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A six-week group program of emotion focused family therapy for parents of children with mental health challenges: protocol for a randomized controlled trial

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Abstract

Background Children with mental health difficulties are at increased risk of many adverse psychological, academic, and social outcomes. Emotion regulation is a key transdiagnostic factor in the development and maintenance of mental health challenges. Parents and the family system (e.g., parental functioning, parenting, parent-child relationship) play a central role in children's development of emotion regulation and, in turn, their mental health. Therefore, continued efforts are needed to understand the effectiveness of emotion-focused treatments for child mental health difficulties, particularly those that include a family-based approach. Emotion Focused Family Therapy (EFFT) is an intervention for parents of children with mental health difficulties that teaches parents advanced skills to support their child's emotional development, potentially leading to improvements in the psychological functioning of the affected child as well as the family. Despite this, EFFT's efficacy has yet to be tested empirically via a randomized controlled trial.

Methods A six-week group modality of EFFT was developed based on the standard manualized version of a two-day group modality of EFFT. Efficacy of the six-week group modality of EFFT will be tested in a randomized controlled trial among parents of children aged 7 to 15 with anxiety, depression, or behavioral challenges. Parents will be randomized to the intervention condition or waitlist control condition. Online questionnaires and in-lab assessments will be conducted at pre-treatment, post-treatment, 4-month follow-up and 1-year follow-up. Intervention effects on primary (parent psychological symptoms, child psychological symptoms, parent emotion regulation, child emotion regulation, parent-child co-regulation) and secondary (parental emotion socialization, parent emotion blocks, parental self-efficacy, perceived parental stress, treatment satisfaction, treatment fidelity) outcomes will be analyzed by linear mixed models.

Discussion The study protocol describes the randomized controlled trial of EFFT, a parent group intervention for parents of children with anxiety, depression, and behavioral challenges. Findings contribute to the understanding of the efficacy of EFFT as a time-limited, transdiagnostic intervention for the treatment of child mental health challenges with potential positive impacts on parent and family functioning.

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Background

Background and rationale [6a]

Mental health challenges are a significant concern for Canadian children and adolescents, with nearly 1 in 5 children experiencing a mental health problem between the ages of 4 and 16 (Comeau et al. 2019). Anxiety, depression, and behavioral disorders are some of the most prevalent mental health conditions in this population (Georgiades et al. 2019). These difficulties in childhood increase the risk of various negative outcomes that carry implications into adulthood, including decreased educational attainment, substance misuse, chronic mental illness, and suicide (Groenman et al. 2017; Kremer et al. 2016; Leigh et al. 2023; Liu et al. 2022; Mulraney et al. 2021; Wickersham et al. 2021). This widespread need for intervention coupled with an overburdened mental healthcare system has resulted in nearly 30,000 children in Ontario placed on waitlists for mental health care in 2020, with wait times lagging to over two years (Children's Mental Health Ontario 2020). The COVID-19 pandemic further exacerbated demands on the pediatric mental healthcare system (Vaillancourt et al. 2021). Thus, there is a critical need to develop efficacious interventions that can be delivered efficiently to children, adolescents, and their families presenting with a broad range of mental health challenges.

A robust body of literature has documented deficits in emotion regulation as a transdiagnostic risk factor in the development and maintenance of mental health difficulties in childhood (Cavicchioli et al., 2022). From a family systems perspective, the emotion-related discourse and socialization that occurs within the family plays a central role in how family members manage their intrapersonal and interpersonal emotional experiences (Morris et al. 2007; Zinsser et al. 2021). Dysregulation in either of these domains, over time, can lead to psychological symptoms. Current evidence-based interventions for emotional and behavioral symptoms and disorders include components that teach individuals effective regulation skills to appropriately manage distress and symptoms (Eadeh et al. 2021). For example, cognitive behavioral therapies often include psychoeducation about emotions to help clients identify and correctly label their emotions (e.g., Chorpita & Weisz, 2009). Children with depression and anxiety are taught strategies to challenge their unhelpful and negative thinking as a means of decreasing the intensity and frequency of negative emotion experiences, and develop more realistic and accurate thoughts (i.e., cognitive restructuring; Clark, 2014). Despite this, cognitive behavioral therapy primarily focuses on the identified client (i.e., the child) without fully incorporating the specific family members and interactions that are central to the presenting concerns. We have much to gain by taking a family centered approach.

A family systems framework suggests that working with parents of children with mental health challenges can improve parents' own regulation, well-being, and sense of self-efficacy in navigating challenging situations with their children (Cowan et al. 1998). Furthermore, research has shown downstream effects such that psychological interventions with parents can lead to improvements in child mental health (England-Mason and Gonzalez 2020). Taken together, the research reviewed suggests that a parent and family focused intervention targeting the emotional processes within the family has the potential for a large and lasting positive impact at the parent, child, and family level. Specifically, Emotion Focused Family Therapy addresses these specific targets and is thus a promising intervention.

Emotion focused family therapy

Emotion Focused Family Therapy (EFFT) is a group-based and parent-focused intervention for the treatment of child mental health challenges that empowers parents to support their child by enabling parents to provide more effective emotional and behavioral support to their child (Lafrance et al., 2013, 2016, 2020). Originally developed for the treatment of eating disorders, the evidence base of EFFT has expanded to include a variety of child mental health problems for which emotion regulation is a critical maintenance factor, including anxiety, depression, and defiant behavior (Foroughe et al. 2019; Wilhelmsen-Langeland et al., 2019). Prior research into the modality primarily focuses on an intensive group workshop that spans 2 days (6.5 hours each day, including breaks). The 2-day workshop is delivered solely to parents; it has been delivered to parents of affected children ranging from early childhood to adulthood (e.g., Foroughe et al. 2019; 2023; Nash et al. 2020). Through treatment, parents learn to: (a) become their child's emotion coach and support them in processing and regulating their emotions, (b) become their child's behavior coach and deliver effective behavioral requests and clinically recommended behavioral strategies at home, (c) engage in a Therapeutic Apology chair work exercise to strengthen

the parent-child relationship and heal emotional injuries, (d) work through their own emotion blocks preventing them from fully engaging in treatment. Initial uncontrolled research on the two-day workshop has shown promise for EFFT, such that the intervention is associated with improved parental self-efficacy (Cordeiro et al., 2022; Foroughe et al., 2019; Nash et al. 2020; Wilhelmsen-Langeland et al., 2019), reductions in parental fear and self-blame regarding their child's mental health (Foroughe et al., 2019; Strahan et al. 2017), increased intentions to provide behavioral support surrounding their child's mental health needs immediately post-treatment (e.g., setting limits, ceasing enabling behaviors; Nash et al. 2020; Strahan et al. 2017), and reduced child mental health symptoms (Cordeiro et al., 2022; Foroughe et al. 2019; 2023; Wilhemsen et al., 2020). Several of these outcomes, including increased parental self-efficacy and reduced child mental health symptoms, appear to be sustained at 4-, 8-, and 12-months post-treatment (Foroughe et al. 2023). These studies have demonstrated promising results for the efficacy of EFFT for a variety of child developmental stages and presenting mental health concerns.

