BMJ Open Ontario COVID-19 and Kids Mental Health Study: a study protocol for the longitudinal prospective evaluation of the impact of emergency measures on child and adolescent mental health during the COVID-19 pandemic

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ABSTRACT

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Correspondence to Dr Daphne J Korczak; daphne.korczak@sickkids.ca Introduction The COVID-19 pandemic has impacted the mental health (MH) of children, adolescents and parents. Whereas youth with MH disorders and neurodevelopmental disorders (NDD) may be at higher risk for exacerbations in emotional and behavioural distress, children and adolescents without pre-existing MH disorders or NDD may also experience MH deterioration due to increases in stress, changes in health behaviours, loss of activities/ school closures or loss of resources. Little is known about the impact of the COVID-19 emergency measures (EMs) on children's MH over the course of the pandemic.

Methods and analysis Longitudinal study of four well-established, pre-existing cohorts in Ontario (two recruited in clinical settings, two recruited in community settings). Primary outcomes include the impact of EMs on six MH domains: depression, anxiety, irritability, inattention, hyperactivity and obsessive-compulsive behaviours. Risk and protective factors related to youth MH profiles and trajectories will be identified. In addition, the effects of school mitigation strategies, changes in MH services and family factors (ie, parental MH, economic deprivation and family functioning) on children's MH will be examined. Data will be collected via repeated online survey measures selected to ensure reliability and validity for the proposed populations and distributed through the pandemic periods.

Ethics and dissemination The study was approved by institutional research ethics boards at participating research sites. Results will be disseminated through a robust knowledge translation partnership with key knowledge users. Materials to inform public awareness will be co-developed with educators, public health, and MH and health service providers. Connections with professional associations and MH advocacy groups will be leveraged to support youth MH policy in relation to EMs. Findings will further be shared through conference presentations, peer-reviewed journals and open-access publications.

Strengths and limitations of this study

- Longitudinal study of the impact of COVID-19 public health emergency measures on the mental health of children, adolescents and parents among a large participant group.
- Comprised of an enriched sample of children and youth with pre-existing mental health and neurodevelopmental concerns and includes a wide age range of children, allowing for the examination of the impact of the pandemic over the entirety of the child and adolescent developmental period.
- The study is strengthened by the incorporation of validated measures of both mental health symptoms and health behaviours (eg, physical activity, screen time and sleep) and further includes child and youth reports, in addition to parent-report measures, to directly assess child and adolescent experiences and symptoms.
- As a convenience sample based on existing cohorts, ethnically diverse and low-income participants may be under-represented.

INTRODUCTION

In Canada, the COVID-19 pandemic has had an immense impact on society and has been equated to a disaster. At national, provincial and municipal levels, governments have imposed public health directives that necessitate physical (social) distancing and selfisolation measures (COVID-19 emergency measures, EM).

Brief timeline and reference points of EMs in Ontario, Canada

The first 'lockdown' (ie, the strictest EM) began with the announcement of an extended March Break in public schools,¹ followed

by the declaration of a state of emergency on 17 March 2020.² Two lockdowns have since been implemented corresponding with waves of the virus (26 December 2020³ and 7 April 2021.⁴ For an abbreviated overview of the EM timeline in Ontario until the third wave, see online supplemental figure 1.

Despite community spread of the virus, attempts were made to maintain or modify services and activities for children and adolescents. Elementary school students resumed in-person learning full time in September 2020; for high school students, a hybrid model of virtual and in-person learning was implemented on a modified quadmester-based schedule. Schools were closed for in-person learning during the second viral wave from December 2020 to February 2021 and again during the third viral wave from April to June 2021. Daycares and preschools remained open (after initially closing) following the original lockdown in Spring 2020. Students had the option to resume in-person learning or continue virtual learning in September 2021.⁵ School sports and extracurricular activities have been largely cancelled or modified (ie, offered virtually) since March 2020.⁴⁶

Following the first lockdown, youth organised sports resumed under 'Return to Play' guidelines,⁷ adjusted to practice-only directives,⁸ and eventually, cancelled.⁹ Outdoor recreational facilities (ie, parks/playgrounds, sports fields, skating rinks) were intermittently opened as determined by municipalities for informal play, as long as social distancing directives were maintained to December 2020¹⁰ and then had access reduced into spring of 2021.¹¹ Outdoor recreation was ultimately opened and permitted beginning 22 May 2021.¹² Indoor activities (ie, day camps, sports, community groups and clubs) largely remained closed throughout the first year of pandemic, with some exceptions during Fall 2020.¹³ New mandates were released in Fall 2021 permitting indoor sports to resume with modfications.¹⁴

