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Abstract

Introduction: Patient engagement in health care research is a necessity to ensure that research objectives align with priorities, outcomes, and needs of the population under study, and to facilitate ease of implementation and adoption of findings. In clinical trials, there is an increasing focus on patient engagement during the planning and conduct of clinical trials due to the potential for ethical and methodological benefits. As patient engagement in clinical trials increases, there is a need to evaluate the approaches of these activities to contribute evidence on what is most appropriate and successful. The purpose of this study is to evaluate patient engagement processes and the activities of patient partners during and after a pediatric mental health care trial.

Methods and analysis: Using a mixed-methods study design, we will evaluate patient partners' engagement activities across set time points during the trial and after trial completion. In this study, the term "patient partner" is inclusive of two groups of people with lived experience: (1) caregivers (parents, formal/informal caregivers, and family), and (2) youth (ages 15-24 years). Engagement will be measured using the participant and project questionnaires of the Public and Patient Engagement Evaluation Tool (PPEET), followed sequentially by semi-structured interviews. Quantitative data from the PPEET questionnaire will be analyzed and reported using descriptive statistics. Data from open-ended questions from the PPEET questionnaires and semi-structured interviews will be analyzed using thematic analysis.

Ethics and dissemination: Approval from Athabasca University Research Ethics Board will be obtained for this project. Findings will be disseminated at both academic and public venues in-person and online using platforms that are caregiver and youth friendly.

Strengths and limitations of this study

- Patient engagement activities will be widely applicable to other pediatric clinical trials
- Evaluation findings will inform future patient engagement plans for pediatric clinical trials
- Potential to advance the science of patient engagement in research as a whole
- Given the length of the trial, we may encounter challenges with sustained parent and youth engagement over the course of the trial

Introduction

Within the last decade, research funding organizations in the United Kingdom, United States, Canada, Australia, and New Zealand have required that patient engagement be an integral part of the design, conduct, dissemination, and implementation of findings emerging from social and health care research (1-5). Patient engagement occurs when patients become partners through meaningful and active collaboration across the research process (2, 6). A recent systematic review has reported ethical, methodological, and study quality benefits from engaging patients as partners in health research (6). These benefits have also been demonstrated through youth engagement in research, in particular, in the areas of health promotion (7), mental health (8, 9), chronic pain (10), and community development (11). When youth have been engaged in research, the results have also been more likely to be implemented and adopted widely (12, 13).

There is the emerging evidence around the benefits to engage patients as partners in clinical trials aimed to evaluate non-pharmacological or pharmacological interventions (14-17). These benefits include: (i) more appropriate and sensitive/ethical research designs; (ii) more appropriate wording and timing of administration of research instruments and interventions; (iii) improved readability and accessibility of research materials (*ethical benefits*); (iv) more patient and/or caregiver relevant research outcomes or endpoints (*methodological benefits*); (v) improved recruitment, retention, diversity, and trial experience/satisfaction of study participants; (vi) better adherence to the trial protocol; and (vii) faster study completion (*study quality benefits*) (17). Given this evidence, we saw the benefits of prioritizing engagement with patients as partners across the lifespan of our pediatric mental health care trial.

Overview: Mental Health Care Pediatric Clinical Trial

Trial development began in 2018, when members of our research team alongside a group of patients, families, and health care providers identified the need to make improvements to pediatric mental health care in emergency departments (EDs) (18). This group recognized EDs as a vital clinical care setting for children and youth experiencing acute mental health or substance misuse crises (19). Such crises were acknowledged to be stressful and overwhelming, leaving the youth and family vulnerable in the absence of appropriate care. The team reinforced the position that ED-based care should be: (1) family centred and multidisciplinary, (2) informed by evidence-based approaches that identify risk, inform ED care and disposition decision-making, and (3) consider family needs and preferences (19, 20). In response to this position, a novel 'bundle' of mental health care was created with feedback from patient partners. The bundle combines three evidence-based approaches to ED care, as follows:

1. Ask Suicide-Screening Questions (ASQ) to identify suicide risk at ED triage and to facilitate faster access to appropriate treatment pathways (21-23);
2. HEADS-ED, a clinical mnemonic (Home, Education, Activities/peers, Drug/alcohol, Suicidality, Emotions and behaviour, Discharge Resources), for a focused mental health psychosocial evaluation to guide ED care and disposition decision-making (20, 24); and
3. A 'Choice' appointment post-ED care, in accordance with the Choice And Partnership Approach (CAPA) to care. This is a family-centred approach to mental health service organization (25), and its use recognizes the value of connecting children and youth to follow-up services after a crisis.

The bundle will be evaluated using a type 1 comparative effectiveness-implementation hybrid design (26). A cluster randomized trial will evaluate the effectiveness of the bundle compared to current standards of ED mental health care, while bundle implementation will be

evaluated using multi-methods to better understand barriers and facilitators to the adoption in ED care. The trial will take place in eight pediatric EDs across Canada in partnership with Pediatric Emergency Research Canada (PERC), a national research network. The Conjoint Health Research Ethics Board (CHREB), University of Calgary approved this study effective January 4, 2021 (Reference ID: REB20-1825). This trial was registered at clinicaltrials.gov (Identifier: NCT04902391) with an estimated start date of November 1, 2021 and completion date of August 1, 2025. The protocol for this trial was submitted elsewhere for publication.

A patient engagement plan was created for the trial that was informed by principles of patient engagement from many sources, including those specific to youth and caregivers (2, 27-31). The plan will be evaluated in a trial sub-study that aims to evaluate the engagement of youth and caregivers in the design and conduct of the trial as well as research team member involvement in patient engagement.

Patient and Public Involvement

The study protocol was conceptualized by JR (lead for patient engagement sub-study) with support from ASN (co-principal investigator of the primary mental health care pediatric trial). LM (caregiver lead) and MP (youth lead) with lived experience reviewed and provided feedback on this study protocol. According to the patient engagement plan described below, all caregiver and youth advisory members, will be invited to provide feedback on both process and findings at different time-points across the primary mental health care pediatric trial. For the patient engagement evaluation study described below, caregiver and youth advisory group members will be invited to partake in the interpretation of the aggregate results, editing, and preparation of the manuscript for publication. Caregiver and youth advisory group members will be invited to contribute to the overall knowledge integration and dissemination plan. Both patient

partner contributors (LM and MP) met the ICMJE criteria for authorship and as such we acknowledge their valuable contributions through coauthorship of this study protocol. Engagement of patient partners has ensured further accuracy, readability, and relevance of this protocol to the science and practice of patient engagement in pediatric clinical trials.

