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ORIGINAL RESEARCH

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Study protocol for a randomized controlled trial of a child and parent mindfulness intervention for pediatric venipuncture

Rachel L. Moline[1] | Christine Chambers[2,3,4] | C. Meghan McMurtry[1,5,6]

[1]Department of Psychology, University of Guelph, Guelph, ON, Canada

[2]Department of Psychology and Neuroscience, Dalhousie University, Halifax, NS, Canada

[3]Department of Pediatrics, Dalhousie University, Halifax, NS, Canada

[4]Centre for Pediatric Pain Research, IWK Health Centre, Halifax, NS, Canada

[5]Pediatric Chronic Pain Program, McMaster Children's Hospital, Hamilton, ON, Canada

[6]Department of Paediatrics, Schulich School of Medicine & Dentistry, Western University, London, ON, Canada

Correspondence
Rachel L. Moline, Department of Psychology, University of Guelph, 87 Trent Lane, Guelph, ON N1G 2W1, Canada.
Email: rmoline@uoguelph.ca

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Abstract

Children commonly undergo painful needle procedures. Unmanaged procedural pain can have short- and long-term consequences, including longer procedure times, greater distress at future procedures, and vaccine hesitancy. While parent behaviors are one of the strongest predictors of children's response to acute pain, pediatric procedural pain management interventions focus almost exclusively on the child. Further, existing parent-involved pediatric pain management interventions typically fail to improve child self-reported pain during painful procedures. The current protocol offers the first randomized controlled trial involving a mindfulness intervention for pediatric acute pain that includes children and their parents. This study aims to conduct a single-site, two-arm, parallel-group RCT to examine the effects of a mindfulness intervention for parents and children before child venipuncture compared to a control group on primary (child self-report of pain and fear), secondary (parent self-report and child report of parent distress), and tertiary outcomes (parent report of child pain and fear). Parent-child dyads (n = 150) will be recruited from the McMaster Children's Hospital outpatient blood laboratory. Dyads will be randomly assigned to either a mindfulness group guided through a mindfulness intervention or control group guided through an unfocused attention task. Parents will accompany their child for their venipuncture. Postvenipuncture measures will be collected (eg, child pain-related outcomes as reported by parents and children). The first enrollment occurred in October 2019. We offer a novel intervention that aims to facilitate both parent and child coping during child venipuncture.

KEYWORDS
mindfulness, needle, pediatric pain, RCT

1 | INTRODUCTION

Parents are an integral part of children's pain experiences and can influence child responses to pain.[1,2] The Social Communication Model of pain[1] captures how parents play a critical role in children's experiences of acute pain through both interpersonal processes, such as procedural behaviors during child pain,[3] and intrapersonal processes, such as parent trait anxiety or coping style.[1,4] Despite the consensus that parents are critical to child outcomes, procedural pain management interventions focus almost exclusively on the child.[4,5] Furthermore, parents commonly experience distress during their child's pain, and this distress is associated with increased child

procedural distress.[6] Thus, there is a need for pain management interventions that target parents in order to improve the experience of both children and parents during pediatric acute pain.

Troublingly, extant pain management interventions for pediatric acute pain involving parents have not consistently yielded the desired effects.[7] As parent procedural behavior accounts for large variance in child pain outcomes[4] and is presumably modifiable, parent-involved pain management interventions have focused narrowly on changing parent procedural behaviors (eg, what they say or do during child pain). The majority of these interventions target interpersonal variables by including parent training, such as psychoeducation on how parent procedural behaviors impact child pain experiences,[8] and training parents to engage in helpful (coping "promoting"), and avoid harmful (distress "promoting") behaviors during painful procedures.[9] In particular, the majority of these interventions involve promoting parent use of distraction.[10-14] While these studies collectively demonstrate increases in helpful parent procedural behaviors, such as increased parent distraction,[8] they fail to demonstrate reductions in child self-reported pain.[8-14] Indeed, a Cochrane review indicated that parent coaching plus distraction was not effective in reducing needle-related pain and distress in children and adolescents.[7] Authors cautioned that although parents could assist with distraction, the efficacy of this intervention is questionable for parents with higher levels of anxiety.[7]