Impacts of EMs on mental health in children and adolescents

As there has been considerable variability in social permissions granted to children and adolescents throughout the pandemic, their daily routines have been significantly disrupted. Daily routines are instrumental in maintaining physical health, regulating sleep cycles and providing social interactions, all of which are key protective factors for children's and adolescents' mental health (MH).¹⁵⁻¹⁷ Initial findings from cross-sectional studies conducted in China suggested COVID-19 EMs had a significant psychological impact on children and adolescents.¹⁸ In adolescents specifically, there were significant associations between fear of COVID-19 and increased depressive and anxiety symptoms (44% and 37%, respectively),18 19 as well as significant elevations overall in irritability, inattention, anxiety and depression.^{18 20} However, cross-sectional studies yield little understanding of the MH trajectories of children and families throughout the fluctuating, socially restricting periods of the pandemic.²¹ This is further compounded by the lack of knowledge regarding

the impact of EMs on the potentially more vulnerable proportion of children $(1 \text{ in } 5)^{22}$ with pre-existing MH disorders as well as children with neurodevelopmental disorders (NDD) diagnoses (ie, autism spectrum disorder (ASD), obsessive–compulsive disorder (OCD), attention-deficit/hyperactivity disorder (ADHD)) who are 3–6 more times likely to develop MH difficulties.²³

To date, research on the impact of the pandemic has suggested both deleterious²⁴⁻²⁷ and beneficial²⁶ effects on MH in children with previous MH and/or NDD diagnoses. For example, authors have suggested that children with a previous depression diagnosis may experience exacerbations of feelings of loneliness and despair due to social isolation, whereas youth with social anxiety may experience improvements in MH^{28 29} secondary to reduced social exposures. Moreover, for youth with ASD, consistent routines are integral to their mental well-being.³⁰ Abrupt disruptions to regular services and supports for children with ASD lead to increased risk of behavioural outbursts and emotional distress.^{31 32} Parents and families of children with NDD may require access to in-person support services and specialised advice to manage their child's behavioural and MH difficulties which may have become unavailable or virtual during the pandemic, apart from those in acute settings such as emergency departments.^{33 34}

In addition, concerns about prolonged use of screens,^{35–41} social media^{42–46} and increased sedentary behaviour^{45–47–49} among children and adolescents have been raised. The potential impact on parent stress and family routines and dynamics,^{50–54} as well as concerns regarding the disproportionate impacts of EMs on children within racialised groups and lower income families^{50–55–56} have also been highlighted during the pandemic.^{52–57} Loss of services and supports may further impact these families as resource deficits (ie, reliable internet and device access) may prevent access to health, developmental and educational virtual services.^{50–58}

To date, a growing body of research²⁷ ⁵² ⁵³ ⁵⁹⁻⁶⁴ has provided compelling data regarding the relative impacts of COVID-19 exposure and EM implementation on child, youth and parent MH functioning (including caregivers and legal guardians). Yet very few studies have examined child, youth and family MH, particularly in child populations identified with MH and/or NDD diagnoses, over the longitudinal course of the pandemic.²¹ It may be that imposed EMs influence MH differentially across youth age groups (infancy to 18 years) and previous diagnoses (MH or NDD). Together, these distinctive aims will demonstrate the MH trajectories of children and youth throughout the course of the pandemic to justify and inform policy and investment for children's MH, both during and after the COVID-19 pandemic.

