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STUDY PROTOCOL

Title of Study:
CHILD-BRIGHT READYorNot™ Brain-Based Disabilities Trial

Nominated Principal Investigator:
Dr. Jan Willem Gorter – McMaster University, McMaster Children's Hospital, Hamilton

Co-Principal Investigator:
Dr. Ariane Marelli – McGill University & McGill University Health Centre, Montreal

CORE Investigators:
Dr. Khush Amaria – CBT Associates of Toronto: Cognitive Behavioural Therapy Services
Dr. Adrienne Kovacs – Oregon Health & Science University, Portland (Co-PI CHILD-BRIGHT)
Dr. Ronen Rozenblum – Brigham and Women's Hospital and Harvard Medical School, Boston

Co-Investigators (alphabetic order):
Dr. John Andersen – University of Alberta, Glenrose Rehabilitation Hospital, Edmonton
Dr. Rima Azar - Mount Allison University, New Brunswick
Dr. Shelley Doucet – University of New Brunswick, Saint John
Dr. Anne Fournier – CHU Mère-Enfant, Sainte Justine Hospital, Montreal
Dr. Andrew Mackie – University of Alberta, Stollery Children's Hospital, Edmonton
Dr. Maryam Oskoui – McGill University & Montreal Children's Hospital, McGill University Health Centre, Montreal
Dr. Janet Rennick – McGill University & Montreal Children's Hospital, McGill University Health Centre, Montreal
Dr. Michael Shevell – McGill University & Montreal Children's Hospital, McGill University Health Centre, Montreal
Dr. Lehana Thabane – McMaster University, Hamilton
Dr. Lonnie Zwaigenbaum – University of Alberta, Glenrose Rehabilitation Hospital, Edmonton

Current Active Members of Patient-Family Advisory Committee (PFAC):

Donna Thomson, Parent/Family Advisor
Roger Stoddard, Parent/Family Advisor
JoAnne Mosel, Parent/Family Advisor
Connie Putterman, Parent/Family Advisor
Kinga Pozniak, Parent/Family Advisor
Nathan Tasker, Young Adult/Patient Advisor
Julia Hanes, Young Adult/Patient Advisor
Kyle Chambers, Young Adult/Patient Advisor
Jessica Havens, Young Adult/Patient Advisor
Claire Dawe-McCord, Young Adult/Patient Advisor
Dana Arafeh, Young Adult/Patient Advisor
Musa Arafeh, Young Adult/Patient Advisor
Michael Frost, Young Adult/Patient Advisor

Project Staff:
MyREADY Design & Development Project Manager: Alicia Via-Dufresne Ley, McGill University
Qualitative/Stakeholder Engagement Research Coordinator: Sonya Strohm, McMaster University

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Randomized Controlled Trial (RCT) Research Coordinator: Barb Galuppi, McMaster University; Nadilein Mahlberg, McMaster University.

Current Active Trainees:
Linda Nguyen, PhD Candidate, Rehabilitation Science, McMaster University (Supervisor: Dr. Gorter)

Sponsor: The READYorNot™ Brain-Based Disabilities Trial is funded by the CHILD-BRIGHT Network, under the Canadian Institutes of Health Research (CIHR) Strategy for Patient-Oriented Research (SPOR) initiative, and with partner support from McMaster University Faculty of Health Sciences, Hamilton Health Sciences, McMaster Children's Hospital Foundation, Montreal Children's Hospital Foundation, and New Brunswick Health Research Foundation.

PLAIN LANGUAGE DESCRIPTION:

Youth with brain-based disabilities (BBD) see a variety of pediatric doctors and health care providers during their childhood years. Pediatric doctors and care teams are trained to manage the health of children, including physical, behavioural, and mental health issues. Typically, by their eighteenth birthday, youth in Canada will need to leave their pediatric doctors and health care providers and go to adult providers instead. Generally, there are more expectations for youth to take charge of their own care when they see an adult care provider. Yet, if youth are not ready for this responsibility, or it is not clear where youth should go for care as adults, their health can sometimes be affected (for example when appointments or medications are missed). We also know that this change can be especially difficult and stressful for youth with BBD and for their families.

In the first part of this project, researchers, healthcare professionals, technology designers, youth and families have worked together, to co-create an e-health application called **MyREADY Transition™ BBD App** for Brain-Based Disability. In this next part of the project, we will ask pediatric health care providers to share it with their patients who are between 15 and 17 years of age, and who have one of the following conditions: autism spectrum disorder, cerebral palsy, epilepsy, spina bifida, or fetal alcohol spectrum disorder. The MyREADY Transition™ BBD App is designed to help youth with health care transition planning, in preparation for their transfer out of the child health system and into the adult health system. We want to see how youth will use the MyREADY Transition™ BBD App as they are getting ready to go from pediatric to adult health care services. And, we want to see if it will help them to be more prepared and knowledgeable to manage their own health. We hope to see youth taking steps to be better managers of their health. For example, this would include knowing about their condition or knowing when to ask for help from parents/caregivers and health care providers.

BACKGROUND AND RATIONALE:

Large care gaps during pediatric to adult transition years have been shown in half of Canadian patients with increases in emergency room visits and resulting costs.[1] The goal of transition is to maximize "lifelong functioning and potential through the provision of high-quality, developmentally-appropriate health care services and coordination that continue uninterrupted as the individual moves from adolescence to adulthood".[2] Youth with BBD, as well as their parents/caregivers, often feel ill-prepared

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for the transfer from pediatric to adult health care services, typically at a system-defined age of 18 years in Canadian jurisdictions.

Pediatric health care providers are encouraged to talk to children and youth about taking on more responsibility for their own health as they mature. Yet many providers report that they do not have the time, resources or helpful tools, nor do they have engaging ways to talk about making a smooth move to the adult system. This study proposes to overcome these barriers by applying interventions based on individual functional needs to promote transition readiness (self-management and self-advocacy skills) through an innovative e-health intervention. The overall objective of this project is to improve readiness for transition of care in youth with BBD who are between 15 and 17 years of age, are beginning to manage their own or have the potential for self-management.

We acknowledge the input from youth, parent/caregiver and health care stakeholders, who emphasized that a youth's transition to adulthood involves many systems beyond health care. In this study, however, we focus primarily on health care transition. Transition from pediatric to adult health care systems is a critical turning point for a growing population of youth with lifelong conditions. When the transition to adult health care is unplanned or poorly supported, patients' and parents'/caregivers' adverse experiences of care are higher, as is risk for poor health outcomes, costly hospitalizations, inequity of health care services, and "other" costs such as missed school or work [3].

Patient-centred care and patient engagement have become central components of the modern clinical encounter. Enhancing patient engagement via information technology is shown to directly impact patient behaviour that promotes positive health outcomes, patient satisfaction, care delivery efficiency, reduces costs and improves quality of care and patient safety.[4-5]

This project proposes to provide an e-health intervention to youth patients to improve education, empowerment and navigation of their health and the health care system, with the goal of improving transition readiness. Specifically, the intervention includes important elements such as personal identity, knowledge and understanding of living with a health condition, personal control, decision-making, and knowing when and how to seek support from others.[6] Our study responds to the needs of families, and the need for systematically well-designed research approaches to co-create evidence-based e-health transition interventions through ongoing youth, parent/caregiver and health care stakeholder engagement. As well, we have formed partnerships with e-health industry, so that our intervention can be affordable, easily implemented in health care systems, and applicable to the majority of all youth with BBD. We have engaged a core group of youth, parent/caregiver and health care stakeholders, including a Patient and Family Advisory Council (PFAC), composed of representative youth (adolescents and young adults) and parents/caregivers. We have collaborated with the PFAC during the first part of the project to inform the design and tailor the MyREADY Transition™ BBD App. We plan to continue to leverage our stakeholder partnerships throughout the RCT and Knowledge Transition (KT) parts of the project to promote uptake and benefit.