Benefits of group interventions

Group interventions offer various practical benefits such as financial and resource savings, which may make them particularly appealing to organizations and institutions facing high demand. This mode of delivery also enables mental health professionals to serve a greater number of families over a briefer span of time. In addition to these practical benefits, there are process-oriented benefits that warrant mentioning. For example, group delivery formats involve group processes that offer incremental effects above and beyond effects related to treatment content and the client-clinician relationship that are present in individual therapy. Group members develop rapport with one another through discussions, activities, and interactions, and this rapport serves as its own therapeutic agent such as by normalizing other group members' experiences (Burlingame et al., 2018). Participants of group interventions report vicarious learning through other members, thus increasing the relevance and applicability of intervention content (Yalom and Leszcz 2005). Indeed, robust literature supports the effectiveness of group-based interventions for youth, adults, and parents (Bennet et al., 2013; Huntley et al. 2012; Bortoncello et al., 2022; Davis et al. 2023; Payne et al., 2008).

Current study and objectives

In this protocol, we outline a randomized controlled trial of a six-week EFFT group program for parents. The primary aim of the trial is to establish the efficacy of a six-week EFFT group intervention for parents (herein used to refer to biological parents, stepparents, adoptive parents, grandparents, or other primary caregivers) of children ages 7 through 15 presenting with anxiety, depression, and/or behavioral difficulties. The present study will examine child and parent psychological functioning outcomes post-treatment, as well as maintained treatment gains at 4-month and 1-year follow-ups.

Primary question

Is a six-week EFFT group intervention for parents of children with emotional and behavioral difficulties efficacious at improving child and parent mental health and functioning compared to a waitlist control group post-treatment, at 4 months, and at 12 months?

Hypothesis

The six-week EFFT intervention will be more efficacious at improving child and parent functioning than the waitlist control group. We expect that these gains will be maintained at 4 and 12 months.

Secondary question

Do parent factors (pre-treatment stress and psychopathology) or child factors (internalizing and externalizing symptoms, age) moderate the efficacy of EFFT?

Hypothesis

While EFFT is expected to be effective across levels of parental stress, psychopathology, and child symptomology, EFFT will exhibit significantly greater relative change for parents with high levels of stress and psychopathology and child symptomology compared to those with lower levels. We do not expect differential effects by child symptom type.

Secondary question

Do changes in parental emotion regulation, socialization behaviors, and self-efficacy mediate improvement in child emotion regulation and symptoms post-treatment?

Hypothesis

It is anticipated that the efficacy of EFFT on child emotion regulation and symptoms will be partially mediated by improvements in parental emotion regulation and self-efficacy, increased supportive emotion socialization behaviors, and decreased unsupportive emotion socialization behaviors.

Intervention

The authors modified the original 2-day intensive workshop into six two-hour weekly sessions. An extended six-week group more closely mirrors what providers would offer in their practice and agencies. While content

remains largely the same, the present iteration includes newly created activities and materials, more opportunities for vicarious learning via group discussion, consolidation of skills via weekly home practice, therapist feedback, and opportunities to scaffold new skills (e.g., behavior coaching) onto skills mastered in prior weeks (e.g., emotion coaching). New activities and materials were added to the six-week EFFT group program given the expanded therapy length (approximately 9.5 hours versus 12 hours of intervention content) and format (e.g., six weekly homework activities and worksheets); these materials were based on the core EFFT principles and original activities. Revisions to the intervention were undertaken by the Principal Investigator (PI) alongside two doctoral students in clinical psychology who received training on the original, two-day workshop EFFT manual. Input was sought from two senior doctoral students and two doctoral-level psychologists (all trained in EFFT) prior to the study's launch. Following the initial creation of the manual, an initial pilot run of the 6-week intervention was run to assess the 'real-world' applicability of the manual. Feedback was solicited from the study therapists (three doctoral students and one doctoral level psychologist certified as an EFFT trainer) regarding content organization and flow. The feedback was incorporated into the finalized manual prior to proceeding with the trial (Seddon, Reaume, Foroughe, & Thomassin, unpublished manuscript).

Multiple spaced-out sessions (compared to the two-day intensive workshop) facilitate maximal opportunity for information retention (Carpenter et al., 2012). The six-week model also affords parents with more scheduling flexibility to attend (e.g., weekly evening therapy sessions vs. two full days), which optimize the intervention's accessibility. Each session (with the exception of the first week) begins with a review of last week's content and homework, and opportunities for group discussion and troubleshooting regarding challenges applying newly learned skills.

Explanation for the choice of comparators [6b]

The use of a waitlist control has the benefit of alleviating burden on participating clinicians and minimizing resource expenditure compared to the provision of an alternative evidence-based treatment as a comparator (i.e., an active control). This was an appropriate choice given there is no existing randomized controlled trial testing the efficacy of EFFT.

Objectives [7]

The primary aim of this study is to test the efficacy of a six-week group EFFT program for parents of children aged 7 to 15 years experiencing emotional and/or behavioral difficulties. The trial aims to test the efficacy of a six-week group EFFT program at decreasing parent and child emotion dysregulation and psychological symptoms and improving parent-child relationship functioning and co-regulation. The trial also aims to test whether treatment gains at post-treatment are maintained at 4-months and 1-year follow-up.

Trial design [8]

This trial is an investigator-led, single-site study designed as a two-arm, double-blinded explanatory randomized controlled trial with 1:1 allocation for treatment: control arms. The group intervention is offered to the waitlisted participants after the 4-month follow-up, therefore creating a delayed intervention option. The 1-year follow-up is therefore within-group. The present protocol conforms to SPIRIT guidelines for protocols of clinical trials (Chan et al. 2013).

Methods

Participants, interventions, and outcomes

Study setting [9]

The trial takes place within a community outpatient mental health agency in Ontario, Canada. Clinicians providing the intervention are Registered Clinical Psychologists and doctoral-level clinical psychology students.

Eligibility criteria [10]

Participants are considered eligible for enrolment in this trial if they fulfill all the inclusionary criteria and none of the exclusionary criteria.

Participant *inclusionary criteria* include:

1. Parent (i.e., biological parents, stepparents, adoptive parents, grandparents, or other primary caregivers) of a child aged 7 to 15 years.
2. Parent was referred to or seeking service for child emotional and/or behavioral symptoms (i.e., anxiety, depression, and behavioral challenges). Children do not need to have a diagnosis to be eligible.
3. At least one parent is willing to participate in the EFFT group.
4. Parent lives at home with the child.

