Cohen, J. (1994). The earth is round ($p < .05$). *American Psychologist, 49*(12), 997-1003.

Colquhoun, H., Leeman, J., Michie, S., Lokker, C., Bragge, P., Hempel, S., … Grimshaw, J. (2014). Towards a common terminology: A simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies. *Implementation Science, 9*(781). doi: 10.1186/1748-5908-9-51

Connolly, P., Keenan, C. & Urbanska, K. (2018). The trials of evidence-based practice in education: A systematic review of randomised controlled trials in education research 1980–2016. *Educational Research*, 60(3), 276-291.

Copay, A.G., Subach, B.R., Glassman, S.D., Polly, D.W. & Schuler, T.C. (2007). Understanding the minimum clinically important difference: A review of concepts and methods. *Spine Journal, 7*(5), 541-546. doi: 10.1016/j.spinee.2007.01.008

Cornish, F. & Gillespie, A. (2009). A pragmatist approach to the problem of knowledge in health psychology. *Journal of Health Psychology, 14*(6), 800-809. doi: 10.1177/1359105309338974

Coulter, A. & Ellins, J. (2006). *Patient-focused interventions: A review of the evidence*. The Health Foundation.

Coulter, C. & Ellins, J. (2007). Effectiveness of strategies for informing, educating, and involving patients. *BMJ, 335*(7609), 24-27. doi: 10.1136/bmj.39246.581169.80

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. & Petticrew, M. (2008). Developing and evaluating complex interventions: The new Medical Research Council Guidance. *BMJ, 337*, a1655. doi: 10.1136/bmj.a1655

Dane, A.V. & Schneider, B.H. (1998). Program integrity in primary and early secondary prevention: Are implementation effects out of control? *Clinical Psychology Review, 18*(1), 23-45. doi: 10.1016/s0272-7358(97)00043-3

Davies, P., Walker, A.E. & Grimshaw, J.M. (2010). A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. *Implementation Science, 5*(114). doi: 10.1186/1748-5908-5-14

Deaton, A. & Cartwright, N. (2018). Understanding and misunderstanding randomized controlled trials. *Social Science & Medicine, 210*, 2-21. doi: 10.1016/j.socscimed.2017.12.005

Delp, C. & Jones, J. (1996). Communicating information to patients: The use of cartoon illustrations to improve comprehension of instructions. *Academic Emergency Medicine, 3*(3), 264-270. doi: 10.1111/j.1553-2712.1996.tb03431.x

Dempsey, A.F., Zimet, G.D., Davis, R.L. & Koutsky, L. (2006). Factors that are associated with parental acceptance of human papillomavirus vaccines: A randomized intervention study of written information about HPV. *Pediatrics, 117*(5), 1486-1493. doi: 10.1542/peds.2005-1381

Dennis, J.L. & Lomas, J. (2003). Convergent evolution: The academic and policy roots of collaborative research. *Journal of Health Services Research & Policy, 8*(S2), 1-6. doi: 10.1258/135581903322405108

Dhand, N.K. & Khatkar, M.S. (2019, December 13). *Sample size calculator for comparing two paired means*. Statulator.com. http://statulator.com/SampleSize/ss2PM.html.

Doll, M.K., Gagneur, A., Tapiero, B., Chrest, H., Gonzales, M., Buckeridge, D.L. & Quach, C. (2016). Temporal changes in pediatric gastroenteritis after rotavirus vaccination in Quebec. *Pediatric Infectious Disease Journal, 35*(5), 555–560. doi: 10.1097/INF.0000000000001077

Domecq, J.P., Prutsky, G., Elraiyah, T. Wang, Z, Nabhan, M., Shippee, N., …Murad, M.H. (2014). Patient engagement in research: A systematic review. *BMC Health Services Res*earch*, 14*(89). doi: 10.1186/1472-6963-14-89

Edwards, C.H., Bekkevold, T. & Flem, E. (2017). Lost workdays and healthcare use before and after hospital visits due to rotavirus and other gastroenteritis among young children in Norway. *Vaccine*, *35*(28), 3528-3533. doi: 10.1016/j.vaccine.2017.05.037

Edwards, V., Wyatt, K., Logan, S. & Britten, N. (2011). Consulting parents about the design of a randomized controlled trial of osteopathy for children with cerebral palsy. *Health Expectations, 14*(4), 429-438. doi: 10.1111/j.1369-7625.2010.00652.x

Effective Practice and Organisation of Care (EPOC). (2015). *EPOC Taxonomy*. Cochrane.org. https://epoc.cochrane.org/epoc-taxonomy

Effective Public Health Panacea Project. (2016, January 8). Quality assessment tool for quantitative studies. Ephpp.ca. https://www.ephpp.ca/PDF/Quality%20Assessment%20Tool_2010_2.pdf

Efird, J. (2011). Blocked randomization with randomly selected block sizes. *International Journbal of Environmental Research and Public Health, 8*(1), 15-20. doi: 10.3390/ijerph8010015

Eldridge, S.M., Chan, C.L., Campbell, M.J., Bond, C.M., Thabane, L., Lancaster, G.A. & PAFS consensus group. (2016). CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. *Pilot and Feasibility Studies, 2*(64). doi 10.1186/s40814-016-0105-8

Elliot EJ. (2007). Acute gastroenteritis in children. *BMJ*, *334*(7583), 35-40.

Elliott, J.H., Turner, T., Clavisi, O., Thomas, J., Higgins, J.P.T., Mavergames, C. & Gruen, R.L. (2014). Living systematic reviews: An emerging opportunity to narrow the evidence-practice gap. *PLoS Medicine, 11*(2): e1001603. doi: 10.1371/journal.pmed.1001603

Elliot, J.H., Synnot, A., Turner, T., Simmonds, M., Akl, E.A., McDonald, S., …Thomas, J. (2017). Living systematic review: 1. Introduction – the why, what, when, and how. *Journal of Clinical Epidemiology, 91*, 23-30. doi: 10.1016/j.jclinepi.2017.08.010

Engel, K.G., Heisler, M., Smith, D.M., Robinson, C.H., Forman, J.H. & Ubel, P.A. (2009). Patient comprehension of emergency department care and instructions: Are patients

aware of when they do not understand? *Annals of Emergency Medicine, 53*(4), 454-461. doi: 10.1016/j.annemergmed.2008.05.016

Evans, S., Daly, A., Hopkins, V., Davies, P. & MacDonald, A. (2009). The impact of visual media to encourage low protein cooking in inherited metabolic disorders. *Journal of Human Nutrition and Dietetics, 22*(5), 409-413. doi: 10.1111/j.1365-277X.2009.00953.x

EverAge Consulting. (2019, December 1). *iCare Adventure*. EverageConsulting.com. https://www.everageconsulting.com/icare-adventure/.

Fedorowicz, Z., Jagannath, V.A. & Carter, B. (2011). Antiemetics for reducing vomiting related to acute gastroenteritis in children and adolescents. *Cochrane Database of Systematic Reviews,* (9), CD005506. doi: 10.1002/14651858.CD005506.pub5

Feilzer, M.Y. (2010). Doing mixed methods research pragmatically: Implications for the rediscovery of pragmatism as a research paradigm. *Journal of Mixed Methods Research, 4*(1), 6-16.

Fereday, J. & Muir-Cochrane, E. (2006). Demonstrating rigor using thematic analysis: A hybrid approach of inductive and deductive coding and theme development. *International Journal of Qualitative Methodology, 5*(1), 80-92.

Field, B., Booth, A., Ilott, I. & Gerrish K. (2014). Using the Knowledge to Action Framework in practice: A citation analysis and systematic review. *Implementation Science, 9*(172). doi:10.1186/s13012-014-0172-2

Freedman, S.B., Deiratany, S., Goldman, R.D. & Benseler, S. (2008). Development of a caregiver gastroenteritis knowledge questionnaire. *Ambulatory Pediatrics, 8,* 261-265. doi: 10.1016/j.ambp.2008.02.003

Freedman, S.B., Etorky, M., Gorelick, M. & Pediatric Emergency Research Canada Gastroenteritis Study Group. (2010). Evaluation of a gastroenteritis severity score for use in outpatient settings. *Pediatrics, 125*, e1278-e1285. doi: 10.1542/peds.2009-3270

Freedman, S.B., Couto, M., Spooner, L. & Haladyn, K. (2011). The implementation of a gastroenteritis education program. *American Journal of Emergency Medicine, 29*, 271-277. doi: 10.1016/j.ajem.2009.09.032

Freedman, S.B., Sivabalasundaram, V., Bohn, V., Powell, E.C., Johnson, D.W. & Boutis, K. (2011). The treatment of pediatrics gastroenteritis: A comparative analysis of pediatric emergency physicians' practice patterns. *Academic Emergency Medicine, 18*, 38-45. doi: 10.1111/j.1553-2712.2010.00960.x

Freedman, S.B., Gouin, S., Bhaat, M., Black, K.J.L., Johnson, D., Guimont, C. …. Pediatric Emergency Research Canada. (2011). Prospective assessment of practice pattern variations in the treatment of pediatric gastroenteritis. *Pediatrics, 127*(2), e287-e295. doi: 10.1542/peds.2010-2214

Freedman, S.B., Ali, S., Oleszczuk, M., Gouin, S. & Hartling, L. (2013). Treatment of acute gastroenteritis in children: An overview of systematic reviews of interventions commonly used in developed countries. *Evidence-Based Child Health, 8*, 1123-1137. doi: 10.1002/ebch.1932

Freedman, S., Lowerison, K. & Alberta Provincial Pediatric EnTeric Infection Team (APPETITE). (2015, February 2). Seminar series. http://gotgastro.ca/training/seminar-series-2/.

Freedman, S.B., Lee, B.E., Louie ,M., Pang, X.L., Ali, S., Chuck, A.… Vanderkooi, O.G. (2015). Alberta Provincial Pediatric EnTeric Infection Team (APPETITE):

Epidemiology, emerging organisms, and economics. *BMC Pediatrics*, *15*(89). doi: 10.1186/s12887-015-0407-7

Gagliardi, A.R., Berta, W., Kothari, A., Boyko, J. & Urquhart, R. (2016). Integrated knowledge translation (iKT) in health care: A scoping review. *Implementation Science, 11*(38). doi: 10.1186/s13012-016-0399-1

Gardner, M.J. & Altman, D.G. (1986). Confidence intervals rather than P values: Estimation rather than hypothesis testing. *BMJ, 292*, 746-750.

Gardner, H., Fraser, C., MacLennan, G. & Treweek, S. (2016). A protocol for a systematic review of non-randomised evaluations of strategies to improve participant recruitment to randomised controlled trials. *Systematic Reviews, 5*(131). doi: 10.1186/s13643-016-0308-3

Gartlehner, G., Hansen, R.A., Nissman, D., Lohr, K.N. & Carey, T.S. (2006). A simple and valid tool distinguished efficacy from effectiveness studies. *Journal of Clinical Epidemiology, 59*, 1040-1048. doi: 10.1016/j.jclinepi.2006.01.011

Glick, A.F., Farkas, J.S., Nicholson, J., Dreyer, B.P., Fears, M., Bandera, C., …Yin, H.S. (2017). Parental management of discharge instructions: A systematic review. *Pediatrics.140*(2), e20164165. doi: 10.1542/peds.2016-4165

Graham, I.D. & Tetroe, J. (2007). How to translate health research knowledge into effective healthcare action. *Healthcare Quarterly*, *10*(3), 20-22. doi: 10.12927/hcq..18919

Graham, I.D., Logan, J., Harrison, M.B., Straus, S.E., Tetroe, J., Caswell, W. & Robinson, N. (2006). Lost in translation: Time for a map? *Journal of Continuing Education for Health Professionals, 26*(1), 13-24. doi: 10.1002/chp.47

Graham, I.D., Kothari, A., McCutcheon, C. & Integrated Knowledge Translation Research Network Project Leads. (2018). Moving knowledge into action for more effective practice, programmes and policy: Protocol for a research programme on integrated knowledge translation. *Implementation Science, 13*(22). doi: 10.1186/s13012-017-0700-y

Graphpad Software Inc. (2015, November 15). *QuickCalcs: Quantify agreement with kappa*. https://graphpad.com/quickcalcs/kappa2/.

Green, L.W., Ottoson, J.M., Garcia, C. & Hiatt, R.A. (2009). Diffusion theory and knowledge dissemination, utilization, and integration in public health. *Annual Review of Public Health, 30*, 151-174. doi: 10.1146/annurev.publhealth.031308.100049

Gresham, F.M., Gansle, K.A., Noell, G.H. (1993). Treatment integrity in applied behavior analysis with children. *Journal of Applied Behaviour Analysis, 26*(2), 257-263. doi: 10.1901/jaba.1993.26-257

Grimshaw, J.M., Eccles, M.P., Lavis, J.N., Hill, S.J. & Squires, J.E. (2012). Knowledge translation of research findings. *Implementation Science, 7*(50). doi: 10.1186/1748-5908-7-50

Grol, R. (2001). Successes and failures in the implementation of evidence-based guidelines for clinical practice. *Medical Care, 39*(8 Suppl 2), II46–54. doi: 10.1097/00005650-200108002-00003

Goldman, R.D., Mehrotra, S., Pinto, T.R. & Mounstephen, W. (2004). Follow-up after a pediatric emergency department visit: Telephone vs email? *Pediatrics, 114*(4), 988–991. doi: 10.1542/peds.2004-0015

Hartling, L., Bellemare, S., Wiebe, N., Russell, K., Klassen, T.P. & Craig, W. (2006). Oral versus intravenous rehydration for treating dehydration due to gastroenteritis in children. *Cochrane Database of Systematic Reviews,* (3), CD004390.

Hartling, L., Scott, S.D., Johnson, D.W., Bishop, T. & Klassen, T.P. (2013). A randomized controlled trial of storytelling as a communication tool. *PLoS One, 8*(10), e77800. doi: 10.1371/journal.pone.0077800

Health Quality Council of Alberta. (2019). *Focus on Healthcare: Patient time to see an emergency doctor*. Focus.HQCA.ca. https://focus.hqca.ca/emergencydepartments/patients-time-to-see-an-emergency-doctor/.

Healy, P., Galvin, S., Williamson, P.R., Treweek, S., Whiting, C., Maeso, B. … Devane, D. (2018). Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership – the PRioRiTy (Prioritising Recruitment in Randomised Trials) study. *Trials, 19*(1), 147. doi: 10.1186/s13063-018-2544-4.

