

BMJ Open LIVES for families psychological first aid training programme to address COVID-19 psychological distress: a mixed methods acceptability and feasibility protocol

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ABSTRACT

Introduction Best practice approaches for addressing COVID-19-related psychological distress among young people (<25 years) and their families remain unclear. Psychological first aid (PFA) is promoted by public health authorities to provide psychological support in the context of extreme events; however, there is limited evidence for its effectiveness. As a prerequisite to conducting a randomised controlled trial to examine programme effectiveness, this project is evaluating the acceptability and feasibility of implementing and evaluating a PFA training programme ('LIVES for Families') for mental health (MH) practitioners to improve their ability to recognise and respond to COVID-19-related psychological distress among their clients.

Methods and analysis We are using a triangulation mixed methods research design; complementary strands of quantitative and qualitative data are being collected in parallel and will be merged at the interpretation phase of the project. The quantitative strand uses a repeated measures design; a consecutive sample of MH practitioners (n=80) providing MH support to young people or their families are being recruited to participate in the LIVES for Families PFA training programme and complete quantitative measures at baseline (pretraining), 2-week and 6-month follow-up time points. The qualitative strand uses fundamental description and semistructured interviews with a subset of practitioners (n=30), as well as managers of MH agencies (n=20). A mixed methods joint display and associated narrative will generate a comprehensive understanding regarding acceptability and feasibility.

Ethics and dissemination The Hamilton Integrated Research Ethics Board approved the study (project number: 11295). Results will be shared broadly with the policy and practice community through publications, presentations and public webinars. As a brief, evidence-informed intervention, the LIVES for Families PFA training programme is suitable in its mode of delivery across care settings. The outcomes of this study could have international implications for mitigating the MH impacts of viral pandemics.

Strengths and limitations of this study

- Although our projected sample size meets methodological guidelines for acceptability and feasibility studies, it is small and estimates of statistical significance must be interpreted with caution.
- Our sample will include mental health clinicians from diverse sectors of mental health services, which will enhance the relevance and applicability of findings in different regions.
- This study uses a mixed methods design; the combination of qualitative and quantitative data strengthens the credibility and applicability of acceptability and feasibility findings.
- A limitation of this work is the absence of data collection from youth and adults with psychological distress related to COVID-19.
- A strength of this work is a strong collaborative relationship with community-based mental health agencies and a local Youth and Family Engagement Co-Development Team, whose members have lived experience with mental health challenges and who are consulting on this research.

INTRODUCTION

There is increasing evidence about the widespread negative psychological effects of COVID-19.¹⁻³ These include direct effects of the virus on neurobiological vulnerability to mental health (MH) conditions,⁴⁻⁶ as well as the indirect effects of financial, occupational and relational stressors related to restricted social mobility, extended periods of social isolation, as well as reduced availability of education, health and childcare services via public measures to contain the spread of COVID-19.⁷⁻¹⁰ A recent position paper on this issue highlighted additional risks for psychological distress during the pandemic, including exposure to substance misuse,

gambling and disruption of social networks.¹ This statement is supported by increasing epidemiological studies using self-reported and caregiver-reported measures of MH functioning, which note rise in depressive and anxiety symptoms, as well as sleep disturbances, and general psychological distress in children and youth.^{11–16} Equally concerning is the high level of caregiver-related stress documented among parents (and grandparents) of children and youth during the pandemic,^{17–25} and elevated reports of intimate partner violence and couple conflict.^{26–32} All of these factors highlight the urgent need to evaluate interventions that target COVID-19-related psychological distress in caregivers, children and youth.

With permission from the World Health Organization (WHO), we adapted the LIVES psychological first aid (PFA) framework (detailed below) to develop a novel PFA training programme for front-line MH practitioners to address COVID-19-related psychological distress among children and youth (up to the age of 25; referred to as ‘young people’) and their family members. Called ‘LIVES for Families’, this training programme includes several pedagogical elements, including three virtual training sessions, the application of the PFA intervention in clinical practice and the completion of practice logs to support practitioners’ use of the intervention during their clinical encounters. This paper outlines the methodological protocol for determining the acceptability and feasibility of conducting a future randomised controlled trial (RCT) to evaluate the effectiveness of the ‘LIVES for Families’ PFA training programme to improve psychological well-being among young people and their families via improvements to MH practitioners’ preparedness and self-efficacy for addressing pandemic-related psychological distress in their practice encounters.

PFA during viral pandemics and extreme events

PFA is defined by the WHO as ‘a humane, supportive response to someone who is suffering and may need support’ in the context of an extreme event, disaster or large-scale crisis (p 3).³³ Originally developed for the purposes of training ‘lay persons’ to provide widespread support during environmental disasters, PFA training has since expanded to paraprofessionals and licensed practitioners, as well as a broader range of extreme events. Based on a decade of reviews,^{34–37} PFA has been used to support young people^{37–41} and adults^{37 42 43} following weather disasters,^{38 42 44 45} civil war and politically based violence,^{39 40 44} and more recently in acute responses to viral epidemics, such as Ebola.^{37 41 46} In a few small non-randomised studies, PFA training significantly improved PFA provider perceptions of their self-efficacy in addressing adversity among crisis survivors;^{45 47–49} this was recently confirmed in an RCT that evaluated the effectiveness of a 1-day PFA training on provider knowledge for appropriate responses and skills following an Ebola outbreak in Sierra Leone.⁵⁰

