The Cold Pressor Task: Is it an Ethically Acceptable Pain Research Method in Children?

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Objectives The cold pressor task (CPT) is an experimental method of inducing pain. Ethical concerns have been raised regarding the nontherapeutic induction of pain in children. The objectives of this study were to describe the ethical challenges and acceptability of the CPT from the perspective of researchers, children and parents. Methods Study 1: 16 researchers completed a survey regarding their experiences obtaining ethical approval and use of the CPT in pediatric research. Study 2: 175 children and 194 parents answered questions about their experiences participating in studies that used the CPT. Results Full ethics board review was generally required. Adverse events were rare and transient. The majority of researchers, children, and parents reported positive experiences with the CPT. Conclusions The CPT is judged by researchers, children, and parents to be an acceptable research method. The CPT can be used ethically in pediatric research with appropriate study safeguards.

Key words pain; ethical issues; children; parents.

The cold pressor task (CPT) is a commonly used experimental method of inducing pain. Completion of the CPT typically requires an individual to submerge his/her hand or forearm in cold water for as long as can be tolerated, lasting up to several minutes. Laboratory pain induction techniques, such as the CPT, are scientifically valuable as they afford a higher degree of control over the environment and reduce the impact of potential confounding variables, thereby maximizing the internal validity of the research. Studies have used the CPT to address important research questions that were not possible to address adequately in a clinical setting. Although the CPT was originally developed for use with adults, its first employment with children dates back to 1937 when it was used to assess changes in blood pressure in children aged 6–19 years (Hines, 1937). Subsequent CPT studies continued to examine blood pressure in children (McIlhany, Shaffer, & Hines, 1975; Wood, Sheps, Elveback, & Schirger, 1984) and also investigated autonomic reactivity in healthy children and children with recurrent abdominal pain (Apley, Haslam, & Grant Tulloh, 1971; Feuerstein, Barr, Emmett Francoeur, Houle, & Rafman, 1982; Rubin, Barbero, & Sibinga, 1967).

In the late 1980’s the CPT began to be used more specifically as a pain induction method in pediatric studies (LeBaron, Zeltzer, & Fanurik, 1989; Zeltzer, Fanurik, & LeBaron, 1989). Since that time, a number of studies have utilized the CPT (typically with 10°C water) to investigate a range of topics in pediatric pain, such as the role of psychological variables in children’s pain (Dufton et al., 2008; Tsao et al., 2004, 2006), the impact of parental behavior on children’s pain (Chambers, Craig, &
Birnie, Noel, Chambers, von Baeyer, and Fernandez

In their sample of 141 8- to 12-year-olds, two children

duress for reporting on pain intensity during the CPT itself.

healthy pediatric sample, and further refined CPT proce-

ined the influence of psychological and personal variables

investigation by Trapanotto and colleagues (2009) exam-

reported adverse events (von Baeyer et al., 2005). A recent

over 1,700 child participants had been published with no

vasovagal stress response (von Baeyer et al., 2005). At the

time these guidelines were published, CPT studies with

mum immersion time to prevent cold-induced tissue

Safety considerations were highlighted with reference to

sore, or fracture of the limb to be immersed, and any his-

lar disease, fainting, seizures, or frostbite, with any cut,

risk of the CPT were suggested as follows (von Baeyer et al.,

important of child assent to participation, and whether or not a dif-

benefit to the participating child, the accurate assessment

issues which entail a minor increase over minimal risk,

children were published by von Baeyer and colleagues

Children maintain control over the process by being

46.406 (2009), which describes as acceptable pro-

Identification of concerns raised by institutional review

boards (IRBs) with respect to CPT research will be helpful

investigators in preparing protocols that address these

area exists to guide investigators.