Hennessy, M., Hunter, A., Healy, P., Galvin, S. & Houghton, C. (2018). Improving trial recruitment processes: How qualitative methodologies can be used to address the top 10 research priorities identified within the PRioRiTy study. *Trials, 19*(1), 584. doi: 10.1186/s13063-018-2964-1

Herman, A., Young, K., Espitia, D., Fu, N. & Farshidi, A. (2009). Impact of a health literacy intervention on pediatric emergency department use. *Pediatric Emergency Care, 25*(7), 434-438

Higgins, J.P.T. & Green, S. (eds). (2011). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0*. The Cochrane Collaboration. www.handbook.cochrane.org.

Higgins, J.P.T., Altman, D.G., Gøtzsche, P.C., Jüni, P., Moher, D., Oxman, A.D. … Cochrane Statistical Methods Group. (2011). The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ, 343*, d5928. doi: 10.1136/bmj.d5928

Higgins, K.S., Tutelman, P., Chambers, C.T., Witteman, H.O., Barwick, M., Corkum, P…. Jordan, I. (2018). Availability of eHealth tools for pediatric pain Assessment and management: Barriers, facilitators, costs, and design. *Pain Reports, 3*(Supp 1), e686. doi: 10.1097/PR9.0000000000000686

Houts, P.S., Bachrach, R., Witmer, J.T., Egeth, H.E., Tringala, C.A., Bucher, J.A. & Localio, R.A. (1998). Using pictographs to enhance recall of spoken medical instructions. *Patient Education and Counseling, 85*(2), 83-88.

Hullegie, S., Bruijning-Verhagen, P., Uiterwaal, C.S.P.M., van der Ent, C.K., Smit, H.A. & de Hoog, M.L.A. (2016). First-year daycare and incidence of acute gastroenteritis. *Pediatrics, 137*(5), e20153356. doi: 10.1542/peds.2015-3356

IBM Corp. (2013). IBM SPSS Statistics for Windows (version 22). 2013. https://www.ibm.com/products/spss-statistics?p1=Search&p4=p50715561164&p5=e&cm_mmc=Search_Google-_-1S_1S-_-WW_NA-_-spss_e&cm_mmca7=71700000060951760&cm_mmca8=kwd-98310549&cm_mmca9=EAIaIQobChMInrWk2M6z6AIVleNkCh2Olw0bEAAYASAAEgKT9PD_BwE&cm_mmca10=407020396680&cm_mmca11=e&gclid=EAIaIQobChMInrWk2M6z6AIVleNkCh2Olw0bEAAYASAAEgKT9PD_BwE&gclsrc=aw.ds

IBM Corp. (2019). IBM SPSS Statistics for Windows (version 26). https://www.ibm.com/products/spss-statistics?p1=Search&p4=p50715561164&p5=e&cm_mmc=Search_Google-_-1S_1S-_-

WW_NA-_-spss_e&cm_mmca7=71700000060951760&cm_mmca8=kwd-98310549&cm_mmca9=EAIaIQobChMInrWk2M6z6AIVleNkCh2Olw0bEAAYASAAEgKT9PD_BwE&cm_mmca10=407020396680&cm_mmca11=e&gclid=EAIaIQobChMInrWk2M6z6AIVleNkCh2Olw0bEAAYASAAEgKT9PD_BwE&gclsrc=aw.ds

Institute of Medicine. (2000). *Crossing the quality chasm: a new health system for the 21st century*. http://www.nap.edu/books/0309072808/html/.

Institute of Medicine. (2007). *Emergency care for children: Growing pains*. The National Academies Press.

Ioannidis, J.P.A. (2005). Why most published research findings are false. *PLoS Medicine, 2*(8), e124. doi: 10.1371/journal.pmed.0020124

Ioannidis, J.P.A. (2014). How to make more published research true. *PLoS Medicine, 11*(10), e1001747. doi: 10.1371/journal.pmed.1001747

Isaacman, D.J., Purvis, K. & Gyuro, J. (1992). Standardized instructions: Do they improve communication of discharge information from the emergency department? *Pediatrics, 89*(6), 1204-1208.

Jackson, C. & Dickinson, D. (2006). Enabling parents who smoke to prevent their children from initiating smoking: Results from a 3-year intervention evaluation. *Archives of Pediatric and Adolescent Medicine, 160*(1), 36-62. doi: 10.1001/archpedi.160.1.56

Jagosh, J., Macaulay, A.C., Pluye, P., Salsberg, J., Bush, P.L., Henderson, J., …Greenhalgh, T. (2012). Uncovering the benefits of participatory research: Implications of a realist review for health research and practice. *The Milbank Quarterly, 90*(2), 311-346. doi: 10.1111/j.1468-0009.2012.00665.x

Jakobsen, J.C., Gluud, C., Wetterslev, J. & Winkel, P. (2017). When and how should multiple imputation be used for handling missing data in randomised clinical trials – A practical guide with flowcharts. *BMC Medical Research Methodology, 17*(1), 162. doi: 10.1186/s12874-017-0442-1

Johnson, R.B. & Onwuegbuzie, A.J. (2004). Mixed methods research: A research paradigm whose time has come. *Educational Researcher, 33*(7), 14–26.

Johnson, R.B., Onwuegbuzie, A.J. & Turner, L.A. (2007). Towards a definition of mixed methods research. *Journal of Mixed Methods Research, 1*(2), 112-133.

Jones, S.R., Carley, S. & Harrison, M. (2003). An introduction to power and sample size estimation. *Emergency Medicine Journal, 20*(5), 453-458. doi: 10.1136/emj.20.5.453

Jones, T.F., McMillian, M.B., Scallan, E., Frenzen, P.S., Cronquist, A.B., Thomas, S., Angulo, F.J. (2007). A population-based estimate of the substantial burden of diarrhoeal disease in the United States; FoodNet, 1996-2003. *Epidemiology & Infection, 135*(2)*,* 293-301. doi: 10.1017/S0950268806006765

Jorgensen, L., Paludan-Muller, A.S., Laursen, D.R.T., Savovic, J., Boutron, I., Sterne, J.A.C., … Hrobjartsson, A. (2016). Evaluation of the Cochrane tool for assessing risk of bias in randomized clinical trials: Overview of published comments and analysis of user practice in Cochrane and non-Cochrane reviews. *Systematic Reviews, 5*(80). doi: 10.1186/s13643-016-0259-8

Jusko Friedman, A., Cosby, R., Boyko, S., Hatton-Bauer, J. & Turnbull, G. (2011). Effective teaching strategies and methods of delivery for patient education: A systematic review and practice guideline recommendations. *Journal of Cancer Education, 26*(1), 12-21. doi: 10.1007/s13187-010-0183-x

Kaushik, V. & Walsh, C.A. (2019). Pragmatism as a research paradigm and its implications for social work research. *Social Sciences, 8*(255), 1-17. doi: 10.3390/socsci8090255

Kessels, R. (2003). Patients' memory for medical information. *Journal of Royal Society of Medicine, 96*(5), 219-22. doi: 10.1258/jrsm.96.5.219

King, C.K., Glass, R., Brese, J.S., Duggan, C. & Centres for Disease Control and Prevention. (2003). Managing acute gastroenteritis among children: Oral rehydration, maintenance, and nutritional therapy. *Morbitity and Mortality Weekly Report Recommendations & Reports, 52*(RR-16), 1-16.

Kinlin, L.M., Bahm, A., Guttmann, A. & Freedman, S.B. (2013). A survey of emergency department resources and strategies employed in the treatment of pediatric gastroenteritis. *Academic Emergency Medicine, 20*(4), 361-366. doi: 10.1111/acem.12108

Kothari, A. & Wathen, C.N. (2013). A critical second look at integrated knowledge translation. *Health Policy, 109*, 187-191. doi: 10.1016/j.healthpol.2012.11.004

Lancaster, G.A., Dodd, S. & Williamson, P.R. (2004). Design and analysis of pilot studies: Recommendations for good practice. *Journal of Evaluation in Clinical Practice, 10*(2), 307-312. doi: 10.1111/j..2002.384.doc.x

Lateef, F. (2011). Patient expectations and the paradigm shift of care in emergency medicine. *Journal of Emergencies, Trauma & Shock, 4*(2), 163-167. doi: 10.4103/0974-2700.82199

Lee, E.C., Whitehead, A.L., Jacques, R.M. & Julious, S.A. (2014). The statistical interpretation of pilot trials: Should significance thresholds be reconsidered? *BMC Medical Research Methodology, 14*(41).

Leshem, E., Tate, J.E. & Steiner, C.A. (2015). Acute gastroenteritis hospitalizations among US children following implementation of the rotavirus vaccine. *JAMA, 313*(22), 2282-2284. doi:10.1001/jama.2015.5571

Levesque, M., Hovey, R.B. & Christope, B. (2013). Advancing patient-centered care through transformative educational leadership: A critical review of health care professional preparation for patient-centered care. *Journal of Healthcare Leadership, 3*(5), 35-46.

Li, S.T., Klein, E.J., Tarr, P.I. & Denno, D.M. (2009). Parental management of childhood diarrhea. *Clinical Pediatrics, 48*(3), 295-303. doi: 10.1177/0009922808327057

Lipstein, E.A., Brinkman, W.B. & Britto, M.T. (2012). What is known about parents' treatment decisions? A narrative review of pediatric decision making. *Medical Decision Making, 32*(2), 246-258. doi: 10.1177/0272989X11421528

Logibec Canada. (2019, December 4). *Clinical solutions: Emergency Department Information System (EDIS)*. Logibec.com. https://www.logibec.com/en/products/emergency-department-information-system-edis/.

Long, K.M., McDermott, F. & Meadows, G.N. (2018). Being pragmatic about healthcare complexity: our experiences applying complexity theory and pragmatism to health services research. *BMC Medicine*, *16*(94).

Mairs, K., McNeil, H., McLeod, J., Prorok, J.C. & Stolee, P. (2013). Online strategies to facilitate health-related knowledge transfer: A systematic search and review. *Health Information and Libraries Journal, 30*(4), 261-277. doi: 10.1111/hir.12048

Mallidou, A.M., Frisch, N., Doyle-Waters, M.M., MacLeod, M.L.P., Ward, J. & Atherton, P. (2018). Patient-oriented research competencies in health (PORCH) for patients,

healthcare providers, decision-makers, and researchers: Protocol of a scoping review. *Systematic Reviews, 7*(101).

Mancusco, J.M. (2008). Health literacy: A concept/dimensional analysis. *Nursing and Health Science, 10*, 248-255. doi: 10.1111/j.1442-2018.2008.00394.x

Marlow, R., Finn, A. & Trotter, T. (2015). Quality of life impacts from rotavirus gastroenteritis on children and their families in the UK. *Vaccine, 33*(39), 5212-5216. doi: 10.1016/j.vaccine.2015.07.012

Mast, T.C., DeMuro-Mercon, C., Kelly, C.M., Floyd, L.E. & Walter, E.B. (2009). The impact of rotovirus gastroenteritis on the family. *BMC Pediatrics, 9*(11). doi: 10.1186/1471-2431-9-11

May, M., Brousseau, D.C., Nelson, D.A., Flynn, K.E., Wolf, M.S., Lepley, B. & Morrison, A.K. (2018). Why parents seek care for acute illness in the clinic or the ED: The role of health literacy. *Academic Pediatrics, 18*(3), 289-296. doi: 10.1016/j.acap.2017.06.010

Mayer, R.E. & Moreno, R. (2003). Nine ways to reduce cognitive overload in multimedia learning. *Educational Psychologist, 31*(1), 43-52.

McCaslin, M.L. (2012). Pragmatism. In L.M. Given (Ed.), *The SAGE Encyclopedia of Qualitative Research Methods: Volume 3* (672-675). SAGE Publications.

McCormack, L., Sheridan, S., Lewis, M., Boudewyns, V., Melvin, C.L., Kistler, C., …Lohr, K.N. Communication and dissemination strategies to facilitate the use of health-related evidence. In Evidence Report/Technology Assessment No. 213. AHRQ Publication No. 13(14)-E003-EF.

McDonald, A.M., Knight, R.C., Campbell, M.K., Entwistle, V.A., Grant, A.M., Cook, J.A. …Snowdon, C. (2006). What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials, 7*(9).

McGlynn, E.A., Asch, S.M., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A. & Kerr, E.A. (2003). The quality of health care delivered to adults in the United States. *New England Journal of Medicine, 348*(26), 2635–2645. doi: 10.1056/NEJMsa022615

McKibbon, K.A., Lokker, C., Keepanasseril, A., Colquhoun, H., Haynes, R.B. & Wilczynski, N.L. (2013). WhatisKT wiki: A case study of a platform for knowledge translation terms and definitions – descriptive analysis. *Implementation Science, 8*(13).

Medical Research Council. (2019, December 8). *Developing and evaluating complex interventions*. MRC.ukri.org. https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/.

Michie, S., Fixsen, D., Grimshaw, J.M. & Eccles, M.P. (2009). Specifying and reporting complex behaviour change interventions: The need for a scientific method. *Implementation Science, 4*(40).

Moncher, F.J. & Prinz, R.J. (1991). Treatment fidelity in outcome studies. *Clinical Psychology Review, 11*(3), 247-266.

Morgan, D.L. (2014). Pragmatism as a paradigm for social research. *Qualitative Inquiry*, *20*(8), 1045-1053.

Morrison, A.K., Myrvik, M.P., Brousseau, D.C., Hoffman, R.G. & Stanley, R.M. (2013). The relationship between parent health literacy and pediatric emergency department utilization: A systematic review. *Academic Pediatrics, 13*(5), 421-429. doi: 10.1016/j.acap.2013.03.001

Morrison, A.K., Schapira, M.M., Gorelick, M.H., Hoffman, R.G. & Brousseau, D.C. (2014). Low caregiver health literacy is associated with higher pediatric emergency department use and nonurgent visits. *Academic Pediatrics, 14*(3), 309-314. doi: 10.1016/j.acap.2014.01.004

Morrison, A.K., Chanmugathas, R., Schapira, M.M., Gorelick, M.H., Hoffman, R.G. & Brousseau, D.C. (2014). Caregiver low health literacy and nonurgent use of the pediatric emergency department for febrile illness. *Academic Pediatrics, 14*(5), 505-509. doi: 10.1016/j.acap.2014.05.001

Morse, J. & Field, P. (1995). Qualitative research methods for health professionals. 2nd ed. Sage Publications.