SYNOPSIS:

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Our overall project consists of several parts. In Part 1 of the project, we have developed the MyREADY Transition™ BBD App intervention designed to improve transition readiness of youth prior to transfer of care. This current protocol is focused on Part 2, a mixed methods design featuring an RCT to test whether the MyREADY Transition™ BBD App intervention improves readiness for transition. Our RCT will use a pragmatic approach designed to test whether the intervention works under the usual conditions. The PRECIS-2 website[7] (PRECIS – PRagmatic Explanatory Continuum Indicator Summary) is a tool for designing clinical trials on the pragmatic/explanatory continuum. The PRECIS-2 tool has nine domains: eligibility criteria, recruitment, setting, organization, flexibility-delivery, flexibility-adherence, follow-up, primary outcome, and primary analysis. All domains are scored from 1 (very explanatory) to 5 (very pragmatic). We will use the PRECIS-2 planning tool to facilitate discussion and consensus and to ultimately match design decisions with how the trial results are intended to be used. Integrated knowledge translation throughout the years of the project will draw on patient, parent/caregiver and health care stakeholder partnerships.

Outcome metrics are based on the Institute for Health care Improvement (IHI)'s Triple Aim framework[8] (better health, better experience, at lower cost) with analysis stratified by region to account for local contextual factors. This comprehensive framework is poised for the creation of effective and efficient systems to optimize child and family outcomes.

CHILD-BRIGHT intentionally addresses a wide range of chronic diseases that share common functional limitations and health care needs. This non-categorical approach (i.e. including more than one medical condition or disability) enables interventions that can impact on larger populations of children above and beyond any diagnostic specific needs. The focus on BBD is strategically more integrative than diagnosis-specific research, thus promoting broader applicability.

STUDY AIMS AND HYPOTHESIS:

The MyREADY Transition™ BBD App intervention includes elements of transition planning to empower youth with BBD as they prepare for transfer into the adult health care system.

The primary aim of the study is to determine whether the MyREADY Transition™ BBD App intervention will result in improved self-management and self-advocacy skills (major components of transition readiness), compared to usual care for youth with BBD between 15 and 17 years of age. The MyREADY Transition™ BBD App intervention has the potential to improve perception of quality of care and youth and parent/caregiver experiences during the transition process; and a potential also for cost efficiencies across pediatric and adult provincial health care systems. Analysis for the primary aim of the study will be led by Dr. Gorter at McMaster University.

Hypothesis: Youth who use the MyREADY Transition™ BBD App intervention will have higher self-management change scores (a major component of transition readiness), over a 6-month period compared with youth receiving usual care. Self-management change scores will be measured using the Transition Readiness Assessment Questionnaire (TRAQ).[9]

Secondary aims of the study include exploring the contextual experiences of youth using the MyREADY Transition™ BBD App (e.g., their satisfaction with the App and its content, *how* it is being used and

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integrated during transition, and perceived value); as well as the interactive processes of youth, their parents/caregivers and health care providers around use of the intervention (e.g., that support/hinder use). Analysis for the secondary aim of the study will be led by Dr. Marelli at McGill University.

In addition, both Dr. Gorter and Dr. Marelli will work with the Health Economics team within the CHILD-BRIGHT network who will support the data collection and analysis for the health economics outcomes, with a few key objectives across all projects:

- To compare the patterns of health service use for the intervention compared to current standard of care.
- To compare the incremental cost of the intervention compared to current standard of care per unit of effectiveness (using standardized measures across the network including the Health Utilities Index®[10], PedsQL™ [11], Resource Use Questionnaire[12]).

RESEARCH PLAN AND METHODOLOGY:

METHODOLOGY

We will take a mixed methods approach that utilizes both quantitative and qualitative research methods and techniques. This methodology is commonly used in patient-centred care research as these methods combined can serve to answer complex research questions and allow for stronger and richer evidence than could be accomplished by a single method alone. Contextual qualitative data is important where the complexity of different sites throughout Canada might create challenges for evaluating the effectiveness of the intervention and will be essential for eventually understanding and explaining any potential variations that emerge from the RCT.

DESIGN

We will use an embedded experimental model design[13], which will involve embedding a qualitative component within the randomized controlled trial (RCT). We will seek to collect qualitative data from a subset of participants in the intervention group, at the end of exposure or after 6 months (whichever comes first) and after the 6 Month quantitative data collection point. The qualitative data will be supplementary to help explain or interpret the quantitative results of the RCT (primary aim) as well as to understand user experience (secondary aim). The two data types will complement each other to provide a comprehensive understanding of the effectiveness of the app, both from the quantitative questionnaires and from the perspectives of youth, parents/caregivers and health care providers through qualitative interviews/open-ended questions. The qualitative sampling, data collection and analysis will be guided by the principles of interpretive description – an applied qualitative methodology that provides a structure for answering questions that arise in clinical practice.[14]

Usability Testing (completed during the App Development phase)

Usability testing aims to ensure that interactive systems are adapted to the users and their tasks and is considered a fundamental component of the user-centred design process.[15] Throughout the development of the MyREADY Transition™ BBD App, iterative cycles of participatory design sessions were used to elicit patient, parent/caregiver and health care provider feedback on elements of the tools

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(i.e. to learn what was working, what wasn't, and where gaps existed). This rigorous process was instrumental in refining the App intervention prior to the start of the RCT, thus *enhancing the likelihood of success of the intervention itself.*

Internal Pilot Phase

The British Medical Research Council explicitly recommends the use of feasibility studies prior to Phase III clinical trials.[16] In order to guide the planning and to *enhance the likelihood of success of our full scale RCT*, the first three months of recruitment will comprise an internal pilot phase. In this internal pilot phase, we will aim to recruit the first 12 patients in each of the four regions, up to 48 participants across all regions.

During the internal pilot phase, we will observe the study procedures and consider key implementation aspects such as recruitment (including refusal rates and screening process), multi-site coordination/collaboration (including communication, documentation and provision of support) and intervention uptake and adherence (including technical support needs among app users). The results will be used to refine and enhance the research design. The RCT will proceed with procedural modifications based on the findings of the internal pilot study and final study analyses will incorporate all data. As long as the alpha-level is controlled, internal pilot designs have, at most, a small adverse effect on the significance level and may greatly improve the power.[17]

After data collection has concluded for the main RCT, we will conduct Optional Research to enhance our pilot and feasibility exploration and reporting. Participants will include health care providers and research assistant staff who were involved in recruiting youth participants for the RCT.

Health care providers who were involved in study recruitment will be invited to complete an electronic survey. The purpose is to help us learn about their experience recruiting youth during the pandemic and about their perspective on integrating the eHealth intervention into practice. Each health care provider participant will have the opportunity to be entered into a draw to win a $250 meal allowance for their next staff meeting. Rather than a guaranteed gift card incentive of low monetary value (e.g., $10 for each of 25 respondents), we have selected a lottery model which will give survey respondents a chance at a more appealing incentive. We feel this incentive is appropriate and reasonable in scope in order to encourage participation without undue inducement.

Research Assistant (RA) staff who were involved in study recruitment will be invited to participate in a focus group interview by Zoom and to complete a short demographic survey. The purpose of the focus group is to help us learn more about the processes, resources, and management of the study. As a token of appreciation for their time to participate, all research assistant participants will be given a $25 gift card. We expect to include 10-12 participants.

SAMPLE

Our primary sample will be comprised of 264 youth with BBD, between 15 and 17 years of age, who are recruited through a participating clinic in one of the four study regions (Alberta, Ontario, Quebec, and Maritimes) and who are at least 6 months pre-transfer to the adult health care system. A parent/caregiver of the youth will also be recruited to the study. The study aims to have an equal

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number of participants in each of two groups: intervention group (132) and control group (usual care) (132). Since participants will be recruited from only four regions, we will model the effect of region as a fixed effect rather than a random effect.[18] This will allow region-specific intervention effects to be modelled (i.e. region by intervention interaction effects). If no region by intervention interactions are found, the interaction terms will be dropped from the model and we will estimate an overall intervention effect. Since the region by intervention interaction is unknown, we take a conservative approach with a sample size calculation that will enable detection of an intervention effect within each site. This will allow for a properly powered analysis of the site by treatment interaction. The primary outcome measure (Transition Readiness Assessment Questionnaire, TRAQ)[9] has been validated on a sample of youth with congenital heart disease and in the absence of literature specific to BBD, we will base our sample size calculations on these findings. We anticipate a mean TRAQ self-management baseline score of 3.01 (SD 1.02) (out of a possible 5.0) as reported for youth (with congenital heart disease) without a transition intervention and an anticipated mean score of 4.0 at 6 months post-intervention resulting in a change score of 1 (i.e., 1 SD), with α=0.05 and 90% power.[19] Therefore, in each region, we will require 23 youth in each of the 2 arms (total of 46) x 4 regions = 184. Estimating 30% attrition, we will enroll 264 participants.

