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Complete List of Authors:	Orkin, Julia; The Hospital for Sick Children, Division of Pediatric Medicine; University of Toronto, Department of Pediatrics Chan, Carol ; The Hospital for Sick Children, Child Health Evaluative Sciences Fayed, Nora; Queen's University, School of Rehabilitation Therapy Lin, Jia Lu Lilian; University of Toronto Dalla Lana School of Public Health, Institute of Health Policy, Management and Evaluation Major, Nathalie; Children's Hospital of Eastern Ontario, Department of Paediatrics Lim, Audrey; Hamilton Health Sciences Center, McMaster University, Department of Pediatrics Peebles, Erin; Western University Moretti, Myla; The Hospital for Sick Children, University of Toronto, Clinical Trials Unit Soscia, Joanna; The Hospital for Sick Children, Division of Pediatric Medicine Sultan, Roxana; The Hospital for Sick Children, The Provincial Council for Maternal & Child Health Willan, Andrew; The Hospital for Sick Children, Clinical Trials Unit-Ontario Child Health Support Unit Offringa, Martin; The Hospital for Sick Children, Child Health Evaluation Sciences Guttmann, Astrid; Institute for Clinical Evaluative Sciences, ; The Hospital for Sick Children, Division of Pediatric Medicine Bartlett, Leah; Royal Victoria Regional Health Centre Kanani, Ronik; North York General Hospital, University of Toronto, Pediatrics Culbert, Erin; Trillium Health Partners, The Credit Valley Hospital Hardy-Brown , Karolyn ; Peterborough Regional Health Centre Gordon, Michelle; Orillia Soldier's Memorial Hospital Perlmutar, Marty; Michael Garron Hospital Cohen, Eyal; The Hospital for Sick Children, Division of Pediatric Medicine ; University of Toronto, Department of Pediatrics
Keywords:	complex care, medical complexity, health services, children, randomized controlled trial, parents

Complex Care for Kids Ontario: Protocol for a mixed-methods evaluation of a population-level care coordination initiative for children with medical complexity

Authors: Julia Orkin[1,2,3], Carol Y Chan[3], Nora Fayed[4], Jia Lu Lilian Lin[5], Nathalie Major[6], Audrey Lim[7], Erin Peebles[8], Myla E Moretti[5,9], Joanna Soscia[1], Roxana Sultan[10], Andrew R Willan[9], Martin Offringa[2,3], Astrid Guttmann[1,2,3,5,11,18], Leah Bartlett[12], Ronik Kanani[13], Erin Culbert[14], Karolyn Hardy-Brown[15], Michelle Gordon[16], Marty Perlmutar[17], and Eyal Cohen[1,2,3,18]

Author Affiliations: [1]Division of Pediatric Medicine, The Hospital for Sick Children, Toronto, Ontario, Canada, [2]Department of Pediatrics, University of Toronto, Toronto, Ontario, Canada, [3]Child Health Evaluative Sciences, The Hospital for Sick Children, Toronto, Ontario, Canada, [4]School of Rehabilitation Therapy, Queen's University, Kingston, Ontario, Canada, [5]Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada, [6]Department of Paediatrics, Children's Hospital of Eastern Ontario, University of Ottawa, Ottawa, Ontario, Canada, [7]Department of Pediatrics, Hamilton Health Sciences Centre, McMaster University, Hamilton, Ontario, Canada, [8]Western University, London, Ontario, Canada, [9]Clinical Trials Unit-Ontario Child Health Support Unit, The Hospital for Sick Children, Toronto, Ontario, Canada, [10]The Provincial Council for Maternal & Child Health, The Hospital for Sick Children, Toronto, Ontario, Canada, [11]Dalla Lana School of Public Health, Ontario Child Health Support Unit, Research Institute, The Hospital for Sick Children, Toronto, Ontario, Canada, [12]Royal Victoria Regional Health Centre, Barrie, Ontario, Canada, [13]North York General Hospital, Toronto, Ontario, Canada, [14]Trillium Health Partners, The Credit Valley Hospital, Mississauga, Ontario, Canada, [15]Peterborough Regional Health Centre, Peterborough, Ontario, Canada, [16]Orillia Soldier's Memorial Hospital, Orillia, Ontario, Canada, [17]Michael Garron Hospital, Toronto, Ontario, Canada, [18]Institute for Clinical Evaluative Sciences, Toronto, Ontario, Canada

Keywords: Complex Care, medical complexity, health services, coordination, children, parents, randomized controlled trial

Abbreviations:
CCKO: Complex Care for Kids Ontario
CMC: children with medical complexity
FECC: Family Experiences with Coordination of Care
KT: knowledge translation
MFTD: Medically Fragile and/or Technology Dependent
PCMCH: The Provincial Council for Maternal & Child Health

Correspondence: Dr. Julia Orkin, The Hospital for Sick Children, 555 University Avenue, Toronto, Ontario, Canada, M5G 1X8, Email: julia.orkin@sickkids.ca Telephone: 416-813-7654 ext 201150

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ABSTRACT

Introduction: Technological and medical advances have led to a growing population of children with medical complexity (CMC) defined by substantial medical needs, healthcare utilization, and morbidity. These children are at a high risk of missed, fragmented and/or inappropriate care, and families bear extraordinary financial burden and stress. While small in number (<1% of children), this group uses approximately 1/3 of all child healthcare resources, and need coordinated care to optimize their health. Complex Care for Kids Ontario (CCKO) brings researchers, families, and healthcare providers together to develop, implement and evaluate a population-level roll-out of care for CMC in Ontario, Canada through a randomized controlled trial design. The intervention includes dedicated key workers and the utilization of coordinated shared care plans.

Methods and analysis: Our primary objective is to evaluate the CCKO intervention using a randomized waitlist control design. The waitlist approach involves rolling out an intervention over time, whereby all participants are randomized into two groups (A and B) to receive the intervention at different time points determined at random. Baseline measurements are collected at month 0, and Groups A and B are compared at months 6 and 12. The primary outcome is the Family Experiences with Coordination of Care (FECC) survey at 12 months. The FECC will be compared between groups using an analysis of covariance with the corresponding baseline score as the covariate. Secondary outcomes include reports of child and parent health outcomes, health system utilization, and process outcomes.

Ethics and Dissemination: Research ethics approval has been obtained for this multicentre randomized controlled trial. This trial will assess the effect of a large population-level complex

care intervention to determine whether dedicated key workers and coordinated care plans have an impact on improving service delivery and quality of life for CMC and their families.

Registration: ClinicalTrials.Gov identifier: NCT02928757

ARTICLE SUMMARY

Strengths and limitations of this study:

- This is the first large population-level implementation and mixed methods evaluation assessing the effectiveness of a complex care program for children with medical complexity (Complex Care for Kids Ontario (CCKO)).
- The study cohort represents a diverse sample of complex care patients across Ontario and the utilization of broad outcomes that encompass multiple potential targets of care with parent co-development in terms of the selection of outcome measures used.
- A limitation of this study relates to the challenge of the patient population as many are too unwell to be safely randomized to a waitlist design and therefore are excluded from the study. However, we will be able to use routinely collected health administrative data to describe heath care utilization as a single outcome for this population as to not lose the significance of their data.

INTRODUCTION

Medical and surgical advances have led to improved survival for many previously life-threatening conditions of childhood, such as prematurity[1], complex congenital anomalies[2], and congenital or acquired brain injury[3]. Technologic advances such as ventilator support, feeding tubes and transplantation have successfully prolonged the lives of children with lung, gut and other organ failure. This epidemiologic transition[4] has created a burgeoning population of children with medical complexity (CMC) – children with new morbidities, which are caused by longer survival itself as well as the complications of their life-sustaining therapies and created a new population that requires specialized care delivery in order to meet their complex healthcare needs.

CMC have been defined as "children with chronic conditions with elevated service needs, functional limitations and high healthcare utilization"[5]. Data from Ontario, Canada suggests that while CMC only account for approximately 0.7% of all children, they use about one-third of all child health resources [6]. Studies from the United States have also reported that CMC account for 43% of child deaths, 49% of hospital days, and 75-92% of consumed assistive health technology[7, 8]. CMC and their parental caregivers endure enormous challenges, including: multiple and prolonged hospitalizations[9], frequent medical errors[10], poor care coordination[9, 11], and extraordinary stress[12]. The consequences include poor caregiver health[13], marital discord[14], and profound negative financial impact[15].

Previous research has shown through a series of before- and after- studies, that targeted and integrated Complex Care interventions, most commonly within structured clinical program, may improve the health outcomes of CMC[16] , including reducing the burden of caregiving[17] and

mitigating costly and unnecessary healthcare expenditures[18, 19] . However, the validity of these findings has been limited by small sample sizes, lack of control groups and incomplete outcome measures[20]. Published randomized controlled trials (RCTs) report improved parental satisfaction with care, but mixed results for other outcomes. One parallel-group RCT described a decrease in both rates of severe illness and health care costs[21] among children enrolled in a structured Complex Care program, while another cluster RCT reported increased costs with no change in functional status or hospital-based utilization[22].

The Provincial Council of Maternal and Child Health (PCMCH) is a provincial organization, supported by Ontario's public single-payer of healthcare (the Ministry of Health and Long-Term Care). PCMCH implemented Complex Care Kids Ontario (CCKO), a population-health strategy to improve care for CMC who are Medically Fragile and/or Technology Dependent by providing an integrated approach to medical care and coordination. The strategy aims to improve service delivery, health, and quality of life of the patient-families involved through care coordination across acute and primary care, rehabilitation, home and community care, facilitated by dedicated nurse practitioners[23, 24], who function as key workers to establish seamless integrated care through the development and maintenance of a single, comprehensive and collaborative care plan that is designed to meet the child's/family's goals and optimize health outcomes (see Appendix 1). The aim of this study is to compare the effectiveness of the CCKO intervention to usual care for CMC in Ontario.

METHODS/DESIGN

Design

CCKO will utilize a waitlist variation of a randomized controlled trial design (Figure 1). The waitlist approach involves rolling out an intervention over time, whereby all participants are randomized into two groups (A and B) to receive the intervention at different time points determined at random[22, 25]. Group A receives the intervention at the next available appointment time. Group B is placed on a waitlist and receives the intervention after 12 months. This study design uses the time period before the intervention as the control period/baseline, to be compared in parallel to those receiving the intervention[26]. Baseline measurements would be collected at month 0, and Groups A and B would be compared at months 6 and 12.

The waitlist design is used in scenarios where it is considered unethical to withhold an intervention with likely benefits, or if there are logistical or financial constraints that prevent the intervention from being administered in whole at one time point[25, 26]. This design generates robust evidence of an intervention program's effectiveness by leveraging real-world operational need for a staggered rollout. For CCKO, it is logistically not feasible for all eligible children to be seen immediately. For example, the initial intake process for key workers is time-intense, requiring the creation of careplans and the development of a patient-provider relationship. A staggered roll out using a waitlist facilitates work-flow and case management, allowing program implementation within the context of human resource limitations. With the exception of patients for whom care coordination is thought to be urgently required (see exclusion criteria a)-c)), all patients referred to CCKO will be randomly assigned to either receive the intervention immediately (at the soonest available clinic appointment) or after the waitlist period (12 months). This approach minimizes the risk of selection bias by retaining the design element of randomization.

Setting

CCKO will be led by four tertiary care children's hospitals with partnership at multiple community led clinics (see Appendix 2). These sites display broad geographical representation of patients.

Participants

The target population includes children in Ontario who satisfy the Standard Operational definition for CMC developed by the Provincial Council for Maternal and Child Health[27]. The specific inclusion criteria are summarized in Figure 2. The criteria adapt existing definitions of CMC[5] to a slightly narrower group with technology dependence and/or medical fragility to focus on those patients who are most expected to benefit from care coordination such as those thought to be at risk of avoidable hospitalizations.

Exclusion Criteria

a) High utilization of hospital level care
   - ≥ 3 hospitalizations, ≥ 2 ICU (intensive care unit) admissions, ≥ 30 days of total hospitalization in previous 3 months, excluding newborn admission

b) Tracheostomy and home ventilation

c) Medical status is deemed highly fragile and the need for close follow-up is essential by both referring and triaging team

d) Already followed by a complex care team

e) >16.0 years of age

f) Inadequate English proficiency to comprehend study questionnaires

g) Parent will not be involved in child's care over entirety of study (2 years)

Patients who satisfy exclusion criteria a)-c) are deemed to urgently require care coordination; as such, it would be unethical to randomize these patients to a waitlist. Patients who satisfy exclusion criteria d) would have experienced the potential benefits of care coordination already. Patients who satisfy exclusion criteria e) would be in the process of being transitioned to adult care. Patients who satisfy exclusion criteria f) would not be able to complete the study questionnaires as the majority are only validated in English. Patients who satisfy exclusion criteria g) would not be able to complete the study questionnaires at all time points. Patients whose caregivers cannot complete questionnaires in English will not be involved in the primary analysis however, they will be enrolled in CCKO and provide health care utilization data via health card linkages to health administrative data housed at the Institute for Clinical Evaluative Sciences that will be used in secondary analyses. Similarly, patients who require urgent care coordination are excluded from the study, but will be able to contribute data through similar linkages.

The CCKO intervention involves intensive care coordination, defined as: "deliberate organization of patient care activities between two or more participants to facilitate the appropriate delivery of health care services. Organizing care involves the marshaling of personnel and other resources needed to carry out required care activities and is often managed by the exchange of information among participants responsible for different aspects of care"[28, 29]. Within CCKO, intensive care coordination will specifically include tailored, family/health care provider co-creation and management of care coordination plans which will be facilitated and accounted for by key workers partnering with families. The key worker would have an advanced practice nursing (e.g., nurse practitioner) background and will support providers in

enacting, developing and creating the coordinated care plan between acute care, primary care, rehabilitation, home and community care. Further details about care plan development are available online[30]. The key worker would be available to provide advice from Monday to Friday, 9 AM – 5 PM, and will also develop plans of care for emergencies after hours as part of care plan development. Resources to maintain intervention fidelity among key workers will be maintained with oversight by PCMCH.

The waitlist group consists of CMC who are receiving care from primary and specialty providers, and are waitlisted for Complex Care clinic (pre-enrolment control period). Standard of care during the control period will involve care delivered through a primary care provider (family physician or pediatrician) for routine health care such as vaccination and acute care visits with subspecialty consultation as needed. Currently, this model of care for the vast majority of CMC in Ontario; among ~6,200 patients who are estimated to meet CCKO criteria in Ontario, only ~500 receive care in a structured complex care clinic. At the end of year 1, all CMC randomized to the waitlist group will be enrolled in the complex care clinic and data will continue to be collected for 1 additional year on all participants in an extension phase.
Criteria for discontinuing study intervention: participants in the waitlisted arm that experience a change in clinical status and now meet exclusion criteria (e.g., prolonged hospital stay >30 days), will be taken out of the waitlist-arm and will be seen at the next available appointment.