Murtagh, M.J., Thomson, R.G., May, C.R., Rapley, T., Heaven, B.R., Graham, R.H., … Eccles, M.P. (2007). Qualitative methods in a randomised controlled trial: The role of an integrated qualitative process evaluation in providing evidence to discontinue the intervention in one arm of a trial of a decision support tool. *Quality and Safety in Health Care, 16*, 224-229.

Naquin, V., Manson, S.M., Curie, C., Sommer, S., Daw, R., Maraku, C…. Deaux, E. (2008). Indigenous evidence-based effective practice model: Indigenous leadership in action. *International Journal of Leadership in Public Services, 4*(1), 14-24.

Navanandan, N., Schmidt, S.K., Cabrera, N., DiStefano, M.C. & Mistry, R.D. (2017). The caregiver perspective on unscheduled 72-hour return visits to pediatric acute care sites: A focus on discharge instructions. *Academic Pediatrics, 17*(7), 755-761. doi: 10.1016/j.acap.2017.02.003

Nicholls, S.G., Carroll, K., Zwarenstein, M., Brehaut, J.C., Weijer, C., Hey, S.P., …Taljaard, M. (2019). The ethical challenges raised in the design and conduct of pragmatic trials: An interview study with key stakeholders. *Trials, 20*(765). doi: 10.1186/s13063-019-3899-x

Nordfeldt, S. & Ludvigsson, J. (2002). Self-study material to prevent severe hypoglycaemia in children and adolescents with type 1 diabetes: A prospective intervention study. *Practical Diabetes International, 19*(5), 131-136.

Nordfeldt, S., Johansson, C., Carlsson, E. & Hammersjo, J.A. (2003). Prevention of severe hypoglaecemia in type 1 diabetes: A randomized controlled population study. *Archives of Disease in Childhood, 88*(3), 240-245. doi: 10.1136/adc.88.3.240

Nordfeldt, S., Johansson, C., Carlsson, E. & Hammersjo, J.A. (2005). Persistent effects of a pedagogical device targeted at prevention of severe hypoglycaemia: A randomized, controlled study. *Acta Paediatrica, 94*, 1395-1401. doi: 10.1111/j.1651-2227.2005.tb01810.x

Nowell, L. (2015). Pragmatism and integrated knowledge translation: Exploring compatibilities and tensions. *Nursing Open, 2*(3), 141-148. doi: 10.1002/nop2.30

Oakley, A., Strange, V., Bonell, C., Allen, E., Stephenson, J. & RIPPLE Study Team. (2006). Process evaluation in randomised controlled trials of complex interventions. *BMJ, 332*, 413-416.

O'Cathain, A., Murphy, E. & Nicholl, J. (2007). Why, and how, mixed methods research is undertaken in health services research: A mixed methods study. *BMC Health Services Research, 7*(85). doi: 10.1186/1472-6963-7-85

O'Cathain, A., Murphy, E. & Nicholl, J. (2008). The quality of mixed methods studies in health services research. *Journal of Health Services Research & Policy, 13*(2), 92-98. doi: 10.1258/jhsrp.2007.007074

O'Cathain, A. (2009). Mixed methods research in health sciences: A quiet revolution. *Journal of Mixed Methods Research, 3*(1), 1-6. doi: 10.1177/1558689808326272

O'Cathain, A., Thomas, K.J., Drabble, S.J., Rudolph, A. & Hewison, J. (2013). What can qualitative research do for randomised controlled trials? A systematic mapping review. *BMJ Open, 3(*e002889). doi:10.1136/ bmjopen-2013-002889

O'Cathain, A., Goode, J., Drabble, S.J., Thomas, K.J., Rudolph, A. & Hewison, J. (2014). Getting added value from using qualitative research with randomized controlled trials: A qualitative interview study. *Trials, 15*(215). doi: 10.1186/1745-6215-15-215

O'Cathain, A., Hoddinott, P. & Lewin, S. (2015). Maximising the impact of qualitative research in feasibility studies for randomized controlled trials: Guidance for researchers. *Pilot and Feasibility Studies,1*(32).

O'Connor, A.M. (2003, April 12). *User manual – Decision regret scale*. Ohri.ca. www.ohri.ca/decisionaid

O'Laughlin, E.V., Notaras, E., McCullough, C., Halliday, J. & Henry, R.L. (1995). Home-based management of children hospitalized with acute gastroenteritis. *Journal of Paediatric Child Health*, *31*(3), 189-191

Odom, S.I., Brown, W.H., Frey, T., Karasu, N., Smith-Canter, L.L. & Strain PS. (2003). Evidence-based practices for young children with autism: Contributions for single-subject design research. *Focus on Autism and Other Developmental Disabilities, 18*, 166-175.

Partha Sarathy, P., Kottan, L., Parker, A., Brealey, S., Coleman, E., Keding, A….Rangan, A. (2020). Timing of electronic reminders did not improve trial participant questionnaire response: A randomized trial and meta-analyses. *Journal of Clinical Epidemiology, S0895-4356*(19), 30953-30959.

Patient-Centered Outcomes Research Institute. (2020, March 19). *Compensation framework*. PCORI.org. https://www.pcori.org/document/compensation-framework.

Patsopoulos, N.A. (2011). A pragmatic view on pragmatic trials. *Dialogues in Clinical Neuroscience*, *13*(2), 217-224.

Pawson, R. (2019). Pragmatic trials and implementation science: Grounds for divorce? *BMC Medical Research Methodology, 19*(176). doi: 10.1186/s12874-019-0814-9

Pediatric Emergency Research Canada. (2020, January 13). *Who we are*. PERC-Canada.ca. https://www.perc-canada.ca/.

Pham, M.T., Rajic, A., Greig, J.D., Sargeant, J.M., Papadopoulos, A. & McEwen, S.A. (2014). A scoping review of scoping reviews: Advancing the approach and enhancing the consistency. *Research Synthesis Methods, 5*(4), 371-85. doi: 10.1002/jrsm

Pushor, D. (2008). Collaborative research. In L.M. Given (Ed.), *The SAGE Encyclopedia of Qualitative Research Methods: Vol 2* (92-95). SAGE Publications.

QSR International Pty Ltd. (2015). NVivo qualitative data analysis software (version 11). https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home

Rahman Morgan, S., Change, A.M., Alqatari, M. & Pines, J.M. (2013). Non-emergency department interventions to reduce ED utilization: A systematic review. *Academic Emergency Medicine, 20*(10), 969-985. doi: 10.1111/acem.12219

Ranjit, N., Menendez, T., Creamer, M., Hussaini, A., Potratz, C.R. & Hoelscher, D.M. (2015). Narrative communication as a strategy to improve diet and activity in low-income families: The use of role model stories. *American Journal of Health Education, 46*, 99-108.

Reelick, M.F., Faes, M.C., Esselink, R.A.J., Kessels, R.P.C. & Olde Rikkert, M.G.M. (2011). How to perform a preplanned process evaluation for complex interventions in geriatric medicine: Exemplified with the process evaluation of a complex falls-prevention program for community-dwelling frail older fallers. *Journal of the American Medical Directors Association, 12*(5), 331-336. doi: 10.1016/j.jamda.2011.01.006

Reich, S.M., Bickman, L., Saville, B.R. & Alvarez, J. (2010). The effectiveness of baby books for providing pediatric anticipatory guidance to new mothers. *Pediatrics, 125*(5), 997-1002. doi: 10.1542/peds.2009-2728

Richards, D.A., Bazeley, P., Borglin, G., Craig, P., Emsley, R., Frost, J., … O'Cathain, A. (2019). Integrating quantitative and qualitative data and findings when undertaking randomized controlled trials. *BMJ Open, 9*(e032081). doi: 10.1136/bmjopen-2019-032081

Rising, K.L., Carr, B.G., Hess, E.P., Meisel, Z.F., Ranney, M.L. & Vogel, J.A. (2016). Patient-centered outcomes research in emergency care: Opportunities, challenges, and future directions. *Academic Emergency Research, 23*(4), 498-502.

Ritzert, B. (2015). Multimedia educational interventions for consumers about prescribed and over-the-counter medications. *Public Health Nursing, 32*(2), 186-188. doi: 10.1111/phn.12102

Rolfe, G. (2006). Validity, trustworthiness and rigour: quality and the idea of qualitative research. *Journal of Advanced Nursing, 53*, 304–310. doi: 10.1111/j.1365-2648.2006.03727.x

Rothwell, P.M. (2005). External validity of randomised controlled trials: "To whom do the results of this trial apply?" *Lancet, 365*, 82-93.

Rycroft-Malone, J.O. (2008). Evidence-informed practice: From individual to context. *Journal of Nursing Management, 16*(4), 404–408.

Sacristan, J.A. (2013). Patient-centered medicine and patient-oriented research: Improving health outcomes for individual patients. *BMC Medical Informatics and Decision Making, 13*(6). doi: 10.1186/1472-6947-13-6

Saidinejad, M. & Zorc, J. (2014). Mobile and web-based education: Delivering emergency department discharge and aftercare instructions. *Pediatric Emergency Care, 30*, 211-216. doi: 10.1097/PEC.0000000000000097

Salari, P., Nikfar, S. & Abdollahi, M. (2012). A meta-analysis and systematic review on the effect of probiotics in acute diarrhea. *Inflammatory Allergy Drug Targets, 11*(1), 3–14. doi: 10.2174/187152812798889394

Samuels-Kalow, M.E., Stack, A.M. & Porter, S.C. (2012) Effective discharge communication in the emergency department. *Annals of Emergency Medicine, 60*(2), 152-159. doi: 10.1016/j.annemergmed.2011.10.023

Sandelowski, M. (1995). Sample size in qualitative research. *Research in Nursing & Health, 18*, 179-183.

Sandelowski, M. (2000). Whatever happened to qualitative description? *Research in Nursing & Health*, *23*, 334-40.

Sandelowski, M. (2010). What's in a name? Qualitative description revisited. *Research in Nursing & Health, 33*, 77-84.

Sanders, L.M., Federico, S., Klass, P., Abrams, M.A. & Dreyer, B. (2009). Literacy and child health: A systematic review. *JAMA Pediatrics, 163*(2), 131-140. doi: 10.1001/archpediatrics.2008.539

Scheinmann, R., Chiasson, A.M., Hartel, D. & Rosenberg, T.J. (2010). Evaluating a bilingual video to improve infant feeding knowledge and behaviour among immigrant Latina mothers. *Journal of Community Health, 35*, 464-470. doi: 10.1007/s10900-009-9202-4

Schuster, M., McGlynn, E. & Brook, R.H. (1998). How good is the quality of health care in the United States? *The Milbank Quarterly, 76*, 517–563. doi: 10.1111/j.1468-0009.2005.00403.x

Schutz, A. (1973). Collected papers I: The problem of social reality. (A., Broderson, Ed.). Martinus Nijhoff.

Scott, S.D., Harlting, L., O'Leary, K.A., Archibald, M. & Klassen, T.P. (2012). Stories – a novel approach to transfer complex health information to parents: A qualitative study. *Arts & Health, 4*(2), 162-173.

Senecal, M., Brisson, M., Lebel, M.H., Yaremko, J., Wong, R., Gallant, L.A., …Mansi, J.A. (2008). Measuring the impact of rotavirus acute gastroenteritis episodes (MIRAGE): A prospective community-based study. *Canadian Journal of Infectious Disease Medicine & Microbiology, 19*(6), 397-404. doi: 10.1155/2008/451540

Shah, M.P., Tate, J.E., Steiner, C.A. & Parashar, U.D. (2016). Decline in emergency department visits for acute gastroenteritis among children in 10 US states following implementation

of a rotavirus vaccination, 2003-2013. *Pediatric Infectious Disease Journal, 35*(7), 782–786. doi:10.1097/INF.0000000000001175

Shannon-Baker, P. (2016). Making paradigms meaningful in mixed methods research. *Journal of Mixed Methods Research, 10*(4), 319-334. doi: 10.1177/1558689815575861

Shanyinde, M., Pickering, R.M. & Weatherall, M. (2011). Questions asked and answered in pilot and feasibility randomized controlled trials. *BMC Medical Research Methodology, 11*(117). doi: 10.1186/1471-2288-11-117

Sheridan, S., Schrandt, S., Forsythe, L., Hilliard, T.S., Paez, K.A. & Advisory Panel on Patient Engagement (2013 inaugural panel). (2017). The PCORI engagement rubric: promising practices for partnering in research. *Annals of Family Medicine, 15*(2), 165–170. doi: 10.1370/afm.2042

Silagy, C., Lancaster, T., Gray, S. & Fowler, G. (1994). Effectiveness of training health professionals to provide smoking cessation interventions: Systematic review of randomized controlled trials. *Quality & Safety in Health Care, 3*(4), 193-198. doi: 10.1136/qshc.3.4.193

Skranes, L.P., Lohaugen, G.C.C. & Skranes, J. (2015). A child health information website developed by physicians: The impact of use on perceived parental anxiety and competence of Norwegian mothers. *Journal of Public Health, 23*, 77-85.

Snowdon, C. (2015). Qualitative and mixed methods research in trials. *Trials, 16*(558).

SoftLayer. (2017, March 1). *HIPPA & SoftLayer: Protecting patient privacy*. Softlayer.com. http://www.softlayer.com/info/hipaa.

Spandorfer, J.M., Karras, D.J., Hughes, L.A. & Caputo, C. (1995). Comprehension of discharge instructions by patients in an urban emergency department. *Annals of Emergency Medicine, 25*(1), 71-74. doi: 10.1016/s0196-0644(95)70358-6

Sparker, A. (2005). Narrative analysis: exploring the what's and how's of personal stories. In I. Holloway (Ed.), *Qualitative research in health care 1st ed*. (191-208). Open University Press.