Together, these findings demonstrate that simply adjusting parent procedural behaviors is likely insufficient as a stand-alone intervention for reducing child pain. Parent intrapersonal factors, such as anxiety, or distress, may limit the effectiveness of interventions targeting parent behavior.[7,15] However, children with parents who have higher levels of anxiety and catastrophizing tend to demonstrate poorer pain outcomes, which indicates a strong need for an intervention that would benefit this population.[16] Thus, a pediatric pain management intervention that addresses parent intrapersonal processes including emotional experiences and aims to reduce parent distress during children's painful procedures is needed. Such an intervention may improve the effectiveness of parent-supported interventions.

1.1 | Study rationale—mindfulness in the context of pain experiences

A mindfulness intervention for both parents and children before child procedural pain may offer a novel solution to the aforementioned issues with existing parent-targeted interventions. Namely, a mindfulness intervention for children and parents may facilitate both child and parent coping during child pain. Mindfulness can be defined as "nonreactive awareness of the present moment".[17] Mindfulness aims to decouple sensations and automatic evaluations; central to this practice is accepting what *is* instead of evaluating and reacting to experiences.[18] Mindfulness can improve pain-related outcomes through complex mechanisms that involve changes in cognitive and affective responses to pain, and related changes in nociception.[19-21] Theoretically, mindfulness interventions aim to promote adaptive appraisals of pain experiences, which can translate into positive pain-related outcomes (eg, reduced pain intensity; reduced anxiety;[22,23]). Despite a growing body of evidence demonstrating that mindfulness positively attenuates pain experiences, the exact neurocognitive processes underlying these mechanisms have yet to be fully illuminated.[24,25]

Mindfulness interventions in the context of pediatric acute pain have been understudied compared to mindfulness interventions for acute pain experienced by adult populations.[24,26,27] To date, few studies have examined the effectiveness of brief mindfulness interventions for acute, experimental pain in school-aged children and adolescents (ie, 7-14 years;[28-30]). Relevant findings demonstrated that a mindful attention and sensory focusing intervention were effective in directing attention to pain, without increasing pain intensity when compared to guided imagery (an established pain management intervention in youth aged 10-14;[28]), and comparable to distraction in the reduction of pain intensity in youth aged 10-14.[29] However, a mindfulness intervention for pediatric acute pain has not been examined in the context of actual medical procedures, such as venipuncture. As such, the current study offers the first investigation into a mindfulness-based intervention for youth during procedural pain.

Parent-targeted mindfulness interventions for pediatric acute pain have not yet been studied. When children are in pain, parent decoding of child experiences occurs spontaneously.[1] This automatic decoding of child experiences can be particularly challenging when parents experience reflexive distress in seeing their child in pain, as this is a known correlate of poorer child pain-related outcomes.[6] Therefore, in our intervention, we seek to adjust parent decoding of child pain. By instructing parents to bring awareness to their reflexive reactions, we hope to engender more reflective appraisals, which includes noticing one's reactions without evaluating them as "right" or "wrong." This may reduce the distress that parents experience, and subsequently communicate to the child. However, to date, no research has investigated the role of a mindfulness intervention for pain observers, despite preliminary evidence for the benefits of high levels of parent trait mindfulness in relation to child pain outcomes.[31] Specifically, higher levels of parent trait mindfulness are associated with reduced child pain during experimentally induced pain[31] (first author's master's thesis). By extension, we hypothesize that cultivating parent nonjudgmental acceptance of present-focused attention during child pain might reduce parent distress without necessitating that parents focus on changing procedural behaviors. The current protocol is the first to investigate a parent mindfulness intervention in the context of pediatric pain. We aim to offer a novel intervention that may improve both parent and child experience during pediatric needle procedures in which unmanaged pain and distress are associated with deleterious effects.[32]

