

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Protocol of the CHILD-BRIGHT READYorNot™ Brain-Based Disabilities Trial: A Randomized Controlled Trial (RCT) investigating the effectiveness of a patient-facing e-health intervention designed to enhance health care transition readiness in youth.
<b>AUTHORS</b>	Gorter, Jan Willem; Amaria, Khush; Kovacs, Adrienne; Rozenblum, Ronen; Thabane, Lehana; Galuppi, Barbara; Nguyen, Linda; Strohm, Sonya; Mahlberg, Nadilein; Via-Dufresne-Ley, Alicia; Marelli, AJ

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Laura Hart, MD, MPH Nationwide Children's Hospital / The Ohio State University College of Medicine, Columbus, Ohio, USA
<b>REVIEW RETURNED</b>	18-Jan-2021

<b>GENERAL COMMENTS</b>	<p>Introduction: It would be helpful if the diagnoses included under the term "brain-based disabilities" were introduced sooner. Based on my reading of the introduction, it sounds like the "ReadyorNot" Trial is testing the "MyREADY Transition" app. If that is the case, I would recommend stating so explicitly. If that is not correct, please clarify.</p> <p>Methods: Regarding eligibility criterion #4: From my quick reading of consent/assent rules in Canada, the age of consent in most places is 16 or older, but it's 18 or older in Quebec, so many of the potential participants may not be legally allowed to provide consent, even if they are deemed to have the cognitive ability to do so. I see in the recruitment section that youth will be providing assent, not consent, so I find the wording of this criteria a bit confusing. I would appreciate the authors clarifying what they mean by this particular eligibility criterion.</p> <p>Regarding eligibility criterion #6: I think clarification for the use of the TRANSITION-Q score as part of the inclusion / exclusion criteria is needed, especially since it is also an outcome of the study. They have already specified that youth need to be able to have the ability to provide consent/assent and that youth must be able to read in English or French. What does this minimum threshold add that earlier eligibility criteria do not? They mention that youth with BBDs were included in the validation sample for choosing their minimum score. However, the reference is from a presentation, and so I was not able to see if they did a separate analysis of just the youth with BBDs to ensure that the floor was appropriate for that population. If possible, it would be helpful to have this information.</p>
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	<p>Outcomes: I would recommend mentioning that the 29-item version of the TRAQ is being used because the power calculations are based on that measure in the main text, not just the supplement. I would also clarify whether or not you are including the "not needed for my care" response option that was in the 29-question version. Ideally, this information would be in the manuscript, but at least mention in the supplement.</p> <p>I found the description of the interviews unclear until I read the sample size section. If possible, I would recommend that the authors move the sample size section ahead of the outcomes section. If this is not possible, I would use similar wording in the description of the interviews as they do in the sample size description. Either way, I think it would also be helpful to clarify why they are doing separate interviews with the youth and how they intend to deal with overlap. For example, if a question in the qualitative study leads to a discussion about app user experience or a user experience question leads to youth talking about what they learned from the app, is that information going to be "traded" among the two sets of interviews?</p> <p>Sample Size: A 1-point increase in TRAQ score in 6 months seems like a big increase. Do the authors have data to support this assumption? Also, they say in this section that the increase is happening "6 months post-intervention," which implies 6 months from when the person finishes with the app, rather than 6 months from baseline. Supplement 4 says they are doing baseline and 6-month measurements. It would be helpful if the authors could clarify.</p> <p>Analysis: this section was clear and well-organized. I have no specific comments or questions.</p>
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<b>REVIEWER</b>	<p>Knut Brockmann Interdisciplinary Pediatric Center for Children with Developmental Disabilities and Severe Chronic Disorders</p> <p>Children's Hospital University Medical Center Göttingen</p> <p>Robert Koch Str. 40 37075 Göttingen Germany</p>
<b>REVIEW RETURNED</b>	22-Jan-2021

<b>GENERAL COMMENTS</b>	Congratulation to this sound and very well elaborated protocol.
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<b>REVIEWER</b>	John Berens, MD Baylor College of Medicine, United States of America
<b>REVIEW RETURNED</b>	22-Jan-2021