Speros, C. (2005) Health literacy: Concept analysis. *Journal of Advanced Nursing, 50*(6), 633-640. doi: 10.1111/j.1365-2648.2005.03448.x

Squires, J.E., Grimshaw, J.M., Talijaard, M., Linklater, S., Chasse, M., Shemie, S.D. & Knoll, G.A. (2014). Design, implementation, and evaluation of a knowledge translation intervention to increase organ donation after cardiocirculatory death in Canada: A study protocol. *Implementation Science, 9*(80). doi: 10.1186/1748-5908-9-80

Stewart, M., Brown, J.B., Weston, W.W., McWhinney, I.R., McWilliam, C.L. & Freeman, T. (2003). *Patient-Centered Medicine, Transforming the Clinical Method*, 2nd ed. Radcliffe Medical Press Ltd.

Sustersic, M., Jeannet, E., Cozon-Rein, L., Marechaus, F., Genty, C., Foote, A., …Bosson, J.L. (2012). Impact of information leaflets on behavior of patients with gastroenteritis or tonsillitis: A cluster randomized trial in French primary care. *Journal of General Internal Medicine, 28*(1), 25-31. doi: 10.1007/s11606-012-2164-8

Sweller, J., van Merrienboer, J.J.G., Paas, F. (2019). Cognitive architecture and instructional design: 20 years later. *Educational Psychology Review, 31*, 261-292.

Taddio, A., Shah, V., Leung, E., Wang, J., Parikh, C., Smart, S. … Franck, L. (2013). Knowledge translation of the HELPinKIDS clinical practice guideline for managing

childhood vaccination pain: Usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatrics, 13*(23). doi: 10.1186/1471-2431-13-23

Taddio, A., MacDonald, N.E., Smart, S., Parikh, C., Allen, V., Halperin, B. & Shah, V. (2014). Impact of a parent-directed pamphlet about pain management during infant vaccinations on maternal knowledge and behaviour. *Neonatal Network, 33*(2), 74-82. doi: 10.1891/0730-0832.33.2.74

Tashakkori, A. & Teddlle, C. (1998). Mixed methodology: Combining qualitative and quantitative approaches. In *Applied Social Research Methods Series Volume 46*. SAGE Publications.

Teare, M.D., Dimairo, M., Shephard, N., Hayman, A., Whitehead, A. & Walters, S.J. (2014). Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: A simulation study. *Trials, 15*(264). doi: 10.1186/1745-6215-15-264

Tellstar. (2019, December 11). *Call Recorder – IntCall*. Tellstarint.net. https://www.telestarint.net/call-recorder.

Thabane, L., Hopewell, S., Lancaster, G.A., Bond, C.M., Coleman, C.L., Campbell, M.J. & Eldridge, S.M. (2016). Methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials. *Pilot and Feasibility Studies, 2*(25). doi: 10.1186/s40814-016-0065-z

Thabane, L. & Lancaster, G. (2017). Improving the efficiency of trials using innovative pilot designs: The next phase in the conduct and reporting of pilot and feasibility studies. *Pilot and Feasibility Studies, 4*(14). doi: 10.1186/s40814-017-0159-2

Thabane, L., Ma, J., Chu, R., Cheng, J., Rios, L.P., Robson, R., …Goldsmith, C.H. (2010). A tutorial on pilot studies: The what, why and how. *BMC Medical Research Methodology, 10*(1). doi: 10.1186/1471-2288-10-1

The Change Foundation. (2020, March 19). *Should money come into it? A tool for deciding whether to pay patient-engagement participants*. Changefoundation.ca. https://changefoundation.ca/patient-compensation-report/.

Thomas, H., Ciliska, D., Dobbins, M. & Micucci, S. (2004). A process for systematically reviewing the literature: Providing evidence for public health nursing interventions. *Worldviews on Evidence-Based Nursing, 2*, 91-9. doi: 10.1111/j.1524-475X.2004.04006.x

Thomas, A., Menon, A., Boruff, J., Rodriguez A.M., & Ahmed, S. (2014). Applications of social constructivist learning theories in knowledge translation for healthcare professionals: A scoping review. *Implementation Science, 9*(54). doi: 10.1186/1748-5908-9-54

Thompson, D.S., O'Leary, K., Jensen, E., Scott-Findlay, S.D., O'Brien-Pallas, L., Estabrooks, C.A. (2008). The relationship between busyness and research utilization: It is about time. *Journal of Clinical Nursing, 7*(4), 539-548. doi: 10.1111/j.1365-2702.2007.01981.x

Thomson, A.M., Cunningham, S.J.& Hunt, N.P. (2001). A comparison of information retention at an initial orthodontic consultation. *European Journal of Orthodontics, 23*, 169-178. doi: 10.1093/ejo/23.2.169

Tieder, J.S., Robertson, A. & Garrison, M.M. (2009). Pediatric hospital adherence to the standard of care for acute gastroenteritis. *Pediatrics, 124*(6), e1081-e1087. doi: 10.1542/peds.2009-0473

Tijam, A.M., Holtslag, G., Van Minderhout, H.M., Simonsz-Toth, B., Vermeulen-Jong, M.H.L., Borsboom, G.J.J.M., …Simonnsz, H.J. (2013). Randomised comparison of three tools for improving compliance with occlusion therapy: An educational cartoon story, a reward calendar, and an information leaflet for parents. *Graefe's Archives for Clinical and Experimental Ophthalmology, 251*(1), 321-329. doi: 10.1007/s00417-012-2107-4

Translating Emergency Knowledge for Kids. (2015, February 25). *Our mission and values*. Trekk.ca. http://trekk.ca/mission.

Translating Emergency Knowledge for Kids. (25, February 2015). *Phase 1: Needs Assessment*. Trekk.ca. http://trekk.ca/teams/phase-1-needs-assessment.

Translating Emergency Knowledge for Kids. (2020, January 13). *TREKK Parent Advisory Group*. TREKK.ca. https://trekk.ca/pages/43-parent-advisory-group.

Treweek, S., Mitchell, E., Pitkethly, M., Cook, J., Fraser, C., Mitchell, E. … Gardner, H. (2018). Strategies to improve recruitment to randomised controlled trials. *Cochrane Database of Systematic Rev*iews*, 2*(MR000013). doi: 10.1002/14651858.MR000013.pub6

Treweek, S., Lockhart, P., Pitkethly, M., Cook, J.A., Kjeldstrom, M., Johansen, M. … Mitchell, E.D. (2013). Methods to improve recruitment to randomized controlled trials: Cochrane systematic review and meta-analysis. *BMJ Open*, *3*(e002360).

Tugwell, P.S., Santesso, N.A., O'Connor, A.M., Wilson, A.J. & Effective Consumer Investigation Group. (2007). Knowledge translation for effective consumers. *Physical Therapy, 87*(12), 1728-1738. doi: 10.2522/ptj.20070056

Tunis, S.R., Stryer, D.B. & Clancy, C.M. (2003). Practical clinical trials: Increasing the value of clinical research for decision making in clinical health policy. *JAMA*, *290*(12), 1624-1632. doi: 10.2522/ptj.20070056

University of Alberta. (2019, November 19). *Faculty of Medicine & Dentistry: Pediatrics*. Ualberta.ca. https://www.ualberta.ca/pediatrics/divisions/emergency-medicine.

University of Alberta. (2019, December 2). *The use of incentives in research*. Ualberta.ca. https://www.ualberta.ca/research/support/ethics-office/human-research-ethics/use-of-incentives-in-research.

Vaismoradi, M., Turunen H. & Bondas, T. (2013). Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing & Health Sciences*, *15*(3), 398-405. doi: 10.1111/nhs.12048

Vashi, A. & Rhodes, K.V. (2011). "Sign right here and you're good to go": A content analysis of audiotaped emergency department discharge instructions. A*nnals of Emergency Medicine, 57*(4), 315-322. doi: 10.1016/j.annemergmed.2010.08.024

Wakimizu, R., Kamagata, S., Kuwabara, T. & Kamibeppy, K. (2009). A randomized controlled trial of an at-home preparation programme for Japanese preschool children: Effects on children's and caregivers' anxiety associated with surgery. *Journal of Evaluation in Clinical Practice, 15*(2), 393-401. doi: 10.1111/j.1365-2753.2008.01082.x

Walshe, K. (2009). Pseudoinnovation: The development and spread of healthcare quality improvement methodologies. *International Journal for Quality in Health Care, 21*(3), 153–159. doi: 10.1093/intqhc/mzp012

Wells, G., Beaton, D., Shea, B., Boers, M., Simon, L., Strand, V. …Tugwell, P. (2001). Minimal clinically important differences: Review of methods. *Journal of Rheumatol*ogy*, 28*(2), 406-412.

Wensing, M. & Grol, R. (2019). Knowledge translation in health: How implementation science could contribute more. *BMC Medicine, 17*(88). doi:10.1186/s12916-019-1322-9

Whitehead, A., Julious, S., Cooper, C. & Campbell, M.J. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research, 25*(3), 1057–1073. doi: 10.1177/0962280215588241

Williams, D.M., Counselman, F.L. & Caggiano, C.D. (1996). Emergency department discharge instructions and patient literacy: A problem of disparity. *American Journal of Emergency Medicine, 14*(1), 19-22. doi: 10.1016/S0735-6757(96)90006-6

Wilson, E.A.H. & Wolf, M.S. (2009). Working memory and the design of health materials: A cognitive factors perspective. *Patient Education and Counseling, 74*(3), 318-322. doi: 10.1016/j.pec.2008.11.005

Wilson, E.A.H., Makoul, G., Bojarski, E.A., Cooper Bailey, S., Waite, K.R., Rapp, D.N. … Wolf, M.S. (2012). Comparative analysis of print and multimedia health materials: A review of the literature. *Patient Education and Counseling, 89*(1), 7-14. doi: 10.1016/j.pec.2012.06.007

Wilson, F.L., Brown, D.L. & Stephens-Ferris, M. (2006). Can easy-to-read immunization information increase knowledge in urban low-income mothers? *Journal of Pediatric Nursing, 21*(1), 4-12. doi: 10.1016/j.pedn.2005.06.003

Witteman, H.O., Vaisson, G., Provencher, T., Dansokho, S.C., Colquhoun, H., Dugas, M.… Renaud, J.S. (2020). Development and validation of UCD-11: An 11-item measure of user-centered design for patient-centered tools. *Manuscript pre-print.* doi:10.31219/osf.io/w5vnk

Wittenberg-Lyles, E., Parker Oliver, D., Demiris, G., Swarz, J. & Rendo, M. (2014). YouTube as a tool for pain management with informal caregivers of cancer patients: A systematic

review. *Journal of Pain Symptom Management, 48*(6), 1200-1210. doi: 10.1016/j.jpainsymman.2014.02.015

Woolfall, K., Young, B., Frith, L., Appleton, R., Iyer, A., Messahel, S., Hickey, H. & Gamble, C. (2014). Doing challenging research studies in a patient-centred way: A qualitative study to inform a randomised controlled trial in the pediatric emergency care setting. *BMJ Open, 4*(e005045).

Wouters, P., Paas, F. & van Merrienboer, J.J.G. (2008). How to optimize learning from animated models: a review of guidelines based on cognitive load. *Review of Educational Research, 78*(3), 65-67.

Yin, R. (2011). Qualitative research from start to finish. The Guilford Press.

Yin, S.H., Dreyer, B.P., van Schaick, L., Foltin, G.L., Dinglas, C. & Mendelsohn, A.L. (2008). Randomized controlled trial of a pictogram-based intervention to reduce liquid medication dosing errors and improve adherence among caregivers of young children. *Archives of Pediatrics & Adolescent Medicine, 162*(9), 814-82. doi: 10.1001/archpedi.162.9.814

Appendices

Appendix A: Intervention video side-by-side script

Scene	Voice Over – Mom's voice	Visuals
1.	Chris is sick.	Chris (boy), 9-10 years old, of Asian descent with vomiting, diarrhea, losing energy.
2.	We've tried everything to try to make him feel better, but nothing seems to be working.	Mom & Dad are cuddling/reassuring Chris on the couch, giving him liquid to drink, and encouraging rest.
3.	Unfortunately, the doctor is out of the office for a few days and we can't get in to see him until next week.	Dad calling the doctor.
4.	Unsure about what to do next, I remembered a time when Chris was very young and he had a lot of diarrhea and vomited so much that we took him to the emergency department.	Mom cuddling Chris on the couch and thinking back to him as an infant child in the emergency department with a female physician.
5.	It ended up that he was sick with a virus that causes gastroenteritis which made him very dehydrated because more fluids were coming out than staying in.	Scared parents holding baby Chris who is getting an IV to rehydrate.
6.	Luckily, they gave us an information sheet about the virus and what to do in case it happens again.	Lightbulb moment of remembering the information sheet and then retrieving it from a drawer.
7.	It certainly seems like he has gastroenteritis again.	
8.	I'd better check to see if he is dehydrated – that was what made it so serious last time.	Show Mom reading information sheet with the following content: Viral Gastroenteritis: How can I tell if my child is dehydrated? Signs of dehydration include: 1. Thirst 2. No tears when crying 3. Sunken eyes 4. Dry mouth 5. Infrequent peeing 6. Cold hands and/or feet 7. Extreme tiredness
9.	He doesn't seem to be dehydrated. He's just tired and wants to feel better.	Show Mom checking Chris on the couch for these symptoms.
10.	Should we take him to the emergency department?	Mom turning the page to read the back side with the following content: Viral Gastroenteritis: When should I bring my child to the Emergency Department? 1. Child is extremely tired

		2. There are no tears when crying 3. No pee for about 12 hours 4. Overall more fluid coming out (vomiting/diarrhea) that going in (drinking) 5. Stomach pain is not centred around the belly button 6. Persistent dark-green throw up (vomit, puke) 7. Blood in poop (diarrhea)
11.	Since he doesn't have any of these symptoms, I think we can give him Tylenol, a brand of acetaminophen, to reduce his fever and some sips of Pedialyte, a brand of oral rehydration solution, to keep him hydrated and wait to see if he improves. We might even try to give him some sips of clear soup to give him some added energy. If after 2-3 days he still doesn't have any of the symptoms, yet isn't improving, we will take him to a doctor.	Dad brings in a tray with a bottle of acetaminophen, a bottle of rehydration solution, and a bowl of soup on it. Mom is sitting on the couch next to Chris laying down.
12.	This video was brought to you by ECHO, ARCHE & TREKK and it was funded by the Canadian Institutes of Health Research	Logos

Appendix B: Search Strategies

Platform	Database	Date search was run	Number of citations retrieved
Ovid	EBM Reviews – Cochrane Central Register of Controlled Trials	15 June 2015	292
	Embase 1988-	15 June 2015	3238
	MEDLINE 1946-	15 June 2015	2347
	MEDLINE In-Process & Other Non-Indexed Citations	15 June 2015	212
	PsycINFO 1987-	15 June 2015	2210
EBSCOhost	CINAHL	15 June 2015	1242
	SocINDEX	15 June 2015	225
Web of Science	Science Citation Index Expanded 1900-; Social Sciences Citation Index 1900-; Conference Proceedings Citation Index- Science 1990-; Conference Proceedings Citation Index- Social Science & Humanities 1990-; Book Citation Index– Science 2005-; Book Citation Index– Social Sciences & Humanities 2005-	15 June 2015	1039
		Sub-Total	10805

MEDLINE 1946, In-Process & Other Non-Indexed Citations

1. patient education handout/

2. books/ or books, illustrated/ or cookbooks as topic/ or pamphlets/ or Cartoons as Topic/

3. Mass Media/

4. newspapers/ or periodicals as topic/

5. video-audio media/ or "instructional films and videos"/ or interactive tutorial/ or webcasts/

6. internet/ or blogging/ or social media/

7. Music/

8. or/2-7

9. exp Consumer Health Information/

10. 8 and 9

11. (storybook* or comic* or cartoon* or ebook* or e-book* or story or poem* or poetry or comic strip* or photonovella* or photo novella* or fotonovela* or photo diary or photo diaries or photodiary or photodiaries or flipchart* or flip chart* or storyboard* or story board* or printed health material*).tw,kf.