Inclusion Criteria

- Youth with chronological age between 15 and 17 years of age (i.e. before 18th birthday), in one of the four study regions, followed in pediatric care and for whom a discharge from pediatric care is planned but not for at least 6 months.
- A diagnosis of one of the following neurological BBD: autism spectrum disorder, cerebral palsy, epilepsy, spina bifida, or fetal alcohol spectrum disorder.
- Cognitive ability to provide informed consent and the ability to read and understand English or French
- Access to internet and a smartphone, iPad/tablet or desktop computer.
- TRANSITION-Q[20] score >40 (as a screen to define a minimum threshold for transition readiness based on our earlier work).

  In a validation sample of Ontario youth aged 12 -25 years old with chronic health conditions including our target population, the average TRANSITION-Q score for 13 year olds was 40; for 15 year olds was 53; and for 17 year olds was 59.[21] The decision to set the threshold at > 40 aligns with clinical judgement and is conservative given that the youngest age group in the validation sample demonstrated this minimum level of readiness. At the point of screening, we will evaluate several components of cognitive function as well as youth capacity to share the management of their own health. The TRANSITION-Q screen will inherently not include youth who have severe intellectual disability, and/or those who rely significantly on parents/caregivers in most areas of daily functioning, self-care and/or communication.

Exclusion Criteria

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- Youth is in "acute crisis" with unstable physical or mental health that would interfere with the ability to participate in the study.
- Sensory impairments, such as uncorrected vision or hearing loss, which interfere with use of the App.
- Enrolled in a potentially confounding trial (e.g., a different transition intervention study).

Qualitative Subsample

From among the sample of 132 youth participants in the intervention group, we will purposefully sample a subset of up to 50 youth participants to describe and understand primary outcomes, as well as to capture process and user experience (secondary aim). Interviews will be conducted after the 6-month quantitative data collection point. To further describe and understand primary outcomes after 6 months, we will also seek to interview 10 parents/caregivers and 10 health care providers.

METHODS

The current study timeline is described in Appendix A.

Recruitment

Our recruitment approach was modified (prior to recruitment start) to add strategies for the study to proceed even during periods of social distancing due to the COVID-19 global pandemic.

Step 1 – Initial Contact. Someone in the patient's circle of care at the clinic site will approach potential participants who meet the minimum eligibility requirements in order to ascertain interest and obtain permission for the RA to contact them. They may obtain this permission in person (after COVID-19 restrictions are lifted), by telephone or by letter (e.g. using the Invitation Letter and Initial Interest form). Recruitment materials will also be shared on websites and social media so there may be some participants who self-refer to the RA.

Step 2 – RA Contact. Prior to being in contact with study participants, each study RA will complete e-learning module training provided by the research team. When a potential participant learns about the study online or through social media, they will self-refer by contacting the RA directly. Otherwise, after someone in the circle of care has made first contact and obtained permission for the RA to contact, the RA will contact eligible participants by phone to complete the Screening Checklist and confirm eligibility. If there is a clinic appointment scheduled, contact will be made in advance so that they have an opportunity to learn about the study and ask questions. The consent and assent form will be sent to the participants in advance of the scheduled visit. Due to the COVID-19 pandemic, we have added the option for the participant to choose to have these sent to them by email or by mail.

Step 3 – Consent/Assent. The visit will be arranged with the participants in advance and will be done either by phone or in person. Due to the COVID-19 pandemic, we have added a telephone verbal consent procedure. While on the phone with the participant, the RA asks the participants to watch the Assent Video by clicking on the link sent to them. Watching the video together by Zoom meeting link may be offered if the participants prefer. The RA will stay on the phone while the participants watch the video and then will proceed with the Verbal Consent/Assent Telephone scripts and logs. Youth

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participants will provide assent and a parent/caregiver will also provide consent both for their child and for themselves. Ideally the participants will then complete the baseline study visit at the same appointment time. If the participant is unable to complete the baseline visit, the RA will arrange another study appointment that is convenient for the youth and parent/caregiver.

Consent/Assent for Optional Research. Youth participants: The RA will explain to participants that the researchers doing this study are interested in doing additional optional research. Participants will be given an additional optional study consent form to read and sign if they wish to give permission to take part in an optional research project. Participants may decide not to participate in any optional research and still participate in this main study. Up to 50 youth in the intervention group will be contacted about their interest to participate in optional qualitative interviews to describe and understand primary study outcomes, as well as to capture process and user experience related to the secondary aim.) All interviews will take place following the 6 month quantitative data collection point. . We will recruit a heterogeneous sample of youth to explore the experiences of a diverse range of users. We will purposefully sample youth of different genders, different diagnoses, from different geographic regions, and who demonstrate a range of transition readiness as indicated by initial TRANSITION-Q scores. Once the RCT has concluded, and to help with explaining the quantitative results, purposeful sampling may also involve seeking unique cases with respect to study outcomes (e.g., individuals who complete high percentage of app content but who score low on measures of transition readiness, individuals who complete low percentage of app content but who score high on measures of transition readiness, etc.).

Parent/caregiver participants: We will also contact a group of 10 parents/caregivers about their interest to participate in qualitative interviews. We will invite parents/caregivers who RAs have recommended are good candidates for an interview. Prior to collecting any qualitative data, verbal and written informed consent will be obtained.

Health care provider participants: We will invite 25-30 health care providers who were involved in recruiting study participants to complete a short electronic survey to help us collective qualitative information about their experience recruiting youth during the pandemic and about their perspective on integrating the intervention into practice. The survey will begin with an information and consent statement. They will also be asked if they consent to being contacted for a follow-up interview if necessary.

RA participants: We will invite 10-12 Research Assistant (RA) staff who were involved in study recruitment to participate in a focus group interview by Zoom. The purpose is to help us learn more about the processes, resources, and management of the study. In order to ensure accuracy, and with the participants' agreement, the focus group interview will be recorded on Zoom and the conversation will be transcribed. Prior to collecting any qualitative data, verbal and written informed consent will be obtained.

Participants have the right to withdraw their data from the study. There are no limitations on the withdrawal of quantitative data during the data collection phase. However, due to the iterative nature of qualitative research, participants will have up to 2 weeks following the date of an interview or focus group interview to request withdrawal of their data. In contrast to quantitative data analysis, qualitative

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analysis begins as soon as data are collected in a study. This iterative approach is imperative, as early and continuous coding drives ongoing data collection (e.g., new questions that arise). The two-week period reflects the average time it would take for a transcriptionist to complete transcription of an audio file. Once a participant's interview becomes part of the analysis, it begins to shape interpretation and meaning of the data. If someone were to request withdrawal of their data after it has been coded, it would be hard to distinguish if something from their interview might have already contributed to our collective understanding of the data. Once the study analysis has been completed, we cannot withdraw data in order to protect the integrity of the research.

Randomization

Randomization will be stratified by region with a 1:1 allocation ratio for patients: intervention group (receiving MyREADY Transition™ BBD App intervention) or control group (continuing with usual care). The unit of randomization is the patient. We will use variable block randomization with block sizes of 2, 4, 6 and 8. Allocation will be done via REDCap (Research Electronic Data Capture)[22] using a centralized allocation system generated by the Biostatistics Unit at St. Joseph's Hospital in Hamilton, Ontario.