1.2 | Study objectives and hypotheses

See Figure 1 for an overview of the study variables. This study involves a single-site, two-arm, parallel-group RCT conducted at an outpatient blood laboratory of a pediatric hospital. The effects

of a mindfulness intervention for parents and children before child venipuncture will be compared to a control group undergoing an unfocused attention task. Primary outcomes (child self-report of pain and fear), secondary outcomes (parent self-report and child proxy-report of parent distress), and tertiary outcomes (parent proxy-report of child pain and fear) will be assessed. This randomized controlled trial (RCT) was approved by the Hamilton Integrated Research Ethics Board at McMaster Children's Hospital (project #5481), and the Research Ethics Board at the University of Guelph (#19-05-028) on May 24, 2019, and July 6, 2019, respectively. The trial was registered in the clinicaltrials.gov registry on May 8, 2019 (NCT03941717). The study objectives and hypotheses are as follows:

1. The primary objective is to evaluate group differences in order to determine whether child pain-related outcomes during child venipuncture improve following a mindfulness intervention compared to unfocused attention control. Primary outcomes include child self-reported procedural pain and fear. It is hypothesized that the mindfulness intervention will result in lower child pain and fear in the intervention group compared to the unfocused attention control group (controlling for child age and sex).
2. A secondary objective is to evaluate group differences in order to determine whether parent distress during the venipuncture decreases following a mindfulness intervention compared to unfocused attention control. It is hypothesized that the mindfulness intervention will result in lower parent distress during the venipuncture in the intervention group compared to the unfocused attention control group, as rated by both parent self-report and child proxy-report.
3. A tertiary objective is to evaluate group differences in order to determine whether parent proxy-reports of child pain and fear improve following a mindfulness intervention compared to unfocused attention control. It is hypothesized that the mindfulness intervention will result in lower parent report of child pain and fear during the venipuncture in the intervention group compared to the unfocused attention control group (controlling for child age and sex).