Outcomes

A family-engagement strategy was conducted to identify and prioritize outcomes for evaluation[31]. The core set of relevant patient reported outcome measures (PROMs) and patient

reported experience measures (PREMs) was created in a consensus meeting using data collected from a survey completed by 48 families and 86 health care providers[32].

Measures representing these outcomes were selected based on their content applicability to the outcomes, proven psychometric performance (reliability and validity) among children and families. The family-engagement evaluation framework includes general and specific outcomes within the domains of service delivery (primary outcomes); child outcomes (secondary) and parent outcomes (secondary).

Primary Outcome:

1. *Coordination of Care Among Health Providers and Families*
2. *Coordination of Care Between Health Providers and Families*
3. *Utility of Follow-Up Planning Tools*

These outcomes will be assessed with the Family Experiences with Coordination of Care (FECC) survey, our primary outcome measure for this study. The FECC has been validated in a study of 1209 CMC patient-families in the United States, and has internal consistency >0.7 with proven discriminant validity for patient-family socioeconomic status and rurality[33], as well as responsiveness to change demonstrated in a recent CMC randomized control trial[28].

Child-focused (Secondary) Outcomes: (see Table 1)

1. *Quality of Life and Overall Emotional Health*
2. *Child's Physical Pain*

Children's quality of life and emotional wellbeing will be measured using the World Health Organization definition focused on subjective life appraisal[34]and a positive orientation of mood assessment respectively. These outcomes will be assessed using the Feelings subscale

from the KIDSCREEN-52 (6 items), used in over 250 studies in the child health services literature since its publication in 2005[35, 36]; and represents the most suitable content overlap with CMC children. Children's physical pain will be measured using proxy reports of pain according to a 10 cm linear Visual Analog Scale (VAS)[37] **.** Linear VAS is considered superior to other pain reports available for children due to consistencies of interpretation within parent-child dyads, test-retest reliability and measurement precision[38], and is most appropriate for the diverse functional ability of the CMC population.

Parent-focused (Secondary) Outcomes:

1. *Parents' Quality of Life*
2. *Perceived Emotional and Physical Health*
3. *Energy and Fatigue*
4. *Effects of Child's Condition on Parents' Finances and Ability to Work*

Parents' quality of life will be measured by a subjective life appraisal definition with two scales. (1) Diener's Satisfaction with Life Scale (SWLS) (5 items) which is the most validated life satisfaction scale in the health and social sciences literature[39, 40] and (2) an adapted version of the KIDSCREEN Feelings subscale[35]. Parents' perceived health, energy, and fatigue will be assessed with short forms of the Patient Reported Outcomes Measurement Information System (PROMIS) General Health (10 items); Sleep (8 items); and Fatigue (8 items) scales. These scales have been validated, have norm references data for comparison and have shown good to excellent psychometric properties among caregivers[41, 42]. Financial impact on parents' will be measured using an Expense Diary survey created by the study team. This survey will capture financial impact based on lost time and ability to work, as well as out of pocket expenses for

health care services, equipment, and travel using scales customized for CMC and standardized relative to various child health studies with the support of the study health economist (Moretti; see Appendix 3).

Health System (Secondary) Outcomes:

We will link the patient-reported evaluation of the CCKO initiative with encoded health linked administrative data housed at the Institute for Clinical Evaluative Sciences (ICES) for consenting participants (see Appendix 4 for list of datasets). ICES is a not-for-profit research institute listed in Ontario's health privacy legislation as a Prescribed Entity allowing the use of health data on all Ontario residents for the purposes of research. These datasets will be linked using unique encoded identifiers and analyzed at ICES. Outcomes will include:

1. Overall health care cost (using algorithms developed via the Ontario Case Costing Initiative
2. Hospitalizations (number, length of stay, and cost)
3. Emergency department use (number and cost)
4. Outpatient pharmacy use (number of medications and cost)
5. Home health care use (cost)
6. Primary care visits (number and cost)
7. Sub-specialty visits (number and cost)

Sample Size

We determine the sample size to be 140 (70/arm) based on the following criteria: i) Two-sided test of the null hypothesis at the 5% level; ii) Power of 80%; iii) 10% lost-to-follow-up; projected smallest clinically important difference of 0.5 of the within-patient standard deviation[43]. The within-patient standard deviation is needed to obtain a baseline measure from the waitlisted group as reference. The standard deviation of the primary outcome, FECC=0.56 is based on pooled data from the developer's CMC validation sample[33]. The required sample size is considered feasible as it is estimated that a pool of about 250 patients are readily identifiable for recruitment at CCKO sites.

Recruitment

At each site, clinical staff will identify eligible patients who are referred to CCKO from clinicians based on inclusion criteria. A study information letter will be sent to the families of eligible patients who will be contacted by the research assistant. An approximate 50% recruitment rate from a pool of N=400 (200/year) is conservatively estimated based on previous recruitment and current waitlists.

Questionnaires would take place at baseline, 6, 12, and 24 months. Upon completion of each time point, families will receive a $20 gift card to a drug store. A subsample of approximately 10-15 families in the intervention arm will be approached starting at 12 months for qualitative interviewing to explore their experience with the intervention.

Randomization

CCKO randomization will done using a computer-generated algorithm stratified by centre. Blocking will be used to ensure that the two groups are the same size throughout the trial for

each site as well as for the trial as a whole. An allocation ratio of 1:1 with random block sizes between 6 and 8 will be used within each stratum (centre). This will help to ensure that clinicians or investigators will not decipher the block size.

Data Collection

Upon obtaining consent, the Research Assistant will assign a research subject ID number to patients. Study data will be collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools[44]. Patient-families can opt to complete data collection by iPads or hardcopy. At home, patient-families can complete surveys via REDCap. This flexible methods of data collection will maximize diversity of respondents ideally as well as support family needs and preferences for data collection. A demographics survey will be administered at baseline.

Data Management

A REDCap study database will be designed and maintained by the Research Coordinator at The Hospital for Sick Children. The data on the various forms will be linked by a unique research subject ID. The Research Coordinator will extract study data from questionnaires via the REDCap interface to complete the study-specific data collection forms. An external user interface will also be created on REDCap for parents who opt to complete the surveys online. All personal identifying information will be removed from the electronic study database. A separate secure list of research subjects' names and contact information will be maintained in a Microsoft Excel spreadsheet for the purpose of completing the follow-up questionnaires. All study-related electronic data files will be password-protected and reside on the Hospital server.

Only members of the research team will have access to the server study file location via password-protected computers. Password-protected databases from each site will be transferred to the Institute for Clinical Evaluative Sciences through a Virtual Private Network.

Statistical analysis

An overview of the included outcomes and their measures are presented in **Table 1**.

Patient and Caregiver Characteristics

Baseline patient characteristics and descriptive variables will be presented for each treatment arm: age, sex, diagnosis, ethnicity, medications, medical devices and hospitalizations. Baseline caregiver characteristics and descriptive variables will be presented as well: age, sex, education level, employment status, ethnicity, primary language. For continuous variables, means and standard deviations or medians (interquartile ranges) will be presented. For categorical variables, proportions will be presented.

Primary Outcome

The main analysis will be a comparison of service delivery outcomes (i.e., FECC) between the intervention and waitlist groups at 12 months. The principle of intention-to-treat will be applied. For effectiveness each outcome variable at Month 12 will be compared between groups using an analysis of covariance with the corresponding baseline score as the covariate. A two-sided, level 0.05 test of hypothesis will be applied.

Secondary Outcomes

Data collection at 0 and 6 months will be used to perform test-retest reliability, to establish baseline reference measures and to assess for stability of outcome changes (24 months). Secondary child-focused and parent-focused outcomes will be compared at 0, 6 and 12 months

using Bonferroni corrections to account for multiple testing. All secondary health system outcomes will be compared between the intervention and control (wait period) as well.

Additional Analyses

We will examine health system outcomes using regression modeling to explore the relationships between PROMs and health utilization patterns (for example, the relationship of out-of-pocket expenditures with availability of home health care services).

DISCUSSION

While growing attention has been provided to CMC in recent years[45], there are important gaps in the literature regarding the optimal care delivery model for CMC [17-20]. Before- and after-studies have shown possible benefit but there has been few rigorous randomized controlled trials conducted that look at multiple outcomes including service delivery, parent and child health outcomes as well as health system outcomes such as health utilization. Furthermore, this is the first study that prioritized outcomes as identified by patients and families directly in order to understand if a complex care program was successful in the eyes of a family by selecting outcomes that matter most to them. The care delivery model in CCKO - utilizing a key worker and comprehensive care plans - is a time intensive and possibly costly one. Well-designed evaluations are needed to examine how they relate to outcomes of care for this population[46]. Several aspects of this trial are important to highlight as innovative and novel.

First, in contrast to other trials that target CMC within a single health care setting (e.g., a children's hospital), this study focuses on population-level implementation and evaluation in Ontario, Canada's most populous province. This setting allows the implementation of complex

care coordination within a wide geographic area combing both densely populated urban areas with more rural locations for which travel to specialized care is challenging. The large number of sites participating in this study account for the majority of CMC care in Ontario. This environment is unique in terms of the current literature as these patients reflect population-level CMC representation, with outcome data availability across the continuum of care available from a large provincial repository of data. The focus on so many sites creates some challenges in both implementation and evaluation across diverse settings. However, this evaluation also provides an opportunity for the development of generalizable knowledge not only for publically-funded healthcare delivery systems, but also for broad groups of payers focused on other high-need/high-cost populations[47].

Second, the outcome measures used are patient and family-informed. Previous literature has highlighted the need for uniquely developed outcome measures for CMC recognizing the nature of their health care usage and trajectory. Before recruitment began, the outcome measures were determined through a process of direct consultation with parents of CMC[48]. Previous evaluations of CMC care have relied primarily upon readily available data (e.g. claims data or other administrative datasets), with minimal patient- and family-reported input. Previous patient-reported outcome measures utilized in evaluations have not been validated in a CMC population. A strength of this study is the utilization of broad outcomes that encompass multiple potential targets of care. We chose care coordination as the primary outcome measure because it is the primary target for change as in this patient population and the measurement instrument has been validated in CMC. Unfortunately, expectation of a change in disease status is not meaningful or realistic in many CMC, whereas improved navigation of the healthcare system is an important

and improvable target of care. Biomedical endpoints, although important, are not meaningful in such a heterogeneous population.

Third, the study has been designed to mitigate risk of bias. It is anticipated that some patients may be excluded; a concern are those who are marginalized (e.g., non-English speaking), or are deemed too urgent to enroll in a waitlist. We aim to conduct a secondary future study focused on comparing such patients to contemporaneous controls using administrative data to ensure knowledge generation about the impact of CCKO in this group as well, albeit with a higher risk of bias that would otherwise be attenuated with randomization (e.g., unmeasured confounders).

Fourth, the focus of this study is not solely quantitative in nature. We have elicited a mixed methods approach. We will conduct exit interviews with a subset of intervention arm parents to capture the overall experience with the intervention, areas of improvement, barriers as well as perceived benefits and harms. This approach can enable the team to identify what aspects of the CCKO intervention are more or less effective, for whom, in what context and why.

Lastly, the integrated knowledge translation is truly unique in that the direct provincial implementation of the CCKO roll out has been matched directly with the evaluation such that the knowledge end-user was a part of the study team from the outset. The integrated KT approach has included families caring for CMC, policy-makers and widely representative clinicians such as nurses and physicians. This large integrative model allows direct translation of results and seamless integration of knowledge.

ETHICS AND DISSEMINATION

The protocol has been approved by Research Ethics Boards at all sites. The study Research Assistant will obtain informed consent from parental caregivers. Informed consent/assent will be obtained from all those who are able to provide it.

Adverse Event Reporting

While there are no adverse events expected in the context of the intervention being administered, any adverse events will be reported to the Research Ethics Board. All adverse events and adverse reactions will also be reported to the Primary Investigator within 24 hours.

Dissemination

CCKO represents a fully integrated knowledge transfer and exchange paradigm. The research team have worked with patient-families and PCMCH to craft the provincial strategy, providing population-based data to understand the target population (numbers/location of children, patterns of care, health system costs). The committees overseeing implementation and evaluation encompass key knowledge users (patients, families, clinicians, administrators, policy-makers), allowing for seamless KT. Executive Summaries and/or Presentations will be shared for wide dissemination to a variety of organizations/collaboratives. Academic KT will occur through presentation at academic conferences and publications in high-impact, peer-reviewed journals. At study end, results will be available on CCKO's website.

TRIAL STATUS

Recruitment began January 2017 and there are 107 participants of a target of 140 as of October 2018. The study is on track to complete enrolment in 2019. A copy of the full-length protocol is available upon request.

Author Contributions All authors conceived the study and obtained funding. All authors participated in design of the trial. EC and AW provided statistical expertise. JO, EC and CC wrote the first draft of the manuscript. All authors read and approved the manuscript in its final version.

Trial Registration Trial registered at ClinicalTrials.Gov NCT02928757

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Competing interests None declared

Patient consent Not required

Ethics approval This study was approved by the local REB at: The Hospital for Sick Children (REB# 1000053509), Hamilton Health Sciences (project # 2017-2161), Children's Hospital of Eastern Ontario (ROMEO# 20160299), London Health Sciences Center (project ID 108143), Michael Garron Hospital (REB# 702-1701-MNC-009), Credit Valley Hospital (ID# 855), North York General Hospital (REB# 16-0044), Royal Victoria Hospital (REB# 015), Orillia Soldiers' Memorial Hospital, and Peterborough Regional Health Centre.

Provenance and peer review Not commissioned; externally peer reviewed.