Participants who meet the eligibility requirements at the point of screening, and who give consent to participate will be randomized to a group. Once a patient has been randomized to the intervention group, the Research IT team at McGill University will receive the assigned study identification number to associate with the user activation code in the MyREADY Transition™ BBD App. The RA at the recruitment site will use the study identification number and user activation code to facilitate the download and user orientation to the App. The RCT Research Coordinator at McMaster University and the Research IT team at McGill University will support the use of the App and troubleshoot issues as they arise. This will be done using a designated email to capture and respond to queries and will include an automated response, indicating receipt and response time.

Participants allocated to the usual care group will not know the details of the electronic intervention being offered to the intervention group. Due to the nature of the intervention, participants cannot be blinded to group allocation, however outcome assessment and data analysis will be blinded. Our RCT protocol is registered with ClinicalTrials.gov (NCT03852550).

In order to track participants according to the CONSORT guidelines[23-24], a de-identified recruitment log of potential candidates at all participating sites will be kept, recording inclusion/exclusion criteria and reasons for eligible youth patients not being recruited or randomized.

Intervention and Control Conditions

Participants randomized into the control group will receive their clinic's standard of care. Any support the youth (and parents/caregivers) receive as part of any ongoing transition programs in usual care will be documented by youth, parents/caregivers and health care providers. Documentation will include an inventory checklist with a section to add any specific information or individualized approach relevant to the transition process. We will also ask participants and their parents/caregivers what they perceive as supports and if they were received.

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Participants randomized into the intervention group will be provided the link to download the MyREADY Transition™ BBD App. The RA will be trained to facilitate the App download and registration. The RA will demonstrate the App, ensuring that the participant understands how to access all the features. The MyREADY Transition™ BBD App intervention is fully described in Appendix B. The App will be translated into French, and the translation will be done by professional translators of the firm Essentiel Plus.

During the course of study participation, participants will receive regular reminder messages and/or monthly phone calls to promote the use of the MyREADY Transition™ BBD App and to assist with troubleshooting any problems accessing the intervention. The App uses local storage within the device and synchronizes each participant's progress information with the Content Management System (CMS) which is hosted by Amazon and managed jointly by a software company (RootQuotient) and the Research IT team at McGill University. The Research IT team at McGill University will send regular reports to the RAs and/or the RCT Coordinator to monitor when key time points are achieved (e.g. when a participant has completed at least 25%, 50%, 75% and 100% of the App content, or when it has been more than 2 weeks since a participant has accessed the App).

In terms of exposure time, there is planned flexibility to allow participants to proceed through the MyREADY Transition™ BBD App intervention at their own pace. The App has 19 individual sections organized within 5 chapters that are provided within a set order. A timer has been built into the App to ensure that participants will have at least one day between sections. This will allow for time to process and reflect on the take-away message in each section and/or engage in one of the suggested between-session practice activities. The timer will help to moderate pace and align with how young people learn and digest information. We estimate that there are approximately 5-7 hours of content within the 5 chapters of the App, depending on individual pace. For the RCT, the recommended exposure to the intervention is somewhere between 1 section per day (19 days) and 1 section per week (19 weeks). As an example, if a participant completed one of the five chapters per week, they would complete the App in 5 weeks. Games and fun activities are incorporated to encourage youth to visit the App between sections. The tools and resources within the App remain available for users to access throughout the intervention exposure time. The researchers aim to supply the MyREADY Transition™ BBD App to participants in both the intervention and control group for a limited time after their participation in the study. However, if the App intervention turns out not to be effective, or if significant issues are found, study participants may not be able to access the App. We will continually review and update our securities and controls as technology changes to ensure ongoing personal information security. In case of substantial impactful changes of the main technical elements (components and services) including but not limited to iOS, Android, Web or the CMS; the team may discontinue the support of the application and therefore withdraw the App. Any changes we may make to our privacy statement in the future will be posted on the platform page and, where appropriate, notifications will be sent to users by e-mail.

We know that the experiences of youth, parents/caregivers and service providers are interconnected and interdependent.[25] We expect that in both groups, the parent(s)/caregiver(s) and health care

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provider(s) naturally may provide support to participants. Youth, parent(s)/caregiver(s) and health care provider(s) will be provided reference handouts. These guidelines will help to standardize the nature and extent of the App support provided to participants in the intervention group.

Data Collection

Data source triangulation, or the use of multiple data sources (e.g., youth, parents/caregivers, health care providers) is a strategy used to gain understanding, ensure completeness, and confirm the credibility of findings [26]. Triangulation also enables the researcher to ensure construct validity by providing multiple measures of the same phenomenon. In this study, both quantitative and qualitative data types will be collected, including: 1) in-depth semi-structured interviews; and 2) quantitative implementation and outcome data.

All data collection forms will be available in both English and French.

Baseline Visit

In case the baseline visit is not done in-person (e.g. due to COVID-19 pandemic), we have added the option to conduct the baseline visit via Zoom meeting. In order to better establish rapport with participants, the RA may conduct the Zoom meeting with their own camera on. Participants will have the option to turn on their camera or keep it off. Zoom meetings will not be recorded.

Following consent, all participants will be asked to complete a questionnaire package. All participants will complete the same baseline measures regardless of group assignment. All youth will be provided with sufficient time and support to complete the questionnaire package. Parents/caregivers will also complete a separate questionnaire package. Participants will complete the questionnaire package electronically or in printed form.

Participants randomized into the intervention group will also have an introduction to the MyREADY Transition™ BBD App intervention at the baseline visit. They will be provided with brief verbal and written instructions about how to use and engage with the intervention. The RA will navigate through the MyREADY Transition™ BBD App intervention with the participant to give a short demonstration. The baseline visit for participants in the intervention group will take an estimated one and a half hours to complete in order to ensure that the participants feel able to use the MyREADY Transition™ BBD App intervention. All RAs will receive intervention-facilitation training and treatment fidelity will be monitored.

Follow-Up Visits

Participants will repeat the questionnaire package at 6-months following baseline. The RA will arrange these visits at a mutually convenient time during follow-up appointments in clinic if possible, or otherwise outside of clinic time. If an in-person visit is not possible, the questionnaire package can be completed online, by mail or by phone interview according to the participant's preference.

Qualitative Data Collection

In addition to the quantitative follow-up at 6-months, qualitative data will be collected for a subset of participants using interviews. Up to 50 youth in the intervention group will be interviewed after the 6-

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month quantitative data collection point to describe and understand primary study outcomes, as well as to capture process and user experience related to the secondary aims. We will purposefully select some participants who have completed only a low percentage of App content to learn about the experiences of those participants.

One-on-one, semi-structured interviews will be carried out for the collection of in-depth description. These sessions lasting approximately 30-60 minutes will be conducted with a subset of youth participants, and separately with parents/caregivers and health care providers. All interviews will take place following the 6-month quantitative data collection point, will be conducted over virtual teleconference or phone, and will be audio-recorded. Qualitative interviews will be conducted by project staff supervised by Dr. Marelli at McGill University and/or by project staff supervised by Dr. Gorter at McMaster University.

Data Safety Monitoring

Due to the nature of the intervention as short term and low-risk, a formal Data Safety Monitoring Board is not necessary. In accordance with the core principles in the Tri-Council Policy Statement (TCPS 2) guidelines (http://www.pre.ethics.gc.ca), our safety monitoring plan will aim to ensure that (a) foreseeable risks to participants are minimized, and appropriately evaluated alongside potential benefits, (b) participants are clearly informed as to the nature of these foreseeable risks and potential benefits, (c) participant safety is monitored and accurately reported, and (d) any new information that may impact on the welfare of participants, or their decision to remain involved in a trial, be shared appropriately. The plan balances patient safety with study operations and doesn't influence the care given to a patient if an adverse event, such as a mental health issue, occurs during the study.

Data Storage and Transfer

Prior to starting recruitment, McMaster University will put a data transfer agreement in place with each participating centre (listed in Appendix C) to govern the collection, storage, transfer, analysis, ownership, archiving, and destruction of study data.