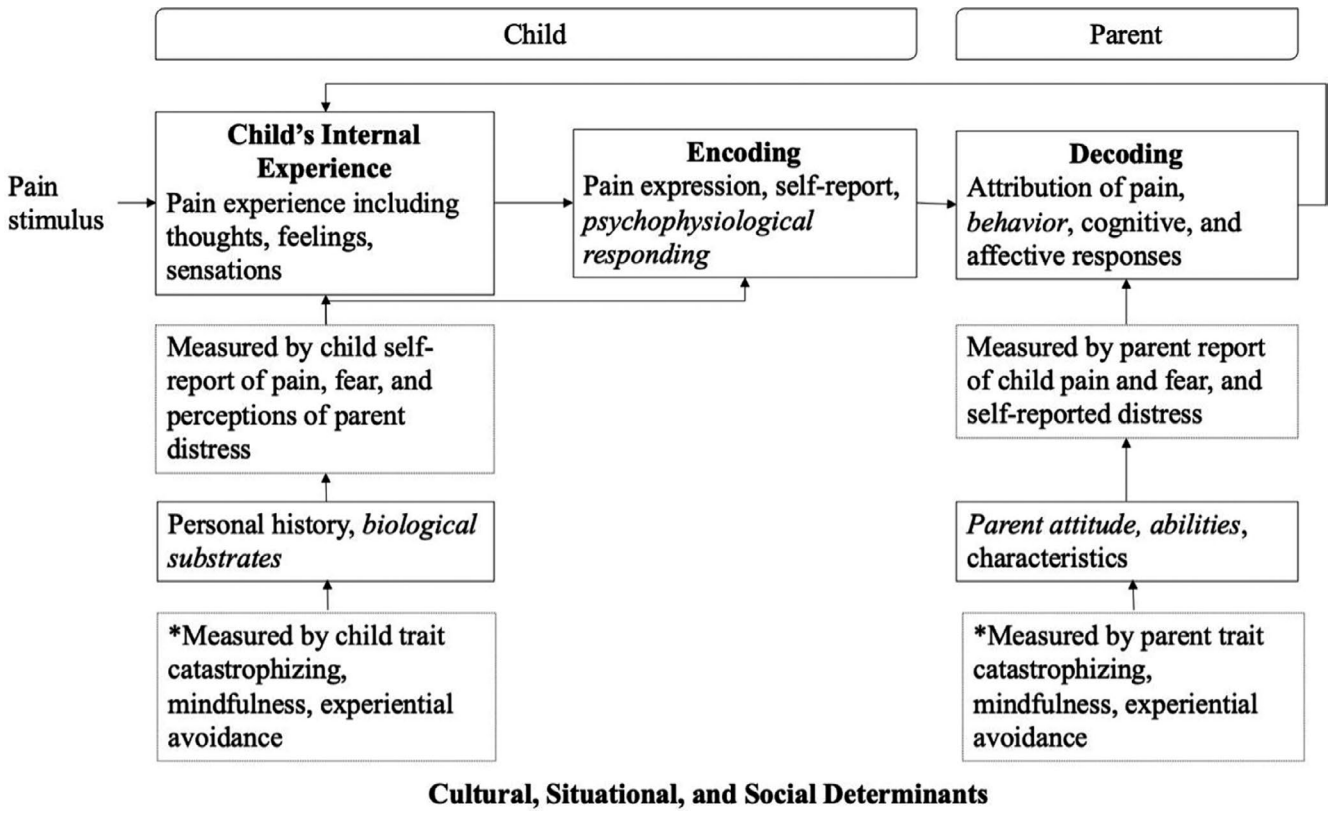

FIGURE 1 *Variables captured in Study 2 (see Appendix S1). Italicized text indicates variables not captured in the study. This is an adapted image of study variables mapped onto the Social Communication Model of Pain.[1] In considering the Social Communication Model,[1] the proposed randomized controlled trial aims to target the intrapersonal processes of both the child and parent in addition to indirectly seeking to address the interpersonal process. Specifically, child intrapersonal factors targeted in the intervention include the sensory, emotional, and cognitive aspects of the pain experience. Parent intrapersonal factors targeted in the intervention include parent decoding of the child's pain experience. Thus, we hypothesize that the dyadic mindfulness intervention will improve child pain and related outcomes and parent experience of child pain. We aim to reduce parent distress by changing their decoding of child pain expression to be reflective instead of reflexive. This may improve parent ability to support child coping via reduced parent distress. Study 2 will investigate parent and child trait levels of catastrophizing, experiential avoidance, and mindfulness to assess whether these intrapersonal variables impact responding to condition (see Appendix S1)

A secondary study that will be conducted upon trial completion is detailed in the Appendix S1. Study 2 will build upon this RCT by investigating potential factors that may impact intervention effectiveness in considering the role of selected intrapersonal factors of parents and children. It is crucial to determine whether the treatment effects of a given intervention differ as a function of intrapersonal factors, or to whom the treatment is administered. Further objectives pertaining to these moderation analyses also appear in the Appendix S1.

2 | METHODS

2.1 | Study setting and sample

Children between 7 and 12 years of age undergoing a venipuncture and their caregiver will be recruited from the outpatient blood-draw laboratory at McMaster Children's Hospital. Children will be eligible for participation if they are undergoing a venipuncture for clinical purposes and are (a) aged 7-12 years, (b) are with their caregiver, and (c) have sufficient knowledge of the English language to understand and complete the study intervention and measures. Children with major developmental delays precluding their ability to complete study measures will be ineligible for participation.

An a priori power analysis was conducted using G* Power to determine sample size (Test family: *F* tests; statistical test: MANOVA, global effects; Effect size $f^2 = 0.08$ Alpha error probability: 0.05; power = 0.80 Number of groups = 2; and response variables = 2). In the absence of established global effect size estimates for mindfulness-based interventions in pediatric acute pain, estimates using Cohen's *d* for other parent-involved psychological interventions for child pain were used, which typically demonstrate small to moderate effects.[7] Given the absence of clear effect size estimates, we sought power to detect medium effect sizes given the literature above. Thus, it was estimated that 124 dyads would be needed. We planned to collect 150 dyads to account for missing data, technical issues, and address a common source of bias in the relevant literature, including small samples and lacking the power to detect treatment effects.[7] See the Appendix S1 for Study 2 and the associated power analysis.