Despite these promising findings, there are significant methodological weaknesses in the existing evidence for

PFA. Available studies are at high risk for bias and there have been few replications across contexts.^{34–37 51–53} PFA programmes have focused on training ‘lay persons’ and medical professionals, as well as reducing psychological distress and sequelae (eg, post-traumatic stress disorder) in these populations. PFA interventions delivered by MH practitioners have been less studied, as has the longitudinal impact of PFA interventions on a broader set of MH outcomes. Finally, few PFA studies have simultaneously considered the impacts of PFA on the MH outcomes of PFA providers and their clients. This is despite research which indicates that vulnerability to psychological distress may be amplified among practitioners who are simultaneously supporting crisis-affected individuals, while attempting to cope with their own crisis-based responses.^{54–59} Furthermore, few studies have considered the influence of PFA educational and implementation outcomes (eg, provider readiness, preparedness, adherence) on the MH impacts of PFA interventions. This is concerning given evidence from the field of implementation science, which indicates that therapist readiness and adherence to intervention protocols can influence intervention impacts.^{60–63}

LIVES for Families PFA programme

Our evidence review suggested that PFA models generally focus on: (A) providing connection and calm to those emotionally distressed by the crisis; (B) orienting individuals to the potential impacts of the crisis on community and individual well-being (ie, psychoeducation); (C) improving self-efficacy related to managing one’s emotional and practical needs; (D) recognising the possibility for safety vulnerabilities (eg, risk for pandemic-related harm) and developing safety plans; and (E) facilitating access to more intensive MH assessment and intervention, where indicated.^{34–36 64–66} The delivery of PFA builds on the use of empathy and active listening skills and is distinct from psychological counselling, debriefing and psychotherapy.³³ PFA’s focus is on providing non-intrusive, emotional and practical support to individuals to assist them with managing distress that is related to *their specific experience of the large-scale crisis or event*.

Our team developed the LIVES for Families PFA training programme (hereafter referred to as LIVES for Families) by adapting the WHO LIVES framework, which was developed to support front-line practitioners to provide PFA to women who have experienced sexual violence or intimate partner violence.^{67 68} The framework has been broadly disseminated by the WHO across low and middle-income countries and is used as a model for PFA. Given its emphasis on meeting the emotional and practical needs of those in crisis, we received permission from the WHO to: (A) adapt the core elements of the LIVES framework to align with delivering PFA for COVID-19-related psychological stressors among young people and families; and (B) evaluate LIVES for Families during the COVID-19 context.

LIVES for Families follows an interactive and practice-based curriculum over the course of one ‘core’ and two

'practice' sessions; sessions are focused on improving the practitioner's knowledge, skills and self-efficacy related to supporting young people and their caregivers to recognise and address their own (and if relevant, their child's) COVID-19 psychological stressors. Informed by the cumulative stress model⁶⁹⁻⁷¹ and self-efficacy theory,⁷²⁻⁷⁵ the core (3 hours) and practice (1.5 hours each) training sessions include up to 20 trainees, are delivered virtually by two trained facilitators and occur 2 weeks apart. Training sessions are standardised via the use of a structured facilitators guide and include brief didactic instruction, experiential role-play,⁷⁶ case-based learning⁷⁷ and associated learning tools (eg, knowledge summaries, clinician scripts). Blended learning strategies focus on learner engagement through active learning,^{78 79} deliberate practice,⁸⁰ test-enhanced learning⁸¹ and experiential learning to support knowledge acquisition, skill development and self-efficacy in model elements. The two follow-up 'practice' sessions were added based on evidence that 1-day

training sessions result in inconsistent practice change and PFA delivery.⁸²⁻⁸⁸ To further support the integration of newly learnt concepts into their clinical practice, enrolled practitioners are asked to track their use of the PFA intervention in their clinical encounters using a practice log. Core and practice training sessions cover the following content areas: (1) specific COVID-19-related psychological stressors, (2) the use of PFA in pandemics, (3) the PFA framework, and (4) case application. **Table 1** provides an overview of the intended learning outcomes, pedagogical strategies, as well as supporting resources used in each of the LIVES for Families training sessions.

The overall aim of the present project is to determine the acceptability and feasibility of LIVES for Families, as a prerequisite to conducting an RCT to evaluate the effectiveness of LIVES for Families in reducing COVID-19 psychological stressors among young people and their caregivers. **Table 2** provides the detailed objectives of our acceptability and feasibility research programme.