Participant *exclusionary criteria* include:

1. Parent or child does not speak or understand English sufficiently well to understand study measures or participate in the EFFT intervention.
2. Child has a severe mental health disorder that is not considered suitable for EFFT due to an acute clinical

need for immediate intervention (e.g., active suicidality, psychosis). This is determined collaboratively between the assessors and a Registered Clinical Psychologist.
3. Parent or child is actively receiving intensive psychological intervention focused on cognitive and/or behavioral strategies to intervene with emotional or behavioral difficulties at the time of the assessment or due to receive such intervention during the active phase of the trial.
4. Parent or child is allergic to the adhesive electrode gel (i.e., sodium chloride) used for the in-lab experimental tasks.

Who will obtain consent [26a]

Written informed consent is obtained by trained assessors who are blind to randomization status.

Additional consent provisions for collection and use of participant data and biological specimens [26b]

Not applicable.

Intervention

Intervention description [11a]

Following guidance on optimal size for group-based interventions (Biggs et al., 2020; Yalom and Leszcz 2005), the EFFT intervention is delivered in-person to groups of five to ten parents over six weekly sessions that are each two hours in length. While prior research has utilized a two-day version of EFFT, the primary change in the present study is extending the same content across six sessions. All content from prior EFFT research is included within the present study. One major change is the addition of homework at the end of each session that is pertaining to the content discussed, as this is something that was not previously feasible within the two-day workshop format. There is also a minor addition of content in the fifth session (behavior coaching) which elaborates on evidence-based principles of behavior and behavior coaching to ensure understanding for parents.

The primary goal of EFFT is to teach and empower parents to support their child to process the emotions at the source of their mental health symptoms, to increase their child's adaptive behaviors, and to strengthen the parent-child relationship. EFFT also targets parents' own emotional challenges (termed 'parent emotion blocks') that may prevent them from feeling capable of supporting their child's mental health treatment and from utilizing skills learned in treatment. With these treatment foci in mind, EFFT is comprised of four primary domains: emotion coaching, behavior (and recovery) coaching, Therapeutic Apology, and parent emotion blocks.

Emotion coaching is a parent skill to support children's emotion regulation. In this module, parents are taught the steps of emotion coaching: (1) attend to and validate the child's emotional experience; (2) identify and meet the emotional need of the child; and (3) identify and meet the practical need of the child.

Behavior coaching supports parents to maximize behavioral requests of their children by learning how to provide an effective request. The steps of behavior coaching include: (1) confirm that you are calm, and your expectation of the child is reasonable; (2) genuinely connect with child; (3) make the behavioral request in a kind but authoritative manner; (4) validate the child's reaction; (5) make request again if needed. Parents also learn about evidence-based behavior strategies for their child's specific mental health symptoms (e.g., exposure for anxiety, behavioural activation for depression, positive reinforcement for behavioral challenges).

The Therapeutic Apology focuses on situations where there may be blame by parent or child related to the child's mental health challenges and/or where there is strain in the parent-child relationship. Clinicians support parents in reflecting on and identifying conflicts, patterns, or traumas that may have contributed to the child's emotional or behavioral challenges. Clinicians guide parents to construct a structured apology to their child. The Therapeutic Apology is processed in the group through chair work and then may be used with the child in person, if appropriate. The Therapeutic Apology serves to release the parent and child from self-blame and shame and strengthen the parent-child relationship.

The parent emotion blocks domain is focused on processing potential emotion blocks (e.g., fear, self-blame) that the parent experiences that may interfere with implementing learned skills or effectively supporting their child. Clinicians guide parents in processing these emotion blocks by increasing their awareness of common blocks through psychoeducation and self-assessment tools, and then engaging in chair work to process them.

Each of these domains are covered through six group sessions. Each session is structured in a similar way wherein psychoeducation is provided, then the skill is introduced, taught, practiced through experiential activities, and reviewed and processed via group discussion. Finally, homework activities are assigned weekly for parents to practice using the skills with their children. Group sessions are delivered by a Registered Clinical Psychologist and two to three senior doctoral

Table 1 Content included in the six group EFFT sessions

Session Number	Session Topic	Specific Session Content
1	Introduction to EFFT	Orientation to group format; psychoeducation about role of emotions in mental health; introduction to central principles of EFFT
2	Emotion Coaching	Purpose/function of emotion coaching; emotion coaching steps; clinician demonstration of emotion coaching; role-play practice of emotion coaching
3	Parent Emotion Blocks	Psychoeducation about parent blocks; animal models of emotional response styles and caregiving styles; interaction of co-parent styles; parental self-compassion
4	Therapeutic Apology	Purpose/function of Therapeutic Apology; Therapeutic Apology steps; clinician demonstration of Therapeutic Apology; Therapeutic Apology chair work
5	Behavior Coaching	Psychoeducation about undesirable behavior/ways to address it; purpose/function of behavior coaching; clinician demonstration of behavior coaching steps; role-play practice of behavior coaching
6	Working Through Blocks and Wrap-Up	Examples of behavioral strategies for specific mental health symptoms (recovery coaching); review of parent blocks interfering with coaching skills taught; clinician demonstration of parent block chair work; parent block chair work; review of skills learned and parent takeaways

students. At the beginning of each session, parents are provided with worksheets and handouts containing content about skills and strategies taught in each session and homework sheets. Consistent with the delivery of the two-day workshop, treatment content for each session is presented visually via PowerPoint presentations. See Table 1 for an overview of content for each of the six sessions.

Criteria for discontinuing or modifying allocated interventions [11b]

In consenting to the trial, participants are consenting to trial treatment and data collection. A participant may stop treatment early, or treatment may be terminated early for any of the following reasons:

- Serious adverse event.
- Any change in the participant's condition that, in the clinician's opinion, justifies the discontinuation of the trial intervention.
- Withdrawal of consent for the trial intervention by the participant.

Given that participation in the trial is entirely voluntary, the participant may choose to discontinue trial treatment at any time without penalty. The participant may also choose to withdraw consent for data collection but continue receiving trial treatment.

Strategies to improve adherence to interventions [11c]

Clinicians providing the EFFT interventions are required to attend ongoing (weekly) supervision to ensure consistency across clinicians and groups. Additional supervision is available as needed. Adherence to the intervention is assessed by coding a random subset (20%) of therapy group session recordings.

Relevant concomitant care permitted or prohibited during the trial [11d]

Children may be taking psychotropic medications during the trial. Children and parents may not be receiving active psychological intervention focused on cognitive and/or behavioral strategies to address child emotional or behavioral difficulties.