<b>GENERAL COMMENTS</b>	<p>This manuscript is a clearly written, thorough protocol description of a mixed-methods randomized control trial investigating the effect of a patient-facing App on transition readiness of adolescents with brain-based disabilities. The rationale/need for the study, the primary and secondary outcomes, and the various instruments that will measure these outcomes are clearly described. The setting, timeline, participant factors, sample size, randomization, and allocation are adequately discussed, as are the statistical</p>
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	<p>methods/analysis plan. Ethical considerations are described and the protocol has been approved by an IRB. The protocol is reviewed alongside the SPIRIT guidelines, which are followed with a few small exceptions discussed below. There is a great need for rigorous, randomized control trials investigating interventions to improve transition readiness for this vulnerable population, and I recommend acceptance of this manuscript with the following minor revisions:</p> <ol style="list-style-type: none"> <li>1) No contact information included for the trial sponsor (SPIRIT 5b).</li> <li>2) While the study regions are mentioned, there is no mention or reference to a list of study sites (SPIRIT 10).</li> <li>3) There is not a clear description of the plan for data entry, coding, security, or storage as it relates to assurance of data quality and participant confidentiality (SPIRIT 19, 27).</li> <li>4) On Page 21 (second page of Supplementary File 3), the text is incomplete on the second bullet point of the "age 14-15" section.</li> </ol>
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### VERSION 1 – AUTHOR RESPONSE

#### Response to Reviewer 1

Dr. Laura Hart, Nationwide Children's Hospital

##### Introduction:

- 1) It would be helpful if the diagnoses included under the term "brain-based disabilities" were introduced sooner.  

The diagnoses included under the term "brain-based disabilities" are now described when the term is first introduced in the Introduction section on page 4, "Poor health care transition can have negative health outcomes and result in poor quality of life for youth with brain-based disabilities (BBD), such as autism spectrum disorder cerebral palsy, epilepsy, fetal alcohol spectrum disorder and spina bifida."
- 2) Based on my reading of the introduction, it sounds like the "ReadyorNot" Trial is testing the "MyREADY Transition" app. If that is the case, I would recommend stating so explicitly. If that is not correct, please clarify.  

The READYorNot™ Trial is testing the MyREADY Transition™ BBD App, and we have revised the following sentence: Since the policy-driven age of transfer cannot be changed, we designed the READYorNot™ (READiness in Youth fOR traNsition Out of pediaTric care) Brain-Based Disabilities Trial to evaluate a patient-facing e-health intervention (MyREADY Transition™ BBD App) aimed at fostering self-management.

##### Methods:

- 3) Regarding eligibility criterion #4: From my quick reading of consent/assent rules in Canada, the age of consent in most places is 16 or older, but it's 18 or older in Quebec, so many of the potential participants may not be legally allowed to provide consent, even if they are deemed to have the cognitive ability to do so. I see in the recruitment section that youth will be providing assent, not consent, so I find the wording of this criteria a bit confusing. I would appreciate the authors clarifying what they mean by this particular eligibility criterion.  

We have changed the wording to indicate informed assent for eligibility criterion #4 on page 5. We also clarified in the Recruitment section on page 9 that all youth will provide assent and all parents/caregivers will provide consent.
- 4) Regarding eligibility criterion #6: I think clarification for the use of the TRANSITION-Q score as part of the inclusion / exclusion criteria is needed, especially since it is also an outcome of the study. They have already specified that youth need to be able to have the ability to provide consent/assent and that youth must be able to read in English or French. What does this minimum threshold add that earlier eligibility criteria do not? They mention that youth with BBDs were included in the validation sample for choosing their minimum score. However, the reference is from a presentation, and so I was not able to see if they did a separate analysis of just the

youth with BBDs to ensure that the floor was appropriate for that population. If possible, it would be helpful to have this information.

While transition readiness is the primary outcome of the study, we want to reemphasize that the TRAQ is the primary outcome measure and the Transition-Q is a secondary outcome measure. The app has been co-created with youth with BBD and their families, clinicians and researchers targeting youth who are thinking about being more independent in taking charge of their own care, such as asking or answering questions when they are with a doctor or nurse. Therefore, we designed the trial for youth who, in addition to having the cognitive ability to provide informed assent and the ability to read and understand English or French, also are meeting a minimum threshold of readiness. We have updated reference 14 to reflect a recent (2021) presentation of the information which can be accessed electronically.

Outcomes:

- 5) I would recommend mentioning that the 29-item version of the TRAQ is being used because the power calculations are based on that measure in the main text, not just the supplement. I would also clarify whether or not you are including the "not needed for my care" response option that was in the 29-question version. Ideally, this information would be in the manuscript, but at least mention in the supplement.

This explanation is included in the Measures section on page 7. We have edited the response set description there and in the Supplementary File 4./span>

We are using the original 29-item TRAQ response set based on the 5 levels in the stages of change theoretical framework per reference 15 and so we have not included a sixth response option of "not needed for my care".