Figure 1. Complex Care for Kids Ontario Evaluation Flow Chart for Referrals

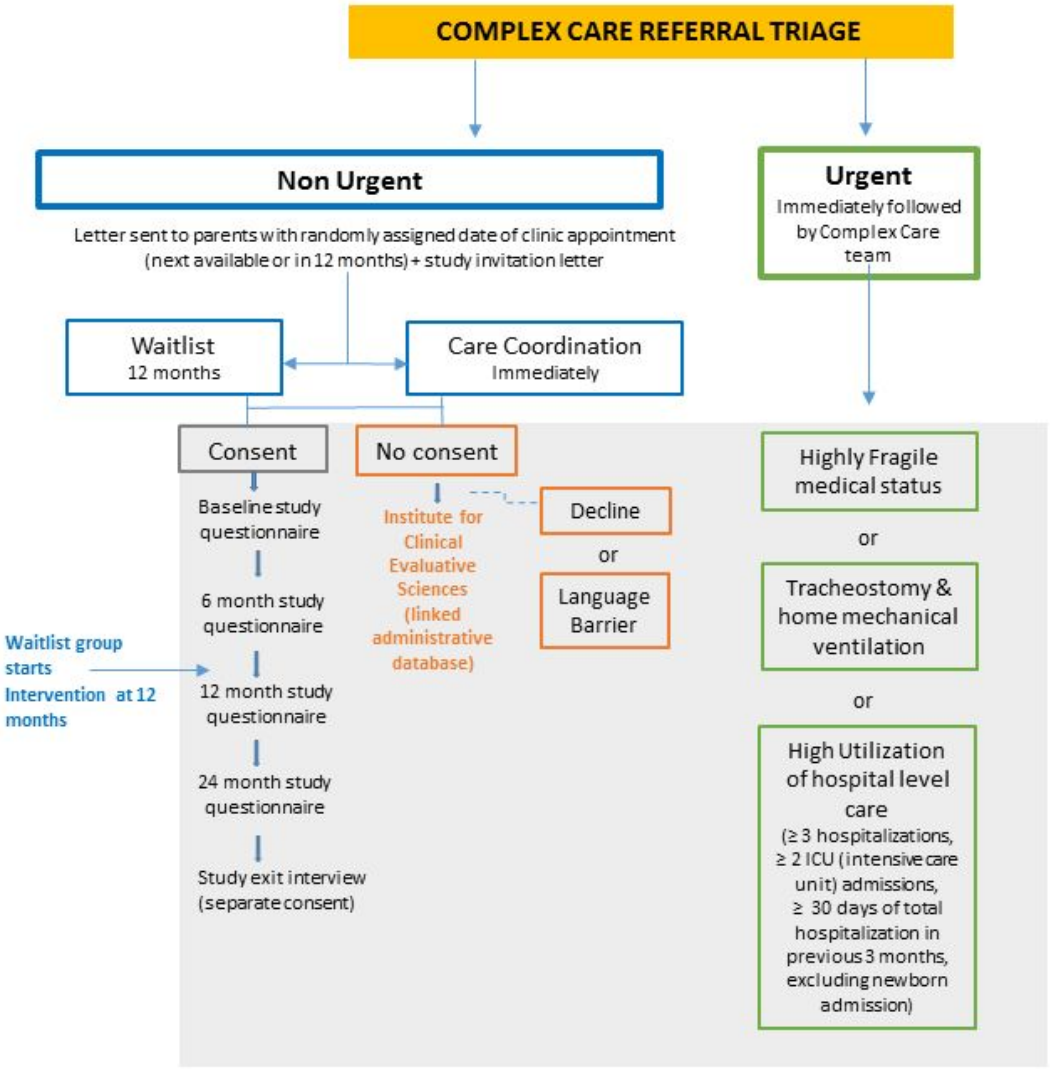


Figure 2. Complex Care for Kids Ontario Inclusion Criteria[27]

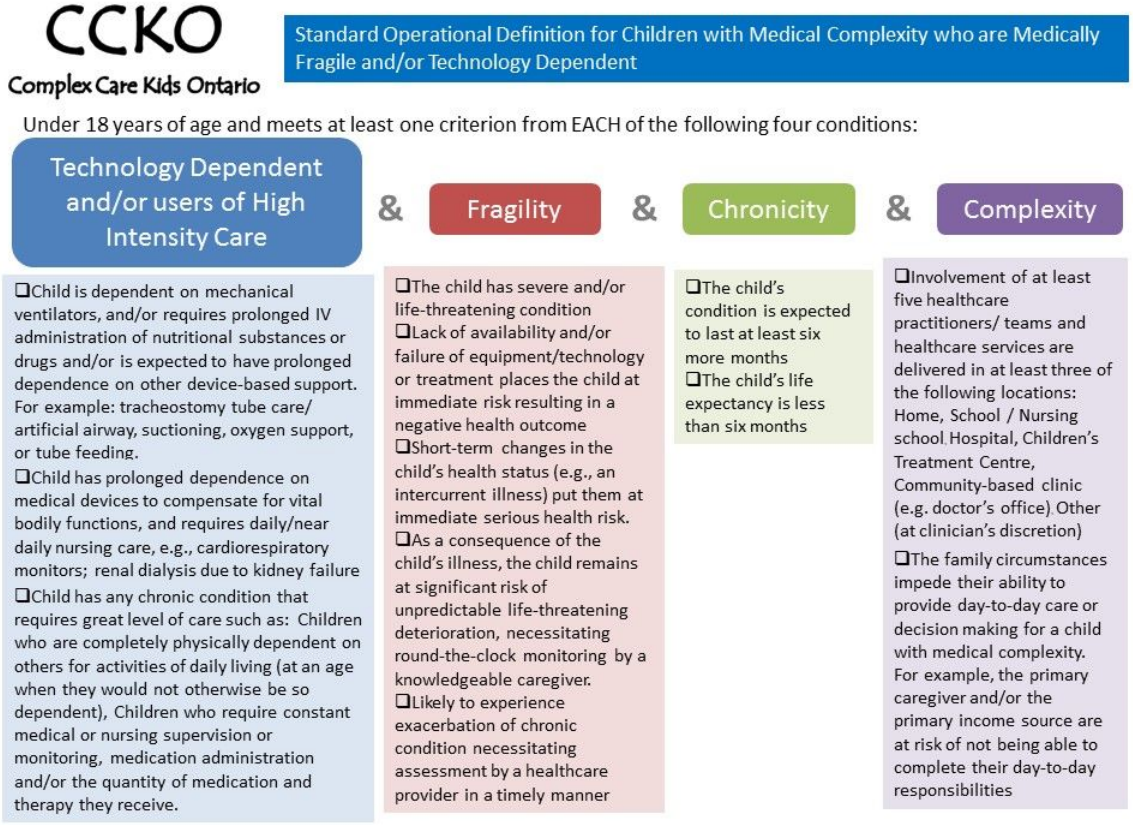
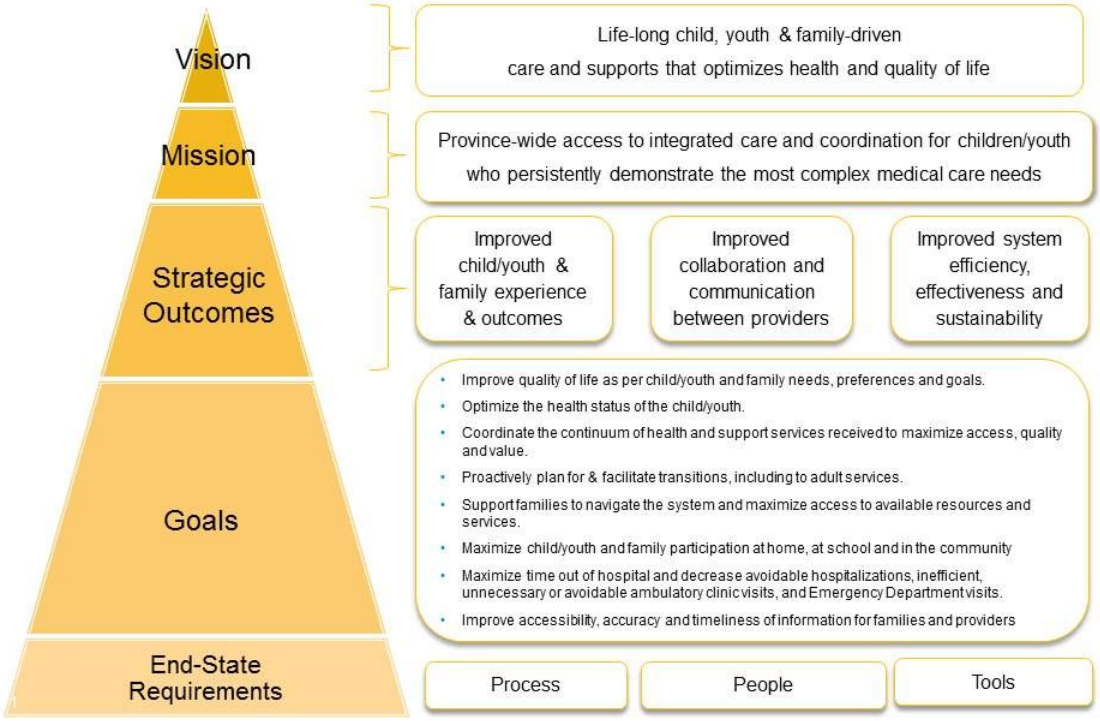


Table 1. Overview of outcomes & associated measures

Service Delivery Outcomes (Measurement Tool)	Parent Outcomes (Measurement Tool)	Child Outcomes (Measurement Tool)	System Outcomes (Measurement Tool)	Process Outcomes (Measurement Tool)
Coordination Among Providers (Family Experiences with Care. Coordination)[33]	Life Satisfaction (KIDSCREEN[35], Satisfaction with Life Scale[39, 40])	Life Satisfaction (KIDSCREEN)[35]	Health Utilization e.g. Hospital admissions, ER visits, etc. (available for all Ontario residents in linked administrative databases housed at the Institute for Clinical Evaluative Sciences – see Appendix 4 for list of databases)	Patient and family experience (Qualitative Interviews)
Coordination Between Providers and Families (Family Experiences with Care Coordination)[33]	Overall Health (Patient-Reported Outcomes Measurement Information System)[41, 42]	Physical Pain (Visual Analog Scale)[37]		
Utility of Planning/Follow-Up Tools (Family Experiences with Care Coordination)[33]	Energy and Fatigue (Patient-Reported Outcomes Measurement Information System)[41, 42]			
Patient Centered Information (Family Experiences with Care Coordination)[33]	Out of Pocket Expenses (Expense Diary – see Appendix 3)			
Parental Support in the Community (Family Experiences with Care Coordination)[33]				

Appendix 1. Complex Care for Kids Ontario Strategic Framework[49]



Appendix 2. Complex Care for Kids Ontario Study Sites

Site Name	Location
The Hospital for Sick Children (SickKids)	Toronto, ON
Children's Hospital of Eastern Ontario	Ottawa, ON
London Health Sciences Centre	London, ON
Hamilton Health Sciences Centre	Hamilton, ON
North York General Hospital	Toronto, ON
Peterborough Regional Health Centre	Peterborough, ON
Orillia Soldiers' Memorial Hospital	Orillia, ON
Royal Victoria Hospital	Barrie, ON
Michael Garron Hospital	Toronto, ON
Credit Valley Hospital	Mississauga, ON

Appendix 3. Expense Diary

CQ1-EXTRACURRICULAR ACTIVITIES

CQ1a. Does your child participate in extracurricular activities (outings/sports/hobbies)?	☐Yes ☐ No (continue to CQ2a) ☐ Don't Know (continue to CQ2a)
CQ1b How many hours of extracurricular activities does your child participate on average per month? (Describe to the best of ability)	_____ hours of activity on average per month

CQ2-ACADEMIC ACTIVITIES

CQ2a. Is your child currently enrolled in school outside the home?	☐Yes ☐ No Reason: _____ (continue to CQ3a)
CQ2b. If Yes, does your child attend full-time (every day) or part time?	☐ Full-time (continue to CQd) ☐ Part time (continue to CQ2c)
CQ2c. If your child attends school part time, how many days of school do they attend per week on average?	☐ 1 day ☐ 2 days ☐ 3 days ☐ 4 days ☐ N/A
CQ2d. Thinking back over the past 6 months, how many days of school does your child miss on average per month?	_____ days missed on average per month
CQ2e. Thinking back over the past 6 months, how much do you spend on travel to/from school for your child on average per month?	$_____ on average per month AND Distance travelled daily to get child to schooling _____ km

CQ3. DOCTOR VISITS

These questions are only about when your child visited the doctor's office or clinic. This does not include emergency room visits or hospital stays.

CQ3a. Does your child use public transit, taxi or accessible transit services (e.g. Wheel trans)?	□Yes □ No (continue to CQ3b)
CQ3ai.If your child uses public transit, taxi, or Wheel Trans, how much money do you usually spend traveling to and from the doctor's office/clinic per visit?	$_____
CQ3b. Do you or another family member drive to your child's doctor's office/clinic?	□Yes □ No (continue to CQ3c)
CQ3bi. If you or another family member drives, what is the distance to your child's doctor's office/clinic?	_____km
CQ3c. On average how much do you spend on parking at the doctor's office/clinic?	$ _____ per visit ---------- □ Nothing □ Not applicable

CQ4-INSURANCE COVERAGE

CQ4a. Do you have a drug plan that pays for any of your child's medications (ie. Employee benefit package, Ontario Drug Benefit, OHIP+)?	□Yes (continue to CQ5b) □ No (continue to CQ5h) □ Don't Know (continue to CQ5h)
CQ4b What is your Drug Plan?	□ 1. Employee benefit package □ 2. Government program (ie. Ontario Drug Benefit, OHIP+) □ 3. Other (Please specify:_____) □ 4. Don't know, don't remember
CQ4c. When you have to pay for prescription drugs, what is the percentage of prescription medication costs that you pay on average?	_____% □ Don't know
CQ4d. Do you have a private health plan that covers other medical expenses such as physical therapy, ambulance services, medical devices etc?	□Yes □ No (continue to CQ6a) □ Don't Know (continue to CQ6a)
CQ4e. How much do you or your partner pay into this plan or how much is deducted from your pay cheque per month?	$_____ per month □ Nothing □ Don't Know

CQ5. MEDICATION

CQ5a. Has [YOUTH] taken any prescription or over-the-counter medication in the last 6 months?	□Yes (complete table below) □ No

If yes, please list any medication that you have taken in the last 6 months.

Name of medication	Reason [CHILD] takes this medication	Dose (mg)	Formulation (pill, liquid, inhaler, etc)	Frequency per day?

CQ5ba. Has your child used any over-the-counter medications, dietary supplements (e.g. vitamins), naturopathic, or homeopathic treatments in the last 6 months?	☐Yes (complete table below) ☐ No

If yes, please list items below:

Name of item	Reason [child] needs this	Financial coverage Check all that apply	If you paid some or all, please state the amount you paid ($)
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	

CQ6. MEDICAL DEVICES

CQ6a. Has your child needed to use any medical/assistance devices or equipment in the last 6 months (wheelchair, crutches, brace, syringes, VitaMix blender for special food preparation)?	□Yes (complete table below) □ No

If yes, please list devices below:

Name of item	Reason [child] needs this	Financial coverage Check all that apply	If you paid some or all, please state the amount you paid ($)
		□ ADP (Assistive Devices Program) □Insurance □ Self Paid □ Donated	
		□ ADP (Assistive Devices Program) □Insurance □ Self Paid □ Donated	
		□ ADP (Assistive Devices Program) □Insurance □ Self Paid □ Donated	
		□ ADP (Assistive Devices Program) □Insurance □ Self Paid □ Donated	

CQ7. EMERGENCY ROOM VISITS

These questions are only about when you had to bring your child to the emergency room. This does not include to doctor visits or to days when your child was admitted to the hospital.

CQ7a. Has your child gone to the hospital in an ambulance in the last 6 months?	☐Yes ☐ No (continue to CQ8g)
CQ7b. How many times did your child do so?	_____ # of times
CQ7e. Did you have to pay for the ambulance services?	☐Yes ☐ No (continue to CQ8g) ☐ Don't know/can't remember (continue to CQ8g)
CQ7f. How much did you spend on these ambulance services per visit?	$_____
CQ7g. Has your child gone to the emergency room **by some other method of transportation** in the last 6 months?	☐Yes ☐ No (continue to CQ9)
CQ7h. How many times did your child do so?	_____ # of times
CQ7i. On average, how much did you spend on transportation to the emergency room (including parking, if applicable)?	$_____/visit

CQ8. HOSPITAL ADMISSIONS

These questions are only about when your child was admitted to hospital. This does not include emergency room visits.