2.2 | Random assignment

Allocation will remain blinded using a block randomization method. Blocks have predetermined group assignment ratios, which will enable a balance between treatment arms throughout the study.[33] The randomization schedule was generated using an electronic researcher randomization tool, conducted by McMurtry (senior author but not directly involved with trial execution or data analyses). Sequentially numbered opaque sealed envelopes (SNOSE;[29]) were created by an independent research assistant not involved in any other aspects of the research. Two research assistants (RA) facilitate data collection. RA 2 will open the SNOSE immediately prior to the intervention and select the corresponding audio file (ie, intervention or the control) on the tablet for each participant. RA 1 will be blinded to participant assignment to condition. Due to the type of intervention, it is possible that participants may recognize a mindfulness activity. However, given that participants are unaware of the specific study objectives and hypotheses, they will remain blinded from the treatment allocation.

2.3 | Interventions

All participants will receive usual care during the venipuncture; if they are using topical anesthetic cream, or are receiving other pain management interventions, this will be allowed, monitored, and recorded. Adverse events and noncompliance will be monitored. RA 1 and 2 will explain the study to participants as follows, "You and your child will be asked to listen to instructions on a tablet with headphones and be guided through an activity that will last 5 minutes. You and your child will be asked to direct or focus your attention and thoughts in particular ways. You and your child will be selected to receive one of two activities. Which activity you and your child will be led through will be assigned at random. Half of the caregiver and child pairs will participate in the first activity while the second half will participate in the second activity. You will not be told about the differences between the activities. This allows us to determine if one of the activities is more helpful in improving caregiver and child experiences during the needle procedure compared to the other activity. We will ask you and your child a few questions after this activity." Parents and children will be provided with a tablet and accompanying headphones and will listen to a 5-minute audio recording of either the mindfulness or unfocused attention script at the time of the intervention. There are parent and child versions of each activity. Please see Appendices A and B for the parent and child mindfulness intervention scripts that are slightly modified from Siegel and Bryson.[34]

2.3.1 | Experimental: Mindfulness-based condition

The mindfulness intervention targets worries and anxiety, which are related to pain and related outcomes.[32] The parent and child scripts were developed by Siegel and Bryson.[34] Adjustments to the child script were informed by the work of Petter et al.[28] Scripts were slightly modified to fit the context of venipuncture and begin with instructions to take two deep breaths. The intervention aims to cultivate present moment awareness of experiences, curiosity, nonjudgment, and acceptance of experiences as they unfold. Participants are asked to visualize their worries and feelings as a cloud in the sky, which eventually clears to reveal blue skies. One difference between the parent and child interventions is that parents are asked to envision their worries pertaining to "when your child is about to get a needle," while children are asked to imagine "any of your worries about your needle." In both interventions, the temporary nature of sensations is described, and participants are asked to remain open and curious about their experiences during the procedure. The complexity of language used also differs between the two versions. For

example, the child script uses child-friendly language, such as feeling terms like "scared" and "angry," while more complex vocabulary is present in the parent script (eg, descriptors such as "ominous" and "worrisome"). See Appendices A and B.

2.3.2 | Sham comparator: Unfocused attention condition

Each script for the unfocused attention task instructs participants to allow their minds and thoughts to roam as usual. The parent script has been successfully used in other research with healthy adults as a control for a mindfulness intervention.[35] This script was condensed in time from the original reading. The child version of the activity was adapted from a mind-wandering script used for children aged 7-12 in past research.[36] The aim is to encourage the participant to continue thinking and mind wandering as they typically would.[36] See Appendices C and D.

2.4 | Recruitment and data collection

Potential participants will be approached and introduced to the study. If interested and eligible for participation, informed consent will be obtained. Next, dyads will be randomly assigned to the mindfulness group guided through a meditation, or the control group guided through an unfocused attention task as described above. Parents will accompany their child for their venipuncture. Postvenipuncture measures will be collected, including child and parent reports of child pain, fear, and parent distress (see next section). Participants will be asked to complete a manipulation check following the venipuncture.