12. (pamphlet* or information sheet* or newsletter* or digital animation* or cartoon* or gif or infographic* or podcast* or social media or twitter or facebook or blog or blogs or face book or song or songs or youtube).tw,kf.

13. (book or books or video or videos or website or web site* or game or games or app or smart phone* or smartphone*).tw,kf.

14. or/11-13

15. ((health or consumer* or patient* or parent* or caregiver*) adj2 (information or education*)).tw,kf.

16. exp Consumer Health Information/

17. 15 or 16

18. 14 and 17

19. 1 or 10 or 18

20. exp health behavior/ or illness behavior/

21. self care/ or self medication/ or risk reduction behavior/ or disease management/ or "Medication Therapy Management"/

22. ((health or illness) adj behavio?r).tw,kf.

23. (self adj (manag* or care or administ* or monitor* or efficac* or medicat* or mainten* or treat*)).tw,kf.

24. or/20-23

25. 19 and 24

26. "diffusion of innovation"/

27. (research adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or support)).tw,kf.

28. (knowledge adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)).tw,kf.

29. (evidence adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)).tw,kf.

30. (implementation adj1 (science or research or intervention)).tw,kf.

31. exp Translational Medical Research/

32. exp Organizational Innovation/

33. exp Information Dissemination/

34. exp Translations/

35. exp Evidence-Based Practice/

36. knowledge/

37. Health Knowledge, Attitudes, Practice/

38. knowledge.ti.

39. or/26-38

40. 19 and 39

41. 25 or 40

42. or/27-30

43. (game or games or app or smart phone* or smartphone*).tw,kf.

44. (book or books or video* or website or web site*).ti.

45. (book or books or video or videos or website or web site*).ab. /freq=2

46. or/11-12,43-45

47. 42 and 46

48. 41 or 47

49. limit 48 to yr="2000 -Current"

EBM Reviews Cochrane Central Register of Controlled Trials

1. patient education handout/

2. books/ or books, illustrated/ or cookbooks as topic/ or pamphlets/ or Cartoons as Topic/

3. Mass Media/

4. newspapers/ or periodicals as topic/

5. video-audio media/ or "instructional films and videos"/ or interactive tutorial/ or webcasts/

6. internet/ or blogging/ or social media/

7. Music/

8. or/2-7

9. exp Consumer Health Information/

10. 8 and 9

11. (storybook* or comic* or cartoon* or ebook* or e-book* or story or poem* or poetry or comic strip* or photonovella* or photo novella* or fotonovela* or photo diary or photo diaries or photodiary or photodiaries or flipchart* or flip chart* or storyboard* or story board* or printed health material*).tw.

12. (pamphlet* or information sheet* or newsletter* or digital animation* or cartoon* or gif or infographic* or podcast* or social media or twitter or facebook or blog or blogs or face book or song or songs or youtube).tw.

13. (book or books or video or videos or website or web site* or game or games or app or smart phone* or smartphone*).tw.

14. or/11-13

15. ((health or consumer* or patient* or parent* or caregiver*) adj2 (information or education*)).tw.

16. exp Consumer Health Information/

17. 15 or 16

18. 14 and 17

19. 1 or 10 or 18

20. exp health behavior/ or illness behavior/

21. self care/ or self medication/ or risk reduction behavior/ or disease management/ or "Medication Therapy Management"/

22. ((health or illness) adj behavio?r).tw.

23. (self adj (manag* or care or administ* or monitor* or efficac* or medicat* or mainten* or treat*)).tw.

24. or/20-23

25. 19 and 24

26. "diffusion of innovation"/

27. (research adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or support)).tw.

28. (knowledge adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)).tw.

29. (evidence adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)).tw.

30. (implementation adj1 (science or research or intervention)).tw.

31. exp Translational Medical Research/

32. exp Organizational Innovation/

33. exp Information Dissemination/

34. exp Translations/

35. exp Evidence-Based Practice/

36. knowledge/

37. Health Knowledge, Attitudes, Practice/

38. knowledge.ti.

39. or/26-38

40. 19 and 39

41. 25 or 40

42. or/27-30

43. (game or games or app or smart phone* or smartphone*).tw.

44. (book or books or video* or website or web site*).ti.

45. (book or books or video or videos or website or web site*).ab. /freq=2

46. or/11-12,43-45

47. 42 and 46

48. 41 or 47

49. limit 48 to yr="2000 -Current"

Embase

1. book/

2. exp mass communication/

3. music/

4. or/1-2

5. consumer health information/

6. patient information/

7. 5 or 6

8. 4 and 7

9. (storybook* or comic* or cartoon* or ebook* or e-book*or story or poem* or poetry or comic strip* or photonovella* or photo novella* or fotonovela* or photo diary or photo diaries or photodiary or photodiaries or flipchart* or flip chart* or storyboard* or story board* or printed health material*).tw.

10. (pamphlet* or information sheet* or newsletter* or digital animation* or cartoon* or gif or infographic* or podcast* or social media or twitter or facebook or blog or blogs or face book or song or songs or youtube).tw.

11. (book or books or video or videos or website or web site* or game or games or app or smart phone* or smartphone*).tw.

12. or/9-11

13. ((health or consumer* or patient* or parent* or caregiver*) adj2 (information or education*)).tw.

14. consumer health information/ or patient information/

15. 13 or 14

16. 12 and 15

17. 8 or 16

18. exp health behavior/

19. illness behavior/

20. exp self care/

21. disease management/

22. ((health or illness) adj behavio?r).tw.

23. (self adj (manag* or care or administ* or monitor* or efficac* or medicat* or mainten* or treat*)).tw.

24. or/18-23

25. 17 and 24

26. (research adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or support)).tw.

27. (knowledge adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)).tw.

28. (evidence adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)).tw.

29. (implementation adj1 (science or research or intervention)).tw.

30. translational research/

31. information dissemination/

32. exp evidence based practice/

33. knowledge/

34. knowledge.ti.

35. or/26-34

36. 17 and 35

37. 25 or 36

38. or/26-29

39. (game or games or app or smart phone* or smartphone*).tw.

40. (book or books or video or videos or website or web site*).ti.

41. (book or books or video or videos or website or web site*).ab. /freq=2

42. or/9-10,39-41

43. 38 and 42

44. 37 or 43

PsycINFO

1. mass media/ or films/ or exp news media/ or exp printed communications media/ or animation/ or public service announcements/

2. digital video/ or audiovisual communications media/ or videotapes/

3. internet/ or exp social media/ or exp telecommunications media/ or websites/

4. music/ or rock music/

5. or/1-4

6. exp health education/

7. health promotion/

8. 6 or 7

9. 5 and 8

10. (storybook* or comic* or ebook* or e-book* or story or poem* or poetry or comic strip* or photonovella* or photo novella* or fotonovela* or photo diary or photo diaries or photodiary or photodiaries or flipchart* or flip chart* or storyboard* or story board* or printed health material*).mp.

11. (pamphlet* or information sheet* or newsletter* or digital animation* or cartoon* or gif or infographic* or podcast* or social media or twitter or facebook or blog or blogs or face book or song or songs or youtube).mp.

12. (book or books or video* or website or web site* or game or games or app or smart phone* or smartphone*).mp.

13. or/10-12

14. ((health or consumer* or patient* or parent* or caregiver*) adj2 (information or education*)).mp.

15. 13 and 14

16. exp health behavior/

17. exp behavior modification/

18. ((health or illness) adj behavio?r).mp.

19. (self adj (manag* or care or administ* or monitor* or efficac* or medicat* or mainten* or treat*)).mp.

20. or/16-19

21. 9 or 15

22. 20 and 21

23. knowledge transfer/

24. (research adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or support)).mp.

25. (knowledge adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)).mp.

26. (evidence adj2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)).mp.

27. (implementation adj1 (science or research or intervention)).mp.

28. information dissemination/

29. evidence based practice/

30. health knowledge/ or "knowledge (general)"/

31. knowledge.ti.

32. or/23-31

33. 21 and 32

34. 22 or 33

35. or/24-27

36. 13 and 35

37. (game or games or app or smart phone* or smartphone*).mp.

38. (book or books or video* or website or web site*).ti.

39. (book or books or video* or website or web site*).ab. /freq=2

40. 37 or 38 or 39

41. 23 or 24 or 25 or 26 or 27

42. 40 and 41

43. 34 or 42

44. limit 43 to yr="2000 -Current"

CINAHL

S1	(MH "Books") OR (MH "Pamphlets") OR (MH "Audiorecording") OR (MH "Communications

	Media") OR (MH "Multimedia") OR (MH "Videorecording+") OR (MH "Electronic Books") OR (MH "Print Materials") OR (MH "Social Media") OR (MH "Internet+") OR (MH "Music")
S2	(MH "Consumer Health Information")
S3	S1 AND S2
S4	(storybook* or comic* or ebook* or "e-book*" or story or poem* or poetry) OR ("comic strip*" or photonovella* or "photo novella*" or fotonovela*) OR ("photo diary" or "photo diaries" or photodiary or photodiaries) OR (flipchart* or "flip chart*" or storyboard* or "story board*" or "printed health material*") OR (pamphlet* or "information sheet*" or newsletter* or "digital animation*") OR (cartoon* or gif or infographic* or podcast* or "social media" or twitter or facebook) OR (blog or blogs or face book or song or songs or youtube) OR (book or books or video* or website or "web site*" or game or games or app or "smart phone*" or smartphone*)
S5	(caregiver* N0 (information or education*)) OR (parent* N0 (information or education*)) OR (patient* N0 (information or education*)) OR (consumer N0 (information or education*)) OR (health N0 (information or education*))
S6	(MH "Consumer Health Information")
S7	S5 OR S6
S8	S4 AND S7
S9	S3 OR S8
S10	(MH "Health Behavior+") OR (MH "Self Care+") OR (MH "Self Medication") OR (MH "Disease Management")
S11	("health behavio#r" OR "illness behavio#r") OR (self N0 (manag* or care or administ* or monitor* or efficac* or medicat* or mainten* or treat*))
S12	S10 OR S11
S13	S9 AND S12

S14	(MH "Diffusion of Innovation") OR (MH "Professional Practice, Evidence-Based+") OR (MH "Knowledge+") OR (MH "Health Knowledge")
S15	research N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or support)
S16	knowledge N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)
S17	evidence N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)
S18	(implementation N1 (science or research or intervention))
S19	S14 OR S15 OR S16 OR S17 OR S18
S20	S9 AND S19
S21	S13 OR S20
S22	TI evidence N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)
S23	TI knowledge N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)
S24	TI research N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or support)
S25	S22 OR S23 OR S24
S26	S18 OR S25
S27	S4 AND S26
S28	S21 OR S27
S29	S21 OR S27 Limiters - Published Date: 20000101-20161231; Research Article

SocINDEX

S1	(storybook* or comic* or ebook* or "e-book*" or story or poem* or poetry) OR ("comic strip*" or photonovella* or "photo novella*" or fotonovela*) OR ("photo diary" or "photo diaries" or photodiary or photodiaries) OR (flipchart* or "flip chart*" or storyboard* or "story board*" or "printed health material*") OR (pamphlet* or "information sheet*" or newsletter* or "digital animation*") OR (cartoon* or gif or infographic* or podcast* or "social media" or twitter or facebook) OR (blog or blogs or face book or song or songs or youtube) OR (book or books or video* or website or "web site*" or game or games or app or "smart phone*" or smartphone*)
S2	(caregiver* N0 (information or education*)) OR (parent* N0 (information or education*)) OR (patient* N0 (information or education*)) OR (consumer N0 (information or education*)) OR (health N0 (information or education*))
S3	S1 AND S2
S4	("health behavio#r" OR "illness behavio#r") OR (self N0 (manag* or care or administ* or monitor* or efficac* or medicat* or mainten* or treat*))
S5	S3 AND S4
S6	research N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or support)
S7	knowledge N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)
S8	evidence N2 ("use" or utili#ation or adopt* or implement* or disseminat* or uptake or transfer* or translat* or support)
S9	(implementation N1 (science or research or intervention))
S10	S6 OR S7 OR S8 OR S9
S11	S3 AND S10
S12	S5 OR S11
S13	S5 OR S11

S14	TI (storybook* or comic* or ebook* or "e-book*" or story or poem* or poetry) OR ("comic strip*" or photonovella* or "photo novella*" or fotonovela*) OR ("photo diary" or "photo diaries" or photodiary or photodiaries) OR (flipchart* or "flip chart*" or storyboard* or "story board*" or "printed health material*") OR (pamphlet* or "information sheet*" or newsletter* or "digital animation*") OR (cartoon* or gif or infographic* or podcast* or "social media" or twitter or facebook) OR (blog or blogs or face book or song or songs or youtube) OR (book or books or video* or website or "web site*" or game or games or app or "smart phone*" or smartphone*)
S15	S10 AND S14
S16	S13 OR S15
S17	S13 OR S15 Limiters - Date of Publication: 20000101-20151231