Study aims

The overarching aim of this research collaborative is to examine the longitudinal impact of EMs on the MH status of children, youth and their parents/caregivers over the course of the COVID-19 pandemic and beyond. The current protocol describes the programme of research to be undertaken by the collaborative. Specific aims, listed below, will be addressed in separate publications:

- ► Aim 1: To determine the impact of COVID-19 EMs on child and youth MH profiles including anxiety, depression, attention, hyperactivity and irritability for children and adolescents with and without known psychiatric and NDD over time.
- ► Aim 2: To identify risk and protective factors associated with child and youth MH symptoms (anxiety, depression, attention, hyperactivity, irritability and OCD) during COVID-19 EMs.
- ► Aim 3: To compare the effects of EMs on trajectories of MH symptoms for children and youth with known psychiatric and NDD compared with children and youth without known disorders over time.
- ► Aim 4: To examine the effect of school mitigation strategies (eg, virtual learning, mandatory face masks and physical distancing, and cancellation of events, activities, and sports) and their impact on MH symptoms, school engagement and academic outcomes for children and youth with and without known MH/ NDD diagnoses.
- ► Aim 5: To assess the impact of COVID-19 EMs on MH care service use (eg, family doctor appointments, urgent care or emergency department visitations for MH concerns, in-school learning supports, therapies, counselling and MH and psychiatric supports) and its impact on MH for children and youth with and without known psychiatric and NDD.
- Aim 6: To determine the effects of EM stressors on parent, child and youth MH including parent stress and MH symptoms, economic deprivation, family functioning, and social isolation.

Study design

This is a longitudinal observational study, employing repeated measures and embedded within four unique but complementary pre-existing research cohorts (see figure 1 and study population for descriptions). Research teams worked to harmonise core MH and health behaviour constructs and implement validated measures across age

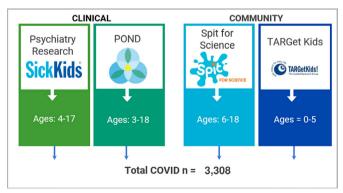


Figure 1 Characterisation of included research cohorts. POND, Province of Ontario Neurodevelopmental Disorder.

groups. Where possible, consistency in survey design, item order, information letters and participant instructions were maintained among cohorts to alleviate potential selection effects within cohorts. We have continued to allow rolling recruitment. Data collection will continue as long the initial study funds provide with opportunity for extension into transition and recovery pandemic periods.

Study setting

Parents who previously consented to be contacted for research within each cohort were approached regarding participation in the study. Using electronic data capture software, parents of children 2–18 years old and children and youth (10–18 years old) complete surveys online.

Study population

- 1. SickKids Psychiatry (SK Psychiatry): a clinical sample of children/adolescents (ages 6–18 years) and their families from diverse socioeconomic backgrounds in the Greater Toronto Area. These families were referred to an outpatient MH clinic at SK, a tertiary care centre for children, for evaluation of MH concerns including depression and anxiety disorders, ADHD, OCD and disruptive behaviour disorders.
- The Province of Ontario Neurodevelopmental Disorder (POND)⁶⁵: a clinical sample of children/adolescents (ages 6–18 years) throughout Ontario receiving care at outpatient clinics for NDD include ASD, ADHD, OCD and intellectual disabilities.
- 3. The Applied Research Group for Kids (TARGet Kids!)⁶⁶: a community sample of healthy children and their parents, recruited from primary care practices in the Greater Toronto Area, Ontario. Children in TAR-Get Kids! were initially recruited to TARGet Kids! before they were 6 years of age, and followed until 18 years of age.
- 4. Spit for Science (S4S)⁶⁷: a population-based sample of children, adolescents (ages 6–18 years), and parents recruited at an urban science museum (Ontario Science Centre) to explore the impact of genes and environment on health and MH.

Sample size justification

The current sample is one of convenience from four existing cohorts as participants are not selected for invitation or inclusion based on any specific characteristics. All participants within each of the four cohorts with data from the previous 18 months were approached and invited to participate without exclusion. The sample is composed of children and adolescents from the province of Ontario, Canada.

Inclusionary and exclusionary factors

Inclusion criteria: Parent with child 2–18 years of age and/or child 10–18 years of age Exclusion criteria: Parents unable to read/communicate in English, unable to complete study measures electronically (online). Children and adolescents with developmental delay or moderate/severe ASD are excluded from the child and youth self-report component.