Provisions for post-trial care [30]

There is no expectation of harm from participating in this trial. If any changes in clinical care during treatment are warranted, these will be managed by the Registered Psychologist (either the PI or EFFT group leader) and referrals will be arranged as applicable. Either the study PI or the EFFT group leader, both of which are Registered Clinical Psychologists, will monitor participants and arrange for follow-up services as needed, following best clinical practice.

Outcomes [12]

Primary outcomes

Demographic information Parents complete a demographic questionnaire where they provide information about themselves (age, ethnicity), their child (age, sex, ethnicity), and their family (household income).

Parent psychological symptoms The Kessler Psychological Distress Scale (K10; Kessler et al., 2002) is a 10-item self-report measure of psychological symptoms. Parents rate the extent to which they are affected by various anxiety and depressive symptoms (e.g., "Feeling no interest

in things," "Feeling restless") on a five-point Likert scale from 1 (*None of the time*) to 5 (*All of the time*). A total score made up of all 10 items is used (score range: 10 to 50), wherein higher scores indicate greater psychological distress. The K10 has established high internal consistency and convergent validity, and very good reliability (Andrews & Slade, 2001; Kessler et al., 2002; Sakurai et al., 2011; Sampasa-Kanyinga et al., 2018).

Child psychological symptoms The Behavior and Feelings Survey (BFS; Weisz et al., 2020) is a brief 12-item measure of child psychopathology symptoms. Parents (parent-report) and children (youth-report) rate items on a five-point Likert scale from 0 (*Not a problem*) to 4 (*A very big problem*). Items load onto three subscales: Internalizing Problems (e.g., "Feeling down and depressed," "Feeling nervous or afraid"), Externalizing Problems (e.g., "Doing things s/he is (I am) not supposed to do," "Breaking rules at home or at school"), and Total Problems which comprises all items. The Total Problems score (score range: 0 to 48) is used for the current study, wherein higher scores indicate greater levels of psychopathology symptoms. If group sizes allow, we will consider examining the Internalizing and Externalizing subscales separately. The BFS shows good internal consistency, test-retest stability, and convergent and discriminant validity (Weisz et al., 2020).

Parent emotion regulation The Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004) is an 18-item self-report measure of emotion regulation difficulties. Parents indicate the frequency with which they experience difficulties with emotion regulation on a five-point Likert scale ranging from 1 (*Almost never*) to 5 (*Almost always*). Items are divided into six subscales: Nonacceptance of Emotions (e.g., "When I'm upset, I become irritated at myself for feeling that way"), Difficulties Engaging in Goal-Directed Behavior (e.g., "When I'm upset, I have difficulty concentrating"), Impulse Control Difficulties (e.g., "When I'm upset, I lose control over my behavior"), Lack of Emotional Awareness (e.g., "I am attentive to my feelings"; reverse scored), Limited Access to Emotion Regulation Strategies (e.g., "When I'm upset, I believe there is nothing I can do to make myself feel better"), and Lack of Emotional Clarity (e.g., "I have difficulty making sense out of my feelings"). The DERS shows high internal consistency (Gratz & Roemer, 2004). A total score of all items (score range: 18 to 90) is used for the current study, wherein higher scores indicate greater levels of emotion regulation difficulties.

Child emotion regulation The Negative Emotionality subscale of the Child and Adolescent Dispositions Scale (CADS; Lahey et al., 2010) is a 10-item measure of child emotion regulation difficulties. Parents (parent-report) and children (youth-report) rate how well the ten items describe the child (e.g., "Does s/he (do you) get upset easily?" "Does s/he (do you) react intensely?") on a 4-point Likert scale ranging from 0 (*Not at all*) to 3 (*Very much/very often*). The Negative Emotionality subscale of the CADS (mean score range: 0 to 3) has established internal and external validity and high reliability (Lahey et al., 2010). Higher scores on this subscale indicate greater levels of emotion regulation difficulties.

Parent-child relationship functioning and co-regulation Parent-child co-regulation is measured via behavioral observations and physiology obtained during a parent-child conflict discussion task and puzzle challenge task. Parent-child dyads attend an in-person assessment where they complete the conflict discussion and puzzle challenge tasks together. Each task lasts 5 minutes and is videorecorded. To select the conflict for discussion, parent and child separately identify three topics that create conflict in their relationship (e.g., chores, homework), and the research assistant selects the topic most relevant to both the parent and child. If all three topics are shared by both parent and child, the research assistant will select the coinciding topic that is most aligned with the main presenting problem the family was referred for. Research assistants have training in the administration of this task, including the selection of the conflict. For the challenging puzzle task, parents are instructed to help their child complete a puzzle using only their words, and not physically complete the task for the child. Tasks are counterbalanced and conflict discussion topics and puzzle designs vary between the pre-treatment (baseline; T1), post-treatment (six weeks post-baseline; T2), and follow-up (4-month; T3, and 1-year; T4) assessments to prevent practice effects. Tasks are video-recorded and coded behaviorally and affectively for level of co-regulation between parent and child using the Observer XT software (Noldus 1991). Research assistants are trained by the study PI and graduate students with extensive experience with observational coding. The coding scheme includes child and parent affect, adapted from the Specific Affect Coding System (Lougheed & Hollenstein, 2014), as well as parental emotion socialization behaviors, adapted from the coding scheme developed by Lunkenheimer et al. (2007).

Parent and child heart rate variability and electrodermal activity are acquired using the Biopac MP160 (Biopac Systems, Inc., Goleta, CA) simultaneously and in real-time throughout both tasks as well as through a baseline measurement task wherein parents and children are

asked to sit quietly for three minutes. Dyads are outfitted with electrocardiogram electrodes (in a Lead II configuration) and two electrodes on the palm to measure electrodermal activity. Regulation is measured by the change in heart rate and electrodermal activity from baseline to the conflict discussion task and baseline to the challenging puzzle task.

Secondary outcomes

Parental emotion socialization The Coping with Children's Negative Emotions Scale (CCNES; Fabes et al. 2002) is a 12-item self-report measure of parental emotion parenting practices in response to children's expression of negative emotion. Parents are presented with a series of vignettes describing situations in which their child is expressing negative emotions. For each vignette (e.g., "If my child falls off his/her bike and breaks it, and then gets upset and cries, I would…"), parents rate the likelihood that they would respond in six different ways on a seven-point Likert scale from 1 (*Very unlikely*) to 7 (*Very likely*). Responses are divided into six subscales: Minimizing Reactions, Punitive Reactions, Distress Reactions, Expressive Encouragement, Problem-Focused Reactions, and Emotion-Focused Reactions. Following previous research, we grouped the six response types into two overall mean scores: Supportive (Expressive Encouragement, Problem-Focused, and Emotion-Focused reactions; score range: 1 to 7) and Unsupportive (Punitive, Minimizing, and Distress reactions; score range: 1 to 7) practices (e.g., Denham & Kochnakoff, 2002), wherein higher scores indicate greater reported likelihood to use the respective emotion socialization practices. The CCNES shows good internal consistency and test-retest reliability, and adequate construct validity (Fabes et al. 2002).