Patient Engagement Plan

Overview

The patient engagement plan has two foci: (i) consultation in trial planning, whereby youth and caregivers had the opportunity as advisors to provide feedback on the trial design, and (ii) partnership, whereby youth and caregivers will be partners alongside research team members during trial conduct, with both groups actively involved in collaborating and leading trial related activities. These foci align with the practices recommended by the Canadian Institute of Health Research when developing partnerships between patients and researchers (33). We will use the term 'patient advisor' to denote those who are involved in a one-time engagement activity versus 'patient partner' who will provide feedback during patient engagement activities throughout the lifespan of the trial.

Participants and Recruitment

We used a multi-pronged approach to recruit patient partners representing two groups of people with lived experience: (1) caregivers (parents, formal/informal caregivers, and family) and (2) youth (ages 15-24 years). 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 2018 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 and trial planning. The participation of these advisors has concluded, with one partner staying as a team member for the trial.

The next phase of recruitment will focus on the participation of youth in a Youth Advisory Group and caregivers in a Caregiver Advisory Group; the groups will be active during trial conduct and post-trial knowledge translation activities. During youth and caregiver recruitment, we will prioritize equity, diversity, and inclusion-based practices in patient engagement (32), and plan to recruit individuals from different demographic groups, based on age, gender identity, cultural identity, disability, or education. We will set up two advisory groups to minimize power differentials amongst youth and caregivers and foster a safe space whereby all members are comfortable sharing their perspectives.

Youth engagement liaisons/coordinators from the Centre for Addiction and Mental Health (https://www.camh.ca/) (led by MP) will assist with recruitment of youth to join the Youth Advisory Group. Caregiver recruitment will be overseen by another team member (JL) who will use convenience sampling to recruit individuals through organizations partnered with the team (Canadian Mental Health Association, Translating Emergency Knowledge for Kids [TREKK], Children's Healthcare Canada).

Youth and caregivers who indicate interest in participating will be invited to attend a virtual introductory meeting (one for youth; one for caregivers) with the trial co-leads (SBF and ASN) and patient engagement leads (JR, MP, and LM). The meeting will provide an opportunity for individuals to learn about the trial and the goal of patient partner engagement. Those interested in joining the team as advisory group members will be asked to contact the trial's patient engagement evaluation study lead (JR) and youth engagement lead (MP) to further discuss and confirm their interest. Informed consent will be obtained at that time. Patient partners

can voluntarily revoke consent at any time during the course of the trial. The goal is to have membership in both advisory groups filled between November 2021 and January 2022; the trial begins February 2022.

Sample Size

We could not find evidence in the literature to support best practice for optimal group size for patient engagement in research. Therefore, we will exercise pragmatic considerations and recommendations from team members and project liaisons with extensive experience working in patient engagement. In particular, the size of the group should foster meaningful engagement, so that we are able to have robust discussion, and patient partners can share ideas in a safe space. Conversely, we do not want a group too large that it is ineffective to engage partners in discussions. We anticipate a target size of five to ten patient partners per advisory group will be sufficient to lead to a meaningful discussion.

Patient partners that do not continue for the full duration of planned patient engagement activities will be included in the sample if they are willing. Patient partners who attend the virtual introductory meeting with the study co-lead, but later decline to participate in an advisory group will be asked if they are willing to share confidentially the reasons that led to the decision to forego participation. If we have attrition of advisory group members at any stage of the engagement process, we want to have the opportunity to formally document their reasons that led to that decision as part of the evaluation of patient engagement.

Advisory Group Activities

Advisory groups will be co-chaired by (MP, LM, and JR). At the first meeting of each group, members will discuss group norms, establish terms of reference for the respective advisory groups, including role description, individual goals as they relate to the patient

engagement activities, frequency of meetings, compensation, and platforms to exchange and share information about the study. Patient partners will have the ability to choose the types of engagement activities that they would like to participate in, and this will be determined on an individual and/or advisory group basis. These activities include co-leading the advisory group alongside the chairs, providing feedback on recruitment materials for the trial and telephone scripts used during data collection with trial participants, informing changes to recruitment and retention processes during trial conduct, providing impressions on the results, and designing/preparing materials to disseminate trial results (e.g., statements for social media use, infographics for families). Patient partners will also have the opportunity to apply for funding to attend conferences and courses related to children's mental health (budgeted within the trial) and/or work with the patient engagement evaluation study lead (JR) to plan and conduct evaluation meetings.

Patient Engagement Evaluation Study

Design

We are using a mixed-method design to evaluate the trial's patient engagement plan (34, 35). This will involve surveying patient advisors and partners as well as research team members on engagement experiences followed by semi-structured interviews of patient partners to gather more detailed information on engagement experiences and activities highlighted in survey responses. We will use the Good Reporting of Mixed Method Study Criteria (38) and the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) (39) to assess the quality of reporting of our mixed method patient engagement evaluation study procedures and findings.

Framework for Measuring Patient Engagement

We are using a framework to guide outcome measurement. This framework contains four domains—integrity of design and process; flexibility; mentorship; influence and impact—and was adapted from the published literature on patient and youth engagement (31, 40). Integrity of design and process will be assessed by examining advisory group representation (e.g., Do members represent different experiences based on age, gender identity, cultural identity, disability, or education?) and how group members are supported in patient engagement activities (e.g., Are members compensated for their involved in activities? Is information produced at an appropriate education level for members?) (31). Flexibility of advisory groups with caregivers and youth will be assessed by examining the terms of reference (role, structure, norms, and frequency of interactions) of the groups and how those terms of reference are carried out across the research project (40). Mentorship will be assessed by asking patient partners about advisory group trial activities and opportunities that aligned with personal goals (40). Influence and impact will be assessed by examining whether patient engagement activities informed or changed trial decisions (31).