Table 1 LIVES for Families PFA training programme

Training session (length)	Intended learning outcomes	Pedagogical strategies	Supporting resources
Core training (3 hours)	<ul style="list-style-type: none"> ▶ Understand what psychological first aid (PFA) is, its distinction from other crisis-based interventions (eg, critical incident debriefing), and other psychotherapeutic interventions.² ▶ Describe the scope of COVID-19-related psychological stressors identified in the literature.¹ ▶ Describe the core elements of the LIVES for Families PFA framework.¹ ▶ Determine when it is appropriate to use the LIVES for Families PFA framework versus acute crisis support.³ ▶ Apply the core elements of LIVES for Families PFA to a common case scenario.⁴ 	<ul style="list-style-type: none"> ▶ Video ▶ Blank page exercise ▶ Guided reflection ▶ Case-based learning 	<ul style="list-style-type: none"> ▶ Facilitators guide ▶ LIVES clinical pathway handout ▶ COVID-19 resources handbook and resource card ▶ Active listening 'Do's and Don'ts' handout ▶ Practice log
Practice session 1 (1.5 hours)	<ul style="list-style-type: none"> ▶ Recall and explain the LIVES for Families PFA framework.^{1 2} ▶ Demonstrate application fluency of the 'L', 'I' and 'V' elements of the LIVES for Families PFA framework to common case scenarios.^{3 4} ▶ Illustrate self-efficacy in the 'V' of the LIVES for Families framework via selection of validation domains and generating of validation scripts.^{5 6} 	<ul style="list-style-type: none"> ▶ Case-based learning ▶ Role-play ▶ Practice log review and case consultation 	<ul style="list-style-type: none"> ▶ Facilitators guide ▶ LIVES clinical pathway handout ▶ COVID-19 resources handbook and resource card ▶ Practice log ▶ Validation scaffold
Practice session 2 (1.5 hours)	<ul style="list-style-type: none"> ▶ Recall and explain the LIVES for Families PFA framework.^{1 2} ▶ Describe the possible COVID-19-related safety vulnerabilities depicted in common case scenarios.¹ ▶ Appropriately evaluate whether using LIVES for Families PFA or initiating acute crisis intervention would be more appropriate for meeting the needs of a client in distress.⁵ ▶ Compose a safety plan collaboratively with clients with the purpose of reducing the spread/transmission of the COVID-19 virus.⁶ 	<ul style="list-style-type: none"> ▶ Case-based learning ▶ Role-play ▶ Practice log review and case consultation 	<ul style="list-style-type: none"> ▶ Facilitators guide ▶ LIVES clinical pathway handout ▶ COVID-19 resources handbook and resource card

Each of the LIVES for Families PFA intended learning outcomes has been mapped to one of the six levels of Bloom's taxonomy of learning,^{133 134} which provides a hierarchical framework for understanding the cognitive processes needed to foster optimal learning related to a complex construct or phenomenon. The assigned level of taxonomy for each intended learning outcome is given by one or more of the following notations: 1=remembering; 2=understanding; 3=applying; 4=analysing; 5=evaluating; 6=creating.

**Table 2** Acceptability and feasibility research objectives

Objectives	
Primary	<p>Determine the number of MH practitioners who meet study eligibility criteria and who enrol in the LIVES for Families PFA training programme (overall and per week of recruitment).</p> <p>Assess the proportion of enrolled MH practitioners who complete the LIVES for Families PFA training programme as a measure of acceptability of the programme; with completion consisting of participation and completion of all three training sessions.</p> <p>Determine the feasibility of collecting training programme outcome (ie, secondary objective) data among eligible and enrolled MH practitioners at baseline, 2-week and 6-month follow-up time points.</p> <p>Explore the acceptability of the LIVES for Families PFA training programme and evaluation procedures in a subsample of eligible and participating MH practitioners and their managers.</p>
Secondary	<p>Determine whether completion of the LIVES for Families PFA training programme among enrolled MH practitioners leads to significant improvements in their self-reported preparedness and self-efficacy related to recognising and responding to COVID-19-related stressors among their clients.</p> <p>Determine whether completion of the LIVES for Families PFA training programme among enrolled MH practitioners leads to significant changes in self-reported measures of burn-out and secondary traumatic stress.</p>

MH, mental health; PFA, psychological first aid.

METHODS

Design

We are using a triangulation mixed methods research design (see [figure 1](#)); quantitative and qualitative strands of data collection are occurring in parallel, being given equal priority, and will be merged at the analytical and interpretation phases of the project.⁸⁹ The strands of data collection are being connected via purposefully sampling a subgroup of enrolled practitioners to complete both strands. The quantitative strand will follow a non-experimental, repeated measures design.⁹⁰ A consecutive, convenience sample of MH practitioners (n=80) are being recruited to participate in LIVES for Families training and complete quantitative assessments. This quantitative strand will provide acceptability and feasibility metrics related to enrolment, retention, attrition and data completeness. The qualitative strand will follow the principles of qualitative description^{91 92} to complete individual, semistructured qualitative interviews with: (A) MH practitioners who completed all LIVES for Families training sessions (n=30); and (B) managers of local MH agencies (n=20). The qualitative data will provide contextual information about our quantitative metrics from the

perspective of multiple stakeholders, including participating practitioners and managers.^{93 94}

Setting

The primary study location is Hamilton, Canada, a diverse urban centre in the south-central region of Ontario with a population of more than 500 000 residents, 11.5% of whom are 0–19 years of age.⁹⁵

Quantitative research strand

Design, sampling and recruitment

The quantitative strand is following a non-experimental, repeated measures design.⁹⁰ Practitioner-level outcomes of primary interest for an effectiveness study will be assessed at multiple time points to: (A) determine the acceptability and feasibility of outcome data collection; and (B) generate preliminary estimates of variability in our practitioner outcomes, which can inform sample size estimations for an RCT. A sample size of approximately 40 participants is generally sufficient for acceptability and feasibility studies.^{96–98} Since retention may be challenging due to the pandemic, we plan to recruit a consecutive convenience sample of 80 MH practitioners (18 years of age or older) who provide psychosocial or psychotherapeutic support to young people and/or their caregivers. Sampling and recruitment of practitioners from Hamilton area agencies began in August 2020 and ended in January 2021.