Parent emotion blocks The Caregiver Traps Scale (CTS; Lafrance, 2014) is a 14-item self-report measure of parent emotion blocks. Parents rate the likelihood that they feel vulnerable to different worries and emotions that interfere with their ability to support their child's treatment (e.g., "I worry about being rejected by my loved one," "I worry about being blamed or being to blame if it doesn't go well") on a seven-point Likert scale from 1 (*Not at all likely*) to 7 (*Extremely likely*). A total score made up of all 14 items (score range: 14 to 98) is used for the current study, wherein higher scores indicate greater levels of parent emotion blocks. The CTS shows very good internal consistency and acceptable to excellent reliability (Foroughe et al. 2019; Lafrance et al., 2016; Stillar et al., 2016).

Parental self-efficacy The Me as a Parent Questionnaire (MaaP; Hamilton et al., 2014) is a 16-item self-report measure of parental self-efficacy. Parents rate the degree to which they agree with statements about their feelings of competence in their parental role on a five-point Likert scale from 1 (*Strongly disagree*) to 5 (*Strongly agree*). The MaaP is comprised of four subscales: Self-Efficacy (e.g., "I have confidence in myself as a parent"), Self-Sufficiency (e.g., "I know how to solve most problems that arise with parenting"), Self-Management (e.g., "I meet my expectations for providing emotional support for my child"), and Personal Agency (e.g., "I often feel helpless about my child's behavior"; reverse scored). A total score consisting of all items (score range: 15 to 75) is used, wherein higher scores indicate greater levels of parental self-efficacy. The MaaP shows good internal consistency (Hamilton et al., 2014).

Perceived parental stress The Parental Stress Scale (PSS; Berry & Jones, 1995) is an 18-item self-report measure of parents' levels of stress related to the responsibilities associated with parenting. Parents rate statements regarding their experience with various stressors associated with parenting, including loneliness, guilt, role satisfaction, marital satisfaction, and their and their child's relationship, on a four-point Likert scale from 1 (*Strongly disagree*) to 5 (*Strongly agree*). A total score is calculated by reverse-scoring the necessary items and summing all items (score range: 18 to 90), with higher scores indicating greater parenting stress. The measure shows good internal consistency, test re-test reliability, construct validity, and convergent validity (Berry & Jones, 1995; Zelman et al., 2018).

Treatment satisfaction The Client Satisfaction Questionnaire (CSQ; Larsen et al. 1979) is an 8-item self-report measure of parent satisfaction regarding treatment for their child's mental health. Parents rate statements regarding intervention quality on a four-point Likert scale from 1 (*Poor)* to 4 (*Excellent*). A total score is calculated by reverse-scoring the necessary items and summing all items (score range: 8 to 32), with higher scores indicating greater treatment satisfaction.

Treatment fidelity Consistent with other trials examining treatment fidelity, 20% of group sessions are coded for adherence to EFFT content by trained research assistants. The present study will develop a measure of EFFT treatment fidelity in order to code adherence, given that none currently exists. Coding will be completed by trained undergraduate and graduate-level research assistants.

Table 2 Participant timeline and measurement overview

Measurement	Measure	Reporter	Screening	T1 – T4	Weekly (6 weeks of active phase)
Inclusion/exclusion criteria	-	R	X		
Confirmation of eligibility	-	R	X		
Informed consent, assent	-	P, C		X	
Randomization	-	R		X	
Demographics	Demographic questionnaire	P		T1	
Impact of COVID-19	COVID-19 Family Stressor Scale	P		T1	
EFFT homework/skill use check[a]	Homework/Skill Use worksheet	P			X
Treatment fidelity[a]	Coding of recorded sessions	R			X
Treatment satisfaction[a]	Caregiver Satisfaction Questionnaire	P		T2	
Service access since EFFT	Service Access Survey	P		T3/T4	
Outcomes					
Parent Functioning					
Psychological symptoms	Kessler Psychological Distress Scale	P		X	
Emotion regulation	Difficulties in Emotion Regulation Scale	P		X	
Emotion socialization	Coping with Children's Negative Emotions Scale	P		X	
Parent emotion blocks	Caregiver Traps Scale	P		X	
Parental self-efficacy	Me as a Parent Questionnaire	P		X	
Parental stress	Parental Stress Scale	P		X	
Child functioning					
Psychological symptoms	Behavior and Feelings Survey	P, C		X	X
Emotion regulation	Child and Adolescent Disposition Scale	P, C		X	X
Parent-child relationship					
Parent-child co-regulation	Observational coding, heart rate variability, and electrodermal activity during the Conflict Discussion and Challenging Puzzle Tasks	P, C, R		X	

Note. R = Researcher, P = Parent, C = Child

[a] Active EFFT treatment condition only

Participant timeline [13]

See Table 2 for the measurement overview and participant timeline.

Sample size [14]

To assess necessary sample size for main effects, G*Power was used to conduct a power analysis based on effect sizes from existing EFFT research evaluating the two-day EFFT modality. Effect sizes for parent outcomes in previously published studies range from small to large ($d = 0.33$, $\beta = 2.10$; Cordeiro et al., 2022; Foroughe et al. 2019; 2023; Nash et al. 2020; Strahan et al. 2017; Wilhemsen-Langeland et al., 2020). While child outcomes have been examined to a lesser degree in the EFFT research, effect sizes for child outcomes for the two-day modality also range from small to large ($d = 0.23$, $\beta = 0.79$; Foroughe et al. 2019; 2023; Cordeiro et al., 2022; Wilhemsen-Langeland et al., 2020). Aggregated published effect sizes range from approximately $d = 1.38$ for parent outcomes to $d = 0.64$ for child outcomes. Based on the smaller effect size ($d = 0.64$ or $f = 0.32$), a sample size of 79 is required to detect a treatment effect ($\beta = 0.80$, $\alpha = 0.05$, 2 groups, 2 measurement timepoints). To account for an expected attrition rate of 20% between measurements, the sample size was increased to 99.

Sample size for the moderation analysis was calculated using G*Power. Again, based on previous research, we estimated a medium effect size ($\beta = 0.30$ or $F = 0.15$). For an alpha of 0.05 and power of 0.80, a required $N = 90$ was calculated for the smallest anticipated moderation effect size. Anticipating 20% attrition, the sample size for this hypothesis was increased to $N = 108$.