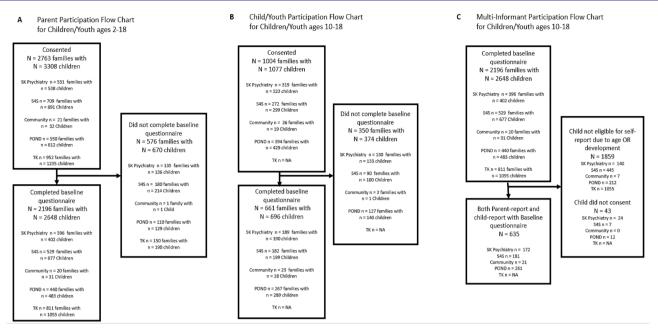


Figure 2 Participant consent and participation of parents and children/youth. NA, not available; POND, Province of Ontario Neurodevelopmental Disorder; SK, Spit for Science; S4S, Spit for Science;

Recruitment, consent, data collection

This study employs rolling recruitment among the cohorts, with participants approached by email or telephone. The first participants were approached during the first active lockdown (wave 1) of the pandemic (May, 2020). Email invitations and study instruments are sent using an Research Electronic Data Capture application (REDCap).^{68 69} Interested participants are directed to a study information form which outlines the purpose of the study, risks and benefits of participation, confidentiality, data management and sharing procedures and compensation information. Consent to use previously collected data, if applicable (eg, medication, MH symptoms), is also included. This study uses implied consent for participation, and parents and eligible children/youth indicate their agreement to participate on the study information form. Once complete, consenting parents receive a subsequent email with survey links.

The current sample of parents who consent to participate in the study within SK Psychiatry, S4S, POND and TARGet Kids! (TK) is 2742 (children and youth ages 2–18 years). A small sample of participants (n=21) were recruited outside of the cohorts, within the community. The number of children and youth ages 10–18 years who have consented to participate in the study is 1077. The number of parents and children who consented but did not complete the baseline questionnaire is 576 and 350, respectively. Greater detail of study consent and participation is presented in figure 2.

Patient and public involvement

Children, youth, parents and educators were involved in the design of study instruments and provided pilot testing and feedback on these tools to ensure that items and outcomes were clear, comprehensible and relevant to children and families. Children, youth, parents and educators will continue to be involved in this capacity. Results will be disseminated to study participants by plain language reports, infographics, invited and public presentations to parent, school, and community groups, and media releases (see Ethics and Dissemination section below for further detail)

Procedure

Questionnaires are distributed electronically via REDCap and will continue to be administered through the postpandemic period as funding allows. Baseline measures were administered to SK Psychiatry, POND and S4S cohorts beginning 19 May 2020. Subsequent surveys include those specific to the school environment as well as MH outcomes for children and parents.

Participants will receive CDN\$20 in gift cards following each survey completion, in recognition of their time and effort in completing the online survey. In addition, participants are entered in a monthly draw for a CDN\$100 gift card following survey completion. Corresponding EMs at the time of each survey distribution will be tracked by directives mandated by Public Health Ontario and Ontario school boards. An approximated timeline of the study is found in figure 3.

Figure 3. Study Timeline

Quantitative measures

MH measures with demonstrated validity among children and adolescents have been used where possible. Items from the newly developed The CoRonavIruS health Impact Survey (CRISIS),⁷⁰ a large international collaborative MH research project, are included. In the absence of a validated measure, (ie, measure of COVID-19-related public health measures in schools), items will be adapted

	Spring 2020	Summer 2020	Fall 2020	Winter 2021	Spring 2021	Summer 2021	Fall 2021	Winter 2022				
REB and Measure Development	Start-Up											
Recruitment and Data Collection		Longitudinal Data Collection with Rolling Recruitment										
Analyses Schedule				Pla	nned Data	Analyses						
Knowledge Translation					D	issemination						

Note: REB = Research Ethics Board

and/or developed and pilot tested with parents, children and youth, educators, and other stakeholders as appropriate. MH measures are described in tables 1 and 2. Additional measures with regard to distribution timeline, domain assessment, age range and informant are detailed in online supplemental table 1, as not all measures are included in each survey distribution to minimise participant burden. Where possible, psychometric properties are cited from previous studies.

Demographics

Data collected to characterise the sample includes parent education and employment, household income, living situation and household characteristics (eg, numbers of family members and rooms), housing and food insecurities, child age, height and weight, ethnicity, sex assigned to child at birth, gender identity and pre-COVID MH or NDD diagnoses.