Eligible practitioners: (A) are currently employed within a publicly funded MH service agency, school board, primary care clinic, child welfare organisation, tertiary MH programme, or a private counselling or psychotherapy practice; (B) have been providing psychotherapeutic or psychosocial support to young people (ie, <25 years of age) or their caregivers for at least 1 day/week, over the previous year; and (C) intend on continuing to provide support to young people or their caregivers throughout the study period (ie, for a period of 6 months or longer following study enrolment). Managers who are eligible to participate in the qualitative research strand (detailed below) are those who provide oversight or supervision of practitioners in a Hamilton-based MH agency. Exclusion criteria for practitioners and managers include the inability to speak or read English.

Recruitment of practitioners occurred through a three-pronged approach. First, study information letters were distributed to potentially interested participants via Hamilton's lead public child and youth MH agency, Lynwood Charlton Centre (LCC). LCC provides direct MH service to young people and their caregivers, and collaborates with 19 community-based service partners, including 15 other children's MH service agencies, four school boards, two family health team and two child welfare agencies. Recruitment materials were circulated to potentially eligible practitioners via email by the leadership of LCC and each LCC partner. Recruitment materials provide information on study eligibility, consent, enrolment and data collection procedures. This process was

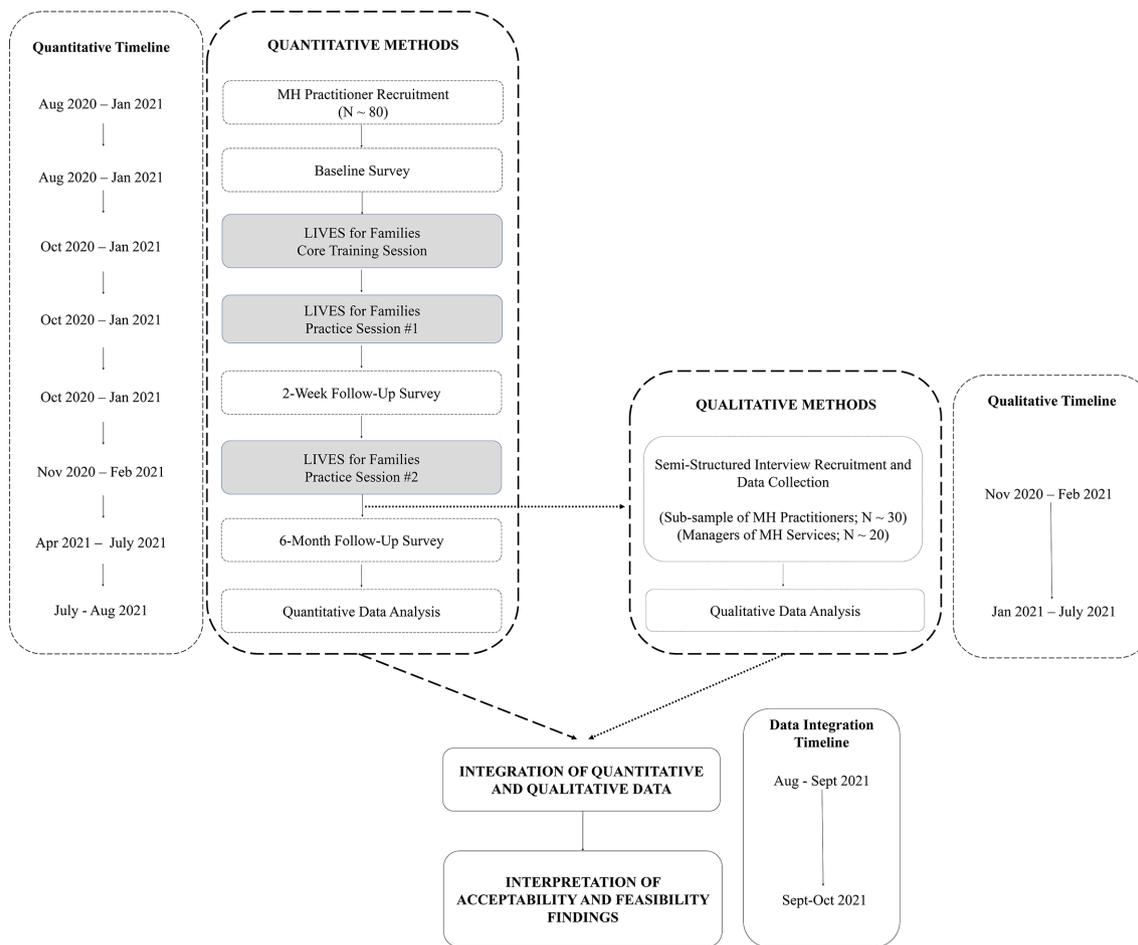


Figure 1 Triangulation mixed methods research design (QUAN+QUAL) and associated timeline for each strand of data collection. Quantitative and qualitative data collection occurs in parallel and then merged after being separately analysed. The strands of data collection are purposefully integrated via a subsample of practitioners who are purposefully recruited to complete qualitative and quantitative data collection procedures. (MH, mental health).

supplemented with an email request to the managers of non-LCC partner organisations to distribute study materials to their staff, as well as posting project recruitment materials on social media platforms. Snowball sampling methods were also used with each ‘source’ participant. Each practitioner will receive a \$120.00 honorarium in the form of an e-gift card after 6-month follow-up assessment; e-gift cards are a token of appreciation for the completion of all three quantitative research assessments.