Sample size for mediation analyses was calculated using the Monte Carlo Power Analysis for Indirect Effects with 1000 replications (Schoemann et al. 2017). Standardized coefficients were derived from previous research examining links between parent emotion regulation and child clinical outcomes (emotion regulation, psychopathology, moderate treatment effect size). Given that effect sizes

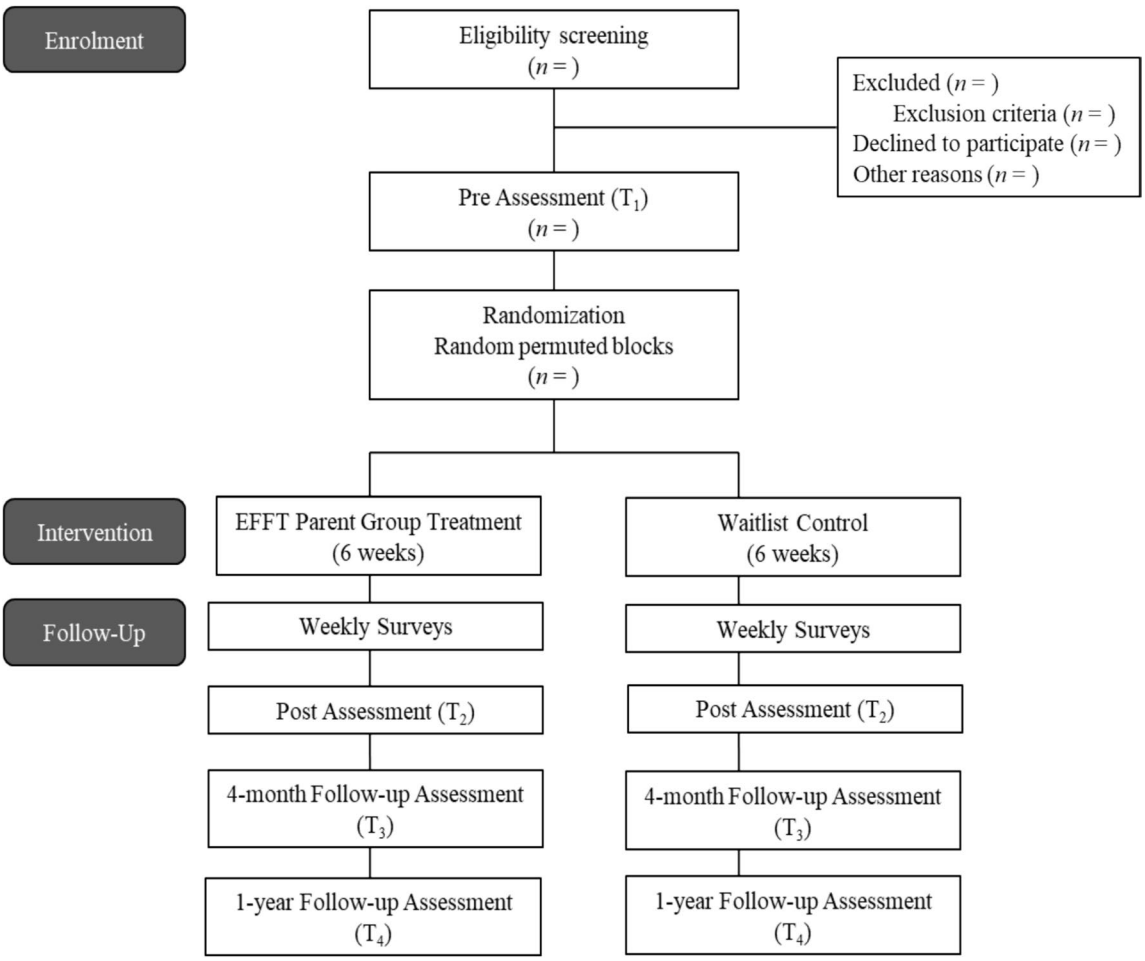

Figure 1 Consort diagram of participant flow

in the EFFT literature range considerably from small to large for both parent outcomes ($d = 0.33$ to $\beta = 2.10$; Cordeiro et al., 2022; Foroughe et al. 2019; 2023; Nash et al. 2020; Strahan et al. 2017; Wilhemsen-Langeland et al., 2020) and child outcomes ($d = 0.23$ to $\beta = 0.79$; Foroughe et al. 2019; 2023; Cordeiro et al., 2022; Wilhemsen-Langeland et al., 2020) and that we theorize an increase in effect size with the six-week intervention compared to the two-day workshop upon which prior research is based, we estimated a medium effect size ($\beta = 0.30$). For an alpha of 0.05 and a power of 0.80, a required $N = 156$ was calculated for the smallest anticipated mediation effect size. Anticipating 20% attrition, the sample size for this hypothesis was increased to $N = 187$.

Recruitment [15]

Parents of children with anxiety, depression, and behavioral challenges who express interest in the study via self- or clinician-referral are invited to complete a screening phone call to determine eligibility for participation in the trial. The enrolment period will extend until the desired sample size is reached. When prospective participants express interest, eligibility is assessed through a brief screening call conducted by a graduate or senior undergraduate student. The flow of participants (including order of screening procedures, consent, pre-randomization assessments, and randomization allocation) is illustrated in Fig. 1.

Assignment of interventions

Sequence generation [16a]

Participants are randomized to either the treatment condition or the waitlist condition using an independent web-based online system (Sealed Envelope, Ltd., 2022). The randomization process consists of a 1:1 ratio within permuted blocks of random sizes to ensure groups are balanced periodically and ensure concealment. Each participant is randomized using their unique participant identification number assigned sequentially after the eligibility screening has been completed and the participant

is determined to be eligible. Participants randomized to the treatment condition receive treatment between the pre-treatment (baseline; T1) and six-week (T2) assessments. Participants randomized to the waitlist condition are eligible to receive treatment after their 4-month follow-up assessment.

Concealment mechanism [16b]

Participants are randomized using Sealed Envelope, an online randomization service (Sealed Envelope, Ltd., 2022). Permuted blocks within the sequence generation consist of various sizes which also occur in random order to ensure concealment. The randomization list generated by Sealed Envelope is provided to an administrative assistant who is not involved in any research or direct clinical service at the community outpatient mental health agency. Randomization information is not revealed to any researcher until after the baseline (T1) assessment has been completed. At this point, the randomization information is shared with a project coordinator, who is not involved in any of the assessments or clinical service.

Implementation [16c]

All participants who fulfill the eligibility criteria, provide consent, and complete the baseline (T1) assessment are randomized. After the completion of the baseline assessment, the project coordinator contacts the non-trial administrative assistant who holds the concealed randomization sequence and asks them to provide the randomization assignment for the specific participant ID number requested. The project coordinator is not involved in data collection or direct clinical services for the project. Therefore, randomization is conducted without influence of the researchers responsible for recruitment or assessment or study therapists. Prior to and at the outset of assessments, participants are informed not to share their group participation with researchers conducting assessments or to share whether (or not) they are in the study to group therapists.