CQ8a. Has been admitted to the hospital in the last 6 months?	☐ Yes ☐ No (continue to CQ10)
CQ8b. How many times was your child admitted to the hospital?	_____ # of times
CQ8c. On average, how much did you spend on transportation to the hospital (including parking, taxis, public transportation mileage)?	$_____/day and Distance from home to hospital _____ km

CQ9. ALLIED HEALTH PROFESSIONALS AND SOCIAL SERVICE PROVIDERS

CQ9a. Has any allied health care or social service provider **COME TO VISIT your** child either at home, residence or school in the last 6 months? (See list of providers below)	☐Yes ☐ No

Providers include:

- *Chiropractor*
- *Psychologist*
- *Physiotherapist*
- *Occupational Therapist*
- *Speech Language Pathologist*
- *Podiatrist or Chiropodist*
- *Nutritionist or Dietitian*
- *Nurse Practitioner*
- *Visiting Nurses (i.e., Home Care) or Private Nurse*
- *Optometrist*
- *Dentist*
- *Social Worker*
- *Naturopath or Homeopath*
- *Adolescent/school counsellor*
- *Children's aid*
- *Family counsellor*
- *Support group*

If yes, please list service provider below (please do not enter provider's name):

Type of Health Professional	Number of visits	Average Amount Spent per Visit ($)	Self paid or insurance?
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____ ☐ Don't know/can't remember
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____ ☐ Don't know/can't remember
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____ ☐ Don't know/can't remember

CQ9b. Has your child **GONE TO VISIT** any health care or social service provider at their place of practice (e.g. their office or at the hospital) in the last 6 months?	☐Yes ☐ No

If yes, please list service provider below (please do not enter provider's name):

Type of Health Professional	**Number of visits**	**Average Amount Spent per Visit ($)**	**Self paid or insurance?**	**Average amount spent on parking per visit ($)**	**Mileage (km)**
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____		
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____		
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____		
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____		

CQ10. LOSS OF TIME FROM WORK (PAID OR UNPAID)

CQ10a. Do you work in paid employment or are you on paid leave?	□Yes □ No
CQ10b. Do you participate in any volunteer activities or unpaid employment?	□Yes □ No
CQ10c. Thinking back over the past 6 months, have you had to miss any time from work/volunteer activities to go to the doctor, emergency room or while your child was admitted to the hospital?	□Yes □ No (continue to CQ10e)
CQ10d. Thinking back over the past 6 months, can you estimate on average how many days per month have you had to take off?	_____ average days per month
CQ10e. Thinking back over the past 6 months, when your child went to the doctor, emergency room or was admitted to the hospital, **has anyone else** (such as another caregiver) had to miss time from paid employment to help you care for your child or accompany your child?	□Yes □ No (continue to CQ10g) □ Not applicable
CQ10f. Thinking back over the past 6 months, can you estimate on average how many days per month this other person had to take off each month?	_____ average days each month
CQ10g. Thinking back over the past 6 months, have you had to pay someone to care for your child (child in study) so that you could continue with your normal activities/homemaking or paid/unpaid employment?	□Yes □ No (continue to CQ10i) □ Don't know/Can't remember
CQ10h.Thinking back over the past 6 months, can you estimate on average how much you spent on this childcare per month?	Average spent per month $: _____ □ Don't know/Can't remember
CQ10i. Thinking back over the past 6 months, were you or other family members prevented from engaging in any activities such as shopping, volunteer, work, visiting friends, going to the movies, etc. to care for your child?	□□Yes □ No (continue to CQ10k) □ Don't know/Can't remember□
CQ10j. Thinking back over the past 6 months, can you estimate on average how many days per month this was?	_____ average days per month

CQ10k. Thinking back over the past 6 months, were you or other family members prevented from engaging in your regular homemaking tasks to care for your child?	□Yes □ No (go to CQ10m)

	☐ Don't know/Can't remember
CQ10l. Thinking back over the past 6 months, can you estimate on average how many days per month this was?	_____ average days per month
CQ10m. Thinking back over the past 6 months, have you had to pay for any individual to assist you with homemaking activities?	☐Yes ☐ No (go to CQ10o) ☐ Not applicable
CQ10n. Thinking back over the past 6 months, can you estimate on average how much you spent per month on assistance with homemaking activities?	Amount spent per month $_____
CQ10o. Thinking back over the past 6 months, have you had to pay for any individual to care for your **other** children while you were caring for child in study?	☐Yes ☐ No (go to CQ11a) ☐ Don't know/Can't remember
CQ10p. Thinking back over the past 6 months, can you estimate on average how much you spent childcare per month?	Amount spent per month $ _____ ☐ Don't know/Can't remember

CQ11 – CHANGES TO HOME SUCH AS RENOVATIONS

CQ11a. Have you had to do any changes to your home such as renovations (a ramp or a special bed) to accommodate your child?	□Yes □ No (continue to CQ12)
CQ11b. How much in total did you pay for these changes to yourhome?	$_____ spent in total on home renovations
CQ11c. What percentage of these costs were covered by other funding sources?	_____%

CQ12 – ACCESSIBLE VAN/VEHICLE

CQ11a. Have you had to purchase an accessible van/vehicle to accommodate your child?	□Yes □ No (continue to CQ13)
CQ11b. How much in total did you pay for the accessible van/vehicle?	$_____ spent in total on accessible vehicle
CQ11c. What percentage of these costs were covered by other funding sources?	_____%

CQ13 – OTHER ONE-TIME EXPENSES

CQ13a. Have you had any other one-time expenses to accommodate your child?	□Yes □ No
CQ13b. What is the total of these costs?	$_____ spent in total on other one-time expenses?

Appendix 4. List of Institute for Clinical Evaluative Sciences (ICES) Datasets

Dataset Name	Dataset Description
ADP	Assistive Devices Program: program which covers customized equipment and specialized supplies for low-income and most medically high-risk children - costing data for equipment and supplies
DAD	Discharge Abstract Database: hospital diagnostic codes
HCD	Home Care Database: provincial government in-home provider and case-management visits – home care data
IPDB	ICES physical database: care provider information
LHIN	Local Health Integration Network: coding and geography data
NACRS	National Ambulatory Care Reporting System: emergency and same-day surgery data
ODB	Ontario Drug Benefit: program which covers medications for low-income and most medically high-risk children – medication costing data
OHIP	Ontario Health Insurance Plan: physician billing – costing data
OMHRS	Ontario Mental Health Reporting System: mental health care services use data
PCCF	Postal Code Conversion File: geography data
RPDB	Registered Persons Database: demographic and vital statistic data for all Ontario residents eligible for public health insurance

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Pages 2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Pages 5-6
	2b	Specific objectives or hypotheses	Page 6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Pages 6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Pages 8-9
	4b	Settings and locations where the data were collected	Page 8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 9-10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Pages 10-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Pages 13-14
	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	Pages 14-15
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Pages 14-15
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	Pages 14-15
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Pages 14-15

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Pages 14-15
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Pages 16-17
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Pages 16-17
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	N/A – protocol paper
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A – protocol paper
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A – protocol paper
	14b	Why the trial ended or was stopped	N/A – protocol paper
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A – protocol paper
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	N/A – protocol paper
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	N/A – protocol paper
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A – protocol paper
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A – protocol paper
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A – protocol paper
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pages 17-19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	N/A – protocol paper
Other information			

Registration	23	Registration number and name of trial registry	Page 21
Protocol	24	Where the full trial protocol can be accessed, if available	Page 20
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 21

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Complex Care for Kids Ontario: Protocol for a mixed-methods randomized controlled trial of a population-level care coordination initiative for children with medical complexity

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Complete List of Authors:	Orkin, Julia; The Hospital for Sick Children, Division of Pediatric Medicine; University of Toronto, Department of Pediatrics Chan, Carol ; The Hospital for Sick Children, Child Health Evaluative Sciences Fayed, Nora; Queen's University, School of Rehabilitation Therapy Lin, Jia Lu Lilian; University of Toronto Dalla Lana School of Public Health, Institute of Health Policy, Management and Evaluation Major, Nathalie; Children's Hospital of Eastern Ontario, Department of Paediatrics Lim, Audrey; Hamilton Health Sciences Center, McMaster University, Department of Pediatrics Peebles, Erin; Western University Moretti, Myla; The Hospital for Sick Children, University of Toronto, Clinical Trials Unit Soscia, Joanna; The Hospital for Sick Children, Division of Pediatric Medicine Sultan, Roxana; The Hospital for Sick Children, The Provincial Council for Maternal & Child Health Willan, Andrew; The Hospital for Sick Children, Clinical Trials Unit-Ontario Child Health Support Unit Offringa, Martin; The Hospital for Sick Children, Child Health Evaluation Sciences Guttmann, Astrid; Institute for Clinical Evaluative Sciences, ; The Hospital for Sick Children, Division of Pediatric Medicine Bartlett, Leah; Royal Victoria Regional Health Centre Kanani, Ronik; North York General Hospital, University of Toronto, Pediatrics Culbert, Erin; Trillium Health Partners, The Credit Valley Hospital Hardy-Brown , Karolyn ; Peterborough Regional Health Centre Gordon, Michelle; Orillia Soldier's Memorial Hospital Perlmutar, Marty; Michael Garron Hospital Cohen, Eyal; The Hospital for Sick Children, Division of Pediatric Medicine ; University of Toronto, Department of Pediatrics
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Secondary Subject Heading:	Health services research, Research methods

Keywords:	complex care, medical complexity, health services, children, randomized controlled trial, parents

Complex Care for Kids Ontario: Protocol for a mixed-methods randomized controlled trial of a population-level care coordination initiative for children with medical complexity

Authors: Julia Orkin[1,2,3], Carol Y Chan[3], Nora Fayed[4], Jia Lu Lilian Lin[5], Nathalie Major[6], Audrey Lim[7], Erin Peebles[8], Myla E Moretti[5,9], Joanna Soscia[1], Roxana Sultan[10], Andrew R Willan[9], Martin Offringa[2,3], Astrid Guttmann[1,2,3,5,17], Leah Bartlett[11], Ronik Kanani[12], Erin Culbert[13], Karolyn Hardy-Brown[14], Michelle Gordon[15], Marty Perlmutar[16], and Eyal Cohen[1,2,3,5,17]

Author Affiliations: [1]Division of Pediatric Medicine, The Hospital for Sick Children, Toronto, Ontario, Canada, [2]Department of Pediatrics, University of Toronto, Toronto, Ontario, Canada, [3]Child Health Evaluative Sciences, The Hospital for Sick Children, Toronto, Ontario, Canada, [4]School of Rehabilitation Therapy, Queen's University, Kingston, Ontario, Canada, [5]Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada, [6]Department of Paediatrics, Children's Hospital of Eastern Ontario, University of Ottawa, Ottawa, Ontario, Canada, [7]Department of Pediatrics, Hamilton Health Sciences Centre, McMaster University, Hamilton, Ontario, Canada, [8]Western University, London, Ontario, Canada, [9]Clinical Trials Unit-Ontario Child Health Support Unit, The Hospital for Sick Children, Toronto, Ontario, Canada, [10]The Provincial Council for Maternal & Child Health, The Hospital for Sick Children, Toronto, Ontario, Canada, [11]Royal Victoria Regional Health Centre, Barrie, Ontario, Canada, [12]North York General Hospital, Toronto, Ontario, Canada, [13]Trillium Health Partners, The Credit Valley Hospital, Mississauga, Ontario, Canada, [14]Peterborough Regional Health Centre, Peterborough, Ontario, Canada, [15]Orillia Soldier's Memorial Hospital, Orillia, Ontario, Canada, [16]Michael Garron Hospital, Toronto, Ontario, Canada, [17]Institute for Clinical Evaluative Sciences, Toronto, Ontario, Canada

Keywords: Complex Care, medical complexity, health services, coordination, children, parents, randomized controlled trial

Abbreviations:
CCKO: Complex Care for Kids Ontario
CMC: children with medical complexity
FECC: Family Experiences with Coordination of Care
KT: knowledge translation
MFTD: Medically Fragile and/or Technology Dependent
PCMCH: The Provincial Council for Maternal & Child Health

Correspondence: Dr. Julia Orkin, The Hospital for Sick Children, 555 University Avenue, Toronto, Ontario, Canada, M5G 1X8, Email: julia.orkin@sickkids.ca Telephone: 416-813-7654 ext 201150

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ABSTRACT

Introduction: Technological and medical advances have led to a growing population of children with medical complexity (CMC) defined by substantial medical needs, healthcare utilization, and morbidity. These children are at a high risk of missed, fragmented and/or inappropriate care, and families bear extraordinary financial burden and stress. While small in number (<1% of children), this group uses approximately 1/3 of all child healthcare resources, and need coordinated care to optimize their health. Complex Care for Kids Ontario (CCKO) brings researchers, families, and healthcare providers together to develop, implement and evaluate a population-level roll-out of care for CMC in Ontario, Canada through a randomized controlled trial design. The intervention includes dedicated key workers and the utilization of coordinated shared care plans.

Methods and analysis: Our primary objective is to evaluate the CCKO intervention using a randomized waitlist control design. The waitlist approach involves rolling out an intervention over time, whereby all participants are randomized into two groups (A and B) to receive the intervention at different time points determined at random. Baseline measurements are collected at month 0, and Groups A and B are compared at months 6 and 12. The primary outcome is the Family Experiences with Coordination of Care (FECC) survey at 12 months. The FECC will be compared between groups using an analysis of covariance with the corresponding baseline score as the covariate. Secondary outcomes include reports of child and parent health outcomes, health system utilization, and process outcomes.

Ethics and Dissemination: Research ethics approval has been obtained for this multicentre randomized controlled trial. This trial will assess the effect of a large population-level complex

care intervention to determine whether dedicated key workers and coordinated care plans have an impact on improving service delivery and quality of life for CMC and their families.

Registration: ClinicalTrials.Gov identifier: NCT02928757

ARTICLE SUMMARY

Strengths and limitations of this study:

- This is the first large population-level implementation and mixed methods evaluation assessing the effectiveness of a complex care program for children with medical complexity (Complex Care for Kids Ontario (CCKO)).
- The study cohort represents a diverse sample of complex care patients across Ontario and the utilization of broad outcomes that encompass multiple potential targets of care with parent co-development in terms of the selection of outcome measures used.
- A limitation of this study relates to the challenge of the patient population as many are too unwell to be safely randomized to a waitlist design and therefore are excluded from the study. However, we will be able to use routinely collected health administrative data to describe heath care utilization as a single outcome for this population as to not lose the significance of their data.