Intervention

Enrolled practitioners will complete the LIVES for Families training virtually, which is cofacilitated by two members of the research team (MK, SH and/or NS). Practice sessions will begin 2 weeks following the core training and will be 2 weeks apart.

Data collection

Primary objectives

Quantitative data (see table 2) are being collected by the project’s research coordinator (RC); these include the number of participants who: (A) inquire about study participation; (B) are eligible/ineligible after screening; and (C) enrol. The RC is also tracking the number of:

(D) contacts needed to complete consent and arrange all research assessments and LIVES for Families training sessions; (E) dropouts following consent; (F) contacts who could not be reached for follow-up; (G) training sessions completed; (H) the quantitative research assessments completed across time points; and (I) those who are approached, agree, complete and withdraw from the qualitative data collection strand.

Secondary objectives

Data are being collected via practitioners’ self-completion of assessments administered by email at three time points: 1 week before their ‘core’ training session (time 1; baseline); immediately following the first practice session (time 2; 2-week follow-up); and 6 months following their baseline research assessment (time 3; 6-month follow-up). Participants can opt to complete measures by phone (see table 2).

Measures related to secondary objectives

In addition to sociodemographic characteristics (sex at birth, gender identification, age, professional discipline, years of practice, socioeconomic status, etc), we will assess the administration of measures that capture

possible outcomes, mediators, moderators and covariates to be included in any subsequent effectiveness trial to determine the acceptability and feasibility of our quantitative assessment approach. A detailed description for each of these measures and their timing is provided in online supplemental appendix 1. Briefly, at each of the three time points, practitioners will self-report on their: (A) readiness to change their practice related to learning about and deliver PFA (adapted version of the Brief Individual Readiness to Change Scale⁹⁹); (B) preparedness to recognise and respond to the COVID-19 psychological stressors experienced by their clients (adapted version of the Preparedness Subscale of the Physician Readiness to Manage Intimate Partner Violence Survey^{100 101}); (C) perceived self-efficacy to deliver PFA (adapted version of the Personal Self-Efficacy Subscale of the Self-Efficacy and Outcome Expectancy Scale for Job-Related Applications measure¹⁰²); and (D) their perceptions of their own stress and well-being related to COVID-19 (adapted version of the CoRonavIruS health Impact Survey version 1.0¹⁰³). The 6-month research assessment will also ask practitioners to self-report their level of burn-out and secondary traumatic stress using adapted versions of the Maslach Burnout Inventory¹⁰⁴ and the Secondary Traumatic Stress Scale,¹⁰⁵ respectively.

Data analysis

Since this project is focused on acceptability and feasibility, an a priori sample size estimation is not required. Our quantitative primary objectives will be addressed via generating estimates of dispersion and central tendency (ie, proportions, means, SDs, etc). A priori thresholds of acceptability and feasibility for our primary objectives (1), (2) and (3) have been established as follows: (1) acceptable levels of eligibility and enrolment will be (i) a 90% or greater screening eligibility rate for practitioners or managers who self-refer to the study; and (ii) a recruitment rate of, on average, 10 practitioners per week and the achievement of our sample aims within 8 weeks; (2) the acceptable proportion of enrolled practitioners who complete all of the LIVES for Families training sessions will be 75% or greater; and (3) the feasibility of collecting quantitative outcome data among enrolled practitioners will be indicated by: (i) less than 20% missing data at the practitioner and group level for each time point, and (ii) our RC is able to generate estimates of effect and variability (with robust SEs) for the measures related to the secondary objectives of the current study. Quantitative secondary objectives will be addressed via generating bivariate correlations and regression coefficients for our selected measures. Measures will be examined for multicollinearity,¹⁰⁶ as well as any needed transformation due to unfavourable skewness and kurtosis.¹⁰⁷

Qualitative research strand

Design, sampling and recruitment

Qualitative description will be used to generate a comprehensive summary of the perceived experience and impact

of the LIVES for Families training programme, as well as perceived burden related to programme completion and research activities.^{92 108} Data from qualitative interviews will corroborate, expand, and extend what's learnt about acceptability and feasibility from the quantitative strand, as well as provide information about potential barriers and facilitators related to PFA training programme implementation *and* evaluation from the perspective of practitioners and managers.