- 6) I found the description of the interviews unclear until I read the sample size section. If possible, I would recommend that the authors move the sample size section ahead of the outcomes section. If this is not possible, I would use similar wording in the description of the interviews as they do in the sample size description. Either way, I think it would also be helpful to clarify why they are doing separate interviews with the youth and how they intend to deal with overlap. For example, if a question in the qualitative study leads to a discussion about app user experience or a user experience question leads to youth talking about what they learned from the app, is that information going to be "traded" among the two sets of interviews?

We have further revised the description for the interviews and moved information about the sample size up to the Interviews section on page 8.

In designing the study, we identified two unique aims that could be achieved by engaging in qualitative interviews with participants in the intervention group.

- 1) We wished to explore outcomes related to youth's developing transition and self-management skills. In these interviews, we plan to ask youth what they feel they learned from the app, how they applied what they learned in their everyday lives and in their interactions with parents/caregivers and healthcare providers, and how they feel the App may have provided them support that influenced their care. These interviews will serve to complement the quantitative findings related to self-management and self-advocacy.
- 2) We wished to explore opportunities for improving the app by providing an understanding of youths' satisfaction with the App and its features, as well as issues or challenges they may have faced and what supports were required to resolve these. These interviews will serve to complement the quantitative findings related to usability.

The rationale to do the interviews separately is twofold. First, we felt that a single interview addressing both aims could be long and burdensome to participants. Additionally, to avoid introducing co-intervention bias, we wanted to wait until after the 6-month follow-up before asking questions about what participants had learned from the App, or how the App may have influenced their care (aim 1 above). At the same time, we recognized that some of the detailed questions we want to ask about participants' user experiences (aim 2 above) will require good recall of the App's features and functions, and that the timing of these interviews should follow as closely as possible the completion of the intervention (rather than completion of the study at 6-months).

We understand it is possible that participants being interviewed about app use may begin to share about their transition outcomes, and likewise, that participants being interviewed about their transition outcomes may begin to share about their satisfaction with the App and its features. In the latter example, this is of little concern. We will plan to “share” any relevant data between the two aims.

However, in the case of participants who are interviewed ahead of the 6-month follow-up visit about their user experience, we will rely on our skilled interviewers to redirect any conversation about transition outcomes. Following the interview, we will invite those participants who seem eager to share more about transition outcomes to take part in a second interview after their 6-month visit.

Sample Size:

- 7) A 1-point increase in TRAQ score in 6 months seems like a big increase. Do the authors have data to support this assumption? Also, they say in this section that the increase is happening "6 months post-intervention," which implies 6 months from when the person finishes with the app, rather than 6 months from baseline. Supplement 4 says they are doing baseline and 6-month measurements. It would be helpful if the authors could clarify.

We have cited reference 24 to support the expected increase in the TRAQ score on page 7. We also edited the Sample Size description on page 9 to reflect that it is at 6-months follow-up rather than 6-months post-intervention.

### Response to Reviewer 3

Dr. John Berens, Baylor College of Medicine

- 1) No contact information included for the trial sponsor (SPIRIT 5b).  
The Sponsor (McMaster University) is listed at the bottom of page 2.
- 2) While the study regions are mentioned, there is no mention or reference to a list of study sites (SPIRIT 10).  
We have added this list as new Supplementary File 6 cited on page 12.
- 3) There is not a clear description of the plan for data entry, coding, security, or storage as it relates to assurance of data quality and participant confidentiality (SPIRIT 19, 27).  
This has been elaborated under Data Collection on page 10.
- 4) On Page 21 (second page of Supplementary File 3), the text is incomplete on the second bullet point of the "age 14-15" section.  
Thank you for taking note of the incomplete text, and we have made the change on the second page of Supplementary File 3.

### VERSION 2 – REVIEW

<b>REVIEWER</b>	Laura Hart, MD, MPH Nationwide Children's Hospital / The Ohio State University College of Medicine United States of America
<b>REVIEW RETURNED</b>	22-Feb-2021

<b>GENERAL COMMENTS</b>	The authors have appropriately addressed my previous comments. I have no additional comments or questions to add.
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<b>REVIEWER</b>	John Berens, MD Baylor College of Medicine USA
<b>REVIEW RETURNED</b>	01-Mar-2021

<b>GENERAL COMMENTS</b>	I have no additional comments or suggestions for revision prior to
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	<p>publication. The manuscript is a well-written description of a much-needed randomized control trial evaluating the efficacy of a patient-facing tool to improve health care transition. I cannot comment fully on the soundness of the statistical analysis planned, but no other concerns were identified and all reviewer comments were addressed in full from the prior iteration.</p>
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