This project is part of a CHILD-BRIGHT's pan-Canadian research program, studying new diagnostic tests, therapies, service models, and technologies to optimize the physical and mental health of Canadian children born with brain-based disorders as well as the well-being of their caregivers and families. Within CHILD-BRIGHT'S twelve patient-oriented research projects, there are several common 'network-wide' data collection forms with the intention to pool results across projects. Relevant health economics data will be shared with the CHILD-BRIGHT network's health economics team. A statement is included in the study consent forms to ensure that participants have consented to this transfer of anonymized data.

Prior to sharing data, data transfer agreements will be established for the secure transfer of data from McMaster University to the Hospital for Sick Children (Dr. Wendy Ungar, CHILD-BRIGHT Health Economics) and; to the University of Alberta (Dr. Rick Watts, CHILD-BRIGHT Data Coordinating Centre.

CORE Investigators will have access to anonymized data consistent with institutional guidelines.

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Data storage, collection and access/transfer is described below for the various types of data being collected for this study.

Data from surveys or questionnaires (related to primary and secondary aims)

Data Collection: Data can be entered into REDCap[22] by designated users or survey respondents from any computer with an internet connection. Surveys will be: a) completed on paper by a study participant and entered into the REDCap form by the RA at the recruitment site, or b) completed online by a study participant directly into the REDCap form. Since no identifying information is stored in REDCap, the link to electronic survey forms will be sent to the RA and the RA will email it to the participant.

Data Storage: Data will be entered online and stored in REDCap[22]. REDCap is a secure web application for building and managing online surveys and databases (www.project-redcap.org). As in several Canadian pediatric academic centers, REDCap has been set up at McGill University and at McMaster University to support Faculty members' research. REDCap questionnaire data for this project will be hosted by the Department of Pediatrics at McMaster University. De-identified data is stored on a secure, firewall protected server with regular backup in the Faculty of Health Sciences Computer Services Unit with only the https port available to the internet.

Data Access/Transfer: Research staff in the Department of Pediatrics at McMaster University will be designated to the 'Super Administator' role in the REDCAp system. Together with Dr. Gorter and Dr. Marelli, this person will establish user accounts and user rights for the project team. User accounts include electronic signatures comprised of a username and password and an audit trail is generated for all activity within each REDCap project. The Computer Services Unit at McMaster University has access to the database, only for the purposes of IT support including regular server maintenance and software updates. A de-identified and encrypted database file of variables for the secondary health economics aim will be uploaded to MacDrop (https://drop.mcmaster.ca/login), an Enterprise File Storage and Synchronization Solution that is endorsed by McMaster, and that is managed by Computer Services Unit to securely house data onsite. Research staff at the Hospital for Sick Children (Dr. Wendy Ungar, CHILD-BRIGHT Health Economics) will be given access to a shared folder where they can upload and access the database file via MacDrop link. Similarly, a de-identified and encrypted database file of variables from the 'network-wide' forms will be shared via MacDrop link with research staff at the University of Alberta (Dr. Rick Watts, CHILD-BRIGHT Data Coordinating Centre). The license with Insignia Health for the Patient Activation Measure or PAM does have a data-sharing requirement for scoring purposes. The PAM survey scoring form is an Excel-based application that uses macros and requires an Internet connection to calculate PAM Score and Level using non-personally identifiable, individual data captured through participants' use of the PAM.

Data from qualitative interviews

Data Collection: Qualitative interviews will be conducted by project staff supervised by Dr. Marelli at McGill University and/or Dr. Gorter at McMaster University. All interviews will be

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conducted over Zoom or by phone, and will be audio-recorded. Audio recordings will be transcribed as soon as possible after being collected, and recordings will be destroyed following transcription and once the transcripts have been checked for accuracy.

Data Storage: For interview data collected at McMaster University, interview recordings and transcripts will be collected and uploaded to MacDrop (https://drop.mcmaster.ca/login), an Enterprise File Storage and Synchronization Solution that is endorsed by McMaster, and that is managed by Computer Services Unit to securely house data onsite. For interview data collected at McGill University, interview recordings and transcripts will be collected and uploaded to McGill OneDrive for Business, a Microsoft Enterprise File Storage and Synchronization Solution that is provided by Microsoft to McGill. The McGill OneDrive for Business solution is protected by a negotiated a contract between McGill and Microsoft that respects Canadian and Quebec privacy laws and protects the intellectual property of data stored on OneDrive for Business; these commitments are not guaranteed by the consumer class version of OneDrive, or other self-provisioned cloud storage services. McGill OneDrive for Business is managed by McGill IT Resources to securely house data onsite. In addition, McGill data could be entered online and stored in REDCap and administered by the McGill team and CIM (Centre for Intelligent Machines, the inter-departmental inter-faculty research group which was formed in 1985 to facilitate and promote research on intelligent systems). De-identified data will be stored on a secure, firewall protected server with regular backup managed by CIM with only the https port available to the internet. Data can be entered by designated users or survey respondents from any computer with an internet connection.

Data Access/Transfer: For interview data collected at McMaster University, McGill project staff will be given access to a shared folder where they can upload and access de-identified transcripts or qualitative reports via MacDrop link. For interview data collected at McGill University, McMaster project staff will be given access to a secure encrypted file transfer system, endorsed by the Research Institute of the McGill University Health Centre. Recordings will not be shared between the two sites.

Data from the App (primary and secondary aims)

Data Collection: Intervention User Metrics data will be collected and stored within the MyREADY Transition™ BBD App hosted and maintained by RootQuotient.

Data Storage: In order for the application to sync with the content management system, and in order to provide technical support as needed, the MyREADY Transition™ BBD App retrieves the device brand and model, its Operating System (Apple vs Android), and the name of the device (e.g. "Bert's iPhone"). If the user uses the support request feature it will send an email to the support email address. The email will include the information mentioned above as well as the version number of the application (e.g. RCT2019BBD) that the user has installed. The application also records the level of completion of the sections as the user goes along, and the information the user may have provided during registration process. This information is securely stored in the content management system. The MyREADY Transition™ BBD App will have access to the

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camera and microphone on the device when the user is completing the selfie-audio and selfie-video recording challenges. It will only have access when the application is open, and when activated by the user. These recordings will be stored locally on the phone and only a confirmation that the challenge has been completed will be sent to the content management system, not the audio-video files themselves.

Datacenter Security Policies: RootQuotient is using services of Amazon Web Services, and their datacenter is hosted in Montreal, Quebec, Canada. Datacenter policies are described in a document "Amazon Web Services: Overview of Security Processes (May 2017)" created by Amazon (https://d1.awsstatic.com/whitepapers/Security/AWS_Security_Whitepaper.pdf)

Service Provider Security Policies:

- SSH access to server is restricted to access only through our corporate VPC or through corporate static IP address.
- CMS and API's are secured with https protocol and authentication with different roles.
- Users have different security levels in S3 Bucket to upload and read the application materials.
- Client App (iOS & Android) authenticate the users, request the content and meta files to download the application materials.
- All the persistent data are stored in the application container inside the mobile apps and it's not accessible anywhere outside the App.

Backup Management: Backups are scheduled to run on daily, weekly and monthly basis over the persistent data such as database, files & folders.

Configuration Management:

Hardware	Environment	Details
	Test Server	cms.childbright.360medlink.net & api.childbright.360medlink.net
	RAM (in MB)	8000
	CPUs	2 vCPUs
	Virtual/Physical	Virtual
	Server Type	Web /App server
OS	OS Type	Ubuntu
	Vendor (for OS)	Open Source
	OS version	16.04 LTS
	Patch	-

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Application/Web Server Details	Application Server version	nginx/1.10.3
	Application Server	Nginx
Database	Type	MySQL
	Vendor (Database vendor)	Oracle
	Version	5.7
Storage	Amazon Elastic Block Store (Amazon EBS)	Persistent block storage volumes for the server instance - 50 GiB
	AWS S3	Object storage service

Data Access/Transfer: Intervention User Metrics data from the MyREADY Transition™ BBD App will be exported to Excel and will also be presented in a website dashboard ("Compliance Dashboard"). The Content Management System (CMS) is hosted by Amazon and managed jointly by a software company (RootQuotient) and the Research IT team at McGill University. To support the primary aims analysis that will take place at McMaster University, McMaster project staff will be given access to the intervention user metrics data. Research staff in the Research Institute of the McGill University Health Centre will be designated to the 'Super Administator' role in the CMS system dashboard. Together with Dr. Gorter and Dr. Marelli, this person will establish user accounts and user rights for project staff.