According to methodological guidelines for the triangulation design and fundamental description, sample size expectations should be made in consideration of the function of the qualitative strand of data collection.^{109 110}

We are using purposive, criterion-based and maximum variation sampling strategies to recruit a subsample of practitioners (n~30) who complete all LIVES for Families training sessions to contribute qualitative research data. We are also recruiting a sample of managers (n~20) responsible for supporting MH practitioners on the front lines of the pandemic. Criterion sampling is a form of purposeful sampling which selects participants on the basis of predetermined criteria (eg, completion of all training sessions) that are deemed critical to addressing the study's research objectives.¹¹¹ Maximum variation sampling is a form of group-based purposeful sampling capable of identifying both diverse and shared perspectives across a range of participants.¹¹² We are operationalising maximum variation sampling via inviting practitioners and managers who are working in diverse practice contexts in the Hamilton region, as well as practitioners who represent diverse levels and types of training to participate in this strand of data collection. Qualitative interview data are being collected in parallel to the quantitative strand of data collection. Manager sampling and recruitment follows the same process outlined for practitioners above and began following completion of the first LIVES for Families training cohort. Given the homogenous nature of the qualitative sample of participants, we anticipate that these expected sample sizes will achieve data sufficiency.

Data collection

Practitioners and managers are being asked to participate in a one-on-one, semistructured interview with a member of the project team. Rubin and Rubin¹¹³ describe the use of qualitative interviews as a strategy to examine an issue/phenomenon in a natural manner and identify similar and contradictory perceptions. A semistructured interview guide consisting of five to seven key, open-ended questions (see [table 3](#)) is guiding data collection and is informed by primary objective 4. In keeping with the traditions of inductive qualitative inquiry, interview probes are being adapted throughout data collection to explore emerging patterns in the data.¹¹⁴ Practitioner and manager interviews are scheduled between 45 and 60 min via Zoom at a time that is convenient for participants. Each individual interview will be audio recorded and transcribed verbatim. Qualitative interview participants

Table 3 Core qualitative interview questions for practitioners and managers

Questions for practitioners

Question No	Question
1	What is your perspective on the potential value of psychological first aid during the COVID-19 pandemic?
2	How would you describe your experience with the LIVES for Families PFA training?
3	How would you describe your experience of living through the pandemic while having to provide psychosocial/psychotherapeutic support to your clients?
4	What has it been like for you to incorporate the 'LIVES for Families' psychological first aid intervention in your clinical practice?
5	What has it been like for you to complete the research components as part of your participation in the LIVES for Families PFA training programme?
6	From your perspective as a practitioner, what are some important aspects of diversity that come to mind for you when we think about providing psychological first aid in a pandemic?

Questions for managers

1	What is your perspective on the value of psychological first aid during the COVID-19 pandemic?
2	As a manager, how would you describe your comfort level (or lack thereof) in supporting your staff to participate in a psychological first aid training during a pandemic?
3	What kind of supports would need to be in place to enable your team's participation in a psychological first aid training opportunity?
4	What, from your perspective, are the factors that can create challenges for your practitioners and/or agency to participate?
5	During a pandemic, practitioners are simultaneously coping with public health restrictions, while also supporting their clients with pandemic-related stressors. Please describe for us how this point resonates with you, if at all?
6	From your perspective as a manager, what are some important aspects of diversity that come to mind for you when we think about providing psychological first aid in a pandemic?

PFA, psychological first aid.

are being provided a \$40.00 honorarium in the form of an e-gift card at the completion of the interview. Field notes completed by the interviewer are documenting observations, patterns or dialectical positions which may be relevant to our analysis.

Data analysis

Transcripts of interviews with practitioners and managers, as well as associated field notes, will be imported into

NVivo for data management and will be analysed using: (1) directed (deductive) content analysis; (2) reflective (inductive) thematic analysis; and (3) summative content analysis.^{115 116} Directed content analysis will include the RC's establishment of a codebook with a set of a priori codes corresponding to the acceptability and feasibility objectives (eg, enrolment, compliance, measurement burden) and indexing their application to the interview transcripts. Reflective thematic analysis¹¹⁷ and analytical memoing¹¹⁸ allow for the codebook to expand via the identification of new concepts, constructs or factors (and their relationships). Summative content analysis and constant comparison will allow for quantifying the number and salience of finalised codes within and across interviews from our data sources. The codebook will contain the following key elements: code name, full definition, instructions for the application of the code and a brief excerpt of data relevant to the code.¹¹⁹ The initial iteration of the codebook will be generated by the RC. Research team members with expertise in qualitative research methods, health profession education, psychotherapeutic interventions and intervention science (MK, SH, AA) will also independently code a sample of the interview data; consistency of code application will be assessed via consensus-based discussion. The initial codebook will be revised as needed and applied in its finalised format to all interview data.