Measurement of Patient Engagement

Public and Patient Engagement Evaluation Tool

We will use the Public and Patient Engagement Evaluation Tool (PPEET) to measure patient engagement across our domains of interest: integrity of design and process, flexibility, mentorship, and influence and impact. The PPEET is comprised of two questionnaires which will allow us to evaluate perspectives and experiences of advisory group members (participant questionnaire) and research team members (project questionnaire). The participant questionnaire also contains questions to measure one-time and ongoing patient engagement experiences, which will ensure that patient partners with different experiences contribute to the evaluation. At this

time, we are aware of at least twenty-seven tools to evaluate patient and public engagement (1, 36, 37). We chose the PPEET because it was used to evaluate patient and public engagement within the context of health research, and the tool was highly rated by the Centre of Excellence on Partnership with Patients and the Public (CEPPP) (1, 36, 37).

In Table 1, we outline how our domains of interest will be measured using the PPEET participant and project questionnaires. We also identify time-points of when each questionnaire will be administered. Advisory group members will also be asked to fill out a six-item demographic questionnaire, as part of the PPEET, to provide to allow us to measure representation as part of integrity of design and process. The questions include year of birth, sex, group of people or communities one identifies with, highest level of education completed, current work status, and paid experience in a health care profession.

PPEET Participant Questionnaire

The one-time engagement questionnaire is comprised of 19 questions: 13 questions based on a five-point Likert scale (range: strongly disagree to strongly agree) and six open-ended questions. The questionnaire will be administered to each patient advisor immediately after the conclusion of an engagement activity. The on-going engagement questionnaire will be administered to patient partners every three to six months during trial conduct. This questionnaire is comprised of a total of 20 questions: 14 questions based on a five-point Likert scale (range: strongly disagree to strongly agree) and six open-ended questions.

PPEET Project Questionnaire

We will use the PPEET three-module project questionnaire to assess involvement in patient engagement among the principal investigators, project manager, implementation site leads, and youth engagement liaisons/coordinators. The first module (Module A) consists of 12

questions on a five-point Likert scale (range: strongly disagree to strongly agree) and three open-ended questions to assess how and whether study team members have chosen appropriate patient engagement activities during the planning stage. This module will be administered prior to trial conduct and after the run-in period. The second module (Module B) identifies how well patient engagement activities were executed (10 five-point Likert questions; six open-ended questions) and will be administered after the trial engagement activities are completed. The third module (Module C) will evaluate the impact of patient engagement activities. This module includes four questions (five-point Likert scale; range: strongly disagree to strongly agree) and four open-ended questions, that will be administered three to six months after the completion of the engagement activities.

Semi-Structured Interviews

We will interview patient partners at the end of the trial after the completion of all engagement activities. Interview questions will be developed based on the themes that emerge from the open-ended responses collected at different time-point using the PPEET with the intent to gather more information on engagement experiences and activities (43). Patient partners will be offered the choice to participate in individual or focus group interviews. Focus group interviews will be held separately for youth and caregivers. A final forum inviting all patient partners and research team members to attend will be held to discuss and obtain feedback on synthesized questionnaire results and interview findings.

Additional Data Sources: Supporting Documents and Trial Protocol Documents

Supporting documents for the pediatric mental health care trial such as meeting agendas, minutes, or tailored resources for advisory group members will be reviewed monthly and will serve as additional data sources to understand patient engagement activities. Trial protocol

documents will be collected annually from the trial research coordinator to determine how feedback from advisory group members were used to inform/modify trial decisions.

Data Collection and Management

We will administer the PPEET online using the Research Electronic Data Capture (REDCap©) tools (44) hosted and supported by the Women and Children's Health Research Institute at the University of Alberta. Data collected through this platform will be de-identified and will not be tracked to any individual participant. In exceptional cases, such as limited participant access to online environments, the PPEET will be administered via telephone with answers entered by the interviewer into the REDCap© database. Data will be stored in REDCap© until exported for analysis.

Semi-structured interviews will be conducted via telephone/video-conferencing platform hosted by the University of Calgary (Zoom©) and the audio will be recorded. Interview recordings will be transcribed verbatim, checked for accuracy against the original recordings, and identifiers will be removed from the transcripts to maintain confidentiality. Data from the semi-structured interviews and the audio recordings will be stored securely in a server at the University of Alberta until the data are transcribed and subsequently analyzed.

Field notes will be kept when additional data sources are reviewed. Supporting documents will be reviewed during regular advisory group meetings to keep informed of the trial progress. Trial protocol documents will be collected and reviewed annually from the trial research coordinator to note modifications that have been implemented across sites based on advisory group members' feedback.

Table 1. Overview of the approach to measuring patient engagement.

Integrity of design and process; Flexibility; Mentorship		
PPEET questionnaire	**Questionnaire outcomes**	**Administration time-point**
Participant Questionnaire*:* One-time engagement activities (Module A – Parts A and B)	• Advisory group members represent diverse range of views • Advisory group members are provided supports that enable participation in engagement activities • Online platforms suitable for communication with patient partners • Clear and bi-directional communication achieved among patient partners and researchers • Mentorship opportunities created and tailored to patient partners' interests	At the end of the activity on the same day
Participant Questionnaire*:* Ongoing engagement activities (Module B – Parts A and B)		Between 3-6 months
Project Questionnaire (Module A – Parts A, B, and C)		Pre-trial conduct (pre-recruitment of trial participants)
Influence and impact		
Participant Questionnaire*:* One-time engagement activities (Module A – Parts C and D)	• Engagement activities inform planning and/or decision making in the trial • Engagement activities improve patient partners' knowledge of mental health and substance use crises in emergency departments • Engagement activities improve patient partners' knowledge of the patient and family-centred acute mental health care bundle and need for implementation • Increased confidence and trust of patient partners in members of the team • Increased confidence of patient partners in the study purpose • Increased confidence of patient partners in the impact of bundle implementation on mental health	At the end of the activity on the same day
Participant Questionnaire: Ongoing engagement activities (Module B – Parts C and D)		Between 3-6 months
Project Questionnaire (Module B – Parts A, B, and C)	• Clinicians, staff, and researchers improve knowledge on patient partners' perspectives about the bundle	Post-activity
Project Questionnaire (Module C – Parts A, B, and C)		3-6 months after engagement has concluded

Data Analysis

Data from the PPEET will be entered into SPSS© Version 27. We will use descriptive statistics (e.g., means and standard deviations, medians with interquartile range) to report group characteristics and responses to the Likert scale questions. Frequency and percentages will be reported for categorical information. Data from open-ended questions (45) and semi-structured interviews will be imported into NVIVO © Version 12. We will undertake thematic analysis (45) to analyze these data. Data from open-ended questions will be grouped by question and then coded for common themes that arise across the data. The primary coder (research nurse or graduate student) and first author (JR) will meet at least three times during the development and application of the coding scheme as part of an iterative process to ensure coding reliability. Coding reliability by the study co-lead (ASN) will be completed to resolve inconsistencies or disputes and to review independent coding of selected data excerpts.