Web of Science: Science Citation Index Expanded 1900-; Social Sciences Citation Index 1900-; Conference Proceedings Citation Index- Science 1990-; Conference Proceedings Citation Index- Social Science & Humanities 1990-; Book Citation Index– Science 2005-; Book Citation Index– Social Sciences & Humanities 2005-

#1	TS=(storybook* or cartoon* or comic* or ebook* or "e-book*" or story or poem* or poetry) OR TS=("comic strip*" or photonovella* or "photo novella*" or fotonovela*) OR TS=("photo diary" or "photo diaries" or photodiary or photodiaries) OR TS=(flipchart* or "flip chart*" or storyboard* or "story board*" or "printed health material*") OR TS=(pamphlet* or "information sheet*" or newsletter* or "digital animation*") OR TS=(cartoon* or gif or infographic* or podcast* or "social media" or twitter or facebook) OR TS=(blog or blogs or "face book" or song or songs or youtube) OR TS=(book or books or video* or website or "web site*" or game or games or app or "smart phone*" or smartphone*) Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH Timespan=2000-2015
#2	TS=("caregiver* information" or "caregiver* education*" OR "parent* information" or "parent* education*" OR "patient* information" or "patient* education*" OR "consumer information" or "consumer education*" OR "health information" or "health education*") Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH Timespan=2000-2015
#3	TS=("health behavior" OR "health behaviour" or "illness behavior" or "illness behaviour" or "self manag*" or "self care" or "self administ*" or "self monitor*" or "self efficac*" or "self medicat*" or "self mainten*" or "self treat*") Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH Timespan=2000-2015
#4	#1 AND #2 AND #3
#5	TS=("research use" or "research utilisation" or "research utilization" or "research adopt*" or "research implement*" or "research disseminat*" or "research uptake" or "research support")

	Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH Timespan=2000-2015
#6	TS=("knowledge use" or "knowledge utilisation" or "knowledge utilization" or "knowledge adopt*" or "knowledge implement*" or "knowledge disseminat*" or "knowledge uptake" or "knowledge support" or "knowledge transfer" or "knowledge translation") Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH Timespan=2000-2015
#7	TS=("evidence use" or "evidence utilisation" or "evidence utilization" or "evidence adopt*" or "evidence implement*" or "evidence disseminat*" or "evidence uptake" or "evidence support" or "evidence transfer" or "evidence translation") Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH Timespan=2000-2015
#8	TS=("implementation science" or "implementation research" or "implementation intervention") Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH Timespan=2000-2015
#9	#5 OR #6 OR #7 OR #8
#10	#1 AND #9
#11	#4 OR #10

Appendix C: Secondary screening criteria

Guiding Screening Question: **Does the study evaluate the effectiveness of a knowledge translation tool for health consumers?**

Yes = include
No = exclude

To answer "Yes" to the above guiding question, the study must meet the following parameters:

1. Is effectiveness evaluated?

The focus of effectiveness evaluation is 'did this work' not accessibility, usability, feasibility, whether it was used/accessed.

Yes = move to next question
Unsure = move to next question
No = exclude study

2. Is the target audience a recipient of healthcare and/or a participant in the health decision-making process for/with a healthcare recipient?

Other audiences (i.e., clinicians) can be included, but the healthcare consumer intervention must be described and outcome measures and results reported separately.

Yes = move to next question
Unsure = move to next question
No = exclude study

3. **Is the intervention a stand-alone (i.e., not embedded in another program/KT intervention), user-mediated (i.e., on-demand) product designed to put synthesized health research knowledge into practice?**

Can be included if it is one-arm of a multi-arm study. Examples include: website, video, pamphlet, booklet, etc. An intervention is not user-mediated if the product is only viewed 1 time within the control of the research team (i.e., in a hospital/clinic, in a lab) immediately followed by post-intervention evaluation measures.

Yes = include study
Unsure = mark study as unsure
No = exclude study

Appendix D: WIDER recommendations to improve reporting of the content of behavior change interventions

WIDER Recommendations	Supplementary Recommendations
Detailed description of interventions in published papers	1) characteristics of those delivering the intervention 2) characteristics of the recipients 3) the setting 4) the mode of delivery 5) the intensity 6) the duration 7) adherence/fidelity to delivery protocols 8) detailed description of the intervention content provided for each study group
Clarification of assumed change process and design principles	1) the intervention development 2) the change techniques used in the intervention 3) the causal processes targeted by these change techniques
Access to intervention manuals/protocols,	Submit protocols or manuals for publication to make these supplementary materials easily accessible (*i.e.*, online).
Detailed description of active control conditions	1) control intervention described 2) control intervention not described 3) no active control (i.e., standard care/no intervention control) 4) no control group

Appendix E: Outcomes of interest for assessing patient-focused interventions

Outcome category	**Examples**
Patients' knowledge	• Knowledge of condition and long term complications • Self-care knowledge • Knowledge of treatment options and likely outcomes • Comprehension of information • Recall of information
Patients' experience	• Patient satisfaction • Doctor-patient communication • Quality of life • Psychological wellbeing • Self-efficacy • Patient involvement
Service utilization and costs	• Hospital admissions • Emergency admissions • Length of hospital stay • GP visits • Cost-effectiveness • Cost to patients • Days lost from work/school
Health behaviour and health status	• Self-care activities • Treatment adherence • Disease severity/activity • Symptom control • Functional ability • Clinical indicators

Appendix F: Scoping review summary of included studies (n=18)

Author (Year) Country	Study Focus (child health topic)	Study Population (sample size)	Intervention & Comparison Groups	Primary outcome(s) category(ies) (specific outcome)	Results by outcome category	Author Conclusions
Cross-sectional studies (n=4)						
Dempsey et al. (2006) USA	Public health (Vaccination)	Parents of children 8-12 years old (n=1600 parents)	**KT[1] tool intervention**: Information sheet **Comparison**: No intervention control	Patients' experience (vaccine acceptability)	No effect	"Providing parents with a written information sheet about HPV did lead to improvement in their knowledge about HPV but did not result in substantial increases in HPV vaccine acceptability" (p. 1492).
Evans et al. (2009) United Kingdom	Chronic (Inherited metabolic disorders)	Children on low protein diet & their caregivers (n=102 patients)	**KT tool intervention:** Video + book **Comparison:** None	Health behaviour/health status (self-reported change in frequency of low protein cooking)	**Unclear:** Descriptive statistics provided for child & caregiver on related outcome (willingness to try new recipe); self-reported change in frequency of low protein cooking not reported.	"The book and/or DVD did not engage families who chose not to routinely cook with low protein ingredients" (p. 412).
Ranjit et al. (2015) USA	Public health (Healthy diet & physical activity)	Parents (n=322 parents)	**KT tool intervention**: book (bilingual)	Patients' knowledge (healthy eating, physical activity)	No effect	"A narrative communication approach presented as a book of role model stories can bring about a positive change in lifestyle behaviours and associated cognitions" (p. 99).
				Patients' experience (self-efficacy, perceived barriers related to healthy eating & physical activity)	**Mixed effect:** Significant +ve effect on self-efficacy measures, but no effect on perceived barrier measures.	
			Comparison: Participants who did not read book	Health behaviour/health status (intentions related to healthy eating & physical activity)	No effect	

[1] KT = Knowledge translation

Sustersic et al. (2013) France	Acute (Gastroenteritis, tonsillitis)	Adult parents of pediatric patients[2] (n=154 pediatric patients)	**KT tool intervention**: Pamphlet **Comparison**: Usual care control	Health behaviour/health status (related to pediatric tonsillitis or gastroenteritis)	**Mixed effect:** No effect for child health groups (n=2) regardless of condition. Significant +ve effect for childhood gastroenteritis group compared to control, no effect for childhood tonsillitis group compared to control.[3]	"The four PIL studies significantly improved patient knowledge and increased patient autonomy by inducing behaviour closer to that recommended by the guidelines" (p. 30-31).
Before-after studies (n=1)						
Skranes et al. (2015) Norway	Public health (Child health, minor conditions)	Mothers of young children (n=99 mothers)	**KT tool intervention**: website **Comparison**: Same participants before viewing website	Patients' knowledge (child health) Patients' experience (self-perceived anxiety)	Significant +ve effect No effect	"Regular use of a website about child health developed by experienced physicians enhanced perceived parents' competence, reduced anxiety and increased knowledge among Norwegian mothers of young children" (p. 83)
Controlled before-after studies (n=2)						
Scheinman et al. (2010) USA	Public health (Infant feeding)	Latina mothers of children ≤ 24 months old (n=439 women)	**KT tool intervention**: Video (bilingual) **Comparison**: No intervention control	Patients' knowledge (age-appropriate infant feeding practices) Health behaviour/health status (actual infant feeding practices)	**Mixed effect:** Significant +ve effects on 3/9 measures at 6 months; no effect on 6/9 measures at 6 months. **Mixed effect:** Significant +ve effects on 1/7 measures at 6 months; no effect on 6/7 measures at 6 months.	"We found that an inexpensive, low-intensity video intervention can positively impact maternal knowledge and behaviour related to infant feeding among Latinas" (p. 464).
Taddio et al. (2014) Canada	Acute (Procedural pain management)	New mothers in hospital following birth of child (n=440 mothers)	**KT tool intervention**: Pamphlet **Comparison:** Pre-intervention group	Patients' knowledge (vaccination pain management)	No effect	"This study did not support passive dissemination of the pamphlet in hospital postnatal discharge packages as a method

[2] Additional study population not included in this review was adult patients with tonsillitis and gastroenteritis.
[3] Significant +ve effect for adult groups (n=2), adult gastroenteritis group, and adult tonsillitis group compared to control.

			Comparison: No intervention control			of educating new parents about pain management during infant vaccinations" (p. 81).
Cohort study (n=1)						
Nordfeldt (2002) Sweden	Chronic (Type I diabetes)	Children with type I diabetes & their caregivers (n=122-139 patients from 1994-1999)	**KT tool intervention**: 2 pamphlets (hypoglycaemia & tools) + 2 videos (hypoglycaemia & tools) with patient/parent Q&A	Patients' experience (perceived benefit)	**Unclear:** Significant +ve effect for 1 video (hypoglycaemia) vs 1 brochure (hypoglycaemia). Overall effect of brochure vs videos + brochures or tools brochure vs tools video not reported.	"Targeted self-study material for home use that supports diabetes self-care and aims at the prevention of severe hypoglycaemia may be used as a complement to regular visits to the diabetes team" (p. 136).
			KT tool comparison: 2 pamphlets (hypoglycaemia & tools)	Health behaviour/health status (episodes of severe hypoglycaemia, HbA1c level)	**Unclear:** No effect for brochure group only on average incidence of severe hypoglycaemia. No results reported for video + brochure group. Significant decrease in HbA1c for brochure group only. No results reported for video + brochure group.	
Randomized controlled trial (n=10)						
Bailey et al. (2015) Australia	Acute (Surgery pain management)	Parents of children undergoing surgery (n=58 patients)	**KT tool intervention**: Information sheet	Patients' knowledge (pain control)	Significant +ve effect	"The primary objective to explore the efficacy of the information sheet has proved to be successful in this setting. Thus, an information sheet included in the parent and patient shared decision model of analgesia leads to improved control in the management of postoperative analgesia" (p. 736).
				Patients' experience (satisfaction with post-surgery pain control)	Significant +ve effect	
			Comparison: Usual care control	Health behaviour/health status (pain as rated separately by child and parent)	**Mixed effect:** Significant +ve effect on pain measures at 2/3 time points (parent measure) and 1/3 time points (child measure).	
Bauchner et al. (2001)	Public health (Antibiotics use)	Parents of children 6	**KT tool intervention**: Video +pamphlet	Patients' knowledge (appropriate use of	No effect	"Overall this video had only a modest effect on

USA		months - 3 years old (n=206 parents)		antibiotics, reasons for development of bacterial resistance)		parent knowledge, beliefs, and self-reported behaviours regarding oral antibiotics. We believe that any campaign promoting the judicious use of oral antibiotics must use a multifaceted approach and target both parents and physicians" (p.845).
			Comparison: No intervention control	Patients' experience (beliefs about antibiotics & bacterial resistance)	No effect	
				Health behaviour/health status (administration and use of antibiotics)	**Mixed effect:** Significant +ve adjusted difference for 1/5 behaviour items	
Christakis et al. (2006) USA	Public health (Preventive care for common childhood conditions)	Parents of children <11 years old attending health clinics for well-child visits (n=887 families)	**Intervention (not KT tool):** Tailored website + HCP notification	Health behaviour/health status (discussion with HCP, implementation of prevention practices)	**Mixed effect:** Significant +ve effect for all interventions combined (n=3) compared to control on behaviour measures. Website + notification group and notification alone group had significant +ve effects on discussion with HCP measures compared to control, but no effect for website-alone group compared to control. Website + notification group and website-alone group had significant +ve effects on implementation measures compared to control, but no effect for notification-alone group compared to control.	"A web-based intervention can activate parents to discuss prevention topics with their child's provider. Delivery of tailored content can promote preventive practices" (p. 1157).
			KT tool intervention: Tailored website			
			Intervention (not KT tool): HCP notification			
			Comparison: Usual care control			
Jackson et al. (2006) USA	Public health (Smoking prevention)	Smoking parents & their non-smoking children attending grade 3 (n=776 children)	**KT tool intervention**: Printed activity guide (n=5) + series of tip sheets for parents + series of newsletters for children	Health behaviour/health status (initiation of smoking)	Significant +ve effect	"Children in the pre-initiation phase of smoking who are exposed to antismoking socialization from their parents are less likely to try smoking, even if their parents smoke" (p. 61).
			KT tool comparison: Information sheet (n=5)			