In addition, while adverse event rates are reported to

be rare, only one study has reported on children’s per-

ceived acceptability of the CPT. LeBaron and colleagues

(1989) used the CPT with 37 children aged 6–12 years

with 15°C water. They cited the willingness of 29 partici-

pants to complete a second exposure to the CPT at a colder

temperature (12°C) 3 months later as evidence supporting

the ethical appropriateness of the CPT with children.

Questionnaires and interviews completed by 27 children

and their parents after study participation indicated that all

children reported enjoying the experience and would par-

ticipate again, all reported feeling safe, and none of the

children reported being bothered by the experiment. The

study was limited by the age range surveyed and the

warmer water temperature than is commonly used for

the CPT. No other published research has empirically

explored ethical considerations associated with using the

CPT with children nor parents’ or researchers’ experiences

with this task.

The purpose of the current research was to address

this gap in understanding of ethical concerns in the use of

the CPT by investigating researchers’, children’s, and par-

ents’ experiences. This was accomplished in two ways.

First, we comprehensively surveyed a group of researchers

who have used the CPT with children about their use of

the task, their experiences with IRBs, their intent to conduct
future research using the task, and their reported participant experiences. Second, a large sample of children who had participated in a variety of studies involving the CPT and their parents were surveyed about their overall experiences participating in research. These studies are the first to document researchers’ and parents’ experiences with the CPT and represent a critical step for evaluating risk and acceptability of using the CPT with pediatric samples.

Study 1—Researcher Experiences

Methods
Participants
A list of researchers who had previously published research studies using the CPT with children was generated following a comprehensive literature search restricted to English language articles using PubMed, PsycINFO, and Google Scholar. In addition, e-mail messages were distributed on pediatric pain and pediatric psychology listservs. In order to mitigate potential changes in IRB practices or CPT use over time, researchers had to have conducted research or have published a study since 2000 using the CPT with children between 0 and 18 years of age. Participants needed to be able to understand English.

The search identified 30 published studies with 21 unique corresponding authors. In total, 16 researchers (81% female; 19% male) completed the online survey (yielding an estimated response rate of 76.2%, although it is possible that some of the respondents were individuals who had received information about the survey via messages posted on listservs or word-of-mouth). The largest proportion of respondents were from the United States (n = 7; 44%) with representation from Canada (n = 4; 25%), Europe (n = 4; 25%), and Australia (n = 1; 6%). Twenty-five percent (n = 4) described themselves as senior career (i.e., more than 20 years post-graduation), 38% (n = 6) as mid-career (i.e., 10–20 years post-graduation), 25% (n = 4) as early career (i.e., less than 10 years post-graduation), and 13% (n = 2) as a student or trainee. Researchers’ disciplines were self-identified to be psychology (n = 9; 56%), pediatrics (n = 4; 25%), anesthesia (n = 2; 13%), nursing (n = 1; 6%), dentistry (n = 1; 6%), biopsychology (n = 1; 6%), and clinical research (n = 1; 6%); some researchers identified as being part of more than one discipline. Overall, survey respondents represented a group of researchers diverse in geography, career stage, and discipline.

Measure
Survey questions were developed based on the authors’ own experiences conducting CPT studies with children and review of the literature. Survey questions pertained to the nature of researchers’ experiences conducting CPT studies (i.e., number of CPT studies conducted and approximate number of participants), a description of the samples included (i.e., age of participants, healthy or clinical), and CPT procedures (i.e., number of CPT exposures in study, water temperature used, maximum immersion time used, monitoring of the child during the task). Specific ethical considerations were queried including information about individual IRBs and researchers’ experiences obtaining ethical approval (i.e., expedited or full IRB review), types of concerns raised by IRBs about CPT studies, ease of obtaining IRB approval compared to other pediatric research, adverse events, and any feedback received from participating children and families. Researchers were asked to rate their overall experience conducting CPT studies with children and about their intent to conduct such studies in the future. These questions were piloted with two researchers who had previously published CPT studies with children prior to distribution of the survey. The final survey included 31 questions and took an estimated 20 min to complete. A complete copy of the survey is available upon request from the first author.