Data from semi-structured interviews will be analyzed using the coding scheme as a guide. Data that cannot be coded to existing codes or themes will be noted. In the later stages of analysis, the study co-lead (ASN) will independently code data excerpts to maintain coding reliability. Advisory group members' feedback on supporting documents and trial protocol documents will be reviewed and synthesized into field notes by a research nurse and research assistant, which will be reported as a narrative.

Ethics and Dissemination

Ethical approval for this study was obtained through the Athabasca University Research Ethics Board (file no: 24575) for one year and is subject for renewal on an annual basis since the project is ongoing beyond one year. All participating advisory group members will receive an information sheet that will provide details on the purpose of the study, identify the potential

risks/benefits, and explain the voluntary nature of their participation. Patient advisors and partners can revoke consent from participating in the parent or youth advisory group and evaluation activities at any time. Patient advisors and partners may choose to omit particular questions while filling out the survey or during the interview (pertains only to patient partners). All data will be de-identified; therefore, individual participant data cannot be removed once collected. Data will be kept confidential. All data will be stored using secured software on a password-protected server and device.

Patient engagement evaluation findings will be shared with parent and youth advisory group members during virtual meetings. Advisory group members will be asked about how the results fit within the organizing framework and whether the patient engagement outcomes were met. Dissemination of findings from this patient engagement evaluation study for the pediatric mental health care trial will be in the form of an academic publication in a reputable peer-reviewed journal, presentations at TREKK and PERC conferences/meetings, public presentations at appropriate venues, and as posts or blogs on the research study website and online platforms that are parent and youth friendly. Research team members and advisory group members will be invited to co-author, co-develop, and co-present these findings targeted at multiple venues.

Contributorship statement:

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Ethics ID: Athabasca University Research Ethics Board review was approved effective November 25, 2021. Reference ID: 24575 (Project title: Evaluation of Parent and Youth Experiences in Advisory Groups as part of a Mental Health Care Clinical Trial: Protocol for a Mixed Method Study)

Ethics ID for primary trial: The Conjoint Health Research Ethics Board (CHREB), University of Calgary review (Primary Site) was approved effective January 4, 2021. Reference ID: REB20-1825 (Project title: A Multi-Disciplinary, Patient-Partnered, Pan-Canadian, Comparative Effectiveness Evaluation of an Innovative Acute Pediatric Mental Health and Addiction Care Bundle)

Trial registration ID: clinicaltrials.gov; ClinicalTrials.gov Identifier: NCT04902391

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Checklist of items for the Good Reporting of A Mixed Methods Study (GRAMMS) guideline [1,2]

Mixed methods reporting within the protocol: Evaluation of Parent and Youth Experiences in Advisory Groups as part of a Mental Health Care Clinical Trial	
GRAMMS guideline	**Reported on Page Number**
1) Describes the justification for using a mixed methods approach to the research question	p. 6-11
2) Describes the design in terms of the purpose, priority and sequence of methods	p. 11
3) Describes each method in terms of sampling, data collection and analysis	p. 10-17
4) Describes the integration of the quantitative and qualitative components	N/A at the protocol stage
5) Describes any limitation of one method associated with the presence of the other method	p. 5 – overall strengths and limitations
6) Describes any insights gained from mixing or integrating methods	N/A at the protocol stage

GRAMMS Good Reporting of A Mixed Methods Study

Reference:

1. O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services research. J Health Serv Res Policy. 2008;13:92-98.

Guidance for Reporting Involvement of Patients and the Public (GRIPP2) Short Form [1]

Involvement of Patients and the Public reporting within the protocol: Evaluation of Parent and Youth Experiences in Advisory Groups as part of a Mental Health Care Clinical Trial		
Section	**Topic Item**	**Reported on Page Number**
1. Aim	Report the aim of patient and public involvement (PPI) in the study	p. 8-10
2. Methods	Provide a clear description of the methods used for PPI in the study	p. 11-15
3. Study results	Outcomes - Report the results of PPI in the study, including both positive and negative outcomes	N/A at protocol stage
4. Discussion and conclusions	Outcomes - Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	N/A at protocol stage
5. Reflections or critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	N/A at protocol stage

Reference:

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Abstract

Introduction: Patient engagement in health care research is a necessity to ensure that research objectives align with priorities, outcomes, and needs of the population under study, and to facilitate ease of implementation and adoption of findings. In clinical trials, there is an increasing focus on patient engagement during the planning and conduct of clinical trials due to the potential for ethical and methodological benefits. As patient engagement in clinical trials increases, there is a need to evaluate the approaches of these activities to contribute evidence on what is most appropriate and successful. The purpose of this study is to evaluate patient engagement processes and the activities of patient partners during and after a pediatric mental health care trial.

Methods and analysis: Using a mixed-methods study design, we will evaluate patient partners' engagement activities across set time points during the trial and after trial completion. In this study, the term "patient partner" is inclusive of two groups of people with lived experience: (1) caregivers (parents, formal/informal caregivers, and family), and (2) youth (ages 15-24 years). Engagement will be measured using the participant and project questionnaires of the Public and Patient Engagement Evaluation Tool (PPEET), followed sequentially by semi-structured interviews. Quantitative data from the PPEET questionnaire will be analyzed and reported using descriptive statistics. Data from open-ended questions from the PPEET questionnaires and semi-structured interviews will be analyzed using thematic analysis.

Ethics and dissemination: Approval from Athabasca University Research Ethics Board will be obtained for this project. Findings will be disseminated at both academic and public venues in-person and online using platforms that are caregiver and youth friendly.