INTRODUCTION

Medical advances have led to improved survival for many previously life-threatening conditions of childhood, such as prematurity[1], congenital anomalies[2], and congenital or acquired brain injury[3]. Technologic advances such as ventilator support, feeding tubes and transplantation have successfully prolonged the lives of children with lung, gut and other organ failure. This epidemiologic transition[4] has created a burgeoning population of children with medical complexity (CMC) – children with new morbidities, which are caused by longer survival itself as well as the complications of their life-sustaining therapies and created a new population that requires specialized care delivery to meet their complex healthcare needs.

CMC have been defined as "children with chronic conditions with elevated service needs, functional limitations and high healthcare utilization"[5]. Data from Ontario, Canada suggests that while CMC account for approximately 0.7% of all children, they use about one-third of all child health resources [6]. Studies from the United States have also reported that CMC account for 43% of child deaths, 49% of hospital days, and 75-92% of consumed assistive health technology[7, 8]. CMC and their parental caregivers endure enormous challenges, including: multiple and prolonged hospitalizations[9], frequent medical errors[10], poor care coordination[9, 11], and extraordinary stress[12]. The consequences may include poor caregiver health[13], marital strain[14], and profound negative financial impact[15].

Previous research has shown through a series of before- and after- studies, that targeted and integrated Complex Care interventions, most commonly within structured clinical program, may improve the health outcomes of CMC[16] , including reducing the burden of caregiving[17], and mitigating costly and unnecessary healthcare expenditures[18, 19]. Other studies have shown

additional benefits such as: a decreased need for medical information and improved satisfaction[20], improved family perceptions of their providers, their overall health care experience, and provider communication[21], as well as decreased unplanned healthcare visits[22]. However, the validity of these findings has been limited by small sample sizes, lack of control groups and incomplete outcome measures[23]. Published randomized controlled trials (RCTs) report improved parental satisfaction with care, but mixed results for other outcomes. One parallel-group RCT described a decrease in both rates of severe illness and health care costs[24] among children enrolled in a structured Complex Care program, while another cluster RCT reported increased costs with no change in functional status or hospital-based utilization[25].

The Provincial Council of Maternal and Child Health (PCMCH) is a provincial organization, supported by Ontario's public single-payer of healthcare (the Ministry of Health and Long-Term Care). PCMCH implemented Complex Care Kids Ontario (CCKO), a population-health strategy to improve care for CMC by providing an integrated approach to medical care and coordination. The strategy aims to improve service delivery, health, and quality of life of the patient-families involved through care coordination across acute and primary care, rehabilitation, home and community care, facilitated by dedicated nurse practitioners[26, 27], who function as key workers to establish seamless integrated care through the development and maintenance of a single, comprehensive and collaborative care plan that is designed to meet the child's/family's goals and optimize health outcomes (see Appendix 1). The aim of this study is to compare the effectiveness of the CCKO intervention to usual care for CMC in Ontario.

METHODS/DESIGN

Design

CCKO will utilize a waitlist variation of a randomized controlled trial design (Figure 1). The waitlist approach involves rolling out an intervention over time, whereby all participants are randomized into two groups (A and B) to receive the intervention at different time points determined at random[25, 28]. Group A receives the intervention at the next available appointment. Group B is placed on a waitlist and receives the intervention after 12 months. This study design uses the time period before the intervention as the control period/baseline, to be compared to those receiving the intervention[29]. Baseline measurements would be collected at month 0, and Groups A and B would be compared at months 6 and 12.

The waitlist design is used in scenarios where it is considered unethical to withhold an intervention with likely benefits, or if there are logistical or financial constraints that prevent the intervention from being administered in whole at one time point[28, 29]. This design generates robust evidence of an intervention program's effectiveness by leveraging real-world operational need for a staggered roll out. For CCKO, it is logistically not feasible for all eligible children to be seen immediately. For example, the initial intake process for key workers is time-intense, requiring the creation of careplans and the development of a patient-provider relationship. A staggered roll out facilitates work-flow, allowing program implementation within the context of human resource limitations. With the exception of patients for whom care coordination is thought to be urgently required (see exclusion criteria a)-c)), all patients referred to CCKO will be randomly assigned to either receive the intervention immediately or after the waitlist period (12 months). This approach minimizes the risk of selection bias by retaining the design element of randomization.

Setting

CCKO will be led by four tertiary care children's hospitals with partnership at multiple community led clinics (see Appendix 2). These sites display broad geographical representation of patients.

Participants

The target population includes children in Ontario who satisfy the Standard Operational definition for CMC developed by PCMCH[30]. The inclusion criteria are summarized in Figure 2. The criteria adapt existing definitions of CMC[5] to a slightly narrower group with technology dependence and/or medical fragility to focus on those patients who are most expected to benefit from care coordination such as those thought to be at risk of avoidable hospitalizations.

Exclusion Criteria

a) High utilization of hospital level care
   - ≥ 3 hospitalizations, ≥ 2 ICU (intensive care unit) admissions, ≥ 30 days of total hospitalization in previous 3 months, excluding newborn admission

b) Tracheostomy and home ventilation

c) Medical status is deemed highly fragile and the need for close follow-up is essential by both referring and triaging team

d) Already followed by a complex care team

e) >16.0 years of age

f) Inadequate English proficiency to comprehend study questionnaires

g) Parent will not be involved in child's care over entirety of study (2 years)

Patients who satisfy exclusion criteria a)-c) are deemed to urgently require care coordination; as such, it would be unethical to randomize these patients to a waitlist. Patients who satisfy exclusion criteria d) would have experienced the potential benefits of care coordination already. Patients who satisfy exclusion criteria e) would be in the process of being transitioned to adult care. Patients who satisfy exclusion criteria f) would not be able to complete the study questionnaires as the majority are only validated in English. Patients who satisfy exclusion criteria g) would not be able to complete the study questionnaires at all time points as these children are placed in out of home care during the study period (social history is provided to the triaging team in each referral).

Patients whose caregivers cannot complete questionnaires in English will not be involved in the primary analysis however, they will be enrolled in CCKO and provide health care utilization data via health card linkages to health administrative data housed at the Institute for Clinical Evaluative Sciences that will be used in secondary analyses. Similarly, patients who require urgent care coordination are excluded from the study, but will be able to contribute data through similar linkages.

The CCKO intervention involves care coordination, defined as: “deliberate organization of patient care activities between two or more participants to facilitate the appropriate delivery of health care services. Organizing care involves the marshaling of personnel and other resources needed to carry out required care activities and is often managed by the exchange of information among participants responsible for different aspects of care”[31, 32]. Within CCKO, care coordination will include family/health care provider co-creation and management of care coordination plans which will be facilitated and accounted for by key workers partnering with

families. The key worker would have an advanced practice nursing (e.g., nurse practitioner) background and will support the development and enactment of the coordinated care plan between acute care, primary care, rehabilitation, home and community care. Further details about care plan development are available online[33]. The key worker would be available to provide advice from Monday to Friday, 9 AM – 5 PM, and will also develop plans of care for emergencies after hours as part of care plan development. Resources to maintain intervention fidelity among key workers will be maintained with oversight by PCMCH.

The waitlist group consists of CMC who are receiving care from primary and specialty providers, and are waitlisted for Complex Care clinic (pre-enrolment control period). Standard of care during the control period will involve care delivered through a primary care provider (family physician or pediatrician) for routine health care such as vaccination and acute care visits with subspecialty consultation as needed. Currently, this model of care for the vast majority of CMC in Ontario; among ~6,200 patients who are estimated to meet CCKO criteria in Ontario, only ~500 receive care in a structured complex care clinic. At the end of year 1, all CMC randomized to the waitlist will be enrolled in complex care and data will continue to be collected for 1 additional year on all participants in an extension phase.

Criteria for discontinuing study intervention: participants in the waitlisted arm that experience a change in clinical status and now meet exclusion criteria (e.g., prolonged hospital stay >30 days), will be taken out of the waitlist-arm and will be seen at the next available appointment.

Patient and Public Involvement

A family-engagement strategy was conducted to identify and prioritize outcomes for evaluation. The core set of relevant patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) was created in a consensus meeting using data collected from a survey completed by 48 families and 86 health care providers[34].

Outcomes

Measures representing these outcomes were selected based on their content applicability to the outcomes, proven psychometric performance (reliability and validity) among children and families. The family-engagement evaluation framework includes general and specific outcomes within the domains of service delivery (primary outcomes); child outcomes (secondary) and parent outcomes (secondary).

Primary Outcome:

1. *Coordination of Care Among Health Providers and Families*
2. *Coordination of Care Between Health Providers and Families*
3. *Utility of Follow-Up Planning Tools*

These outcomes will be assessed with the Family Experiences with Coordination of Care (FECC) survey, our primary outcome measure[35, 36]. The FECC has been validated in a study of 1209 CMC patient-families in the United States, and has internal consistency >0.7 with proven discriminant validity for patient-family socioeconomic status and rurality[37], as well as responsiveness to change demonstrated in a recent CMC longitudinal cohort study[31].

Child-focused (Secondary) Outcomes:

1. *Quality of Life and Overall Emotional Health* (see Table 1)

2. *Child's Physical Pain*

Children's quality of life and emotional wellbeing will be measured using the World Health Organization definition focused on subjective life appraisal[38]and a positive orientation of mood assessment respectively. These outcomes will be assessed using the Feelings subscale from the KIDSCREEN-52 (6 items), used in over 250 studies in the child health services literature since its publication in 2005[39, 40]; and represents the most suitable content overlap with CMC. Children's physical pain will be measured using proxy reports of pain according to a 10 cm linear Visual Analog Scale (VAS)[41] **.** Linear VAS is considered superior to other pain reports available for children due to consistencies of interpretation within parent-child dyads, test-retest reliability and measurement precision[42], and is most appropriate for the diverse functional ability of CMC.

Table 1. Overview of outcomes & associated measures

Service Delivery Outcomes (Measurement Tool)	Parent Outcomes (Measurement Tool)	Child Outcomes (Measurement Tool)	System Outcomes (Measurement Tool)	Process Outcomes (Measurement Tool)
Coordination Among Providers (Family Experiences with Care. Coordination)	Life Satisfaction (KIDSCREEN, Satisfaction with Life Scale)	Life Satisfaction (KIDSCREEN)	Health Utilization e.g. Hospital admissions, ER visits, etc. (available for all Ontario residents in linked administrative databases housed at the Institute for Clinical Evaluative Sciences – see Appendix 4 for list of databases)	Patient and family experience (Qualitative Interviews)
Coordination Between Providers and Families (Family Experiences with Care Coordination)	Overall Health (Patient-Reported Outcomes Measurement Information System)	Physical Pain (Visual Analog Scale)		
Utility of Planning/Follow-Up Tools (Family Experiences with Care Coordination)	Energy and Fatigue (Patient-Reported Outcomes Measurement Information System)			
Patient Centered Information (Family Experiences with Care Coordination)	Out of Pocket Expenses (Expense Diary – see Appendix 3)			
Parental Support in the Community (Family Experiences with Care Coordination)				

Parent-focused (Secondary) Outcomes:

1. *Parents' Quality of Life*
2. *Perceived Emotional and Physical Health*
3. *Energy and Fatigue*
4. *Effects of Child's Condition on Parents' Finances and Ability to Work*

Parents' quality of life will be measured by a subjective life appraisal definition with two scales. (1) Diener's Satisfaction with Life Scale (SWLS) (5 items) which is the most validated life satisfaction scale for adults in the health and social sciences literature[43, 44] and (2) an adapted KIDSCREEN Feelings subscale, which will allow for direct comparisons of child versus parent life satisfaction[39]. Parents' perceived health, energy, and fatigue will be assessed with short forms of the Patient Reported Outcomes Measurement Information System (PROMIS) General Health (10 items); Sleep (8 items); and Fatigue (8 items) scales. These scales have been validated, have norm references data for comparison and have shown good to excellent psychometric properties among caregivers[45, 46]. Financial impact on parents' will be measured using an Expense Diary survey created by the study team. This survey will capture financial impact based on lost time and ability to work, as well as out of pocket expenses for health care services, equipment, and travel using scales customized for CMC and standardized relative to various child health studies with the support of the study health economist (Moretti; see Appendix 3).

Health System (Secondary) Outcomes:

A cost-effectiveness analysis will be performed to estimate the incremental costs (or savings) of the CCKO initiative compared to standard care in reducing hospitalization. Both a health care

system and societal perspective will be used with a time horizon of 12 months. Cost-effectiveness will be expressed as an incremental cost-effectiveness ratio (ICER), calculated by dividing the incremental costs of the intervention by the incremental difference in hospitalizations during the study period. Direct health care costs will include cost of the CCKO intervention and health services use by participants during the 12 month period. Indirect costs include caregiver lost productivity measured by participant survey. Health services use by participants will be obtained by linkage to administrative data housed at the Institute for Clinical Evaluative Sciences (IC\ES) for consenting participants (see Appendix 4 for list of datasets). IC\ES is a not-for-profit research institute listed in Ontario's health privacy legislation as a Prescribed Entity allowing the use of health data on all Ontario residents for the purposes of research. These datasets will be linked using unique encoded identifiers and analyzed at IC\ES. Additional health services use covered by third-party payers and parent out-of-pocket expenses will be obtained through surveys.

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Sample Size

We determine the sample size to be 140 (70/arm) based on the following criteria: i) Two-sided test of the null hypothesis at the 5% level; ii) Power of 80%; iii) 10% lost-to-follow-up; projected smallest clinically important difference of 0.5 of the within-patient standard deviation[47]. The within-patient standard deviation is needed to obtain a baseline measure from the waitlisted group as reference. The standard deviation of the primary outcome, FECC=0.56 is based on pooled data from the developer's CMC validation sample[37]. The required sample size is considered feasible as it is estimated that a pool of about 250 patients are readily identifiable for recruitment at CCKO sites.

Recruitment

At each site, clinical staff will refereligible patients to CCKO.. The triaging team will use the inclusion and exclusion criteria to determine eligibility for CCKO and suitability for the research study. A study information letter will be sent to the families of eligible patients who will subsequently be contacted by the research assistant by telephone. The research assistant will explain the research study to the families and obtain informed consent. An approximate 50% recruitment rate from a pool of N=400 (200/year) is conservatively estimated based on previous recruitment and current waitlists.

Questionnaires would take place at baseline, 6, 12, and 24 months. Upon completion of each time point, families will receive a $20 gift card to a drug store. A subsample of approximately 10-15 parents in the intervention arm will be approached 12 months for qualitative interviewing to explore their experience with the intervention.

Randomization

CCKO randomization will be done using a computer-generated algorithm stratified by centre. Blocking will be used to ensure that the two groups are the same size throughout the trial for each site as well as for the trial as a whole. An allocation ratio of 1:1 with random block sizes between 6 and 8 will be used within each stratum (centre). This will help to ensure that clinicians or investigators will not decipher the block size.

Data Collection

Upon obtaining consent, the Research Assistant will assign a research subject ID number to patients. Study data will be collected and managed using REDCap (Research Electronic Data Capture)[48]. Patient-families can opt to complete data collection by iPads or hardcopy. At home, patient-families can complete surveys via REDCap. This flexible methods of data collection will maximize diversity of respondents ideally as well as support family needs and preferences for data collection. A demographics survey will be administered at baseline (see Appendix 5 for demographic questions).