Health behaviours

Age-specific health behaviours are collected for both parents and children including physical activity, outdoor time, screen modality and time (eg, television, video chatting, online learning and videogames), sleep, parenting behaviours, maintenance of social and family relationships (eg, changes in friend or family relationships due physical distancing), and MH service use. Health behaviour items are based on the Canadian Community Health Survey.⁷¹

The CRISIS⁷² is used to assess the impact of COVID-19 and includes items addressing exposure to COVID-19 infection, compliance with EMs, stress due to public health restrictions, socioeconomic status, employment change/loss, stability of living situations, food insecurity and child health. An adapted version, specific to families of children with ASD/developmental disability/intellectual disability is used in the POND cohort for families where applicable (CRISIS-Adapted for Autism and Related Neurodevelopmental conditions).⁷³

Screen for Child Anxiety Related Disorders (SCARED)⁷⁴ is a reliable and valid 41-item measure with child-report and parent-report versions.⁷⁵ It screens for symptoms of generalised anxiety disorder (GAD), separation anxiety disorder, panic disorder, social phobia and school phobia. Participants rate the nine-item GAD subscale on a three-point Likert scale from 0 (not true or hardly true) to 2 (very true or often true) with a total possible score 18.

Table 1 Primary measures for mental health Domains in the POND Research Cohort												
		Baseline May/June 2020		Follow-up August/September 2020			Follow-up November 2020		Follow-up February 2021			
		Ρ	Y	С	Ρ	Y	С	Р	Y/C	Ρ	Y	С
Anxiety	SCARED	~	~	~	v	v	~			~	V	~
	GAD-7	v			v					~		
Depression	RCADS	~			~					~		
	CESDC		~	~		~	~				~	~
	PHQ-8	~			~					~		
Irritability	TIDES	v	~		v	~		v	~	~	~	
Inattention	SWAN							~				
	Ability to focus*	~			~							
Hyperactivity	SWAN							v				
	Ability to control fidget*	v			v							
OCD	RCADS	~			~					V		
	TOCS	~	~		~	~				~	~	
Adaptive Skills	ABAS-II	v										

*Indicates single-item measure.

ABAS-II, The Adaptive Behaviour Assessment System; C, child self-report (10–12 years); CESDC, The Centre for Epidemiological Studies Depression Scale for Children; GAD-7, The Generalised Anxiety Disorder 7-Item Scale; OCD, obsessive–compulsive disorder; PHQ-8, The Patient Health Questionnaire; POND, Province of Ontario Neurodevelopmental Disorder; p, parent-report on self/child; RCADS, The Revised Child Anxiety and Depression Scale-Parent Report; SCARED, The Screen for Child Anxiety Related Disorders; SWAN, The Strengths and Weaknesses of ADHD Symptoms; TIDES, The Irritability and Dysregulation of Emotions Questionnaire; TOCS, The Toronto Obsessive Compulsive Scale; Y, youth self-report (ages 13–18 years).
 Table 2
 Primary measures for mental health Domains in SickKids Psychiatry, TARGet Kids! and Spit for Science Research

 Cohorts
 Cohorts

		Baseline May/June 2020		Follow-up July 2020		Follow-up August/September 2020			Follow-up November 2020		Follow-up February 2021			
		Ρ	Y	С	Ρ	Y	Р	Y	С	Ρ	Y/C	Р	Y	C C
Anxiety	SCARED	~	V	~			~	v	~			~	v	~ ~
	GAD-7	~					~					~		
Depression	RCADS	~					~					V	,	
	CESDC		~	~				~	~				v	· •
	PHQ-9	~						~				~	,	
Irritability	TIDES	~	~							~	~			
Inattention	SWAN									~		V	,	
	Ability to focus*	~	~	~			~	V						
Hyper-activity	SWAN									~		~	ł	
	Ability to control fidget*	~	~	~			~	V						
OCD	TOCS	~	V				~	V				V		,
Emotions and behaviours	SDQ†	~			~		•					~		

*Indicates single-item measure.

†Indicates completion by TARGet Kids! cohort only.

C, child self-report (10–12 years); CESDC, The Centre for Epidemiological Studies Depression Scale for Children; GAD-7, The Generalised Anxiety Disorder 7-Item Scale; OCD, obsessive-compulsive disorder; PHQ-8, The Patient Health Questionnaire; p, parent-report on self/child; RCADS, The Revised Child Anxiety and Depression Scale-Parent Report; SCARED, The Screen for Child Anxiety Related Disorders; SDQ, The Strengths and Difficulties Questionnaire; SWAN, The Strengths and Weaknesses of ADHD Symptoms; TIDES, The Irritability and Dysregulation of Emotions Questionnaire; TOCS, The Toronto Obsessive Compulsive Scale; Y, youth self-report (ages 13–18 years).