Strengths and limitations of this study

- 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

Within the last decade, research funding organizations in the United Kingdom, United States, Canada, Australia, and New Zealand have required that patient engagement be an integral part of the design, conduct, dissemination, and implementation of findings emerging from social and health care research (1-5). Patient engagement occurs when patients become partners through meaningful and active collaboration across the research process (2, 6). A recent systematic review has reported ethical, methodological, and study quality benefits from engaging patients as partners in health research (6). These benefits have also been demonstrated through youth engagement in research, in particular, in the areas of health promotion (7), mental health (8, 9), chronic pain (10), and community development (11). 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).

There is the emerging evidence around the benefits to engage patients as partners in clinical trials aimed to evaluate non-pharmacological or pharmacological interventions (15-18). These benefits include: (i) more appropriate and sensitive/ethical research designs; (ii) more appropriate wording and timing of administration of research instruments and interventions; (iii) improved readability and accessibility of research materials (*ethical benefits*); (iv) more patient and/or caregiver relevant research outcomes or endpoints (*methodological benefits*); (v) improved recruitment, retention, diversity, and trial experience/satisfaction of study participants; (vi) better adherence to the trial protocol; and (vii) faster study completion (*study quality benefits*) (18). 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.

Overview: Mental Health Care Pediatric Clinical Trial

Trial development began in 2018, when members of our research team alongside a group of patients, families, and health care providers identified the need to make improvements to pediatric mental health care in emergency departments (EDs) (19). This group recognized EDs as a vital clinical care setting for children and youth experiencing acute mental health or substance misuse crises (20). Such crises were acknowledged to be stressful and overwhelming, leaving the youth and family vulnerable in the absence of appropriate care. The team reinforced the position that ED-based care should be: (1) family centred and multidisciplinary, (2) informed by evidence-based approaches that identify risk, inform ED care and disposition decision-making, and (3) consider family needs and preferences (20, 21). 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 (22). 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 (22). The bundle combines three evidence-based approaches to ED care, as follows:

1. Ask Suicide-Screening Questions (ASQ) to identify suicide risk at ED triage and to facilitate faster access to appropriate treatment pathways (23-25);
2. HEADS-ED, a clinical mnemonic (Home, Education, Activities/peers, Drug/alcohol, Suicidality, Emotions and behaviour, Discharge Resources), for a focused mental health psychosocial evaluation to guide ED care and disposition decision-making (21, 26); and
3. A 'Choice' appointment post-ED care, in accordance with the Choice And Partnership Approach (CAPA) to care. This is a family-centred approach to mental health service organization (27), and its use recognizes the value of connecting children and youth to follow-up services after a crisis.

The bundle will be evaluated using a type 1 comparative effectiveness-implementation hybrid design (28). A cluster randomized trial will evaluate the effectiveness of the bundle compared to current standards of ED mental health care, while bundle implementation will be evaluated using multi-methods to better understand barriers and facilitators to the adoption in ED care. The trial will take place in eight pediatric EDs across Canada in partnership with Pediatric Emergency Research Canada (PERC), a national research network. The Conjoint Health Research Ethics Board (CHREB), University of Calgary approved this study effective January 4, 2021 (Reference ID: REB20-1825). This trial was registered at clinicaltrials.gov (Identifier:

NCT04902391) with an estimated start date of November 1, 2021 and completion date of August 1, 2025. The protocol for this trial was submitted elsewhere for publication (see Appendix A for trial timeline).

A patient engagement plan was created for the trial that was informed by principles of patient engagement from many sources, including those specific to youth and caregivers (2, 12, 29-32). 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.

Patient and Public Involvement

The study protocol was conceptualized by JR (lead for patient engagement evaluation study) with support from ASN (co-principal investigator of the primary mental health care pediatric trial). LM (caregiver lead) and MP (youth lead) with lived experience and extensive experience in patient engagement reviewed and provided feedback on this study protocol. According to the patient engagement plan described below, all caregiver and youth advisory members, will be invited to provide feedback on both process and findings at different time-points across the primary mental health care pediatric trial. 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.

For the patient engagement evaluation study described below, caregiver and youth advisory group members will be invited to partake in the interpretation of the aggregate results, editing, and preparation of the manuscript for publication. Caregiver and youth advisory group members will be invited to contribute to the overall knowledge integration and dissemination plan. Both patient partner contributors (LM and MP) met the ICMJE criteria for authorship and as such we acknowledge their valuable contributions through coauthorship of this study protocol. Engagement of patient partners has ensured further accuracy, readability, and relevance of this protocol to the science and practice of patient engagement in pediatric clinical trials.

Patient Engagement Plan

Overview

The patient engagement plan has two foci: (i) consultation in trial planning, whereby youth and caregivers had the opportunity as advisors to provide feedback on the trial design, and (ii) partnership, whereby youth and caregivers will be partners alongside research team members during trial conduct, with both groups actively involved in collaborating and leading trial related activities. These foci align with the practices recommended by the Canadian Institute of Health Research when developing partnerships between patients and researchers (33). We will use the term 'patient advisor' to denote those who are involved in a one-time engagement activity versus 'patient partner' who will provide feedback during patient engagement activities throughout the lifespan of the trial.

Participants and Recruitment

We used a multi-pronged approach to recruit patient partners representing two groups of people with lived experience: (1) caregivers (including parents from diverse family forms), formal/informal caregivers, and family) and (2) youth (ages 15-24 years). 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.

The next phase of recruitment will focus on the participation of youth in a Youth Advisory Group and caregivers in a Caregiver Advisory Group; the groups will be active during trial conduct and post-trial knowledge translation activities. During youth and caregiver recruitment, we will prioritize equity, diversity, and inclusion-based practices in patient engagement (34), and plan to recruit individuals from different demographic groups, based on age, gender identity, cultural identity, disability, or education. We will set up two advisory groups to minimize power differentials amongst youth and caregivers and foster a safe space whereby all members are comfortable sharing their perspectives.

Youth engagement liaisons/coordinators from the Centre for Addiction and Mental Health (https://www.camh.ca/) (led by MP) will assist with recruitment of youth to join the Youth Advisory Group. Caregiver recruitment will be overseen by another team member (JL) who will use convenience sampling to recruit individuals through organizations partnered with the team (Canadian Mental Health Association, Translating Emergency Knowledge for Kids [TREKK], Children's Healthcare Canada).