Data Management

A REDCap study database will be designed and maintained by the Research Coordinator at The Hospital for Sick Children. The data on the various forms will be linked by a unique research subject ID. The Research Coordinator will extract study data from questionnaires via the REDCap interface to complete the study-specific data collection forms. An external user interface will also be created on REDCap for parents who opt to complete the surveys online. All personal identifying information will be removed from the electronic study database. A separate secure list of research subjects' names and contact information will be maintained in a Microsoft Excel spreadsheet for the purpose of completing the follow-up questionnaires. All study-related electronic data files will be password-protected and reside on the Hospital server. Only members of the research team will have access to the server study file location via password-protected computers. Password-protected databases from each site will be transferred to the IC/ESthrough a Virtual Private Network.

Statistical analysis

An overview of outcomes are presented in **Table 1**.

Patient and Caregiver Characteristics

Baseline patient characteristics and descriptive variables will be presented for each arm: age, sex, diagnosis, ethnicity, medications, medical devices and hospitalizations (see Appendix 6 for baseline clinical information form). Baseline caregiver characteristics and descriptive variables will be presented as well: age, sex, education level, employment status, ethnicity, primary language. For continuous variables, means and standard deviations or medians (interquartile ranges) will be presented. For categorical variables, proportions will be presented.

Primary Outcome

The primaryanalysis will be a comparison of service delivery outcomes (i.e., FECC) between the intervention and waitlist groups at 12 months. The principle of intention-to-treat will be applied. For effectiveness each outcome variable at Month 12 will be compared between groups using an analysis of covariance with the corresponding baseline score as the covariate. A two-sided, level 0.05 test of hypothesis will be applied.

Secondary Outcomes

Data collection at 0 and 6 months will be used to perform test-retest reliability, to establish baseline reference measures and to assess for stability of outcome changes (24 months). Secondary child-focused and parent-focused outcomes will be compared at 0, 6 and 12 months using Bonferroni corrections to account for multiple testing. All secondary health system outcomes will be compared between the intervention and control as well.

Additional Analyses

We will examine health system outcomes using regression modeling to explore the relationships between PROMs and health utilization patterns (for example, the relationship of out-of-pocket expenditures with availability of home health care services).

DISCUSSION

While growing attention has been provided to CMC in recent years[49], there are important gaps in the literature regarding the optimal care delivery model for CMC [17-19, 23]. Before- and after- studies have shown possible benefit but there has been few rigorous randomized controlled trials conducted that look at multiple outcomes including service delivery, parent and child health outcomes as well as health system outcomes such as health utilization. Furthermore, this is the first study that prioritized outcomes as identified by patients and families directly in order to understand if a complex care program was successful in the eyes of a family by selecting outcomes that matter most to them. The care delivery model in CCKO - utilizing a key worker and comprehensive care plans - is a time intensive and possibly costly one. Well-designed evaluations are needed to examine how they relate to outcomes of care for this population[50]. Several aspects of this trial are important to highlight as innovative and novel.

First, in contrast to other trials that target CMC within a single health care setting (e.g., a children's hospital), this study focuses on population-level implementation and evaluation in Ontario, Canada's most populous province. This setting allows the implementation of complex care coordination within a wide geographic area combing both densely populated urban areas with more rural locations for which travel to specialized care is challenging. The large number of sites participating in this study account for the majority of CMC care in Ontario. This

environment is unique in terms of the current literature as these patients reflect population-level CMC representation, with outcome data availability across the continuum of care available from a large provincial repository of data. The focus on many sites creates some challenges in both implementation and evaluation across diverse settings. However, this evaluation also provides an opportunity for the development of generalizable knowledge not only for publically-funded healthcare delivery systems, but also for broad groups of payers focused on other high-need/high-cost populations[51].

Second, the outcome measures used are patient and family-informed. Previous literature has highlighted the need for uniquely developed outcome measures for CMC recognizing the nature of their health care usage and trajectory. Before recruitment began, the outcome measures were determined through a process of direct consultation with parents of CMC[52]. Previous evaluations of CMC care have relied primarily upon readily available data (e.g. claims data or other administrative datasets), with minimal patient- and family-reported input. Previous patient-reported outcome measures utilized in evaluations have not been validated in a CMC population. A strength of this study is the utilization of broad outcomes that encompass multiple potential targets of care. We chose care coordination as the primary outcome measure because it is the primary target for change as in this patient population and the measurement instrument has been validated in CMC. Unfortunately, expectation of a change in disease status is not meaningful or realistic in many CMC, whereas improved navigation of the healthcare system is an important and improvable target of care. Biomedical endpoints, although important, are not meaningful in such a heterogeneous population.

Third, the study has been designed to mitigate risk of bias. It is anticipated that some patients may be excluded; a concern are those who are marginalized (e.g., non-English speaking), or are deemed too urgent to enroll in a waitlist. We aim to conduct a secondary study focused on comparing such patients to contemporaneous controls using administrative data to ensure knowledge generation about the impact of CCKO in this group as well, albeit with a higher risk of bias that would otherwise be attenuated with randomization (e.g., unmeasured confounders).

Fourth, the focus of this study is not solely quantitative in nature. We have elicited a mixed methods approach. We will conduct interviews with a subset of intervention arm parents to capture their experience with the intervention, areas of improvement, as well as perceived benefits and harms. This approach will identify what aspects of the CCKO intervention are more or less effective, for whom, in what context and why.

Lastly, the integrated knowledge translation is unique in that the direct provincial implementation of the CCKO roll out has been matched directly with the evaluation such that the knowledge end-user was a part of the study team from the outset. The integrated KT approach has included families caring for CMC, policy-makers and widely representative clinicians such as nurses and physicians. This large integrative model allows direct translation of results and seamless integration of knowledge.

ETHICS AND DISSEMINATION

The protocol has been approved by Research Ethics Boards at all sites. The study Research Assistant will obtain informed consent from parental caregivers. Informed consent/assent will be obtained from all those who are able to provide it.

Adverse Event Reporting

While there are no adverse events expected, any adverse events will be reported to the Research Ethics Board. All adverse events and adverse reactions will also be reported to the Primary Investigator within 24 hours.

Dissemination

CCKO represents a fully integrated knowledge transfer and exchange paradigm. The research team have worked with patient-families and PCMCH to craft the provincial strategy, providing population-based data to understand the target population (numbers/location of children, patterns of care, health system costs). The committees overseeing implementation and evaluation encompass key knowledge users (patients, families, clinicians, administrators, policy-makers), allowing for seamless KT. Executive Summaries and/or Presentations will be shared for wide dissemination to a variety of organizations/collaboratives. Academic KT will occur through presentation at academic conferences and publications in high-impact, peer-reviewed journals. At study end, results will be available on CCKO's website.

TRIAL STATUS

Recruitment began January 2017 and there are 132 participants of a target of 140 as of February 2019. The study is on track to complete enrolment in 2019. A copy of the full-length protocol is available upon request.

Figure Captions

Figure 1: Complex Care for Kids Ontario Evaluation Flow Chart for Referrals

Figure 2: Complex Care for Kids Ontario Inclusion Criteria

Author Contributions JO and EC designed the study and the other authors (CC, NF, JL, NM, AL, EP, MM, JS, RS, AW, MO, AG, LB, RK, EC, KHB, MG, and MP) collaborated in the design of the study. EC and AW provided statistical expertise. JO and CC prepared the initial draft of the manuscript and EC revised the manuscript. All authors read, provided feedback, discussed and approved the final manuscript. All authors gave approval for the manuscript to be submitted.

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Data Availability Statement

Data are available upon reasonable request.

Individual participant data that underlie the results reported in this article, after deidentification, can be shared. The study protocol is also available upon request. The data will be available beginning 12 months and ending 24 months following article publication. The data can be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Data can be requested for analyses that achieve aims in the aforementioned proposal. Proposals should be directed to the corresponding author Dr. Julia Orkin. To gain access, data requesters will need to sign a data access agreement.

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Figure 1. Complex Care for Kids Ontario Evaluation Flow Chart for Referrals

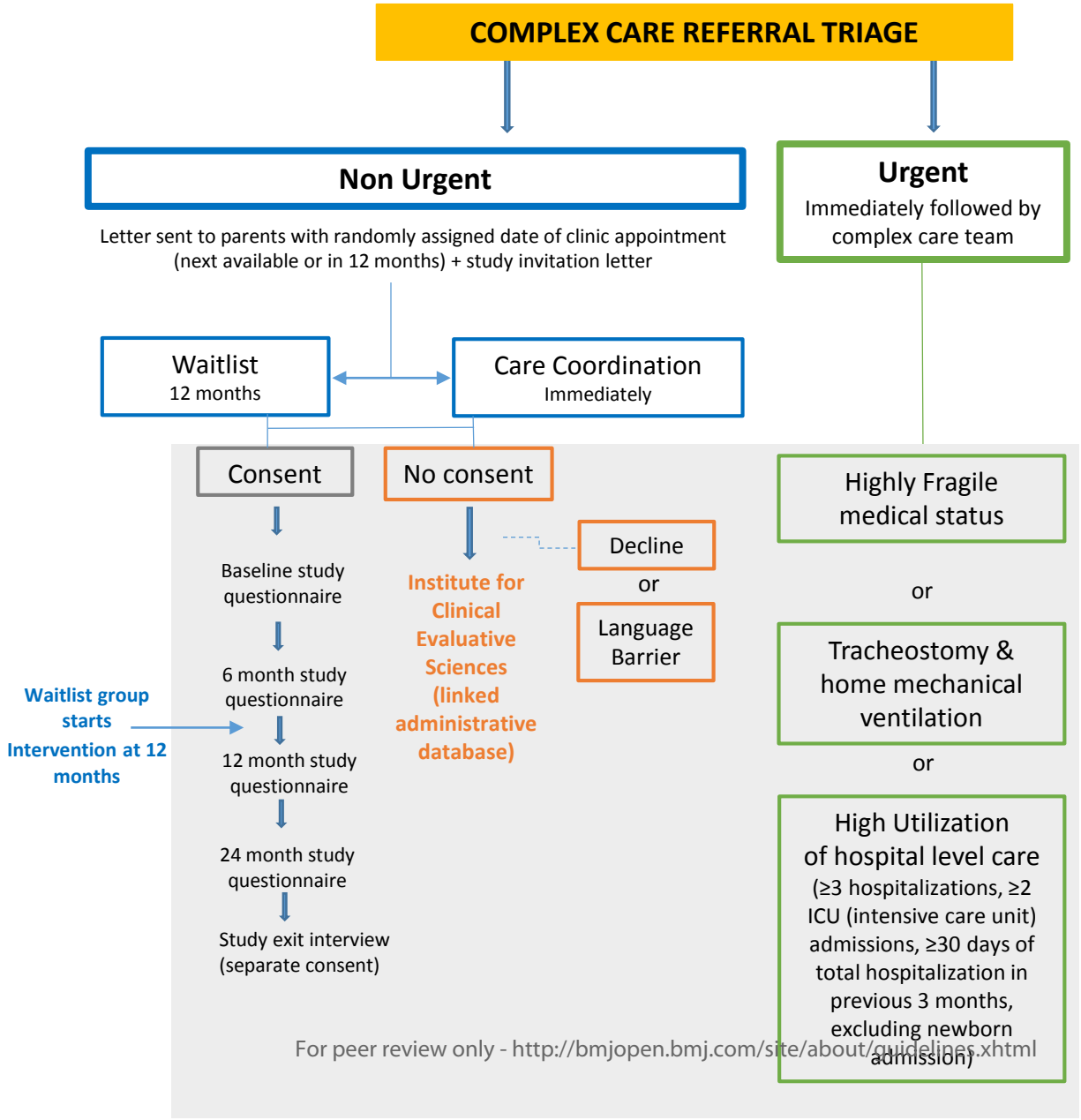


Figure 2. Complex Care for Kids Ontario Inclusion Criteria[30]

CCKO
Complex Care Kids Ontario

Standard Operational Definition for Children with Medical Complexity who are Medically Fragile and/or Technology Dependent

Under 18 years of age and meets at least one criterion from EACH of the following four conditions:

Technology Dependent and/or users of High Intensity Care

- ❑Child is dependent on mechanical ventilators, and/or requires prolonged IV administration of nutritional substances or drugs and/or is expected to have prolonged dependence on other device-based support. For example: tracheostomy tube care/ artificial airway, suctioning, oxygen support, or tube feeding.
- ❑Child has prolonged dependence on medical devices to compensate for vital bodily functions, and requires daily/near daily nursing care, e.g., cardiorespiratory monitors; renal dialysis due to kidney failure
- ❑Child has any chronic condition that requires great level of care such as: Children who are completely physically dependent on others for activities of daily living (at an age when they would not otherwise be so dependent), Children who require constant medical or nursing supervision or monitoring, medication administration and/or the quantity of medication and therapy they receive.