2.5 | Measures

2.5.1 | Primary outcome measures

Primary outcome measures include child pain and fear during the needle. Child self-reported pain intensity will be measured using a Numeric Rating Scale (NRS), completed within two minutes following the needle-poke. The NRS has been used to assess pain intensity in children aged seven and older during acutely painful procedures.[37] The NRS is rated on an 11-point numerical rating scale, ranging from 0 ("no pain") to 10 ("a lot of pain"). Child self-reported fear will be measured using a Numeric Rating Scale (NRS), completed within two minutes following the needle-poke. The NRS has been used to assess child fear in children aged seven and older during acutely painful procedures.[37] The NRS is rated on an 11-point numerical rating scale, ranging from 0 ("not scared") to 10 ("very scared").

2.5.2 | Secondary outcome measures

Secondary outcome measures include child and parent perceptions of parent distress as rated on an NRS (researcher generated). This will be completed within 5 minutes following the needle-poke. Children will be asked to "Tell us how upset you think your parent was during the needle." This item will be rated on an 11-point numerical rating scale, ranging from 0 ("not at all") to 10 ("extremely"). Parents will be asked to provide ratings indicating their level of distress experienced on an NRS (researcher generated): "Tell us how distressed you were during the needle," with response options ranging from 0 ("not at all") to 10 ("extremely").

2.5.3 | Tertiary outcome measures

Tertiary outcome measures include parent proxy-reports of child pain and fear as rated on two separate 11-point NRS,[37] completed within five minutes following the needle-poke. Parents will be prompted to provide ratings corresponding to how much pain they think their child experienced from 0 ("no pain") to 10 ("a lot of pain"). Parents will also be prompted to provide ratings corresponding to how much fear they think their child experienced from 0 ("not scared") to 10 ("very scared").

2.5.4 | Attentional direction (manipulation check)

For the manipulation check, parents and children will be asked to rate, "How often did you notice your thoughts and feelings in your body, and/or your breath during the needle?" (consistent with the mindful attention manipulation), and "How often did you try to distract yourself, or find your mind wandering during the needle?" (inconsistent with the mindful attention manipulation) completed within five minutes following the needle-poke. Answers will be given on 11-point numerical rating scales ranging from 0 ("not at all") to 10 ("all the time"). These questions were modified from Petter et al' research[30] involving a mindfulness intervention. The wording was adjusted to reflect the current intervention and the type of painful procedure.

2.5.5 | Adverse events and noncompliance

RA 1 and 2 will record any adverse events or noncompliance that may occur during the study. This will include monitoring for adherence to the assigned condition (eg, if headphones were taken off prior to finishing the activity), in addition to other adverse events (eg, child restraint during venipuncture). The number of attempts (eg, needle pokes) necessary for the venipuncture will also be recorded.

3 | PROPOSED ANALYSES

Frequency and descriptive statistics will be reported for all variables. Screening for missing data will occur. Both randomization-based (intention-to-treat [ITT]) and adherence-based (per-protocol [PP]) analyses will be conducted. All participant data will be collected regardless of adherence to study protocol (eg, adverse events, noncompliance;[38,39]). ITT is used to generate an unbiased, conservative estimate of the effect of the treatment on the outcome and reduces the risk of Type I error.[39,40] ITT is recommended by the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[41] ITT analyzes the groups based on assignment to condition and includes participants even if they did not complete the intervention.