Youth and caregivers who indicate interest in participating will be invited to attend a virtual introductory meeting (one for youth; one for caregivers) with the trial co-leads (SBF and ASN) and patient engagement leads (JR, MP, and LM). The meeting will provide an opportunity

for individuals to learn about the trial and the goal of patient partner engagement. Those interested in joining the team as advisory group members will be asked to contact the trial's patient engagement evaluation study lead (JR) and youth engagement lead (MP) to further discuss and confirm their interest. Informed consent will be obtained at that time. Patient partners can voluntarily revoke consent at any time during the course of the trial. Patient partners will be supported by the patient engagement leads throughout the course of the project, as described further under advisory group activities. The goal is to have membership in both advisory groups filled between November 2021 and January 2022; the trial begins February 2022.

Sample Size

We could not find evidence in the literature to support best practice for optimal group size for patient engagement in research. Therefore, we will exercise pragmatic considerations and recommendations from team members and project liaisons with extensive experience working in patient engagement. In particular, the size of the group should foster meaningful engagement, so that we are able to have robust discussion, and patient partners can share ideas in a safe space. Conversely, we do not want a group too large that it is ineffective to engage partners in discussions. We anticipate a target size of five to ten patient partners per advisory group will be sufficient to lead to a meaningful discussion.

Patient partners that do not continue for the full duration of planned patient engagement activities will be included in the sample if they are willing. Patient partners who attend the virtual introductory meeting with the study co-lead, but later decline to participate in an advisory group will be asked if they are willing to share confidentially the reasons that led to the decision to forego participation. If we have attrition of advisory group members at any stage of the

engagement process, we want to have the opportunity to formally document their reasons that led to that decision as part of the evaluation of patient engagement.

Advisory Group Activities

Advisory groups will be co-chaired by (MP, LM, and JR). At the first meeting of each group, members will discuss group norms, establish terms of reference for the respective advisory groups, including role description and individual goals as they relate to the patient engagement activities. 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. Patient partners will have the ability to choose the types of engagement activities that they would like to participate in, and this will be determined on an individual and/or advisory group basis. These activities include co-leading the advisory group alongside the chairs, providing feedback on recruitment materials for the trial and telephone scripts used during data collection with trial participants, informing changes to recruitment and retention processes during trial conduct, providing impressions on the results, and designing/preparing materials to disseminate trial results (e.g., statements for social media use, infographics for families). Patient partners will also have the opportunity to apply for funding to attend conferences and courses related to children's mental health (budgeted within the trial) and/or work with the patient engagement evaluation study lead (JR) to plan and conduct evaluation meetings.

Patient Engagement Evaluation Study

Design

We are using a mixed-method design to evaluate the trial's patient engagement plan (35, 36). 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). This will involve surveying patient advisors and partners as well as research team members on engagement experiences followed by semi-structured interviews of patient partners to gather more detailed information on engagement experiences and activities highlighted in survey responses. 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. We will use the Good Reporting of Mixed Method Study Criteria (38) and the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) (39) to assess the quality of reporting of our mixed method patient engagement evaluation study procedures and findings.

Framework for Measuring Patient Engagement

We are using a framework to guide outcome measurement. This framework contains four domains—integrity of design and process; flexibility; mentorship; influence and impact—and was adapted from the published literature on patient and youth engagement (32), (40). Integrity of design and process will be assessed by examining advisory group representation (e.g., Do members represent different experiences based on age, gender identity, cultural identity, disability, or education?) and how group members are supported in patient engagement activities (e.g., Are members compensated for their involved in activities? Is information produced at an appropriate education level for members?) (32). Flexibility of advisory groups with caregivers and youth will be assessed by examining the terms of reference (role, structure, norms, and

frequency of interactions) of the groups and how those terms of reference are carried out across the research project (40). Mentorship will be assessed by asking patient partners about advisory group trial activities and opportunities that aligned with personal goals (40). Influence and impact will be assessed by examining whether patient engagement activities informed or changed trial decisions (32).

Measurement of Patient Engagement

Public and Patient Engagement Evaluation Tool

We will use the Public and Patient Engagement Evaluation Tool (PPEET) to measure patient engagement across our domains of interest: integrity of design and process, flexibility, mentorship, and influence and impact. The PPEET is comprised of two questionnaires which will allow us to evaluate perspectives and experiences of advisory group members (participant questionnaire) and research team members (project questionnaire). The participant questionnaire also contains questions to measure one-time and ongoing patient engagement experiences, which will ensure that patient partners with different experiences contribute to the evaluation. At this time, we are aware of at least twenty-seven tools to evaluate patient and public engagement (1, 41, 42). We chose the PPEET because it was used to evaluate patient and public engagement within the context of health research. 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, 41, 42).

In Table 1, we outline how our domains of interest will be measured using the PPEET participant and project questionnaires. We also identify time-points of when each questionnaire will be administered. Advisory group members will also be asked to fill out a six-item demographic questionnaire, as part of the PPEET, to provide to allow us to measure

representation as part of integrity of design and process. The questions include year of birth, sex, group of people or communities one identifies with, highest level of education completed, current work status, and paid experience in a health care profession. Additionally, we will include a description about advisory members' previous experience with patient engagement in research (information will be obtained when we recruit members).

PPEET Participant Questionnaire

The one-time engagement questionnaire is comprised of 19 questions: 13 questions based on a five-point Likert scale (range: strongly disagree to strongly agree) and six open-ended questions. The questionnaire will be administered to each patient advisor immediately after the conclusion of an engagement activity. The on-going engagement questionnaire will be administered to patient partners every three to six months during trial conduct. This questionnaire is comprised of a total of 20 questions: 14 questions based on a five-point Likert scale (range: strongly disagree to strongly agree) and six open-ended questions.

PPEET Project Questionnaire

We will use the PPEET three-module project questionnaire to assess involvement in patient engagement among the principal investigators, project manager, implementation site leads, and youth engagement liaisons/coordinators. The first module (Module A) consists of 12 questions on a five-point Likert scale (range: strongly disagree to strongly agree) and three open-ended questions to assess how and whether study team members have chosen appropriate patient engagement activities during the planning stage. This module will be administered prior to trial conduct and after the run-in period. The second module (Module B) identifies how well patient engagement activities were executed (10 five-point Likert questions; six open-ended questions) and will be administered after the trial engagement activities are completed. The third module

(Module C) will evaluate the impact of patient engagement activities. This module includes four questions (five-point Likert scale; range: strongly disagree to strongly agree) and four open-ended questions, that will be administered three to six months after the completion of the engagement activities.

