PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluation of Parent and Youth Experiences in Advisory Groups as part of a Mental Health Care Clinical Trial: Protocol for a Mixed Method Study
AUTHORS	Rasiah, Jananee; Freedman, Stephen; Macdonald, Lee; Prisnie, Kassi; Eltorki, Mohamed; Finkelstein, Yaron; Hopkin, Gareth; Santana, Maria-Jose; Thull-Freedman, Jennifer; Stang, Antonia; Prebeg, Matthew; Gagnon, Isabelle; Steele, Margaret; Mater, Ahmed; Katz, Laurence; Greenfield, Brian; Plotnick, Laurie; Monga, Suneeta; Lipman, Ellen; Wright, Bruce; Dimitropoulos, Gina; Porter, Robert; Hurley, Katrina; Al Hamarneh, Yazid; Newton, Amanda

VERSION 1 – REVIEW

REVIEWER	Brütt, Anna Levke University of Oldenburg School of Medicine and Health Sciences, Department of Health Services Research
REVIEW RETURNED	14-Feb-2022

GENERAL COMMENTS	Review for the manuscript Evaluation of Parent and Youth Experiences in Advisory Groups as part of a Mental Health Care Clinical Trial: Protocol for a Mixed Method Study The abstract is well written and clearly structured. The strength that “Patient engagement activities will be widely applicable to other paediatric clinical trials” does not seem attributable to the described study Introduction Page 6/29: You already referred to evidence regarding benefits of partnering with patients in health research. Please make clear, that clinical trials are a further differentiation and that there is growing evidence of the benefits. Page 7/24: Could you please further explain, what “with feedback from patient partners” looked like? Overall, I would like to get more information on the specifics of partnering with youth in the introduction. Could you state a precise research question in the paragraph “A patient engagement plan was created for the trial…” Section patient and public involvement I would prefer referring to involvement activities that occurred when designing the study. Engagement as part of the engagement plan should be described in the methods section. Methods I would prefer a focus on engagement activities during trial conduct and post-trial in the methods section.

	You may think about further diversity criteria such as single-parent in this context. At the first meeting of each group there seem quite a few decisions to be felt. How do you ensure that patient partners have enough information to be able to decide? How are patient partners supported within the project? Are patient partners reimbursed? Is the actual conduct of the engagement activities that open? Who will decide on changes to the trial? Is there an argument related to its content for its use? Does it link to your framework for evaluation? Who will interview the patient partners? May there be a bias when members of the project team who regularly meet the patient partners are the interviewers? Who will analyse the data?

REVIEWER	Tobiano, Georgia Griffith University, Centre for Health Practice Innovation, Menzies Institute for Health (Queensland)
REVIEW RETURNED	22-Feb-2022

GENERAL COMMENTS	It was a pleasure to read this well-written manuscript. The authors address a needed area: evaluating the process of patient engagement in research. This paper provides an exemplar for other planning this type of evaluation. I only have minor suggestions: - The sentence: "the tool was highly rated by the Centre of Excellence on Partnership with Patients and the Public (CEPPP) (1, 36, 37).” it might help the reader to describe what "highly" is defined as, for those not familiar with the CEPPP website and work - Demographics collected: would it also be interesting to know if they have previous experience in patient engagement with research? - Research design: this study sounds like an "exploratory sequential" mixed methods design. I think there is value in being more explicit about the type of mixed methods design being adopted. Will you put more weight on qual or quant findings (or equal weight)? I noticed in the mixed-methods appraisal tool that integration was listed as not applicable at this stage – there could be added rigor in providing your integration plan up front- when will the mixing of quant and qual data occur? I recently read a great article by Anguera et al 2018 “Revisiting the difference between mixed methods and multimethod…” in the journal “Qual Quant”. I think just adding a few more explicit statements that address my comments above will ensure a rigorous mixed methods study occurs.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1’s Comments	**Authors’ Responses**
The abstract is well written and clearly structured.	Thank you for these comments.