Higher scores indicate higher generalised anxiety with the clinical threshold score of 9.

Centre for Epidemiological Studies Depression Scale for Children (CES-DC)⁷⁶ is a reliable and valid 20-item self-report rating scale that measures symptoms of depression.⁷⁷ Children and adolescents are asked to rate their depressive symptoms over the past week from 0 (not at all) to 3 (a lot). Higher scores indicate higher levels of depressive symptoms, with scores of 15 or greater indicating a positive screen.

The Revised Child Anxiety and Depression Scales-Parent Version (RCADS-P)⁷⁸ is a 47-item parent-report measure used to evaluate symptoms of depression and anxiety disorders. Frequency of symptoms on the 10-item Depression subscale is rated on a 4-point scale (1=never; 4=always). Higher scores indicate higher rates of depressive symptoms and depression. The RCADS-P shows strong psychometric properties in both clinical and community (school) samples.⁷⁹

Strengths and Difficulties Questionnaire-Parent Version (SDQ-P)⁸⁰⁻⁸² is a 25-item parent-report scale that screens for emotional and behavioural attributes in children, ages 2–16, with a preschool version for those age 2–4 years. It is composed of five, five-item subscales assessing emotional symptoms, conduct problems, hyperactivity/ inattention, peer relationship problems and prosocial behaviours. Parents rate their children's behaviours

over the past 6 months in terms of the veracity of the provided statements by 'never' (0), 'somewhat true' (1) and 'certainly true' (2). Total scores of 17 and above are considered abnormal. Studies indicate measurement invariance between clinical and community populations on the SDQ.⁸³

The Patient Health Questionnaire (PHQ-8)⁸⁴ is an eight-item self-report measure of depressive symptoms based on DSM-IV (Diagnostic and Statistical Manual of Mental Disorders) diagnostic criteria. Parents rate the frequency of their symptoms using a scale from 1 to 4 (ranging from 'not at all' to 'nearly every day'). Higher scores are indicative of higher depression. The PHQ-8 demonstrates acceptable psychometric properties across American sociodemographic groups including sex, race/ ethnicity and education level.⁸⁵

The GAD 7-item Scale (GAD-7)⁸⁶ is a seven-item selfreport scale used to screen for the presence of anxiety. Parents rate the frequency of their symptoms using a scale from 1 to 4 (ranging from 'not at all' to 'nearly every day'). Higher scores are indicative of higher anxiety. Strict temporal measurement invariance for both the GAD-7 and the PHQ-9 has been previously established.⁸⁷

Child inattention and hyperactivity are assessed globally with two, single-item measures and also using a standardised measure (below), depending on the study time point. Parents rate their child and children and adolescents self-report on their ability to concentrate on a scale 5-point scale (1=very focused/attentive; 5 very unfocused/distracted). Parents further rate their child's ability to control restlessness and fidgeting on a 5-point scale (1=not fidgety/restless at all; 5=extremely fidgety/ restless).

Strengths and Weaknesses of ADHD symptoms (SWAN)⁸⁸ is an 18-item parent-report scale that measures child and youth symptoms of inattention and hyperactivity using a 7-point Likert scale (3=farmore than average; -3=farless than average). Psychometric properties are comparable between clinically-referred children with and without an ADHD diagnosis.⁸⁹

The Toronto Obsessive Compulsive Scale (TOCS)⁹⁰ is a 21-item measure of obsessive-compulsive symptoms on a 7-point Likert scale (3=farmore than average; -3=farless than average). It has both self-report and parent-report versions with higher scores indicating higher reports of OCD symptoms. The TOCS demonstrated excellent psychometric properties with strong internal consistency (α =0.94), and optimal sensitivity (70.7) and specificity (81.6).⁹⁰

The Irritability and Dysregulation of Emotions Questionnaire - Brief (TIDES - brief)⁹¹ is a shortened 6-item version of the TIDES-13, a measure of irritability and dysregulation. Respondent's answer based on a 7-point Likert scale (3 = far more than average; -3 = far less than average). It has both self-report and parent-report versions with higher scores indicating higher reports of irritability. The TIDES-Brief is highly correlated with the TIDES-13: parent-report = 0.97; self-report = 0.96. The TIDES-13 is also moderately-to-strongly correlated with gold standard measures of the same construct (Pearson's Correlation: r(631) = 0.68, p < 0.01, 95 CI's [0.64,72]) and normally distributed as a quantitative trait.