Using Zoom for Research Involving Human Participants

Due to the COVID-19 pandemic, we have added the option for the RA to use the Zoom platform to conduct study visits remotely with participants as well as to carry out qualitative interviews. Zoom gives the ability for people to easily join meetings using either a telephone and/or computer connection, with a shared digital whiteboard. Zoom provides information about compliance with PIPEDA / PHIPA (see Zoom privacy statement for Canadian customers: https://zoom.us/docs/doc/PIPEDA_PHIPA Canadian Public Information Compliance Guide.pdf). McMaster accounts only route traffic through Canadian data centres. We note that Zoom does use 256-bit encryption, however information is not encrypted on the Zoom servers themselves. The RA will not record Zoom meetings so any concerns about how recordings may be stored to do not apply to this study. When security settings for meetings are not properly configured, it is possible for uninvited guests to join meetings. This is called "Zoom bombing" and in some situations, guests have joined meetings with the intent of being disruptive, which could be very troubling for research participants. Therefore, the RA will be trained to take cautionary measures when configuring Zoom meeting options. For example:

- Meeting ID: Generate Automatically
- Meeting Password: Require a meeting password
- Enable waiting room (to prevent uninvited guests)

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- Video: Both host and participant video should be set to 'off' on entry.
- Audio: Participants should be given the option to join by telephone only. Provide a toll-free dial in number to make sure there are no accidental costs to participants.

Health Card Number Data (secondary health economics aim)

Data Collection: The youth participant's Health Card Number is requested and recorded on the local Consent form by parents/caregivers who agree to share it. Participants can choose not to share the child's Health Card Number and still participate in the study.

Data Storage: The youth participant's Health Card Number is requested and recorded on the Consent form by parents/caregivers who agree to share it. They can choose not to share the child's Health Card Number and still participate in the study. Health Card Numbers will not be entered into REDCap. The RA at each recruitment site will record the participant's study identification number and Health Card Number into an excel file which will be stored on a secured drive, separate from other study data.

Data Access/Transfer: The RCT Research Coordinator at McMaster University will create a designated folder with limited privileges on MacDrop (https://drop.mcmaster.ca), an Enterprise File Storage and Synchronization Solution that is endorsed by McMaster, and that is managed by Computer Services Unit to securely house data onsite. An excel file containing only youth participant study identification number and Health Card Number will be encrypted and uploaded to the designated folder by the RA at each recruitment site. We will work with appropriate organizations in each province (Alberta, Ontario, Quebec, New Brunswick, and Nova Scotia) to gain approval to access provincial Health Services Administrative Data repositories. Health care services data recorded in the provincial administrative databases will be linked deterministically to the study data using the Health Card Number, partial date of birth and sex.

The RCT will be centrally managed by the RCT Coordinator at McMaster University's CanChild. Research files will be stored on the CanChild Active Directory at McMaster, on a secure network that is in a tier 3 data facility. The CanChild Active Directory is a firewall protected server to which only the PIs and Research Coordinators will have access. Remote access to the CanChild directory is via VPN. Any personal information collected will be entered into password-protected SPSS or excel files and stored on the CanChild Active Directory, separate from other study data. Qualitative data will be stored on the CanChild Active Directory and managed electronically using NVivo, a qualitative data analysis software system. Research staff will password protect their electronic and audio digital files from the interview sessions, and can transmit these into the secure cloud storage provided through McMaster's MacDrop (https://drop.mcmaster.ca/login), with final storage on the CanChild Active Directory.

Incentives for Participation:

As a token of appreciation for their time to participate, all youth participants will be given a $20 gift card and parents/caregivers will have their parking or travel costs covered at the baseline and 6-month visit.

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With the adaptations due to the COVID-19 pandemic, when study visits are not done in-person, the parking or travel cost no longer applies. The parent/caregiver will receive a $20 gift card at each visit instead as a small token of thanks. E-gift cards will be offered to participants for ease of administration and use due to COVID-19 closures. In addition to the gift card at each visit, we will offer youth participants who are in high school, 1 hour of volunteer community service (which can be used towards the graduation requirement if the high school allows). Those who participate in the qualitative data collection will also be given a $20 gift card as a token of appreciation. All participants will be given the option to receive a plain language report at the end of the study, after the RCT results have been analyzed.

STUDY MEASURES:

The quantitative study measures are briefly described here and the full set of data collection booklets are provided separately. All data collection forms will be available in English and French.

Demographic Information

We will collect detailed demographic information from parents/caregivers at the Baseline visit in order to describe and compare our sample to other youth with BBD in Canada. The CHILD-BRIGHT network has developed a set of standard forms for common reporting among network projects: "Network-wide Demographic Information Form" and "Network-wide Profile Information Form: Child and Parent(s)".

Primary Measures

Transition Readiness Assessment Questionnaire (TRAQ) [9]

While TRAQ measure refinement is ongoing, and other versions are now available, our sample size calculation is based on findings from an intervention trial [19] where the 29-item version of the TRAQ was used. The 29-item version has a Self-management domain (16 items) and a Self-advocacy domain (13 items). Each item is scored 1-5, where 1 = "No, I do not know how" and 5 = "Yes, I always do this when I need to." The TRAQ will be completed by youth participants in both groups at Baseline and at 6-Months. It takes 5-10 minutes to complete.

Utilization of Intervention (Usage, Adherence, and Fidelity)

We will use mixed methods to assess MyREADY Transition™ BBD App usage, adherence and fidelity, and to identify the barriers and facilitators to using the IT platform for users.

Quantitative Data: We will track and analyze quantitative measures of App use for all components of the IT platform using two approaches:

1. MyREADY Transition™ BBD App will include support for utilization data gathering that can be used during the intervention and evaluation phases of the project. For example, it will log data related to end user login to the system (times and dates), section/session/video views (including sub-section features), challenge completion, access to games at the arcade, time spent on a section/session and trends over time. In addition, we will track and assess sections/sessions/videos progress by patient condition and/or other user variables by referencing information from the user profile. Within the App, users are asked to provide

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optional feedback at the end of each section. Thus, we can track and analyze the extent and frequency of use, and the profiles of patients who did or did not use the IT platform. This information will be exported to Excel and will also be presented in a website dashboard ("Compliance Dashboard").

2. For all participants in the intervention group, self-reported usage of the IT platform will also be assessed at the end of the intervention. This assessment will focus on users' utilization of the application and its features, the perceived value and their experience and satisfaction with the intervention. The self-reported survey will provide additional information about the users' adherence, behavior, motivation and experience with the IT platform, as well as about the main reasons for using or not using it. The System Usability Scale (SUS) will be administered to youth in the Experimental Arm at the 6 Month visit. The measure focus is on users' utilization of the App and its features, the perceived value and their experience and satisfaction with the intervention. The self-reported survey will provide additional information about the users' adherence, behavior, motivation and experience with the IT platform, as well as about the main reasons for using or not using it.

   The mHealth App Usability Questionnaire (MAUQ) will be administered after end of exposure (completion of the intervention) as well as at the 6-month follow-up interview. While the SUS has been more widely used, the MAUQ is the first reliable usability questionnaire specifically designed to assess the usability of mHealth Apps created for patients and providers.

   We will administer the MAUQ immediately following completion of the App in an effort to reduce potential recall bias of users' experiences with the App. There may be variation in the length of time that youth take to complete the App; Participants are given 6 months to complete the App, however they may choose to complete it more quickly. Having participants answer the items on the MAUQ as soon as possible after completing the App, will allow for important "in-the-moment" feedback. Since other outcome measures will be administered at the 6-month follow-up visit, we will also re-administer the MAUQ at that time. This will allow for user experience with the App to be captured at the same moment-in-time as the other outcomes, and for clearer interpretation of data analysis that includes variables of user experience.