Nordfeldt et al. (2003) Sweden	Chronic (Type I diabetes)	Caregivers of children < 19 years with Type I diabetes (n=332 patients)	**KT tool intervention**: 2 video + booklet re: skills for self-control & treatment **KT tool comparison**: 1 video + booklet re: general diabetes info **Comparison**: Usual care control	Health behaviour/health status (yearly incidence of severe hypoglycemia needing assistance, Hba1c level – at 1 year)	**Mixed effect**: Significant +ve effect for intervention group on yearly incidence of hypoglycaemia measure. No effect for traditional or control group. No effect for all groups on yearly mean HbA1c level measure.	"We found that a pedagogical device for home use that supports diabetes self-care and is especially targeted at the prevention of severe hypoglycaemia may contribute to a decrease in severe hypoglycaemia without worsened metabolic control" (p. 244).
Nordfeldt et al. (2005) Sweden	Chronic (Type I diabetes)	Caregivers of children < 19 years with Type I diabetes (n=332 patients)	**KT tool intervention**: 2 videos + booklet re: skills for self-control & treatment **KT tool comparison**: 1 video + booklet re: general diabetes info **Comparison**: Usual care control	Health behaviour/health status (yearly incidence of severe hypoglycemia needing assistance – at 2 years)	Significant +ve effect	"We found that a self-study material for home use that supports diabetes self-care targeted at the prevention of severe hypoglycaemia may contribute to a decrease in severe hypoglycaemia" (p. 1400).
Reich et al. (2010) USA	Public health (Child health, minor conditions)	Pregnant women (n=198)	**KT tool intervention**: Books (n=6) **Comparison**: Non-educational books (n=6) **Comparison**: No intervention control	Patients' knowledge (anticipatory guidance topics regarding children from birth to 12 months)	**Mixed effect**: No group-time effect. Significant +ve effect for intervention vs both comparison, no effect between comparison groups (pairwise, time removed from model).	"We found that embedding anticipatory guidance into baby books is an effective was to increase new mothers' knowledge of injury prevention and healthy development in the first year" (p. 1001).
Tijam et al. (2013) The Netherlands	Chronic (Vision impairment)	Parents of children 3-6 years old with low SES[4] (n=114 children)	**KT tool intervention**: Cartoon book **KT tool intervention**: Pamphlet	Health behaviour/health status (compliance with occlusion therapy)	**Mixed effect:** Significant +ve effect for all interventions combined compared to control. Significant +ve effect for 1/3 intervention pairs (cartoon story vs reward calendar), but not 2/3 pairs (reward calendar vs	"While our data only shows that compliance improved significantly in children who used the self-explanatory cartoon story, but not in the control group, we believe that a similarly designed educational cartoon story could also

[4] Socio-economic status

			Intervention (not KT tool): Stickers **Comparison:** Colouring pictures		leaflet; cartoon story vs leaflet).	be useful in the long-term treatment of other diseases in young children" (p. 328).
Wakimizu et al. (2009) Japan	Acute (Herniorrhaphy surgery)	Parents of children undergoing surgery (n=158)	**KT tool intervention:** take home video + booklet	Patients' knowledge (degree of information provided to child)	**Mixed effect:** Significant +ve effect on 2/5 knowledge measures.	"Children and caregivers who watched the video together as frequently as they wanted at home in a relaxed atmosphere were better informed and prepared and they exhibited less anxiety regarding surgical hospitalization than those who watched the same video once at the outpatient clinic a week before surgery" (p.400).
			Comparison (not KT tool): in clinic video + booklet	Patients' experience (child anxiety, parent anxiety)	**Mixed effect:** Significant +ve group - time effect on child anxiety measures and significant +ve effect at perioperative period (but no other periods). No effect for parent anxiety measures, but significant +ve effect at post-operative period (no other period).	
Wilson et al. (2006) USA	Public health (Vaccination)	Low income mothers (n=54 mothers)	**KT tool intervention**: Pamphlet (n=2) **KT tool comparison**: Information sheet (n=2)	Patients' knowledge (vaccines)	No effect	"Although there was a modest increase in immunization knowledge for both groups, it was not significant. Thus, simplifying information alone may not increase parental knowledge" (p.4).

Appendix G: Semi-structured interview guide

1. Tell me about your child that was ill. How old is your child? How was your child ill? Has your child previously had gastroenteritis (vomiting & diarrhea)?
2. Tell me about your experience having your child experience gastroenteritis/vomiting & diarrhea.
3. How did you feel during this experience?
4. What did you do to manage diarrhea and vomiting with your child? Were there any techniques that you used?
5. What strategies were put in place by health care professionals to help your child? Did they ask you to do anything? Did they give you anything?
6. How did your child manage the experience? How did you feel about the outcome of this situation?
7. What did you learn from this experience?
8. If presented with the same situation again, would you do anything differently?

Appendix H: Pre-intervention questionnaire

This first set of questions is about you. These questions are to help us understand the parents in our study as a group. Please answer all questions. Thank you.

1. What is your email address for a short, follow up questionnaire? [open text]

2. What is your gender?
    a. female
    b. male
    c. other [open text]
    d. prefer not to answer

3. What year were you born? [open text – limit to #s only]

4. What is your ethnicity?
    a. White
    b. Aboriginal (e.g., First Nations, Métis or Inuk)
    c. South Asian (e.g., East Indian, Pakistani, Sri Lankan, etc.)
    d. Chinese
    e. Black
    f. Filipino
    g. Latin American
    h. Arab
    i. Southeast Asian (e.g., Vietnamese, Cambodian, Laotian, Thai, etc.)
    j. West Asian (e.g., Iranian, Afghan, etc.)
    k. Korean
    l. Japanese
    m. Other [open text]
    n. prefer not to answer

5. Of what country are you a citizen?
    a. Canada by birth
    b. Canada by naturalization
    c. Other country [open text]
    d. prefer not to answer

6. What is your relationship status?
    a. single
    b. partnered
    c. other [open text]
    d. prefer not to answer

7. What is your highest level of education?
    a. high school diploma/equivalency
    b. certificate of apprenticeship/certificate of qualification as journeyperson
    c. college, CEGEP or other non-university certificate/diploma
    d. university certificate/diploma below bachelor level
    e. bachelor degree, university certificate/diploma above bachelor level
    f. graduate degree

g. other [open text]
h. prefer not to answer

8. How many children do you have [open text]

9. What is your relationship to the sick child?
    a. mother
    b. father
    c. other [open text]
    d. prefer not to answer

10. How old is the sick child? [open text]

11. What gender is the sick child?
    a. female
    b. male
    c. other [open text]

12. Has the sick child had vomiting (throw-up, puke) and diarrhea (poop) before?
    a. yes
    b. no
    c. unsure

13. When did the sick child's vomiting (throw-up, puke) and diarrhea (poop) start?
    a. Today
    b. 1-2 days ago
    c. 3-5 days ago
    d. 6 or more days ago
    e. other [open text]

14. How many vomits (throw-up, puke) has the child had in the last 24 hours? [open text]

15. How many episodes of diarrhea (poop) has the child had in the last 24 hours? [open text]

16. Have other people in the house with the child had vomiting (throw-up, puke) and diarrhea (poop) in the last month?
    a. yes
    b. no
    c. unsure

17. Did you talk to or see another health professional before coming to the emergency department today? *(For example, did you call a doctor or nurse? Did you go to a walk-in clinic? Did you go to a pharmacy?)*
    a. Yes
        i. Who did you talk to/see? [open text]
    b. No

18. Did you look for information before coming to the emergency department today? *(For example did you call a family member or friend or did you look on the internet?)*
    a. yes
        i. Where did you look? [open text]

b. no

Next, is a set of questions about childhood vomiting and diarrhea. Please answer all questions, if unsure about the answer please mark your best guess. Thank you.

1. Fill in the blank. Gastroenteritis is often caused by _____.

2. Choose the best option. Dehydration is when:
   a. more fluids stay in the body than come out
   b. more fluids come out of the body than stay in
   c. you are thirsty
   d. you have an upset stomach
   e. none of the above

3. Check all that apply. A child is likely dehydrated if he/she:
   □ has no tears when crying
   □ has recently urinated
   □ has cold hands and/or feet
   □ has sunken eyes
   □ asks for a drink

4. Check all that apply. You should take your child to the emergency department if he/she has vomiting and/or diarrhea and has:
   □ been crying for more than 1 hour
   □ not urinated (peed) in the last 12 hours
   □ vomited (thrown-up) 2 times in the last 12 hours
   □ multiple episodes of dark green vomit (throw-up, puke)
   □ blood in diarrhea (poop)

5. Choose the best option. What types of fluids are encouraged to prevent/help dehydration?
   a. no fluids
   b. warm fluids
   c. sugary fluids
   d. clear fluids
   e. any fluids the child will drink

6. Check all that apply. Which medications are helpful for a child with gastroenteritis?
   □ medications for fever (like Tylenol)
   □ medications for vomiting (like Gravol)
   □ medications for diarrhea (like Imodium)
   □ medications for upset stomach (like Pepto Bismol)
   □ antibiotics

7. Fill in the blank. _____ is an example of a good oral rehydration solution to prevent and/or help dehydration.

8. True or False If child is not dehydrated, but is vomiting and/or having diarrhea over a few days, you should take him/her to see a doctor.

The last set of questions is about coming to the hospital emergency department today. Please think about your decision to <u>bring your child to the hospital emergency department with vomiting and diarrhea</u>.

Please show how you feel about these statements by circling a number from 1 (strongly agree) to 5 (strongly disagree).

1.	It was the right decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
2.	I regret the choice that was made	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
3.	I would go for the same choice if I had to do it over again	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
4.	The choice did me a lot of harm	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
5.	The decision was a wise one	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

You will now watch a short, 3-minute video.

Appendix I: Post-intervention questionnaire 1

If you would like to view this video again when you leave the hospital emergency department, we can send you a link by email. Would you like to see the video again?

c. yes
d. no

[This question is only for those in the experimental intervention group] Can we contact you for an in-person or telephone interview? The interview will be approximately 30 minutes to 1 hour long.

a. Yes
    a. Name [open text]
    b. Phone [open text]
    c. Best time to contact [open text]
b. No

Next, is a set of questions about childhood vomiting and diarrhea. Please answer all questions, if unsure about the answer please mark your best guess. Thank you.

1. Fill in the blank. Gastroenteritis is often caused by _____.

2. Choose the best option. Dehydration is when:
    a. more fluids stay in the body than come out
    b. more fluids come out of the body than stay in
    c. you are thirsty
    d. you have an upset stomach
    e. none of the above

3. Check all that apply. A child is likely dehydrated if he/she:
    □ has no tears when crying
    □ has recently urinated
    □ has cold hands and/or feet
    □ has sunken eyes
    □ asks for a drink

4. Check all that apply. You should take your child to the emergency department if he/she has vomiting and/or diarrhea and has:
    □ been crying for more than 1 hour
    □ not urinated (peed) in the last 12 hours
    □ vomited (thrown-up) 2 times in the last 12 hours
    □ multiple episodes of dark green vomit (throw-up, puke)
    □ blood in diarrhea (poop)

5. Choose the best option. What types of fluids are encouraged to prevent/help dehydration?
    a. no fluids
    b. warm fluids
    c. sugary fluids
    d. clear fluids
    e. any fluids the child will drink

6. Check all that apply. Which medications are helpful for a child with gastroenteritis?

□ medications for fever (like Tylenol)
□ medications for vomiting (like Gravol)
□ medications for diarrhea (like Imodium)
□ medications for upset stomach (like Pepto Bismol)
□ antibiotics

7. Fill in the blank. _____ is an example of a good oral rehydration solution to prevent and/or help dehydration.

8. True or False If child is not dehydrated, but is vomiting and/or having diarrhea over a few days, you should take him/her to see a doctor.

Compared to when you completed the first questionnaire, has your knowledge about childhood vomiting and diarrhea changed?

[insert 15 point scale]
-7: very great deal worse
-6: great deal worse
-5: good deal worse
-4: moderately worse
-3: somewhat worse
-2: a little worse
-1: almost hardly worse
0: the same
1: almost hardly better
2: a little better
3: somewhat better
4: moderately better
5: good deal better
6: great deal better
7: very great deal better

The next set of questions is about coming to the hospital emergency department today. Please think about your decision to bring your child to the hospital emergency department with vomiting and diarrhea. Please show how you feel about these statements by circling a number from 1 (strongly agree) to 5 (strongly disagree).

1.	It was the right decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
2.	I regret the choice that was made	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
3.	I would go for the same choice if I had to do it over again	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
4.	The choice did me a lot of harm	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
5.	The decision was a wise one	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

Compared to when you completed the first questionnaire, have your feelings about your decision to bring your child to the hospital emergency department with vomiting and diarrhea changed?

[insert 15 point scale]
-7: very great deal worse
-6: great deal worse
-5: good deal worse
-4: moderately worse
-3: somewhat worse
-2: a little worse
-1: almost hardly worse
0: the same
1: almost hardly better
2: a little better
3: somewhat better
4: moderately better
5: good deal better
6: great deal better
7: very great deal better

Thank you for your participation in our research project! Your responses are very valuable for our work. We will be sending you a final questionnaire by email to complete in 4 days. You will have 10 days to

complete the questionnaire at your convenience. The questionnaire will take approximately 7-10 minutes to complete.

Appendix J: Post-intervention questionnaire 2

Thank you for participating in our research project. This is the final questionnaire. It should take approximately 7-10 minutes to complete.

[This question is only for those that selected to receive the video link by email] After receiving the video link by email, did you watch the video again?

1. yes
    a. How many times did you watch the video? [open text]
    b. Why did you watch the video again? [open text]
2. no

The following two questions are about your child's healthcare since you completed the initial questionnaires for our study in the hospital emergency department.

1. Since taking your child to the hospital emergency department for vomiting and diarrhea, have you had to bring your child back to the emergency department because of vomiting and diarrhea?
    a. yes
    b. no

2. Since taking your child to the hospital emergency department for vomiting and diarrhea, did you need to seek additional care from another health professional (not in the emergency department) because of vomiting and diarrhea? *(For example, your pediatrician or family doctor, a walk-in clinic doctor, Health Link telephone advice line, a pharmacist, etc.)*
    a. yes
        i. Who did you talk to/see? [open text]
    b. no

Next, is a set of questions about childhood vomiting and diarrhea. Please answer all questions, if unsure about the answer please mark your best guess. Thank you.