Assignment of interventions: blinding

Who will be blinded [17a]

All assessments are conducted by research assistants blinded to treatment allocation. Given that each therapy group consists of both study and non-study participants, study therapists are not aware of which group participants are part of the trial and which are not and are therefore blind in this respect.

Procedure for unblinding if needed [17b]

Unblinding may be required if a participant requires additional intervention. In this case, the therapist providing the trial treatment may be unblinded, but outcome assessors remain blind.

Data collection, management, and analysis

Research ethics approval [24]

The research has been reviewed and approved by the sponsoring institution's research ethics board (REB #21-10-012CT).

Data collection methods [18a]

At each primary timepoint (T1, T2, T3, T4), parent participants complete questionnaires online via the Qualtrics survey platform. Following this, the family is invited to visit the laboratory where they complete an in-person assessment comprised of child questionnaires and the conflict discussion and challenging puzzle tasks. Heart rate and electrodermal activity are gathered from both parent and child during a baseline task and during the two aforementioned experimental tasks. The in-person assessment is conducted by one graduate-level research assistant and one undergraduate-level research assistant. Research assistants receive training on the assessment protocol and shadow a minimum of two assessments prior to conducting an assessment. Assessments are completed in pairs to minimize procedural error. The project coordinator manages all contact with participants for scheduling assessments.

Over the course of active treatment and waitlist phases, weekly surveys (BFS and CADS) are sent out and completed remotely by both parents and children. Parents complete questionnaires online, whereas children have the option to complete questionnaires either online or over the phone with a blinded research assistant, dependent on age and ability to read and comprehend the questions independently. This is determined by the parent and the child's preference. Both the BFS and CADS surveys have been previously validated in children when administered orally (Lahey et al. 2010; Rognstad et al. 2022).

Retention [18b]

To reduce attrition likelihood, participant education is provided. The importance of attending scheduled intervention group sessions and follow-up visits for the duration of the trial is explained to all participants at the commencement of the trial to ensure that only those able to commit to the protocol are enrolled. Participants are also sent reminders, via email, call, or text, prior to each in-person assessment and after the initial weekly online assessments are sent. Families in both arms of the trial are monitored on a weekly basis, therefore direct contact with families is established weekly during the 6 weeks of active intervention or waitlist.

To further promote retention, participants receive financial incentives commensurate with each timepoint of the trial completed, with increasing amounts for later timepoints. Parents receive $25, $35, $45 and $50 for the T1, T2, T3 and T4 assessments, respectively. Children receive $15, $20, $25 and $25 for the T1, T2, T3 and T4 assessments, respectively. Parents and children are compensated $5 each for completion of the weekly questionnaires. Finally, retention is encouraged by regular mailings of thank you and birthday cards (Nature Editorial Board 2018).

Data management [19]

Participants complete questionnaires online via the Qualtrics survey platform. Survey data are downloaded and stored onto a secure server within an encrypted network. Raw data collected in-lab (i.e., video recordings, physiological data) are immediately transferred onto the secure lab server from the secure software and camera system (Video and Audio Learning Tool [VALT]). Data from video and physiological recordings are cleaned independently of the questionnaire data and added to the master database intermittently. Checks for valid values and ranges are also completed to ensure data quality upon data import. Any modifications to data within the database (e.g., addition of new participants, imputed missing values) is documented through a spreadsheet. Automatic system-wide backups of the Institution's secure server occur on a nightly basis.

Confidentiality [27]

Identifiable participant data are required to register for the trial. Participants' confidentiality is maintained except where information is disclosed that suggests a risk of harm to the parent, child, or others, or if the information is subpoenaed by law. Each participant is assigned a unique participant identification number that is recorded in the database. The identification, screening and enrolment logs linking participant identifiable data to the anonymized identification number are kept electronically in a password-protected document on a secure network hosted by the Institution. The only link between the participant identification number and the participants' name is in the screening and enrolment logs and written consent forms. Email addresses and phone numbers are required to contact participants (e.g., to send electronic links to complete measures and coordinate in-person assessments). Video recordings of in-person assessments and treatment sessions are captured using secure software and the VALT camera system. Videos are downloaded to the secure server immediately upon session completion and subsequently deleted from VALT. Any personal data contained in the research database are kept on a secure, restricted-access drive, accessible only by the primary research team.

Group psychotherapy introduces an additional limit to confidentiality, wherein other group participants are not legally bound to maintain the confidentiality of other group members. We mitigate this risk by communicating to participants that maintaining the security of others' identities in the group is a rule of group participation. Group rules are introduced and discussed at the first group session. Participants are made aware of this confidentiality risk prior to registering for the trial and reminded of this risk at the preliminary in-person assessment.

Statistical methods [20a]

Statistical methods for primary and secondary outcomes

All statistical hypothesis tests will use a two-sided p value of 0.05 unless otherwise specified. All confidence intervals will be two-sided and 95%. Statistical analyses will be performed using SPSS, MPlus, and R.

Analytic plan for primary and secondary outcomes

The primary outcomes include the K10, DERS, BFS, and CADS, and changes in parent-child co-regulation from T1 to T2, and from T2 to T3 and T4, between the treatment group and the control group. Secondary outcomes constitute the CCNES, CTS, CSQ, MaaP, and PSS from T1 to T2 and from T2 to T3 and T4, between the treatment group and the control group.

A series of linear mixed models will be conducted in SPSS for each primary outcome using T2 data from both groups, controlling for T1 data. Treatment condition will be included as a fixed factor, and therapy group (i.e., the specific therapy group that each participant from the treatment group attended) will be included as a random factor in each model. Other covariates will include child age, child sex, and household income. Linear mixed models will also examine T3 outcomes and T4 outcomes, controlling for T2 data.

If the intervention is efficacious, there will be a significantly greater reduction in the BFS Total Problems score, K10 total score, DERS total score, CADS Negative Emotionality score, CTS total score, PSS total score, and CCNES Unsupportive score from baseline (T1) to post-treatment (T2) in the treatment group compared to the waitlist group. There would also be a significantly greater increase in the CCNES Supportive score, MaaP total score, and parent-child co-regulation from baseline (T1) to post-treatment (T2) in the treatment group compared to the waitlist group.

If treatment gains are maintained at 4-months and 1-year post-treatment, the BFS Total Problems score, K10 total score, DERS total score, CADS Negative

Emotionality score, CTS total score, PSS total score, and CCNES Unsupportive score will remain the same or significantly decrase further from post-treatment (T2) to 3-months post (T3) and from post-treatment (T2) to 1-year post (T4) for the treatment group. As well, the CCNES Supportive score, MaaP total score, and parent-child co-regulation will remain the same or increase further from post-treatment (T2) to 4-months post (T3) and from post-treatment (T2) to 1-year post (T4) for the treatment group.