Qualitative Data: After the intervention period, we will conduct semi-structured interviews with a subset of youth in the intervention group, and parents/caregivers. The purpose will be to better understand how the App was used initially and over time, barriers and facilitators to its use, and participants' experience and satisfaction with the App intervention. Our qualitative evaluation will also focus on their perceptions of the MyREADY Transition™ BBD App design and content; implementation; most and least beneficial aspects; and the main challenges and opportunities for improvements. We will develop and use interview guides to facilitate discussion topics and standardize data collection. All interviews will be transcribed verbatim, coded, and themes will be extracted. We will synthesize lessons learned from all these activities into best practices for implementation, adoption, and use of the intervention.

Secondary Measures

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Population Health

Canadian Occupational Performance Measure (COPM)[27]

The COPM is an evidence-based, generic, and individualized outcome measure used to capture a client's self-perception of performance and satisfaction in everyday living, over time.[27] The measure accomplishes this by identifying problems in performing activities of daily living. The patient is encouraged to think about things that they want to do, need to do or are expected to do but can't do, don't do or aren't satisfied with the way they do. Concrete examples are provided for youth: things related to their health and personal care, getting ready for the day, getting around, working, household chores, school, recreation, socializing. The patient is asked to rate current performance of each using a 10-point scale from 'not able to do it' to 'able to do it very well'. The patient is also asked to rate satisfaction with performance on a 10-point scale from 'not satisfied at all' to 'extremely satisfied' with higher scores reflecting better performance and satisfaction with performance as perceived by the patient. The performance and satisfaction can be re-assessed following a period of treatment.[28] The COPM will be administered to all youth participants.

TRANSITION-Q[20]

The TRANSITION-Q is a 14-item transition readiness/self-management ability scale.[20, 29] This short, clinically meaningful and psychometrically sound scale can be used in research and in pediatric and adolescent clinics to help evaluate readiness for transition.[20] Item responses ("never" = 0, "sometimes" = 1, and "always" = 2) are summed to create a raw score, with a possible range from 0 to 28. Raw scores are transformed using a table provided by the developers and the transformed scores range from 0-100. A higher score indicates greater transition readiness; exhibiting more self-management skills with higher frequency.[20, 30]

A TRANSITION-Q score > 40 will be used as an eligibility screen to define a minimum threshold for transition readiness based on our earlier work. At the point of screening and recruitment, we will evaluate several components of cognitive function as well as youth capacity to share the management of their own health. The TRANSITION-Q screen will inherently exclude youth who have severe intellectual disability, and/or those who rely significantly on parents/caregivers in most areas of daily functioning, self-care and/or communication. We will repeat the TRANSITION-Q at the 6-Month Follow-Up Visit.

PedsQL™ Pediatric Quality of Life Instrument, Generic Core, Teen Report (13-18 years) [11]

The PedsQL™ Measurement Model (http://www.pedsql.org/about_pedsql.html) is a modular approach to measuring health-related quality of life (HRQOL) in healthy children and adolescents and those with acute and chronic health conditions.

In this study the PedsQL™ Pediatric Quality of Life Instrument, Generic Core, Teen Report (13-18 years) will be completed by youth participants at Baseline and 6-Months. The form is brief (23 items), practical (less than 4 minutes to complete), multidimensional (Physical, Emotional, Social, School Functioning), reliable (Child Self-Report; 0.90) and valid (Distinguishes between healthy children and children with

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acute and chronic health conditions; distinguishes disease severity within a chronic health condition), and responsive to clinical change over time.

Patient Activation Measure (PAM) (health-related self-efficacy)[31]

The Patient Activation Measure (PAM) (http://www.insigniahealth.com/products/pam-survey) is a valid, reliable, unidimensional, Guttman-like scale based on a developmental model of activation. Activation appears to involve four stages: (1) believing the patient role is important, (2) having the confidence and knowledge necessary to take action, (3) actually taking action to maintain and improve one's health, and (4) staying the course even under stress. The measure has good psychometric properties indicating that it can be used at the individual patient level to tailor intervention and assess changes.[31]

PAM originally included 22 questions, and through subsequent validation of the short-version now has 13 questions. The PAM assesses a patient's confidence in self-managing their condition, and the total score allows individuals to be categorized into four levels:

Level 1 - disengaged and overwhelmed

Level 2 - becoming aware, but still struggling

Level 3 - taking action

Level 4 - maintaining behaviours and pushing further

PAM has been used as a measure of health-related self-efficacy in a relevant study of transition to adult care among adolescents with chronic disease utilizing a technology program.[32] Hibbard et al. [33] reported on the relationship between increased patient activation and improved self-management.

The license with Insignia Health for the PAM Measure does have a data-sharing requirement for scoring purposes. This is necessary to score each survey as there is not a scoring algorithm or rubric that is a static formula.

Health Care Experience

Measure of Process of Care (MPOC) (family-centred care) [34]

The Measure of Processes of Care (https://canchild.ca/en/resources/47-measure-of-processes-of-care) is a well-validated and reliable self-report measure of parents' perceptions of the extent to which the health services they and their child(ren) receive are family-centred. The original version of MPOC is a 56-item questionnaire; as of 1999 there is a shorter, 20-item version. MPOC has been used internationally in many evaluations of family-centred service. Parents/caregivers will complete the MPOC-20 at Baseline and 6-Months. Additional mixed methods questions related to satisfaction with service will be complement the information collected within the MPOC.

Newest Vital Sign [35]

As a complement to our Baseline measures, we will include a health literacy measure called Newest Vital Sign (NVS) http://www.pfizer.com/health/literacy/public-policy-researchers/nvs-toolkit. It is appropriate for our population and research purpose and can be easily administered in 3 minutes. The NVS measures words and numbers, not just word recognition. Since the NVS was published in December

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2005, it has appeared in more than 25 peer-reviewed studies. It has been used to assess health literacy in populations with varying age, among racial/ethnic minorities, and applied to a wide variety of health conditions. The NVS will allow us to describe our population at baseline and explore determinants of change in self-management, as well as tailoring the intervention in the knowledge translation phase.

Cost Utility/Cost Effectiveness

The measure of effectiveness used in the cost effectiveness analysis will be consistent with the primary outcome measures. Additional measures will examine health-related quality of life using the PedsQL™ [11] and the Health Utilities Index (HUI)®[10]. The use of a preference-based measure such as the HUI will permit the calculation of quality-adjusted life years (QALYs) for a cost-utility analysis.

Health Utilities Index® (Hui2/3) Proxy-Assessed (health-related quality of life) [10]

The HUI is a generic health status instrument developed in Canada for use with children and has been incorporated in numerous clinical studies as well as the Canadian Community Health Survey, allowing the generation of norms for most age groups.[10] The HUI Mark II includes 7 attributes: Sensation, Mobility, Emotion, Cognition, Self-care, Pain and Fertility with each attribute divided into 3 to 5 levels. The HUI III includes 8 attributes: Vision, Hearing, Speech, Ambulation, Dexterity, Emotion, Cognition and Pain. Each attribute of the HUI III consists of 5 to 6 levels. The organization of attributes by level of functioning is referred to as the HUI classification system. The HUI II and III use the same questionnaire to map individual responses to classification levels. As the mapping is done at the analysis phase, there is no additional response burden for completing the HUI. A multi-attribute utility function is used to assign weights to each level for each attribute. The weights for each attribute are combined statistically to derive a single utility using a scoring formula. Separate pre-established and validated utility functions and scoring formulae exist for the HUI II and III. Since the attributes in the HUI II and III are structurally independent, the user can produce attribute scores, in addition to overall utility for a health state that range from 0 to 1. To reduce burden on youth participants in this study, we will use the Health Utilities Index® (Hui2/3) Proxy-Assessed which will be self-administered by parent/caregiver proxies. The completion time is 5-7 minutes.

Resource Use Questionnaire (RUQ) [12]

The RUQ [12] is typically an interviewer-administered questionnaire for parents of children aged 11 to 18 years. The original RUQ measures the family resource use of condition-related treatments, services and programs, as well as parent time losses and family out-of-pocket costs. It also documents condition-related government subsidies and funding that families receive. Resources measured include those delivered by a parent, by other providers (e.g. behavioural specialist) or a combination of both. In this project, we will use a modified subset of RUQ questions, self-completed by the parent/caregiver. We have also included some questions to capture information about serious illnesses during the study including information about hospitalizations, ICU admissions, etc.