1. Fill in the blank. Gastroenteritis is often caused by _____.

2. Choose the best option. Dehydration is when:
    a. more fluids stay in the body than come out
    b. more fluids come out of the body than stay in
    c. you are thirsty
    d. you have an upset stomach
    e. none of the above

3. Check all that apply. A child is likely dehydrated if he/she:
    □ has no tears when crying
    □ has recently urinated
    □ has cold hands and/or feet
    □ has sunken eyes
    □ asks for a drink

4. Check all that apply. You should take your child to the emergency department if he/she has vomiting and/or diarrhea and has:
    □ been crying for more than 1 hour

□ not urinated (peed) in the last 12 hours
□ vomited (thrown-up) 2 times in the last 12 hours
□ multiple episodes of dark green vomit (throw-up, puke)
□ blood in diarrhea (poop)

5. Choose the best option. What types of fluids are encouraged to prevent/help dehydration?
   a. no fluids
   b. warm fluids
   c. sugary fluids
   d. clear fluids
   e. any fluids the child will drink

6. Check all that apply. Which medications are helpful for a child with gastroenteritis?
   □ medications for fever (like Tylenol)
   □ medications for vomiting (like Gravol)
   □ medications for diarrhea (like Imodium)
   □ medications for upset stomach (like Pepto Bismol)
   □ antibiotics

7. Fill in the blank. _____ is an example of a good oral rehydration solution to prevent and/or help dehydration.

8. True or False If child is not dehydrated, but is vomiting and/or having diarrhea over a few days, you should take him/her to see a doctor.

Compared to when you last completed a questionnaire for this study, has your knowledge about childhood vomiting and diarrhea changed?

[insert 15 point scale]
-7: very great deal worse
-6: great deal worse
-5: good deal worse
-4: moderately worse
-3: somewhat worse
-2: a little worse
-1: almost hardly worse
0: the same
1: almost hardly better
2: a little better
3: somewhat better
4: moderately better
5: good deal better
6: great deal better
7: very great deal better

The next set of questions is about going to the hospital emergency department a few days ago. Please think about your decision to take your child to the hospital emergency department with vomiting and diarrhea. Please show how you feel about these statements by circling a number from 1 (strongly agree) to 5 (strongly disagree).

1.	It was the right decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
2.	I regret the choice that was made	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
3.	I would go for the same choice if I had to do it over again	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
4.	The choice did me a lot of harm	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
5.	The decision was a wise one	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

Compared to when you last completed a questionnaire for this study, have your feelings about your decision to bring your child to the hospital emergency department with vomiting and diarrhea changed?

[insert 15 point scale]
-7: very great deal worse
-6: great deal worse
-5: good deal worse
-4: moderately worse
-3: somewhat worse
-2: a little worse
-1: almost hardly worse
0: the same
1: almost hardly better
2: a little better
3: somewhat better
4: moderately better
5: good deal better
6: great deal better
7: very great deal better

Thank you for your participation in our research project! Your responses are very valuable for our work.

Appendix K: Pilot Trial Follow-up Survey Email

Email Subject: Stollery Emergency Department research final follow-up survey

Email Content:

Hello - thank you for participating in our research study in the Stollery Emergency Department waiting room. Below is the link to the final follow-up survey. It will take approximately 7-10 minutes to complete.

[INSERT SURVEY LINK]

Thank you for your participation in our research project! Your responses are very valuable and are helping us to improve health education for parents.

All the best,

Lauren Albrecht,
PhD Candidate, Department of Pediatrics, University of Alberta

Appendix L: Pilot trial semi-structured interview guide

Thank you for taking the time to meet with me today. I would like to ask you several questions about your experience viewing a video. I am recording our conversation to ensure that we have an accurate summary of your opinions. All the information I collect will be kept confidential. You may refuse to answer any questions or leave the interview at any time. Do you have questions before we begin? Please feel free to ask questions at any time during the interview. Before we start, let's watch the video again.

play video

1. What do you remember about watching this video in the hospital emergency department on [date]?

2. Tell me about that time your child was ill.
    a. Prompts: How did you know they were sick? What happened? What did you do?

3. Was the video helpful while you were in the hospital emergency department that day? How? Why/why not?

4. Tell me about your thought process as you were viewing the video.
    a. Prompt: Did you get the right information at the right time? Why/why not?

5. What did you do after you saw the video?

6. How did the video make you feel that day?

7. Do you feel that you learned something from the video? Why/why not?

8. Is there anything you would do differently next time your child has vomiting and diarrhea?

9. Thinking back, would it have been helpful to have access to the video after you left the hospital emergency department?
    a. Prompt: Would you have watched it again? When?

10. Is there anything you would change about your decision to go to the hospital emergency department on [date]?
    a. Prompt: Is there anything you know now that you wish you knew at the beginning?

11. Thinking back, when do you think would be the best time for you to have seen this video?

12. What did you think about using an online platform (program on the iPad and emailed link to survey) to participate in this research study?
    a. Prompt: Did you experience any issues with the technology? Was the iPad easy to use? Was it fun or interesting to complete a questionnaire like this while you were waiting in the hospital emergency department? Did having a link emailed to you make it easier to complete the follow-up questionnaire? Why/why not?

13. What did you think about the 3 questionnaires?
    a. Prompt: What did you think about the number of questions that were asked? What were your thoughts about the amount of time it took you to complete?

14. From your perspective, was there any difference between the questionnaires you completed in the hospital emergency department and the questionnaire you completed at home?
    a. Which was easier? Why?

15. Would you participate in future research studies similar to this one? Why/why not?
    a. Prompt: What did you like? What did you not like?

Thank you for participating in this interview.

Appendix M: Trial manual

Evaluating a Knowledge Translation Tool for Parents:

A Pilot Randomized Trial

Study PI: Lauren Albrecht, PhD Candidate, Department of Pediatrics, University of Alberta

Supervisors: Dr. Shannon Scott, Faculty of Nursing, University of Alberta & Dr. Lisa Hartling, Department of Pediatrics, University of Alberta

Contact information:

Office location: 5-147 Edmonton Clinic Health Academy

Phone: 780-492-9682 (office); 780-934-2189 (cell)

Email: lauren.albrecht@ualberta.ca

NOTE: Please contact Mithra, Manasi or Lauren ASAP in event of lost/stolen equipment & technical issues (including Wi-Fi connectivity problems). Please record: 1) date, 2) time, and 3) nature of the problem.

Important study information:

iPad, cord & charger: labeled GASTRO VIDEO STUDY

iPad passcode: 042017

Data collection platform: iCare Adventure app (white icon with heart and +)

Headphones: in white box labeled GASTRO VIDEO STUDY

Study information sheets: in pink folder labeled GASTRO VIDEO STUDY

Disinfecting wipes for iPads: in contained labeled GASTRO VIDEO STUDY

Brief study description

This is a single-site, parallel-arm, randomized, pilot trial. Convenience sampling will be used to randomize parents/caregivers seeking care for a child with vomiting and diarrhea in the emergency department (ED) to receive the intervention of interest or a sham control condition. The purpose of this pilot trial is to determine the feasibility of evaluation methods, including scientific, process, management, and resource trial elements, to optimize future, full-scale, definitive effectiveness evaluation.

This study has been approved by the University of Alberta Health Research Ethics Board. It has also received Alberta Health Services Operational Approval for the Stollery Children's Hospital, and Alberta Health Services Data Disclosure Approval.

Who can participate in this study?

Parents/caregivers presenting to the ED with a child with vomiting and diarrhea from November 2017 to March 2018 will be invited to participate under the following inclusion/exclusion criteria.

NOTE: You will be recruiting for this study and another concurrent study in the same population. Pay special attention to inclusion criteria #2 to avoid overlap with the other study.

Inclusion criteria:

1. Parent or caregiver of a child 16 years old or younger
2. Child is presenting to the ED with **less than** 3 episodes of vomiting and diarrhea in the last 24 hours AND/OR has had vomiting and diarrhea for **7 or more days**
3. Parent is fluent in English
4. Parent is willing to be contacted for follow-up data collection

Exclusion criteria:

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

How will parents be recruited?

To identify participants, Emergency Department Information System (EDIS) will be monitored for a child with a primary complaint of **vomiting and diarrhea**. Consecutive individuals with this concern will be approached in the ED waiting room post-triage assessment to see if they are interested in learning more about the study (see Appendix D for sample script).

For interested potential participants, open the iCare Adventure app on the iPad. From here, you will assess inclusion/exclusion criteria within the app on the iPad (first 4 screens). All non-eligible participants or participants who refuse will be recorded in the app.

How many parents will be recruited?

Sample size calculations are not required for pilot/feasibility studies as hypothesis testing is not the focus of this research design. Rather, recruitment will take place over a 6-month period and will be evaluated as part of the identified process outcome measures. This 6-month period is intended to reflect the seasonal nature of viral gastroenteritis, the most common cause of infection, in temperate climates. Recruitment will take place over the peak infection time of late winter.

What happens when a willing participant meets study eligibility criteria?

If participants meet the study eligibility criteria, you will review the information letter in the app (screen 5); you can also provide them with a hard copy for their records. Participants will then indicate whether they consent or not in the app (screen 6). Intervention delivery and data collection will take place right after participants consent. Disposable headphones will be provided to maintain blinding and minimize disruption in the ED waiting room.

How do you access the electronic data collection platform on the iPads?

To access the electronic data collection platform follow these steps:

1. unlock the iPad (code: 042017)
2. make sure the iPad is connected to Wi-Fi (UAlberta network)
3. open the iCare Adventure app (white icon with heart and an +)

NOTE: If there are updates to the app, a message will be sent to Mithra. To update the app:

- please open a second app called TestFlight (blue icon with propeller)
- click on iCare Adventure
- click open - this will force an update

What data will be collected?

The following data will be collected over the course of this study:

1. **Pre-intervention questionnaire (baseline)**: Participants will complete a pre-intervention questionnaire that includes demographics, knowledge questionnaire, and Decision Regret Scale within the iCare Adventure platform on the iPad.

   **<u>Participants will then be randomized to view the study intervention or the sham control within the iCare Adventure platform on the iPad. This process will be seamless for the participants.</u>

2. **Post-intervention questionnaire 1 (immediately post-intervention)**: After viewing the intervention, participants will complete the knowledge questionnaire and Decision Regret Scale a second time. In addition, participants will complete 2 items assessing their own performance on the knowledge questionnaire and Decision Regret Scale and 1 item regarding the perceived value and benefit of the KT tool. They will also be asked if they would like a video link emailed to them.

   At the end of this questionnaire, parents will be informed that the post-intervention questionnaire 2 will be emailed to them 4 days after this ED visit for completion at their earliest convenience. Experimental intervention group parents will be asked about participation in a qualitative focus group at this time.

THIS IS THE END OF DATA COLLECTION IN THE ED

3. **Post-intervention questionnaire 2 (4-14 days post-ED)**: Participants will be emailed a secure link on day 4 post-ED discharge to complete the knowledge questionnaire and Decision Regret Scale a third time, 2 items assessing their own performance on the knowledge questionnaire and Decision Regret Scale, 3 items related to healthcare utilization, and 3 items related to the perceived value and benefit of the KT tool (if applicable). Reminders to complete post-intervention questionnaire 2 will be sent to those who have not completed the survey every third day (day 7, 10, 13) to complete the survey by day 14 post ED-discharge. Previous research has demonstrated that 82% of AGE cases are resolved in three days or less and 14 days represents the outer limit for pediatric AGE resolution.
4. **Post-intervention semi-structured interview (sub-sample of experimental group)**: Participants in the experimental group indicating willingness to participate in an in-depth,

semi-structured, qualitative interview will be contacted via telephone after completion of post-intervention questionnaire 2. Up to three phone calls will be made to establish interview date/time. Qualitative interviews will focus on satisfaction with iCare Adventure platform, perceived benefit and value of the KT intervention, and willingness to participate in future, similar research.

How do you upload data from the iPad to the server?

Data will be uploaded automatically at 3 points: after eligibility criteria, after consent, at the end of the survey. If a participant does not meet the eligibility criteria or provide consent, the survey will re-start automatically and data will upload. If a participant does not complete the whole survey, you will have to force the survey to restart and the data will automatically upload at that time. To do this, you must force quit the iCare Adventure app.

<u>To force quite the app:</u>

1. double click the home button to see a menu screen
2. swipe the iCare Adventure app upwards to remove it from menu screen, this will force quit
3. press the home button to return to main screen
4. open the iCare Adventure app

Pre-data collection checklist

1. Ensure iPads are fully charged
2. Connect iPads to UAlberta Wi-Fi network
3. Ensure you have the following supplies:
    a. iPad
    b. copies of the Study Information Sheet
    c. headphones

During data collection checklist

1. Approach potential participants
2. Open app for interested participants. App should open to page with: Are you recruiting after 3pm? yes/no
3. Assess eligibility criteria
4. Review study information letter
5. Have parents indicate consent
6. After consent, hand parents iPad + pair of headphones
7. Offer consenting parents a copy of the Study Information Sheet
8. Between participants:
    a. force quit the app if any surveys aren't fully completed
    b. check the iPad charge and re-charge when needed

Post-data collection checklist

1. Store iPads with other research recruitment materials in ED office
2. Charge iPad ahead of next data collection shift
3. Make copies of the Study Information Letter if needed
4. Notify Lauren if more headphones or disinfecting wipes are needed

Appendix N: CONSORT 2010 checklist for pilot or feasibility trials

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	91; 115; 150
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	N/A
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	91-94
	2b	Specific objectives or research questions for pilot trial	94
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	95; 98-99
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	123-130
Participants	4a	Eligibility criteria for participants	95
	4b	Settings and locations where the data were collected	95-96; 118-120
	4c	How participants were identified and consented	95-96; 126-127
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	97-98; 116-117
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	99-106
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	131-137

	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	101-102; 123-124
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	98
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	98
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	98-99
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	98-99
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	99
	11b	If relevant, description of the similarity of interventions	97-98; 116-117
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	100-101; 131-134
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	152; 156-160
	13b	For each group, losses and exclusions after randomisation, together with reasons	159-160
Recruitment	14a	Dates defining the periods of recruitment and follow-up	123-124
	14b	Why the pilot trial ended or was stopped	123-124
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	152-154
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	159-160
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	160-167
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	166-167
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
	19a	If relevant, other important unintended consequences	N/A

Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	137-143; 173-179
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	137-143; 173-179
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	137-143; 173-179
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	137-143; 173-179
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	95; 118
Protocol	24	Where the pilot trial protocol can be accessed, if available	vii-viii; 91; 115
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	v-viii
	26	Ethical approval or approval by research review committee, confirmed with reference number	v; 95; 120