Due to the conservative estimate of the treatment effect generated by using ITT, all analyses will also be conducted using PP. In a PP analysis, only data from adherent participants are included; cases in which there was treatment noncompliance or missing data are excluded.[40,41] Differences in results between the ITT and PP methods will be compared.[38,40] Patterns of missing data will be assessed using Little's missing completely at random (MCAR) test.[42,43] Based on the nature of the missing data, imputation methods will be determined. For the ITT analysis, missing data will be imputed to allow for the completion of the intended analyses.[38]

3.1 | Attentional direction (manipulation check)

A series of one-way, between-subjects ANCOVAs will be conducted for children and parents on the attentional direction of participants during the procedure. Findings will indicate if the mindfulness intervention corresponds with increased mindfulness during the venipuncture and if the unfocused attention group endorses mind wandering. Assumptions for MANCOVA's will be investigated. A series of between-subject MANCOVA's will be completed for primary (child self-report of pain and fear as response variables), secondary (caregiver self-report and child report of caregiver distress as response variables), and tertiary outcomes (caregiver report of child pain and fear as response variables), controlling for child age and sex. Follow-up analyses using post hoc *t* tests will be used to investigate significant group differences and differences between response variables within each MANCOVA.

4 | TRIAL STATUS

Sixty-one parents and sixty-one children participated in the trial to date (October 21, 2019-March 13, 2020). Recruitment was intended to continue until 150 parent-child dyads were included. However, due to COVID-19 pandemic restrictions, the trial has been suspended. If we are unable to continue with the trial completion due to ongoing concerns pertaining to COVID-19, we plan to complete the data analysis as intended. We would be powered to detect medium to large effects for our planned MANCOVA analyses within our current sample (sensitivity power analysis; Effect size $f^2 = 0.17$; medium effect size $f^2 = 0.15$; and large effect size $f^2 = 0.35$).

To our knowledge, this is the first trial of a mindfulness intervention for pediatric needle procedures. If the mindfulness intervention detailed in this study confers a significant benefit to children and parents during child venipuncture, potential clinical implications are worth consideration. This line of research seeks to inform intervention development for pediatric pain management. By targeting parent experiences, this intervention seeks to "manage" pain in a way that is consistent with relevant theoretical models that underscore the importance of social factors. As such, findings will add to our understanding of the individual and dyadic factors that dynamically impact children's pain experiences. Importantly, this intervention might comprise an ideal, low-cost, and feasible intervention for parents and children before painful child procedures. For example, audio recordings can be freely distributed online, allowing parents and children to engage with this intervention independently without requiring trained personnel. The consideration of factors posited to influence the intervention's effectiveness, as detailed in the Appendix S1, will also be critical in guiding future directions.

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CONFLICT OF INTEREST

There are no conflicts of interest to disclose.

ORCID

Rachel L. Moline https://orcid.org/0000-0001-8405-7431
Christine Chambers https://orcid.org/0000-0002-7138-916X

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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APPENDIX A

PARENT MINDFULNESS SCRIPT

During the next few minutes, you will be guided through an activity that you can use before and during your child's needle. When you're ready, you can get your body into a comfortable yet alert position. Close your eyes and take a slow, deep breath…in through your nose… 1,2,3,4,5, and out though your nose… 1,2,3,4,5. Fill your lungs again, breathing through your nose…1,2,3,4,5 and out through your nose…1,2,3,4,5. Think of any negative thoughts or feelings that come up when your child is about to get a needle. Close your eyes, and picture the negative thoughts or feelings as a cloud. Focus on that cloud and notice it's details. What size is it? Is it gray and stormy looking? Or maybe it's white and fluffy. Is it clearly defined or wispy and shapeless? What feelings do you get when you see it–does it feel ominous and threatening, or perhaps more low lying and worrisome? Don't make judgments about your cloud, or about how you should feel about it. Just notice what you notice. While you sit with those sensations, acknowledge that this cloud is important and real and something to pay attention to—just as all of your emotions are. Like any cloud you see in the sky, your cloud may seem to sit still and linger at times. But if you continue to watch it, you'll notice that it's actually floating along and will eventually drift out of sight. You may notice that you have thoughts in your head as you go through this visualization, like "this is weird" or "how long do I have to do this". Let these thoughts, just like your cloud, come into your awareness without judgment. Then let them move along out of your consciousness. You'll notice that as they pass, new thoughts come up. Again, just let those thoughts come up and move on. Stay with this exercise for one to two minutes, or until you see your cloud disappear as it drifts out of sight. During your child's needle, try to notice whatever thoughts arise, again, let these thoughts, just like your cloud, come into your awareness without judgment, and you can just let them go, all on their own. When you are ready, open your eyes and remove your headphones.