Provincial Data on Use of Health Care Services

We will request consent to obtain youth participant's Health Card Number to answer questions about use of health services like physician office visits, visits to emergency rooms and hospitalizations during

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the study period (between the time a participant joins the study up until March 31, 2021). Participants have the option of participating in the study without sharing the youth's Health Card Number. The Health Card Number will allow us to link the information provided in the study with provincial data regarding the participant's use of health services. We will work with appropriate organizations in each province (Alberta, Ontario, Quebec, New Brunswick, and Nova Scotia) to gain approval to access provincial Health Services Administrative Data repositories. Health care services data recorded in the provincial administrative databases will be linked deterministically to the study data using the Health Card Number, partial date of birth and sex.

STATISTICAL ANALYSIS:

We will use regression analysis to adjust for baseline function as a sensitivity analysis to address any residual imbalance from the randomization.

The analysis and reporting of the internal pilot phase and main RCT results with follow CONSORT guidelines[23-24]. Patient demographics and baseline outcome variables (both primary and secondary) will be summarized using descriptive summary measures. All analyses will be performed using SAS 9.4 (Cary, NC). Analysis will be intention to treat. The table below provides a summary of study objectives, corresponding outcomes, hypotheses and methods of analyses. For subgroup analysis we will use interaction test (interaction of subgroup variable with the treatment or intervention variable).

Table 1: Study Objectives, Corresponding Outcomes, Hypotheses and Methods of Analyses

Objective	Outcome	Criterion for Success	Method of Analysis
Primary: To determine whether the MyREADY Transition™ BBD App intervention will result in improved transition readiness	**Primary:** • Change in TRAQ self-management score from Baseline to 6 months.	Intervention > Control	T-Test; p<0.05
	Secondary: • Change in TRAQ self-advocacy score from Baseline to 6 months.	Intervention > Control	T-Test; p<0.05
	Secondary • Health care transition experience	Individual semi-structured interviews	Qualitative Methods
Secondary: What is the effect of the MyREADY Transition™ BBD App intervention for	**Primary:** **Population Health** • Serious illness (hospitalizations, ICU admission questions from Resource Use Questionnaire	Intervention > Control	T-Test for continuous outcomes Chi-square test

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improving health and use of health systems?	• PedsQL™ Pediatric Quality of Life • Patient Activation Measure (PAM) (health-related self-efficacy) • TRANSITION-Q		for hospitalization
	Secondary: • Utilization MyREADY Transition™ BBD App	User metrics built into MyREADY Transition™ BBD App intervention to assess the extent to which various components of the intervention are accessed	Descriptive
	Secondary: **Cost utility/cost-effectiveness** • Health Utilities Index® (Hui2/3) • Resource Use Questionnaire	Evaluate changes in patients' health in relation to changes in cost to assess if the intervention represents an efficient allocation of health care resources	Descriptive; Cost-effectiveness analysis with support from Child-Bright health economics network team
	Secondary: • Achievement of health/life goals • Canadian Occupational Performance Measure (COPM)	Intervention > Control	Paired Student t-tests to compare mean ratings for performance and satisfaction on the COPM scoring system (10-point scale) with > 2 points difference as clinically meaningful difference

Qualitative Data Analysis

In this study, individual interviews will be audio-recorded and transcribed verbatim. Data will be stored and managed electronically using NVivo® Version 11 [36], a qualitative research data management

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software program to facilitate the organization and coding of large quantities of data. Conventional content analysis [37] will be used to code, categorize and synthesize the data to contextualize the analysis of the primary aim of the RCT. In addition, data related to usability of the App will be monitored and analyzed by the Research IT team at McGill to inform ongoing App development.

Health Economic Evaluation

Cost-effectiveness analyses will be conducted from the perspective of the provincial payer, as well as from the perspectives of society and the family, data permitting. Costing relates to the cost to develop and resources to support the intervention as well as resources used for treatment/management of participants' health conditions over the study. Health resource use data include things such as the intervention, physician services, rehabilitation services, emergency services, hospital admissions, and medications. We anticipate that the health economic evaluation in this project will be exploratory since we are engaging youth during the timeframe prior to transition. However, there will also be opportunity to explore provincial jurisdiction patterns. There may be interest to submit a proposal to follow up this cohort in the future once they have landed in adult care, which would give us more of an opportunity to explore these health economics questions.

A decision tree that models the comparison groups will be constructed. The model will include all relevant outcomes and events that may occur with each group throughout the study period. A 3% discount rate will be applied to outcomes and costs extending beyond one year. All measurement and analytic assumptions made for the base case analysis will be clearly stated. The mean cost per child and the mean effectiveness result per child for each group will be represented in an incremental cost-effectiveness ratio (ICER) -- the ratio of the difference between groups in mean cost per patient to the difference in mean effectiveness. Subgroups of patients based on baseline demographic factors may be analyzed separately, if appropriate. Extensive sensitivity analysis including probabilistic sensitivity analysis will be undertaken to test the robustness of the results to variations in underlying assumptions.

PATIENT ENGAGEMENT:

Patient-oriented research refers to a continuum of research that engages patients as partners, focuses on their priorities and ultimately improves the value of research. Under this model, patients and parents/caregivers with "lived experiences," together with health professionals, join researchers as members of the research team. Most importantly, what patients and parents/caregivers contribute is the sharing of their values and priorities. Doing so ensures that the research conducted is meaningful and will have impact on those most affected by its outcomes. The entire team collaborates to plan and conduct the research, and to disseminate its findings. Researchers, research staff, and stakeholders involved in this project are encouraged to participate in the CIHR training curriculum in patient-oriented research to forefront the meaningful engagement of key stakeholders throughout our project.

READYorNot™ Brain-Based Disabilities Trial is a patient-oriented project of CHILD-BRIGHT, a pan-Canadian research program generally aimed at optimizing physical and mental health of youth with BBD and their families. In the READYorNot™ Brain-Based Disabilities Trial, the MyREADY Transition™ BBD

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App has been developed and evaluated to promote transition readiness (self-management and self-advocacy skills) in preparing youth for the transition from pediatric to adult health care.

In Part 1 of the project, Heath Information Technology (HIT) development was based on Agile Programming Best Practices. [38] This gave us flexibility and helped us to integrate feedback from researchers, research staff, as well as youth, parent/caregiver and health care stakeholders. The research team worked in partnership with PFAC to plan interviews, focus groups and other interactive testing activities to ensure the MyREADY Transition™ BBD App matches the needs and interests of youth. In Part 2 of the project, the PFAC will continue to collaborate and guide the research team in planning this RCT to study the MyREADY Transition™ BBD App in health care settings across Canada. Then, in the Part 3 of the project, patients, parents/caregivers and health care stakeholders will continue to be involved to ensure findings of the project are communicated in innovative and understandable ways, and can reach those who need it most. All partners will continue to work together to define future research directions.

Members of our team are working together with CHILD-BRIGHT's Citizen Engagement Council, Ontario SPOR Support Unit (OSSU) and Maritime SPOR Support Unit (MSSU) on some tailored content to be delivered online for all members of our project including researchers, PFAC, clinicians and the research staff who will be part of the RCT. The training is especially timely as we expand the group for the RCT, to give everyone a shared understanding of the partnership, and set the stage for engagement and interaction throughout the project.

DISSEMINATION AND KNOWLEDGE TRANSLATION (KT):

KT activities directed at the academic and stakeholder community will include presentations at scientific meetings, publications in academic journals and dissemination of teaching and training tools through patient associations, and patient and family advocacy groups. All participants will be given the option to receive a plain language report at the end of the study, after the RCT results have been analyzed. We will leverage CHILD-BRIGHT'S Knowledge Translation Program and our PFAC partners to find novel integrated and end-of-study KT strategies for patients, parents/caregivers and health care providers who participated in the RCT and beyond. After the completion of this RCT, our team will explore the potential to make the App more widely available.

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