Analytic plan for moderation and mediation analyses

Analytic considerations for mediation analyses within the context of randomized controlled trials (RCTs) will be utilized to inform analyses within the present study (Cashin & Lee, 2024; Nguyen et al. 2020; Whittle et al. 2017). RStudio will be used to perform causal mediation analyses using the package *mediation* (Tingley et al., 2014), which includes considerations for mediation in RCTs. For each model, the predictor will be specified as EFFT vs. waitlist control to investigate the impact of the six-week EFFT intervention on proposed mediators (T2 parent supportive emotion socialization responses [CCNES Supportive], parent emotion regulation [DERS], and parent-child physiological co-regulation) and child outcomes (change from pre-intervention to post-intervention child emotion regulation [CADS] and psychopathology [BFS]). The weekly BFS can also be used to test child symptoms as a mediator. Covariates will include treatment fidelity and dosage (attendance). Analyses will be bootstrapped to account for nonparametric data and 95% confidence intervals will be used.

To examine categorical moderators of treatment efficacy, RStudio will be used to perform moderation analyses using the package *subtee* (Ballarini et al. 2021), which includes considerations for moderation analyses conducted in the context of RCTs. For analyses examining continuous variables as moderators, the function PROCESS in the package *bruceR* ('Broadly Useful Convenient and Efficient R Functions'; Bao 2023) in RStudio will be utilized. Covariates will include treatment fidelity and dosage (attendance).

All efforts will be made to ensure that the primary outcome data are collected for all participants. All participants with reported outcome data will be included in the analysis. In the event of substantial missing data, reasons for missingness will be explored and the validity of the missingness at random assumption will be investigated with a missing values analysis.

Methods for additional analyses (e.g., subgroup analyses) [20b]

If sample size for groups allow, subgroup analyses will be conducted depending on the child's presenting concern (i.e., internalizing vs. externalizing).

Missing data analyses [20c]

In the case of substantial missing data, reasons for this will be explored and a missing values analysis will be conducted. If the missing at random assumption seems reasonable and within expected limits, multiple imputation will be used. Intent-to-treat analyses will be used for all families who attended at least 1 group session.

Plans to give access to the full protocol, participant level-data and statistical code [31c]

The statistical dataset (i.e., unidentified data) will be uploaded to a public repository.

Oversight and monitoring

Data monitoring committee [21a]

Due to local standards within psychotherapy trials and the low risk of adverse outcomes due to receiving EFFT treatment, a formal data monitoring committee was not established.

Interim analysis [21b]

An interim analysis may be performed for a doctoral student dissertation project.

Adverse event reporting and harms [22]

In this trial, an adverse event is defined as any serious, undesired mental health occurrence (e.g., any child or parent injury, hospitalization or death related to mental health) in a trial participant without consideration of the potential for a causal relationship. All adverse events are collected after the trial participant has enrolled in the study and provided written consent. If a participant experiences an adverse event prior to beginning the intervention (whether they are in treatment or waitlist condition), the event will be recorded but reported as unrelated to the EFFT intervention. Any serious adverse event that occurs between study enrolment and the final timepoint of data collection, whether or not attributed to the trial intervention, will be reported to the Institution's research ethics board. Study investigators will establish the relation between the serious adverse event and the intervention based on temporal relationship between receipt of the intervention and the adverse event, the likelihood of the event given the participant's initial presenting concerns, prior mental health diagnoses, and the description of precipitating factors as reported preceding the event.

Frequency and plans for auditing trial conduct [23]

Audits will be performed as required by the sponsoring institution's research ethics board.

Plans for communicating important protocol amendments to relevant parties [25]

The protocol and all protocol amendments will be documented and submitted for ethical approval to the institution's research ethics board prior to implementation. Approved modifications will be updated in the registered protocol on ClinicalTrials.gov.

Discussion

The present trial will provide important information to clinicians, parents, and families to inform the provision and demonstrate the efficacy of EFFT for children and adolescents with various mental health challenges. There is a considerable disparity between the application of EFFT and its current evidence base, including outcomes related to child functioning and sustained long-term outcomes. To our knowledge, this is the first randomized controlled trial of EFFT as a transdiagnostic intervention for childhood mental health concerns. This trial endeavors to test a six-week group iteration of EFFT that aims to further parent participants' comprehension and use of the material while maximizing clinician and participant time, thus remaining a logistically desirable option for community organizations and private practices alike. Strengths of our trial include recruitment of a sample of varying developmental stages and diverse presenting concerns to maximize applicability and generalizability. Results from this trial could lead to wider overall adoption of EFFT due to the increased empirical support for its efficacy across a wide range of presenting concerns, as well as adoption of this highly logistically feasible six-week EFFT group program in both private practice and community settings.

Authorship eligibility guidelines [31b]

All authors who contribute substantively to study design, ongoing research, analysis and interpretation are recognized through authorship on the manuscript. We follow authorship guidelines by the International Committee of Medical Journal Editors (ICMJE, 2006).

Access to data [29]

The Principal Investigator retains enduring access to the cleaned data set. A selection of project team members is provided access to the dataset to perform analyses as needed. They retain access only insofar as they remain members of the research lab. Given that this is a single-site trial, there is no inter-site data sharing. Data is shared with project team members on a secure drive and is blinded of any identifying participant information.

Dissemination policy [31a]

The research team will publish one primary outcome article, describing the effect of EFFT treatment on primary outcomes detailed above. Another publication will be focused on the secondary outcomes (listed above) achieved by the intervention. Additional analyses using variables assessed for other subprojects (e.g., moderator and mediators of treatment outcomes) may be published. Results of this randomized controlled trial will be also presented at national and international conferences.

Abbreviations

EFFT	Emotion Focused Family Therapy
RCT	Randomized controlled trial
K10	Kessler Psychological Distress Scale
BFS	Behavior and Feelings Survey
DERS	Difficulties with Emotion Regulation Scale
CADS	Child and Adolescent Dispositions Scale
CCNES	Coping with Children's Negative Emotions Scale
CTS	Caregiver Traps Scale
MaaP	Me as a Parent Questionnaire
PSS	Perceived Stress Scale
CSQ	Caregiver Satisfaction Questionnaire
VALT	Video and Audio Learning Tool
SPSS	Statistical Package for the Social Sciences

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12888-024-06382-y.

Supplementary Material 1.

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Trial sponsor

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Authors' contributions

JS: Development of methodology, writing – original draft, funding acquisition; CR: writing – original draft; KT: conceptualization, writing – review & editing, supervision, project administration.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The research has been reviewed and approved by the sponsoring institution's research ethics board (REB#21-10-012CT).

Consent for publication

All authors have reviewed and approved the submission of this manuscript in its current form.

Competing interests
The authors declare no competing interests.

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