Semi-Structured Interviews

We will interview patient partners at the end of the trial after the completion of all engagement activities. Interview questions will be developed based on the themes that emerge from the open-ended responses collected at different time-point using the PPEET with the intent to gather more information on engagement experiences and activities (43). 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. Focus group interviews will be held separately for youth and caregivers. A final forum inviting all patient partners and research team members to attend will be held to discuss and obtain feedback on synthesized questionnaire results and interview findings.

Additional Data Sources: Supporting Documents and Trial Protocol Documents

Supporting documents for the pediatric mental health care trial such as meeting agendas, minutes, or tailored resources for advisory group members will be reviewed monthly and will serve as additional data sources to understand patient engagement activities. Trial protocol documents will be collected annually from the trial research coordinator to determine how feedback from advisory group members were used to inform/modify trial decisions.

Data Collection and Management

We will administer the PPEET online using the Research Electronic Data Capture (REDCap©) tools (44) hosted and supported by the Women and Children's Health Research

Institute at the University of Alberta. Data collected through this platform by a research nurse/graduate student will be de-identified and will not be tracked to any individual participant. In exceptional cases, such as limited participant access to online environments, the PPEET will be administered via telephone with answers entered by the interviewer into the REDCap© database. Data will be stored in REDCap© until exported for analysis.

Semi-structured interviews will be conducted via telephone/video-conferencing platform hosted by the University of Calgary (Zoom©) and the audio will be recorded. Interview recordings will be transcribed verbatim, checked for accuracy against the original recordings, and identifiers will be removed from the transcripts to maintain confidentiality. Data from the semi-structured interviews and the audio recordings will be stored securely in a server at the University of Alberta until the data are transcribed and subsequently analyzed.

Field notes will be kept when additional data sources are reviewed. Supporting documents will be reviewed during regular advisory group meetings to keep informed of the trial progress. Trial protocol documents will be collected and reviewed annually from the trial research coordinator to note modifications that have been implemented across sites based on advisory group members' feedback.

Table 1. Overview of the approach to measuring patient engagement.

Integrity of design and process; Flexibility; Mentorship		
PPEET questionnaire	**Questionnaire outcomes**	**Administration time-point**
Participant Questionnaire*:* One-time engagement activities (Module A – Parts A and B)	• Advisory group members represent diverse range of views • Advisory group members are provided supports that enable participation in engagement activities • Online platforms suitable for communication with patient partners • Clear and bi-directional communication achieved among	At the end of the activity on the same day
Participant Questionnaire*:* Ongoing engagement activities (Module B – Parts A and B)		Between 3-6 months
Project Questionnaire (Module A – Parts A, B, and C)		Pre-trial conduct (pre-recruitment of trial participants)

	patient partners and researchers • Mentorship opportunities created and tailored to patient partners' interests	
Influence and impact		
Participant Questionnaire*:* One-time engagement activities (Module A – Parts C and D)	• Engagement activities inform planning and/or decision making in the trial • Engagement activities improve patient partners' knowledge of mental health and substance use crises in emergency departments • Engagement activities improve patient partners' knowledge of the patient and family-centred acute mental health care bundle and need for implementation • Increased confidence and trust of patient partners in members of the team • Increased confidence of patient partners in the study purpose • Increased confidence of patient partners in the impact of bundle implementation on mental health	At the end of the activity on the same day
Participant Questionnaire: Ongoing engagement activities (Module B – Parts C and D)		Between 3-6 months
Project Questionnaire (Module B – Parts A, B, and C)	• Clinicians, staff, and researchers improve knowledge on patient partners' perspectives about the bundle	Post-activity
Project Questionnaire (Module C – Parts A, B, and C)		3-6 months after engagement has concluded

Data Analysis

Data from the PPEET will be entered into SPSS© Version 27. We will use descriptive statistics (e.g., means and standard deviations, medians with interquartile range) to report group characteristics and responses to the Likert scale questions. Frequency and percentages will be reported for categorical information. Data from open-ended questions (45) and semi-structured interviews will be imported into NVIVO © Version 12. We will undertake thematic analysis (45) to analyze these data. Data from open-ended questions will be grouped by question and then coded for common themes that arise across the data. The primary coder (research nurse or

graduate student) and first author (JR) will meet at least three times during the development and application of the coding scheme as part of an iterative process to ensure coding reliability. Coding reliability by the study co-lead (ASN) will be completed to resolve inconsistencies or disputes and to review independent coding of selected data excerpts.

Data from semi-structured interviews will be analyzed using the coding scheme as a guide. Data that cannot be coded to existing codes or themes will be noted. In the later stages of analysis, the study co-lead (ASN) will independently code data excerpts to maintain coding reliability. Advisory group members' feedback on supporting documents and trial protocol documents will be reviewed and synthesized into field notes by a research nurse and research assistant, which will be reported as a narrative.

Ethics and Dissemination

Ethical approval for this study was obtained through the Athabasca University Research Ethics Board (file no: 24575) for one year and is subject for renewal on an annual basis since the project is ongoing beyond one year. All participating advisory group members will receive an information sheet that will provide details on the purpose of the study, identify the potential risks/benefits, and explain the voluntary nature of their participation. Patient advisors and partners can revoke consent from participating in the parent or youth advisory group and evaluation activities at any time. Patient advisors and partners may choose to omit particular questions while filling out the survey or during the interview (pertains only to patient partners). All data will be de-identified; therefore, individual participant data cannot be removed once collected. Data will be kept confidential. All data will be stored using secured software on a password-protected server and device.

Patient engagement evaluation findings will be shared with parent and youth advisory group members during virtual meetings. Advisory group members will be asked about how the results fit within the organizing framework and whether the patient engagement outcomes were met. Dissemination of findings from this patient engagement evaluation study for the pediatric mental health care trial will be in the form of an academic publication in a reputable peer-reviewed journal, presentations at TREKK and PERC conferences/meetings, public presentations at appropriate venues, and as posts or blogs on the research study website and online platforms that are parent and youth friendly. Research team members and advisory group members will be invited to co-author, co-develop, and co-present these findings targeted at multiple venues.