&

Fragility

- ❑The child has severe and/or life-threatening condition
- ❑Lack of availability and/or failure of equipment/technology or treatment places the child at immediate risk resulting in a negative health outcome
- ❑Short-term changes in the child's health status (e.g., an intercurrent illness) put them at immediate serious health risk.
- ❑As a consequence of the child's illness, the child remains at significant risk of unpredictable life-threatening deterioration, necessitating round-the-clock monitoring by a knowledgeable caregiver.
- ❑Likely to experience exacerbation of chronic condition necessitating assessment by a healthcare provider in a timely manner

&

Chronicity

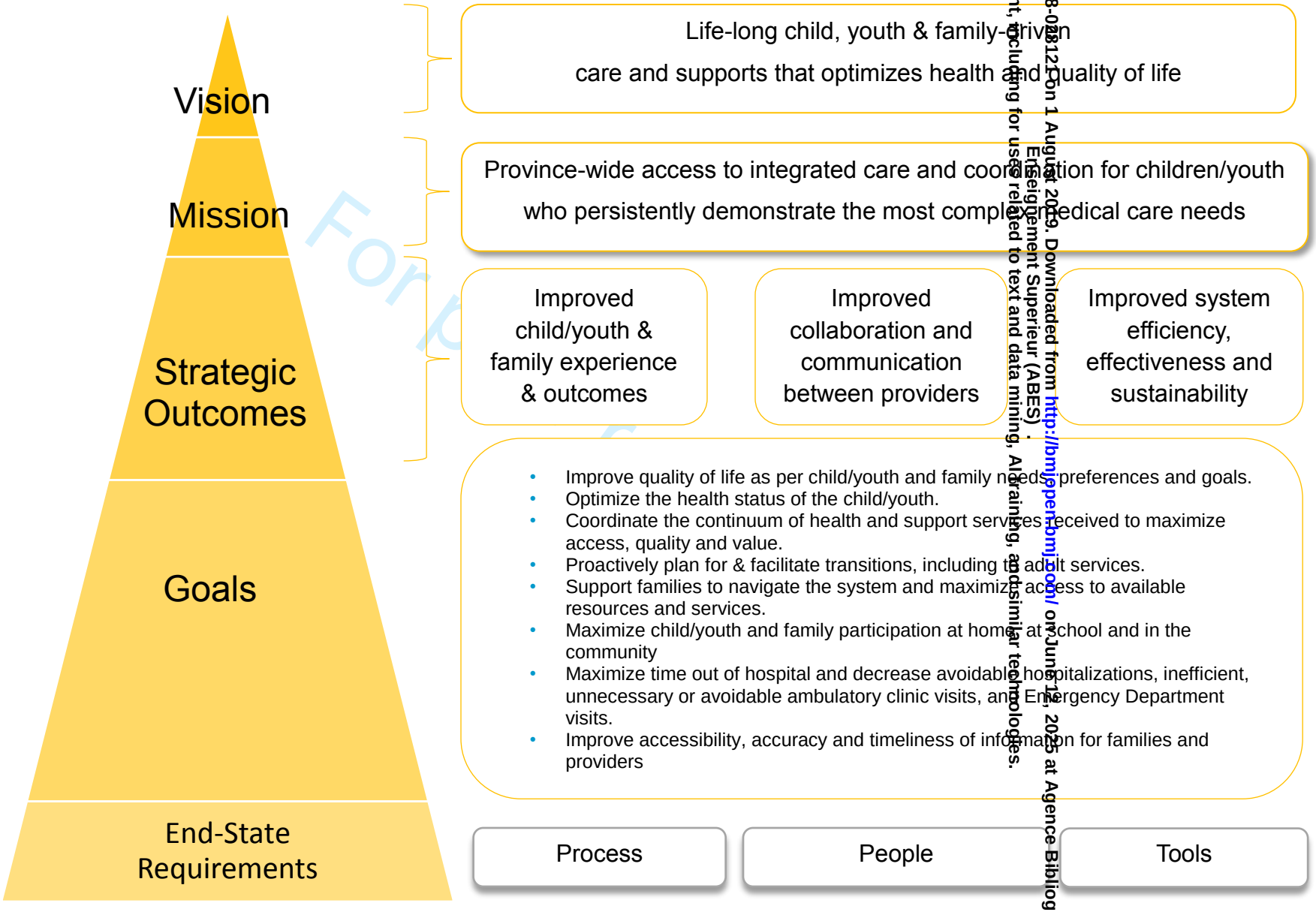
- ❑The child's condition is expected to last at least six more months
- ❑The child's life expectancy is less than six months

&

Complexity

- ❑Involvement of at least five healthcare practitioners/ teams and healthcare services are delivered in at least three of the following locations: Home, School / Nursing school, Hospital, Children's Treatment Centre, Community-based clinic (e.g. doctor's office), Other (at clinician's discretion)
- ❑The family circumstances impede their ability to provide day-to-day care or decision making for a child with medical complexity. For example, the primary caregiver and/or the primary income source are at risk of not being able to complete their day-to-day responsibilities

Appendix 1. Complex Care for Kids Ontario Strategic Framework[53]



Appendix 2. Complex Care for Kids Ontario Study Sites

Site Name	Location
The Hospital for Sick Children (SickKids)	Toronto, ON
Children's Hospital of Eastern Ontario	Ottawa, ON
London Health Sciences Centre	London, ON
Hamilton Health Sciences Centre	Hamilton, ON
North York General Hospital	Toronto, ON
Peterborough Regional Health Centre	Peterborough, ON
Orillia Soldiers' Memorial Hospital	Orillia, ON
Royal Victoria Hospital	Barrie, ON
Michael Garron Hospital	Toronto, ON
Credit Valley Hospital	Mississauga, ON

Appendix 3. Expense Diary

CQ1-EXTRACURRICULAR ACTIVITIES

CQ1a. Does your child participate in extracurricular activities (outings/sports/hobbies)?	□Yes □ No (continue to CQ2a) □ Don't Know (continue to CQ2a)
CQ1b How many hours of extracurricular activities does your child participate on average per month? (Describe to the best of ability)	_____ hours of activity on average per month

CQ2-ACADEMIC ACTIVITIES

CQ2a. Is your child currently enrolled in school outside the home?	□Yes □ No Reason: _____ (continue to CQ3a)
CQ2b. If Yes, does your child attend full-time (every day) or part time?	□ Full-time (continue to CQd) □ Part time (continue to CQ2c)
CQ2c. If your child attends school part time, how many days of school do they attend per week on average?	□ 1 day □ 2 days □ 3 days □ 4 days □ N/A
CQ2d. Thinking back over the past 6 months, how many days of school does your child miss on average per month?	_____ days missed on average per month
CQ2e. Thinking back over the past 6 months, how much do you spend on travel to/from school for your child on average per month?	$_____ on average per month AND Distance travelled daily to get child to schooling _____ km

CQ3. DOCTOR VISITS

These questions are only about when your child visited the doctor's office or clinic. This does not include emergency room visits or hospital stays.

CQ3a. Does your child use public transit, taxi or accessible transit services (e.g. Wheel trans)?	☐ Yes ☐ No (continue to CQ3b)
CQ3ai.If your child uses public transit, taxi, or Wheel Trans, how much money do you usually spend traveling to and from the doctor's office/clinic per visit?	$_____
CQ3b. Do you or another family member drive to your child's doctor's office/clinic?	☐ Yes ☐ No (continue to CQ3c)
CQ3bi. If you or another family member drives, what is the distance to your child's doctor's office/clinic?	_____km
CQ3c. On average how much do you spend on parking at the doctor's office/clinic?	$ _____ per visit --- ☐ Nothing ☐ Not applicable

CQ4-INSURANCE COVERAGE

CQ4a. Do you have a drug plan that pays for any of your child's medications (ie. Employee benefit package, Ontario Drug Benefit, OHIP+)?	□Yes (continue to CQ5b) □ No (continue to CQ5h) □ Don't Know (continue to CQ5h)
CQ4b What is your Drug Plan?	□ 1. Employee benefit package □ 2. Government program (ie. Ontario Drug Benefit, OHIP+) □ 3. Other (Please specify:_____) □ 4. Don't know, don't remember
CQ4c. When you have to pay for prescription drugs, what is the percentage of prescription medication costs that you pay on average?	_____% □ Don't know
CQ4d. Do you have a private health plan that covers other medical expenses such as physical therapy, ambulance services, medical devices etc?	□Yes □ No (continue to CQ6a) □ Don't Know (continue to CQ6a)
CQ4e. How much do you or your partner pay into this plan or how much is deducted from your pay cheque per month?	$_____ per month □ Nothing □ Don't Know

CQ5. MEDICATION

CQ5a. Has [YOUTH] taken any prescription or over-the-counter medication in the last 6 months?	☐ Yes (complete table below) ☐ No

If yes, please list any medication that you have taken in the last 6 months.

Name of medication	Reason [CHILD] takes this medication	Dose (mg)	Formulation (pill, liquid, inhaler, etc)	Frequency per day?

CQ5ba. Has your child used any over-the-counter medications, dietary supplements (e.g. vitamins), naturopathic, or homeopathic treatments in the last 6 months?	☐Yes (complete table below) ☐ No

If yes, please list items below:

Name of item	Reason [child] needs this	Financial coverage Check all that apply	If you paid some or all, please state the amount you paid ($)
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	
		☐Insurance ☐ Self Paid ☐ Donated	

CQ6. MEDICAL DEVICES

CQ6a. Has your child needed to use any medical/assistance devices or equipment in the last 6 months (wheelchair, crutches, brace, syringes, VitaMix blender for special food preparation)?	☐Yes (complete table below) ☐ No

If yes, please list devices below:

Name of item	Reason [child] needs this	Financial coverage Check all that apply	If you paid some or all, please state the amount you paid ($)
		☐ ADP (Assistive Devices Program) ☐Insurance ☐ Self Paid ☐ Donated	
		☐ ADP (Assistive Devices Program) ☐Insurance ☐ Self Paid ☐ Donated	
		☐ ADP (Assistive Devices Program) ☐Insurance ☐ Self Paid ☐ Donated	
		☐ ADP (Assistive Devices Program) ☐Insurance ☐ Self Paid ☐ Donated	

CQ7. EMERGENCY ROOM VISITS

These questions are only about when you had to bring your child to the emergency room. This does not include to doctor visits or to days when your child was admitted to the hospital.

CQ7a. Has your child gone to the hospital in an ambulance in the last 6 months?	☐ Yes ☐ No (continue to CQ8g)
CQ7b. How many times did your child do so?	_____ # of times
CQ7e. Did you have to pay for the ambulance services?	☐ Yes ☐ No (continue to CQ8g) ☐ Don't know/can't remember (continue to CQ8g)
CQ7f. How much did you spend on these ambulance services per visit?	$_____
CQ7g. Has your child gone to the emergency room **by some other method of transportation** in the last 6 months?	☐ Yes ☐ No (continue to CQ9)
CQ7h. How many times did your child do so?	_____ # of times
CQ7i. On average, how much did you spend on transportation to the emergency room (including parking, if applicable)?	$_____/visit

CQ8. HOSPITAL ADMISSIONS

These questions are only about when your child was admitted to hospital. This does not include emergency room visits.

CQ8a. Has been admitted to the hospital in the last 6 months?	☐ Yes ☐ No (continue to CQ10)
CQ8b. How many times was your child admitted to the hospital?	_____ # of times
CQ8c. On average, how much did you spend on transportation to the hospital (including parking, taxis, public transportation mileage)?	$_____/day and Distance from home to hospital _____ km

CQ9. ALLIED HEALTH PROFESSIONALS AND SOCIAL SERVICE PROVIDERS

CQ9a. Has any allied health care or social service provider **COME TO VISIT your** child either at home, residence or school in the last 6 months? (See list of providers below)	☐Yes ☐ No

Providers include:

- *Chiropractor*
- *Psychologist*
- *Physiotherapist*
- *Occupational Therapist*
- *Speech Language Pathologist*
- *Podiatrist or Chiropodist*
- *Nutritionist or Dietitian*
- *Nurse Practitioner*
- *Visiting Nurses (i.e., Home Care) or Private Nurse*
- *Optometrist*
- *Dentist*
- *Social Worker*
- *Naturopath or Homeopath*
- *Adolescent/school counsellor*
- *Children's aid*
- *Family counsellor*
- *Support group*

If yes, please list service provider below (please do not enter provider's name):

Type of Health Professional	Number of visits	Average Amount Spent per Visit ($)	Self paid or insurance?
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____ ☐ Don't know/can't remember
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____ ☐ Don't know/can't remember
	_____ average visits per month		☐Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____ ☐ Don't know/can't remember

CQ9b. Has your child **GONE TO VISIT** any health care or social service provider at their place of practice (e.g. their office or at the hospital) in the last 6 months?	☐ Yes ☐ No

If yes, please list service provider below (please do not enter provider's name):

Type of Health Professional	**Number of visits**	**Average Amount Spent per Visit ($)**	**Self paid or insurance?**	**Average amount spent on parking per visit ($)**	**Mileage (km)**
	_____ average visits per month		☐ Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____		
	_____ average visits per month		☐ Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____		
	_____ average visits per month		☐ Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____		
	_____ average visits per month		☐ Self Paid ☐ Insurance ☐ Both If Both, what % by insurance? _____		

CQ10. LOSS OF TIME FROM WORK (PAID OR UNPAID)

CQ10a. Do you work in paid employment or are you on paid leave?	□Yes □ No
CQ10b. Do you participate in any volunteer activities or unpaid employment?	□Yes □ No
CQ10c. Thinking back over the past 6 months, have you had to miss any time from work/volunteer activities to go to the doctor, emergency room or while your child was admitted to the hospital?	□Yes □ No (continue to CQ10e)
CQ10d. Thinking back over the past 6 months, can you estimate on average how many days per month have you had to take off?	_____ average days per month
CQ10e. Thinking back over the past 6 months, when your child went to the doctor, emergency room or was admitted to the hospital, **has anyone else** (such as another caregiver) had to miss time from paid employment to help you care for your child or accompany your child?	□Yes □ No (continue to CQ10g) □ Not applicable
CQ10f. Thinking back over the past 6 months, can you estimate on average how many days per month this other person had to take off each month?	_____ average days each month
CQ10g. Thinking back over the past 6 months, have you had to pay someone to care for your child (child in study) so that you could continue with your normal activities/homemaking or paid/unpaid employment?	□Yes □ No (continue to CQ10i) □ Don't know/Can't remember
CQ10h.Thinking back over the past 6 months, can you estimate on average how much you spent on this childcare per month?	Average spent per month $: _____ □ Don't know/Can't remember
CQ10i. Thinking back over the past 6 months, were you or other family members prevented from engaging in any activities such as shopping, volunteer, work, visiting friends, going to the movies, etc. to care for your child?	□□Yes □ No (continue to CQ10k) □ Don't know/Can't remember□
CQ10j. Thinking back over the past 6 months, can you estimate on average how many days per month this was?	_____ average days per month

CQ10k. Thinking back over the past 6 months, were you or other family members prevented from engaging in your regular homemaking tasks to care for your child?	□Yes □ No (go to CQ10m)

	☐ Don't know/Can't remember
CQ10l. Thinking back over the past 6 months, can you estimate on average how many days per month this was?	_____ average days per month
CQ10m. Thinking back over the past 6 months, have you had to pay for any individual to assist you with homemaking activities?	☐Yes ☐ No (go to CQ10o) ☐ Not applicable
CQ10n. Thinking back over the past 6 months, can you estimate on average how much you spent per month on assistance with homemaking activities?	Amount spent per month $_____
CQ10o. Thinking back over the past 6 months, have you had to pay for any individual to care for your **other** children while you were caring for child in study?	☐Yes ☐ No (go to CQ11a) ☐ Don't know/Can't remember
CQ10p. Thinking back over the past 6 months, can you estimate on average how much you spent childcare per month?	Amount spent per month $ _____ ☐ Don't know/Can't remember

CQ11 – CHANGES TO HOME SUCH AS RENOVATIONS

CQ11a. Have you had to do any changes to your home such as renovations (a ramp or a special bed) to accommodate your child?	□Yes □ No (continue to CQ12)
CQ11b. How much in total did you pay for these changes to yourhome?	$_____ spent in total on home renovations
CQ11c. What percentage of these costs were covered by other funding sources?	_____%

CQ12 – ACCESSIBLE VAN/VEHICLE

CQ11a. Have you had to purchase an accessible van/vehicle to accommodate your child?	□Yes □ No (continue to CQ13)
CQ11b. How much in total did you pay for the accessible van/vehicle?	$_____ spent in total on accessible vehicle
CQ11c. What percentage of these costs were covered by other funding sources?	_____%

CQ13 – OTHER ONE-TIME EXPENSES

CQ13a. Have you had any other one-time expenses to accommodate your child?	□Yes □ No
CQ13b. What is the total of these costs?	$_____ spent in total on other one-time expenses?