Note. This script is a slightly modified version of an activity created by Siegel and Bryson.[34] Modifications were informed by consultation from the work of Garland et al.[35]

APPENDIX B

CHILD MINDFULNESS SCRIPT

During the next few minutes, you will be guided through an activity that you can use before and during your needle. When you're ready, sit still in your chair. Straighten your back, and take your time to sit up straight and comfortably. Close your eyes and take a slow, deep breath…in through your nose… 1,2,3,4,5. Now blow out though your nose…1,2,3,4,5. Fill your lungs again, breathing through your nose…1,2,3,4,5 and out through your nose…1,2,3,4,5. Good, as you continue to breathe deeply, allow your body to relax into your chair. Now imagine any of your worries about your needle as a cloud in the sky. Look at this cloud closely. Can you see any details? There's no right or wrong answer. What size is it? Is it gray and stormy looking? Or maybe it's white and fluffy. Does the look of the cloud make you feel anything in your body? Do you feel those feelings in a particular place? Can you lay your hand where those sensations are? Sometimes our clouds make us feel scared, or maybe even angry. Whatever you're noticing, just allow yourself to be aware of it. There's no need to change or judge your thoughts—they're all ok to have. Now bring your attention back to your cloud. I want to remind you that your cloud is real and important, and it's something to pay attention to—just like all of your emotions. As you sit and watch it float by in the sky, has your cloud changed shape or color? Is it moving quickly or does it seem to stay in one place? Like any cloud you see in the sky, your cloud may seem to sit still and linger at times. But if you continue to watch it, you'll notice that it's actually floating along and will eventually drift out of sight. As you are taking deep breaths and blowing out, you might imagine that you're blowing your stormy clouds away. With a little time, every cloud moves on and then new clouds—just like new feelings—come into view. That's what I want you to imagine now—your cloud has moved on from your view and new clouds are gently drifting in. They look and feel different from the one that was just there. There are many of them filling the sky in front of you, some gray and dark, some wispy and white, and there's plenty of blue sky as well. When you get your needle, focus on your breathing and imagine blowing away any stormy clouds that come up. Notice how when the clouds pass by there is blue sky behind them. When you are ready, open your eyes and remove your headphones.

Note. This script is a slightly modified version of an activity created by Siegel and Bryson.[34] Modifications were informed by consultation of other mindfulness scripts.[28]

APPENDIX C

UNFOCUSED ATTENTION SCRIPT FOR CAREGIVERS

During the next few minutes, you will be guided through an activity that you will learn and practice before the needle and use during the needle …When you're ready, you can start by allowing your mind to roam; there is no need to focus on anything in particular… Just let your mind wander… Openly let your thoughts flow… Let yourself think freely about whatever you want, just let your mind wander… Think about whatever comes to mind… Allow your mind to roam; there is no need to focus on anything in particular… Just let your mind wander… Openly let your thoughts flow… Continue to let yourself think freely about whatever you want, just let your mind wander… During your child's needle-poke, let your mind roam and act as you normally would for the duration of the procedure…When you are ready, open your eyes and remove your headphones.

Note. This script has been slightly modified, the first and last sentences were added for consistency across conditions.[35,36]

APPENDIX D

UNFOCUSED ATTENTION SCRIPT FOR CHILDREN

During the next few minutes you will be guided through an activity that you will learn and practice before the needle and use during

the needle ....When you're ready, let yourself daydream; think about whatever you want to think about ... Just let your mind wander... Feel free to daydream about anything that crosses your mind ... Think about whatever comes to mind... Allow your thoughts to arise; there is no need to focus on anything in particular... Just let your mind wander, and day dream... Simply sit here and let your mind wander... When you get your needle, let your mind go and wander as you wish, act as you normally would during the procedure... When you are ready, open your eyes and remove your headphones.

Note. This script has been slightly modified, the first and last sentences were added for consistency across conditions.[35,36]