The Adaptive Behaviour Assessment System-II⁹² is a parent-report measure that assesses child adaptive skills in conceptual, social and practical domains. For each item, parents indicate whether their child is able to perform an activity independently on a four-point rating scale and how often they are able to do so (never, sometimes, always). General Adaptive Composite summary scores are calculated and categorised based on skill performance. This questionnaire is completed by the POND cohort only with higher scores indicating higher independent functioning.

The McMaster Family Assessment Device (FAD)⁹³ is a 60-item self-report measure of family functioning. Parents and youth (13–18 years) complete the 12-item General Functioning subscale of the FAD. Respondents indicate the extent to which they agree or disagree with statements about families using a 4-point rating scale (1=strongly agree; 4=strongly disagree), with higher scores indicating better family functioning with good internal consistency (α =0.83) and good concurrent validity (all correlations >0.5).⁹³

The KINDL⁹⁴ is a 24-item child self-report measure, for children ages 11–17 years, regarding the quality of life in the domains of physical well-being, psychological well-being, self-esteem, family, friends and everyday functioning. Participants respond to items on a 5-point Likert style scale (1=never; 5=all of the time). Children and youth complete the self-esteem (α =0.70) and family (α =0.73)⁹⁵ subscales as well as one item from the emotional wellbeing subscale ('I was bored').

The Parenting Scale⁹⁶ is a measure of dysfunctional discipline practices. Parents are presented with discipline scenarios and are asked to indicate their stance along a seven-point continuum. Two items from the Parenting Scale are used in addition to one item that was constructed specifically for the purposes of the current study.

The Childbearing Attitudes Questionnaire⁹⁷ is a 76-item measure that assesses parent feelings surrounding childbirth and parenting. Six items from this scale, assessing parental engagement, are used this study. Items are measured on a seven-point Likert scale ranging from 'disagree strongly' to 'agree strongly' and the scale demonstrates good internal consistency (α =0.77).⁹⁷

Child and Youth Resilience Measure (CYRM-R, and Person Most Knowledgeable (PMK)-CYRM-R)⁹⁸ are measures of social-ecological resilience in children. Each questionnaire is 17-items and can be scored on either 3- or 5-point Likert scales with higher scores indicating greater characteristics of resilience. Children ages 10 years and older complete the CYRM-R; parents complete the PMK-CYRM-R about their child.

Epidemiological Masculinity/Femininity Scale⁹⁹ is a graded measure of gender diversity allowing participants to rate how masculine and feminine they identify. Parents complete the first-order gender scale (ie, how do you see yourself) for both masculine and feminine items on a scale of 0 (not at all) to 6 (very).

Organised sport

Parents report on organised sport participation including frequency, intensity and duration of sport participation and the impact of COVID-19 on these factors ranging from 1 (very little) to 5 (very much so). Items were adapted from a subscale within the Developmental History of Athletes Questionnaire.¹⁰⁰

Services

Data regarding the use, frequency, and impact of the pandemic on medical, MH and allied health service use and availability are collected tackled.

Substance use

Parents and youth are asked two items per substance regarding the frequency of substance use (alcohol, vaping products, cigarettes/tobacco and marijuana/cannabis, eight-item total) both prior to and since the COVID-19 crisis.

Data analysis

Data will primarily be analysed using R Studio V.1.3.1093.^{101 102} For primary measures of MH outcomes, (ie, PHQ-8, GAD-7, RCADS, SCARED, CES-DC, SDQ-Parent version, SWAN, The Irritability and Dysregulation of Emotions (TIDES), TOCS), total scale scores will be standardised (z-scores, t-scores), where applicable, based on scale characteristics when combined to compute total MH composite scores. Statistical procedures will be specific to the individual study objectives within the previously listed aims in order to ensure that analyses are suitable and appropriate to address the research question. Missing data will be managed with full information maximum likelihood methods and multiple imputation methods depending on the characteristics of the data and the missingness to avoid listwise deletion where possible. General analytical principles, including the use of a priori hypotheses and written analysis plans, will be employed to ensure accurate representation of the longitudinal data. Analytical comparisons among cohorts will not be conducted as the cohorts are non-orthogonal, and the aim of the project is to understand the impact of the pandemic across the diversity of the sample. Potential participation bias is considered by examining key sociodemographic variables among participants with and without missing data, by specific study objective. Covariates and confounding variables for each aim will be rooted in existing literature. There will be specific foci on developmental stage (age) and MH history (previous MH and/or NDD diagnoses) as covariates/confounders to understand the impact of public health restrictions on children's development and pre-existing conditions.