The strength that “Patient engagement activities will be widely applicable to other paediatric clinical trials” does not seem attributable to the described study	We have removed this strength and updated this section as follows: • Validated evaluation tool used to measure outcomes of patient engagement across a pediatric mental health care trial • Semi-structured interviews to elicit patient engagement experience • Dedicated resources for patient engagement from concept to end-of-grant knowledge translation activities • Limitation includes the ability to sustain parent and youth engagement over the course of the trial
Introduction Page 6/29: You already referred to evidence regarding benefits of partnering with patients in health research. Please make clear, that clinical trials are a further differentiation and that there is growing evidence of the benefits.	We acknowledge the emerging evidence of patient engagement in clinical trials on page 6 in paragraph 2, which led to our prioritization of patient engagement in this pediatric clinical trial.
Page 7/24: Could you please further explain, what “with feedback from patient partners” looked like?	We have added more details as follows: In response to this position, a novel ‘bundle’ of mental health care was created with feedback from patient partners (comprised of separate groups of youth and parent/caregivers). The bundle components were discussed and prioritized through several in-person meetings and teleconferences that took place between 2017-2019 (21). Patient partners also prioritized study outcomes and selected outcome measures that were most relevant for self-reporting in mental health, satisfaction with care, and family functioning. The results of this engagement were applied to both this trial as well as quasi-experimental study that provided pilot data to inform the trial (21).
Overall, I would like to get more information on the specifics of partnering with youth in the introduction.	Thank you for your comment. We have added additional descriptions in the introduction on page 6. Steps taken to recognize youths’ expertise within engagement practices in research are equally beneficial and include (i) ensuring a youth friendly approach (e.g., listening to what youth have to say and asking questions in a non-judgemental manner); (ii) recognizing diversity among youth (e.g., recruiting youth from different developmental stages and with varied sociodemographic

	characteristics); (iii) formalizing recognition of contributions that are authentic for youth (e.g., providing compensation for engagement, writing references for school/university/jobs, offering co-authorship on findings, or providing certificates of achievement); and (iv) establishing youth-friendly environments (e.g., creating respectful and welcoming spaces for ongoing communication among youth, adult researchers, and adult patient partners whether virtual or in-person and ensuring supports for youth who may find research topics to be potentially triggering) (12). When youth have been engaged in research with these practical recommendations in place, the experiences are youth-friendly, and the results are more likely to be implemented and adopted widely (12-14). We have added a sentence at the end of this paragraph on page 7. Given this evidence, we saw the benefits of prioritizing engagement with patients as partners with lived experience comprised of youth and caregivers (defined in more detail below) across the lifespan of our pediatric mental health care trial.
Could you state a precise research question in the paragraph “A patient engagement plan was created for the trial…”	Thank you for your suggestion. Instead of stating a research question, we have provided a research purpose as follows: The plan will be evaluated in a trial sub-study, which is described below under patient engagement evaluation study. The purpose of the patient engagement evaluation study is two-fold: (1) evaluate the engagement of youth and caregivers in the trial design, conduct, outcomes (and knowledge translation of outcomes) of the trial and (2) obtain research team members’ perspectives on the impact of patient engagement on all stages of the trial.
Section patient and public involvement I would prefer referring to involvement activities that occurred when designing the study.	A brief description was already provided on page 10 and further clarification were added highlighted in yellow: We will specify the group we refer to within the protocol for particular instances as needed, but otherwise we mean both groups. Initial recruitment began in 2017 with youth and caregivers from two family advisory councils for child and adolescent mental health services in Calgary

	and Edmonton, Alberta, Canada invited to provide feedback and perspectives on bundle design, trial planning, and grant submission. The participation of these advisors has concluded, with one partner staying as a team member for the trial, since funded.
Engagement as part of the engagement plan should be described in the methods section.	We described the patient engagement plan in detail as a separate section so as to not confuse it with the design of the patient engagement evaluation study. The methods section solely focusses on the methods used in the patient engagement evaluation study.
Methods I would prefer a focus on engagement activities during trial conduct and post-trial in the methods section.	The patient engagement activities are part of the patient engagement plan, which is separate from the methods to be undertaken as part of the patient engagement evaluation study. A trial timeline is included as an appendix on page 8. In Appendix B, advisory group activities (which include engagement activities) are listed according to trial milestones.
You may think about further diversity criteria such as single-parent in this context.	Thank you for this comment. It has been added on page 9 under recruitment using inclusive language. …caregivers (including parents from diverse family forms)….
At the first meeting of each group there seem quite a few decisions to be felt. How do you ensure that patient partners have enough information to be able to decide? How are patient partners supported within the project?	We have already indicated this on page 11. We have added the following clarification: Patient partners will be supported by the patient engagement leads throughout the course of the project, as described further under advisory group activities.
Are patient partners reimbursed?	Yes, and details added on page 12 under advisory group activities as follows:

	Meetings will occur at least four times/year for up to three years, which is aligned with key milestones within the trial (see Appendix B). Compensation will be provided at a set annual rate per year that was budgeted in the grant. Institutionally approved videoconferencing platforms will be used to exchange and share information about the study.
Is the actual conduct of the engagement activities that open?	Details were already provided on page 12 about this process.
Who will decide on changes to the trial? Is there an argument related to its content for its use? Does it link to your framework for evaluation?	Additional clarification provided on page 9 as follows: Feedback by advisory group members on both trial process and findings will be shared at the executive research team meetings for discussion and deliberation. Post executive research team meetings, a brief written report about how suggestions have been incorporated will be circulated to advisory group members. On page 14 – we have indicated a component of assessment to be “influence and impact will be assessed by examining whether patient engagement activities informed or changed trial decisions”. We have also explicitly showed this link in Table 1.
Who will interview the patient partners? May there be a bias when members of the project team who regularly meet the patient partners are the interviewers? Who will analyse the data?	We have added who will conduct the data collection on page 15 as follows: Patient partners will be offered the choice to participate in individual or focus group interviews that will be conducted by a research nurse/graduate student. We have added who will conduct the data collection on page 16 as follows: Data collected through this platform by a research nurse/graduate student will be de-identified and will not be tracked to any individual participant. On page 18 – we outline who will conduct the analyses.
Reviewer 2’s Comments	**Authors’ Responses**

The sentence: "the tool was highly rated by the Centre of Excellence on Partnership with Patients and the Public (CEPPP) (1, 36, 37).” it might help the reader to describe what "highly" is defined as, for those not familiar with the CEPPP website and work	Thank you for this suggestion and edited as follows: The PPEET was highly rated by the Centre of Excellence on Partnership with Patients and the Public (CEPPP) because of high scores in the domains of scientific rigour, patient and public perspective, comprehensiveness, and usability (1, 40, 41).
Demographics collected: would it also be interesting to know if they have previous experience in patient engagement with research?	Thank you for raising this question and we will describe this information as a narrative and have added at statement on page 15 as follows: Additionally, we will include a description about advisory members’ previous experience with patient engagement in research (information will be obtained when we recruit members).
Research design: this study sounds like an "exploratory sequential" mixed methods design. I think there is value in being more explicit about the type of mixed methods design being adopted. Will you put more weight on qual or quant findings (or equal weight)? I noticed in the mixed-methods appraisal tool that integration was listed as not applicable at this stage – there could be added rigor in providing your integration plan up front- when will the mixing of quant and qual data occur? I recently read a great article by Anguera et al 2018 “Revisiting the difference between mixed methods and multimethod…” in the journal “Qual Quant”. I think just adding a few more explicit statements that address my comments above will ensure a rigorous mixed methods study occurs.	Thank you for this suggestion. We have added additional details as follows: In particular, we chose the exploratory sequential mixed method design because we will first complete data collection and analyses using quantitative methods followed by qualitative methods (37). In addition, we will place equal weighting on both quantitative and qualitative methods (37) because our research purpose is to evaluate engagement and determine impact of that engagement to the pediatric mental health care trial. Thus, to do that effectively, we emphasize that the data collected and analyzed using both methods will address the two-fold purpose.

VERSION 2 – REVIEW

REVIEWER	Brütt, Anna Levke University of Oldenburg School of Medicine and Health Sciences, Department of Health Services Research
REVIEW RETURNED	29-Apr-2022

GENERAL COMMENTS	Thank you for the sound revision. You addressed the reviewers comments, mostly incorporated suggestions in the manuscript or state comprehensive reasons for not revising the manuscript (e.g. structure).