Appendix 4. List of Institute for Clinical Evaluative Sciences (ICES) Datasets

Dataset Name	Dataset Description
ADP	Assistive Devices Program: program which covers customized equipment and specialized supplies for low-income and most medically high-risk children - costing data for equipment and supplies
DAD	Discharge Abstract Database: hospital diagnostic codes
HCD	Home Care Database: provincial government in-home provider and case-management visits – home care data
IPDB	ICES physical database: care provider information
LHIN	Local Health Integration Network: coding and geography data
NACRS	National Ambulatory Care Reporting System: emergency and same-day surgery data
ODB	Ontario Drug Benefit: program which covers medications for low-income and most medically high-risk children – medication costing data
OHIP	Ontario Health Insurance Plan: physician billing – costing data
OMHRS	Ontario Mental Health Reporting System: mental health care services use data
PCCF	Postal Code Conversion File: geography data
RPDB	Registered Persons Database: demographic and vital statistic data for all Ontario residents eligible for public health insurance

Appendix 5.

DEMOGRAPHIC QUESTIONS

Site/Study ID: _ _ _ _ _ _ _ Date m m/d d/ y y y y

Child's Birthday: ____ /_____
mm yyyy

Child's Gender:

- ☐ Male
- ☐ Female
- ☐ Inter-sex
- ☐ Other

DQ1. What is your relationship to the child?

- ☐ Mother
- ☐ Father
- ☐ Guardian
- ☐ Sister
- ☐ Brother
- ☐ Relative (please specify:_____)
- ☐ Stepmother
- ☐ Stepfather
- ☐ Other (please specify:_____)

DQ2. What is your sex?

- ☐ Female
- ☐ Male

DQ3. What is your age?

_____ years old

DQ4. Were you born in Canada?

- ☐ Yes * go to DQ5
- ☐ No

DQ5. When did you immigrate to Canada?

Year: _____

DQ6. How would you describe your ethnic background?

- ☐ African
- ☐ Asian
- ☐ Canadian
- ☐ Caribbean/ West Indian
- ☐ East European
- ☐ European
- ☐ South Asian

DEMOGRAPHIC QUESTIONS

Site/Study ID: _ _ _ _ _ _ _ Date m m/d d/ y y y y

☐ Other (please specify: _____)

DQ7. What language is spoken most often at home?

☐ English
☐ French
☐ Arabic
☐ Bengali
☐ Filipino
☐ Gujarati
☐ Hindi
☐ Italian
☐ Mandarin/Cantonese
☐ Persian
☐ Polish
☐ Portuguese
☐ Punjabi
☐ Somali
☐ Spanish
☐ Tagalog
☐ Tamil
☐ Urdu
☐ Vietnamese
☐ Other (please specify:_____)

DQ8. What is your marital status?

☐ Married or living common-law
☐ Single (never been married)
☐ Widow or widower
☐ Separated or divorced

DEMOGRAPHIC QUESTIONS

Site/Study ID: _ _ _ _ _ _ _ Date m m/d d/ y y y y

DQ9. What is the highest level of education that you have attained?

- ☐ Elementary school (some or completed)
- ☐ Some secondary/high school
- ☐ Completed secondary/high school
- ☐ Some post-secondary (university or college)
- ☐ Received university or college degree/diploma

DQ10. What is the highest level of education that your spouse / partner has attained?

- ☐ Elementary school (some or completed)
- ☐ Some secondary/high school
- ☐ Completed secondary/high school
- ☐ Some post-secondary (university or college)
- ☐ Received university or college degree/ diploma
- ☐ Not applicable

DQ11. Which best describes your current employment status?

- ☐ Employed full-time
- ☐ Employed full-time (self-employed)
- ☐ Employed part-time
- ☐ Employed part-time (self-employed)
- ☐ Unemployed
- ☐ Homemaker
- ☐ Receiving social assistance
- ☐ Receiving disability or retirement pension
- ☐ Student

DQ12. Which best describes your spouse's/partner's current employment status?

- ☐ Employed full-time
- ☐ Employed full-time (self-employed)
- ☐ Employed part-time
- ☐ Employed part-time (self-employed)
- ☐ Unemployed
- ☐ Homemaker
- ☐ Receiving social assistance
- ☐ Receiving disability or retirement pension
- ☐ Student
- ☐ Not applicable

DEMOGRAPHIC QUESTIONS

Site/Study ID: _ _ _ _ _ _ _ Date m m/d d/ y y y y

DQ12. Including yourself, how many members are there living in your home?

Number of persons: _____

Appendix 6

Baseline Clinical Info (RA to Complete)

Study ID _____

Demographic Questions

Child's month of birth	◯ January ◯ February ◯ March ◯ April ◯ May ◯ June ◯ July ◯ August ◯ September ◯ October ◯ November ◯ December
Child's year of birth	◯ 2018 ◯ 2017 ◯ 2016 ◯ 2015 ◯ 2014 ◯ 2013 ◯ 2012 ◯ 2011 ◯ 2010 ◯ 2009 ◯ 2008 ◯ 2007 ◯ 2006 ◯ 2005 ◯ 2004 ◯ 2003 ◯ 2002 ◯ 2001 ◯ 2000 ◯ 1999 ◯ 1998
What is child's biological sex?	◯ Male ◯ Female ◯ Intersex
What is child's ethnic background?	◯ African ◯ Asian ◯ Canadian ◯ Caribbean/West Indian ◯ East European ◯ European ◯ South Asian ◯ Don't Know ◯ Other
If other, please specify:	_____

Child in group home (residential care)?	◯ Yes ◯ No
Child in foster care?	◯ Yes ◯ No
Did this participant change institutions for the duration of the study?	◯ Yes ◯ No
If yes, what is their new institution?	◯ Sickkids ◯ McMaster ◯ CHEO ◯ London ◯ North York General ◯ Royal Victoria ◯ Orillia ◯ Peterborough ◯ Michael Garron ◯ Credit Valley

Parent Demographics

Parent's age	_____

Important Dates

Date of randomization (YYYY-MM-DD)	_____
Date of consent (YYYY-MM-DD)	_____
Date of baseline questionnaire completion (YYYY-MM-DD)	_____

Baseline Hospitalization

Was the child admitted as an in-patient in the time period between randomization, consent, and baseline questionnaire completion?	◯ Yes ◯ No
If the child was an in-patient during this time period, how many times where they hospitalized?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Hospitalization 1: date of admission (yyyy-mm-dd)?	_____
Hospitalization 1: date of discharge (yyyy-mm-dd)?	_____
Hospitalization 1: length of hospitalization (in days)	_____

Hospitalization 2: date of admission (yyyy-mm-dd)?	_____
Hospitalization 2: date of discharge (yyyy-mm-dd)?	_____
Hospitalization 2: length of hospitalization (in days)	_____
Hospitalization 3: date of admission (yyyy-mm-dd)?	_____
Hospitalization 3: date of discharge (yyyy-mm-dd)?	_____
Hospitalization 3: length of hospitalization (in days)	_____
Hospitalization 4: date of admission (yyyy-mm-dd)?	_____
Hospitalization 4: date of discharge (yyyy-mm-dd)?	_____
Hospitalization 4: length of hospitalization (in days)	_____
Hospitalization 5: date of admission (yyyy-mm-dd)?	_____
Hospitalization 5: date of discharge (yyyy-mm-dd)?	_____
Hospitalization 5: length of hospitalization (in days)	_____
Diagnosis	
What is the child's primary diagnosis?	_____
What are the child's secondary diagnoses?	_____

Medication	
Does the child take any medication?	◯ Yes ◯ No
Number of medications:	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 ◯ 11 ◯ 12 ◯ 13 ◯ 14 ◯ 15 ◯ 16 ◯ 17 ◯ 18 ◯ 19 ◯ 20
Medication 1: Name of Medication	_____
Reason for medication:	_____
Medication 2: Name of Medication	_____
Reason for medication:	_____
Medication 3: Name of Medication	_____
Reason for medication:	_____
Medication 4: Name of Medication	_____
Reason for medication:	_____
Medication 5: Name of Medication	_____
Reason for medication:	_____
Medication 6: Name of Medication	_____

Reason for medication:

Medication 7: Name of Medication

Reason for medication:

Medication 8: Name of Medication

Reason for medication:

Medication 9: Name of Medication

Reason for medication:

Medication 10: Name of Medication

Reason for medication:

Medication 11: Name of Medication

Reason for medication:

Medication 12: Name of Medication

Reason for medication:

Medication 13: Name of Medication

Reason for medication:

Medication 14: Name of Medication

Reason for medication:

Medication 15: Name of Medication

Reason for medication:	_____
Medication 16: Name of Medication	_____
Reason for medication:	_____
Medication 17: Name of Medication	_____
Reason for medication:	_____
Medication 18: Name of Medication	_____
Reason for medication:	_____
Medication 19: Name of Medication	_____
Reason for medication:	_____
Medication 20: Name of Medication	_____
Reason for medication:	_____

Diet

Which best describes the child's diet?	◯ Oral ◯ G tube ◯ Oral and G tube
Please describe the details of their [child_diet] diet:	_____

Medical/Technology Devices

Does the child use any medical or technology devices?	◯ Yes ◯ No

Number of medical devices:	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10

Please select all the medical/technology devices the child is currently using:

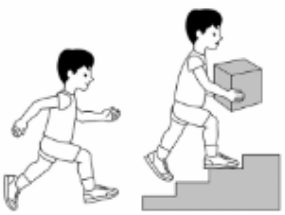
Feeding	☐ G Tube ☐ GJ Tube ☐ NG Tube
Respiratory	☐ Nebulizer ☐ Oxygen ☐ CPap ☐ BiPap ☐ Tracheostomy ☐ Ventilation ☐ Suction
Mobility	☐ Wheelchair ☐ Special Stroller ☐ Special Seating ☐ Walker/Stander ☐ Prosthetics ☐ Ankle and food orthotics
Other	☐ Hearing Aid ☐ Glasses ☐ Feeding pump ☐ Wheelchair van ☐ Mechanical lift ☐ Oxygen saturation monitors ☐ Other
If other, please specify:	_____

Communication

Is the child older than 12 months?	◯ Yes ◯ No
How would you describe their communication skills?	◯ Verbal ◯ Non-verbal

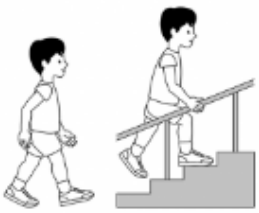
Gross Motor Functioning	
Does the child have difficulties with gross motor functioning?	◯ Yes ◯ No
Is the child older than 2 years of age?	◯ Yes ◯ No
Using the Gross Motor Function Classification System (GMFCS), how would you describe the child's current level of motor functioning?	◯ Level I ◯ Level II ◯ Level III ◯ Level IV ◯ Level V ◯ N/A

Gross Motor Function Classification System (GMFS):



GMFCS Level I

Children walk at home, school, outdoors and in the community. They can climb stairs without the use of a railing. Children perform gross motor skills such as running and jumping, but speed, balance and coordination are limited.



GMFCS Level II

Children walk in most settings and climb stairs holding onto a railing. They may experience difficulty walking long distances and balancing on uneven terrain, inclines, in crowded areas or confined spaces.
Children may walk with physical assistance, a handheld mobility device or used wheeled mobility over long distances. Children have only minimal ability to perform gross motor skills such as running and jumping.

GMFCS Level III

Children walk using a hand-held mobility device in most indoor settings. They may climb stairs holding onto a railing with supervision or assistance. Children use wheeled mobility when traveling long distances and may self-propel for shorter distances.

GMFCS Level IV

Children use methods of mobility that require physical assistance or powered mobility in most settings. They may walk for short distances at home with physical assistance or use powered mobility or a body support walker when positioned. At school, outdoors and in the community children are transported in a manual wheelchair or use powered mobility.

GMFCS Level V

Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control leg and arm movements.

Hospital Visits

Over the past year..

How many hospital visits has the child had?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 ◯ 11 ◯ 12 ◯ 13 ◯ 14 ◯ 15 ◯ 16 ◯ 17 ◯ 18 ◯ 19 ◯ 20 ◯ 21 ◯ 22 ◯ 23 ◯ 24 ◯ 25 ◯ 26 ◯ 27 ◯ 28 ◯ 29 ◯ 30 ◯ 31 ◯ 32 ◯ 33 ◯ 34 ◯ 35 ◯ 36 ◯ 37 ◯ 38 ◯ 39 ◯ 40 ◯ 41 ◯ 42 ◯ 43 ◯ 44 ◯ 45 ◯ 46 ◯ 47 ◯ 48 ◯ 49 ◯ 50 ◯ 50+
If there were over 50 hospital visits, please specify the number:	_____
How many of these were clinic visits:	_____

How many of these were diagnostic visits?	_____
How many of these were emergency visits:	_____
How many of these were day surgery visits:	_____

Misc Comments

_____

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1 – line 3
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts)	Page 2 – lines 28-47
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 5 – lines 3-54 Page 6 – lines 3-52
	2b	Specific objectives or hypotheses	Page 6 - lines 49-52
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 7 – lines 5-54
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Page 8 – lines 15-52 Page 9 – lines 3-36
	4b	Settings and locations where the data were collected	Page 8 – lines 3-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 9 – lines 40-54 Page 10 – lines 3-47
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 11 – lines 15-55

			Page 12 – lines 3-56 Page 13 – lines 3-54 Page 14 – 3-6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Page 14 – lines 10-29
	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	Page 15 – lines 3-22
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 15 – lines 10-22
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	Page 15 – lines 10-22
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 15 – lines 10-22
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods			
	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 16 – lines 26-54 Page 17 – lines 3-20
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 17 – lines 22-29
Results			
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	N/A

recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	N/A
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	N/A
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 19 – lines 24-54 Page 20 – lines 3-8
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 18 – lines 33-40
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	N/A
Other information			
Registration	23	Registration number and name of trial registry	Page 22 – line 9
Protocol	24	Where the full trial protocol can be accessed, if available	Page 21 – lines 8-10
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 22 – lines 11-15

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Correction: *Complex care for kids Ontario: protocol for a mixed-methods randomised controlled trial of a population-level care coordination initiative for children with medical complexity*

Orkin J, Chan CY, Fayed N, *et al*. Complex care for kids Ontario: protocol for a mixed-methods randomised controlled trial of a population-level care coordination initiative for children with medical complexity. *BMJ Open* 2019;9:e028121. doi: 10.1136/bmjopen-2018-028121.

This article was previously published with errors in data.

- In the 'Primary outcome' section, there's a typo: it says "as they hadve content relation to:"; it should instead read "as they have content relation to:"
- In the 'Sample size' section,
  - The last sentence in the first paragraph is missing the second part. It should read: 'projected smallest clinically important difference of 0.5 of the within-patient SD, which is recommended by the developer as a moderate effect size.'
  - The second paragraph should start with 'The required sample size is considered feasible as it is estimated that a pool of about 250 patients are readily identifiable for recruitment at CCKO sites.'

BMJ Open 2019;**9**:e028121corr1. doi:10.1136/bmjopen-2018-028121corr1