Contributorship statement:

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in BMJ Open and any other BMJ products and to exploit all rights, as set out in our licence.

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The study protocol was conceptualized by JR (lead for patient engagement sub-study) with support from ASN (co-principal investigator of the primary mental health care pediatric trial). LM (caregiver lead) and MP (youth lead) with lived experience reviewed and provided feedback on this study protocol. SBF (co-principal investigator of the primary mental health care pediatric trial) critically reviewed the manuscript while considering the pediatric trial timeline. KP was instrumental in creating the first draft of the patient engagement plan and obtaining feedback about the patient engagement activities from patient partners. ME, YF, GH, M-JS, J-TF, ASS, IG, MS, AM, LK, BG, LHP, SM, ELL, BW, GD, RP, KH, and YNAH reviewed the manuscript and provided feedback on feasibility and timing of the patient engagement activities and planned evaluation methods.

Competing interests: None declared.

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Data sharing statement: No, do not send my information to Dryad.

Ethics ID: Athabasca University Research Ethics Board review was approved effective November 25, 2021. Reference ID: 24575 (Project title: Evaluation of Parent and Youth Experiences in Advisory Groups as part of a Mental Health Care Clinical Trial: Protocol for a Mixed Method Study)

Ethics ID for primary trial: The Conjoint Health Research Ethics Board (CHREB), University of Calgary review (Primary Site) was approved effective January 4, 2021. Reference ID: REB20-1825 (Project title: A Multi-Disciplinary, Patient-Partnered, Pan-Canadian, Comparative Effectiveness Evaluation of an Innovative Acute Pediatric Mental Health and Addiction Care Bundle)

Trial registration ID: clinicaltrials.gov; ClinicalTrials.gov Identifier: NCT04902391

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Appendix A: Pediatric Mental Health Care Trial

	Y1		Y2				Y3				Y4				Y5			
	2020		2021				2022				2023				2024			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Experimental Intervention Sites (N=4)																		
	Preparation						Run-In	Bundle Implementation										Data Analysis
Control Intervention Sites (N=4)																		
	Preparation						Run-In	Routine/existing approach to mental healthcare										Data Analysis

Y=: year; Q: quarter

Appendix B: Advisory Group Activities

Trial Milestones	Activities	Status	Year(Y)/Quarter (Q)
Bundle and protocol refinement	Feedback on bundle implementation and study survey	Completed	2018 (during grant application/submission stage)
Trial governance	Caregiver advisory group lead attends national team meetings	Ongoing	Y3:2022/Q1
	Establish lead for youth advisory group	Completed	Y2:2021/Q4
	Finalize contracts with CAMH	Completed	Y2:2021/Q4
	Two advisory groups established to inform trial activities: Youth advisory group (led by CAMH youth lead) and Caregiver advisory group (led by caregiver lead)	Recruitment & Onboarding of advisory group members	Y3:2022/Q1
Integrated knowledge translation	Co-create educational tools for youth, families, and/or health care providers on clinical care changes (intervention sites with info on bundle of care)	Not yet started	Y3:2022/Q1
	Co-create recruitment materials for the study	Not yet started	Y3:2022/Q1
	Co-create newsletter updates for social media; email; website about the study and seed grant calls	Not yet started	Y3:2022/Q2-Q4 Y4:2023/Q1-Q4 Y5:2024/Q1-Q4
Personal development	Seed grant to carry out a project(s) in acute mental healthcare and travel grant to attend meeting or conference	Not yet started	Y3:2022/Q1-Q4 Y4:2023/Q1-Q4
Supporting implementation	Input on trial activities including support in writing trial updates	Not yet started	Y3:2022/Q1-Q4 Y4:2023/Q1-Q4 Y5:2024/Q1-Q4
End-of-grant knowledge translation	Forum with all patient partners and research team members	Not yet started	Y5:2024/Q4
	Co-design 1-2-page bottom-line summaries targeting health care providers on	Not yet started	Y5:2024/Q4 Y6:2025/Q1

	acute mental healthcare recommendations		
	Development of scientific summaries	Not yet started	Y5:2024/Q4 Y6:2025/Q1
	Patient partners with interest in collaborating on manuscripts will be considered for authorship, and may have the opportunity to co-present findings and public and scientific forums/conferences	Not yet started	Y5:2024/Q4 Y6:2025/Q1

Checklist of items for the Good Reporting of A Mixed Methods Study (GRAMMS) guideline [1,2]

Mixed methods reporting within the protocol: Evaluation of Parent and Youth Experiences in Advisory Groups as part of a Mental Health Care Clinical Trial	
GRAMMS guideline	**Reported on Page Number**
1) Describes the justification for using a mixed methods approach to the research question	p. 6-11
2) Describes the design in terms of the purpose, priority and sequence of methods	p. 11
3) Describes each method in terms of sampling, data collection and analysis	p. 10-17
4) Describes the integration of the quantitative and qualitative components	p. 13
5) Describes any limitation of one method associated with the presence of the other method	p. 5 – overall strengths and limitations
6) Describes any insights gained from mixing or integrating methods	N/A at the protocol stage

GRAMMS Good Reporting of A Mixed Methods Study

Reference:

1. O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services research. J Health Serv Res Policy. 2008;13:92-98.

Guidance for Reporting Involvement of Patients and the Public (GRIPP2) Short Form [1]

Involvement of Patients and the Public reporting within the protocol: Evaluation of Parent and Youth Experiences in Advisory Groups as part of a Mental Health Care Clinical Trial		
Section	**Topic Item**	**Reported on Page Number**
1. Aim	Report the aim of patient and public involvement (PPI) in the study	p. 8-10
2. Methods	Provide a clear description of the methods used for PPI in the study	p. 11-15
3. Study results	Outcomes - Report the results of PPI in the study, including both positive and negative outcomes	N/A at protocol stage
4. Discussion and conclusions	Outcomes - Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	N/A at protocol stage
5. Reflections or critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	N/A at protocol stage

Reference:

1. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research BMJ 2017; 358 :j3453 doi:10.1136/bmj.j3453