Methodological rigour and integration of quantitative and qualitative strands of data

Informed by mixed methods guidelines,¹²⁰ the use of investigator and data source triangulation, analytical memos, decision audit trailing, repeated quantitative assessments, as well as psychometrically validated measures of core concepts for our secondary outcomes will ensure the credibility (internal validity), dependability (reliability) and transferability (external validity) of our quantitative, qualitative and mixed methods analyses and interpretations.^{90 94 121–123} Integration of qualitative and quantitative findings will occur during the interpretation phase of our project. Quantitative acceptability and feasibility metrics generated for our primary objectives will be mapped to the counts of perceived barriers and facilitators to acceptability and feasibility (and associated excerpts of qualitative data) via a mixed methods joint display.¹²¹ In addition, a modified stem-and-leaf plot will cross-tabulate scores on measures for our secondary objectives (eg, practitioner preparedness, confidence, secondary traumatic stress, burn-out, etc) with qualitative excerpts describing the perceived value and potential impact of the LIVES for Families training programme.^{115 116 121}

Patient and public involvement

Cofacilitated by one of the team's coinvestigators (MI), our acceptability and feasibility project benefits from the experience of young people and caregivers who participate on the LCC's Youth and Family Engagement Co-Development Team (YFE-CDT), which is a team of



individuals who have lived experience with receiving MH support from practitioners in the Hamilton community. Plans for up to six meetings of approximately 2 hours in duration with members of the YFE-CDT have been developed as part of the project's engagement strategy; two meetings have occurred to date. Engagement thus far has included soliciting YFE-CDT members' input regarding the development and clinical implementation of LIVES for Families (eg, what practitioners should be trained and why; what COVID-19-related psychological stressors should be integrated as appropriate 'training cases' to support the programme's relevance). The YFE-CDT will be consulted on the most appropriate methods for communicating the project findings. Where appropriate, YFE-CDT members will have the opportunity to collaborate in knowledge dissemination and knowledge translation activities. Our approach is supported by evidence noting limited research that includes the voices of individuals who have been impacted by the COVID-19 pandemic and its associated public health restrictions.¹²⁴⁻¹²⁸

ETHICS AND DISSEMINATION

This study was approved by the Hamilton Integrated Research Ethics Board (project number: 11295). Informed consent is being obtained from all potential participants; on consent, each participant is being assigned a randomly generated study identification (ID) code; quantitative study data will be tracked via participant study IDs and all identifying information will be removed from the qualitative interview transcripts.

Several key deliverables and knowledge dissemination strategies will accelerate the translation of our research findings. We will publish our findings in open-access journals according to mixed methods guidelines¹²⁰ and results will be shared broadly with the policy, practice and academic communities via conference presentations and public webinars. The strategic use of digital and social media will be used to disseminate project updates and results, as well as generate brief, professionally produced infographics and summaries for dissemination.

DISCUSSION

The LIVES for Families PFA training programme is an innovative, brief and evidence-informed training programme for MH practitioners to address psychological distress experienced by their clients and which is related to the COVID-19 pandemic. We have proposed a mixed methods study to determine the acceptability and feasibility of the training programme as a prerequisite to examining effectiveness of the programme in an RCT. This complex psychosocial intervention has important attributes that make it applicable to the COVID-19 pandemic; it can be flexibly delivered within and across practitioners, it addresses several different outcomes (eg, secondary traumatic stress, burn-out, anxiety and depressive symptoms, etc) across multiple stakeholders

(eg, practitioners, patients) and can be integrated into existing organisational service models across various contexts during the pandemic. For example, in Canada, MH practitioners provide support in diverse settings (eg, hospitals, clinics, schools, homes, etc). Before implementing an RCT of a complex intervention, it is important to determine its acceptability and feasibility among practitioners, and whether an effectiveness trial can and should be done, and if so, the necessary design and implementation processes.¹²⁹⁻¹³²

The present study has several strengths. First, as a mixed methods protocol, the combination of quantitative and qualitative data will generate a more comprehensive understanding of acceptability and feasibility from the perspective of multiple stakeholders. Second, the triangulation of data types from practitioners with diverse training backgrounds who are providing MH services across an array of settings during the pandemic will enhance the credibility, transferability and trustworthiness of our findings. Another important strength of this project is a strong, collaborative partnership between the research team, Hamilton's lead agency for child and youth MH services, LCC, and their respective YFE-CDT.

There are two principal limitations of this project: (1) the lack of opportunity to collect data regarding the perceived value and impact of the PFA training programme from the perspective of young people and their caregivers; and (2) the quantitative strand of data collection follows a single-arm repeated measures design, which precludes the possibility of making any claims regarding the ability of the PFA training programme to lead to changes in our secondary outcomes of interest (ie, increased preparedness and self-efficacy, reduced burn-out and secondary traumatic stress, etc).

The LIVES for Families training programme was developed with the overall objective of providing a brief and scalable intervention for front-line MH practitioners to deliver practical and emotional support to young people and their family members who are experiencing psychological distress due to COVID-19. Informed by models of cumulative stress and self-efficacy, the programme has also been developed to address the potential for burn-out and secondary traumatic stress in the MH workforce.⁶⁹⁻⁷¹ These models provide a constructive framework for considering how the broader impacts of the LIVES for Families PFA training programme can be quantified, explained and leveraged within and across service contexts and potentially, countries.