Data management and confidentiality

If possible, participant data will be linked to clinical/ research data collected prior to the pandemic as part of their cohort (eg, MH symptoms which were based on completed measures, medication and diagnosis). To minimise the risk of a privacy breach, participants are assigned a unique ID which links the participant to their data. No identifiable information is stored within the databases.

All study data, for the SK Psychiatry, S4S and POND cohorts are stored on a secure REDCap server maintained by the Hospital for Sick Children (SK) in Toronto, Ontario, Canada. The TARGetKids! data are stored at the AHRC (Applied Health Research Centre at St. Michael's Hospital in Toronto, Ontario, Canada) in a REDCap database. Data will be stored on the SK or AHRC secure servers for 7 years following publication of results. All data and backups will subsequently be deleted from the server.

Data sharing

Data transfer agreements are in place to allow for the sharing of participant email addresses and applicable clinical data, for POND (participating sites located at SK, Holland Bloorview Kids Rehabilitation Hospital, McMaster University, Queen's University and Lawson Health Research Institute). POND participants have a unique information letter describing how the data from the current study may be shared, including with the Ontario Brain Institute

ETHICS AND DISSEMINATION

The study was approved by the institutional research ethics board at the lead research site (SK, 1000070222) as well as St. Michael's Hospital (20-080) and participating POND sites including Holland Bloorview Rehabilitation Hospital (0086), McMaster Children's Hospital (10948), Queen's University (6005107) and Lawson Health Research Institute (115934)

The core team of researchers employ a strong and integrated knowledge translation process with key knowledge users. Specifically, the research team will collaborate with educators (eg, Applied Psychology Human Development at Ontario Institute of Studies in Education), public health (Public Health Ontario) and community MH service providers (eg, Children's Mental Health Ontario; School Mental Health Ontario), where appropriate, to codevelop knowledge translation products for dissemination, with the aim of sharing knowledge regarding the impact of EMs on children, youth and families, and to codevelop key messages for educators that support children and youth in schools.

Results will further be disseminated through national/ international conference presentations, and peerreviewed and open-access publications while following Strengthening the Reporting of Observational Studies in Epidemiology guidelines for cohort studies to ensure high quality reporting of results and recommendations.

DISCUSSION

This project will examine the longitudinal impact of COVID-19 pandemic EMs on the MH of children, youth and families in Ontario. Given the continuous waves of community spread of the virus and the intermittent mandates of social isolation to prevent illness, both the immediate and long-term impacts on the MH of children and adolescents must be examined to prevent large-scale MH crises which would be devastating for children as well as the healthcare system. Results of this study will inform policy initiatives to mitigate deleterious impacts of subsequent waves of COVID-19 as well as longer-term impacts, in order to optimise child health outcomes in Ontario and beyond.

Limitations

The proposed study has several strengths; a large, diverse sample of children and youth, the inclusion of child and youth self-report of MH symptoms, and employment of validated, standardised MH measures where possible. Despite these strengths, limitations are also present. As with most research, ethnically diverse and low-income participants are under-represented in our sample, thereby limiting generalisability of study results. In addition, the study is intentionally set during a stressful time in the lives of children and families, during the COVID-19 pandemic, which may limit study retention. However, we will actively employ methods to minimise attrition, including use of a dedicated study team, provision of honoraria to participants at each time point, and regular communication regarding study results and impacts.

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Contributors DJK, EA, CB, AC, KT-C, SM and JC initiated the project, designed and selected data collection measures, created and amended data collection procedures, monitor data collection, wrote and edited statistical analyses plans, revised the finalised protocol manuscript and initiated knowledge translation processes. KL-M supported the design of the data collection instruments and drafted the initial protocol manuscript.

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