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Appendix 1: Secondary Outcome Measures – Description and Frequency

Measures	Description	Assessment Points		
		T1 Baseline	Time 2 (2-weeks)	Time 3 (6-Months)
Brief Individual Readiness to Change Scale (BIRCS) ¹⁰¹	We will ask practitioners to self-report on their readiness to learn about and deliver PFA as a potential control variable for secondary outcome analysis. Readiness for practice change will be evaluated via practitioner self-report on the BIRCS. The BIRCS is a brief, psychometrically validated scale that asks practitioners to indicate the extent to which they agree with five statements related to their ability to make changes to their practice to learn about and deliver a new intervention. ¹⁰¹ Response options are on a 5-point Likert-type scale ranging from Strongly Disagree ('0') to Strongly Agree ('4'). Items are summed (with one item reversed scored) to generate a total score between 0 and 20, with higher	X	X	X

	scores indicative of greater readiness to learn about and make changes related to the new intervention.			
Adapted version of the Preparedness Subscale of the Physician Readiness to Manage Intimate Partner Violence Survey (PS-PREMIS) ¹⁰³	We will ask practitioners to self-report their preparedness to recognize and respond to their clients COVID-19 psychological stressors. Preparedness will be assessed via self-report on an adapted version of the Preparedness Subscale of the Physician Readiness to Manage Intimate Partner Violence Survey (PS-PREMIS); the PREMIS is a 67-item self-report tool that was developed to assess physician management of intimate partner violence across 10 subscales. ¹⁰³ The Preparedness Subscale asks respondents to indicate the extent to which they feel prepared to address various aspects of IPV recognition and response when working with their clients across 11-items; these aspects include the conduct of safety assessments, asking appropriate questions about IPV, responding to IPV disclosures, among others. Response options are on a 7-point Likert type scale ranging from “Not Prepared” (1) to “Quite Well Prepared” (7) and items are averaged to generate a mean score for	X	X	X

	practitioner preparedness, with higher scores indicative of greater preparedness to recognize and respond to IPV. For the purposes of our study, we removed two items (“assess an IPV victim’s readiness to change;” and “fulfill state reporting requirements for IPV, Elder abuse, & Child abuse”) and adapted the remaining items to focus on ‘COVID-19.’			
Adapted version of the Personal Self-Efficacy Subscale of the Self-Efficacy and Outcome Expectancy Scale for Job-Related Applications Questionnaire (P-SES) ¹⁰⁴	We will assess practitioner sense of self-efficacy related to their ability to provide PFA in their clinical encounters. Self-efficacy will be assessed via self-report on an adapted version of the Personal Self-Efficacy Subscale (P-SES) of the Self-Efficacy and Outcome Expectancy for Job-Related Applications Questionnaire. ¹⁰⁴ The P-SES is a 10-item measure that asks respondents to indicate the extent to which they agree with statements related to their ability to provide therapeutic techniques in their practice. We adapted these items to be specific to providing PFA. Negatively worded items are reversed scored and then items are summed to produce a total self-efficacy scale score ranging	X	X	X

	from 0 to 50; higher scores are indicative of greater perceived self-efficacy related to providing PFA in clinical practice.			
Coronavirus Health Impact Survey (CRISIS; V0.1) ¹⁰⁵	We will use the CRISIS instrument to enable the identification of pre-, peri, and post-COVID-19 demographic, social, and clinical predictors of both short- and long-term impairment and distress induced by COVID-19 and its sequelae. ¹⁰⁵ Multiple iterations of the CRISIS survey were developed; currently there are forms for adults aged 19 to 64, a parent report for young people aged 9 to 18, and a youth report form for young people aged 9 to 18. Across each version, the various modules of the CRISIS assess: (1) sociodemographic characteristics; (2) perceptions of physical and mental wellbeing in the 3-months prior to the onset of the pandemic; (3) possible COVID-exposure and diagnosis; (4) changes in social, family and work-related life; (5) worries specific to COVID-19; (6) perception of current physical and mental well-being; and (7) changes in behavioural activities, including sleep hygiene, screen use, physical activity, and substance use. Initial empirical evidence indicates	X	X	X

	it is a feasible, reliable, and valid measure of COVID-19 related psychological distress among adults.			
Adapted Maslach Burnout Inventory (MBI) ¹⁰⁶	We will ask practitioners to self-report on their perceived levels of burnout using an adapted version of the Maslach Burnout Inventory (MBI). ^{59,106} The MBI is a 22-item self-report measure that captures respondents' experiences of the three core elements of burnout: emotional exhaustion (nine items); depersonalization (five items); and personal accomplishment (five items). For each item, respondents are asked to indicate the frequency they felt, if all, the itemized statements. Responses options range from 0 (i.e., Never) to 6 (i.e., Everyday) and are scored using a standardized approach.			X
Adapted Secondary Traumatic Stress Scale (STSS) ¹⁰⁷	We will ask practitioners to self-report on their symptoms of secondary traumatic stress via the completion of an adapted version of the Secondary Traumatic Stress Scale (STSS). ¹⁰⁷ The STSS is a self-report measure that assess the frequency of STS symptoms in professional care providers. Respondents indicate on a 5-point			X

	<p>Likert scale (1 = never to 5 = very often) how often they experienced each of the 17 STS symptoms (e.g., heart started pounding; had trouble sleeping; avoided working with clients, etc.,) during the last week. A total score is generated via summing the responses across items and range from 17 to 85; higher scores are indicative of greater STS. Scores of less than 28 suggest 'little to no STS' whereas scores between 28 and 37, 38 to 43, 44 to 48, and beyond 49 indicating mild, moderate, high, and severe STS, respectively.</p>			
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