Procedure
Corresponding author information was used to send an e-mail outlining the purpose of the survey and providing a link to the online survey itself to 19/21 researchers; e-mail contact information was not provided by two authors and alternate contact information was not available. A follow-up e-mail was sent two weeks after the initial invitation. The same invitation for study participation was also posted on the e-mail listservs. Researchers receiving the e-mail invitation were encouraged to pass on the information to any colleagues who had previously conducted, or were currently conducting, studies using the CPT with children.

The Opinio survey software (ObjectPlanet, Inc.) was used to create and administer the online survey. Consent information was included on the first page of the survey and was assumed through subsequent completion of the survey questions. All responses were anonymous and incomplete survey responses are not reported. A donation of $15 CAD was made to UNICEF on behalf of each individual who completed the survey. This study was approved by the IWK Health Centre Research Ethics Board.

Results
The results of the survey are presented in Tables I–III and are described based on content areas below. The results reported in this section refer to the number and percentage
of researchers endorsing specific responses to survey questions.

Participant Samples
Taken together, the 16 researchers reported conducting more than 41 CPT studies with approximately 3000 pediatric participants1 ranging in age from 1 to 18 years. As shown in Table I, almost all researchers had used the CPT with healthy children and almost half had used it with clinical samples, most frequently with children with headaches and recurrent abdominal pain.

CPT Procedures
See Table II for a summary of CPT procedures reported by researchers. The methodology for most of the CPT studies required that individual participants underwent multiple exposures to the CPT, which were completed in either the same (n = 5; 50%) or subsequent (n = 5; 50%) testing sessions. Regarding the CPT protocol, researchers reported using water from 5 to 15 °C with 10 °C reported as the modal response (n = 12). The maximum allowable immersion time ranged from 1 to 5 min with 4 min reported as the modal response (n = 6). All researchers reported that the children were monitored during the CPT by a researcher or research assistant and sometimes additionally by the parent.

Researchers’ Experiences with IRBs
Table III summarizes researchers’ experiences obtaining ethical approval. IRBs approving the CPT studies were mostly university-based or both university and hospital-based. Most researchers reported that obtaining IRB approval for CPT studies with children was comparable to obtaining approval for other pediatric studies. Full IRB approval (i.e., study protocol deemed above minimal risk and requiring review by all members of the IRB) was required in most instances, although three researchers reported conducting CPT studies qualifying for expedited review (i.e., study protocol deemed minimal risk and not requiring review by all IRB committee members). Individual IRBs appeared fairly consistent in the type of review they required for CPT studies involving children. That is, studies at a particular institution generally qualified for either full IRB review or expedited review. Three researchers (23%) whose CPT studies generally qualified for full board review reported also qualifying for expedited review with the same IRB.

1 The midpoints for categorical variables of number of participants (A = <50; B = 50–100; C = 100–250; D = 250–500; E = 500–1,000) were used to estimate the total number of participants from all surveyed researchers’ CPT studies.

2 No operational definition for adverse events was provided to researchers in the survey. Responding researchers reported adverse events based on their own or their approving IRB’s definitions of an adverse event.

Table I. Responding Researchers’ Reports of Participant Samples Included in CPT Studies

<table>
<thead>
<tr>
<th>Samples Included in CPT Studies</th>
<th>Number of Researchers n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric samples</td>
<td>n (%)</td>
</tr>
<tr>
<td>Healthy children only</td>
<td>9 (56%)</td>
</tr>
<tr>
<td>Clinical samples only</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>Both</td>
<td>6 (38%)</td>
</tr>
<tr>
<td>Clinical samples included (n = 7 researchers)</td>
<td></td>
</tr>
<tr>
<td>Headaches</td>
<td>5 (71%)</td>
</tr>
<tr>
<td>Recurrent abdominal pain</td>
<td>4 (57%)</td>
</tr>
<tr>
<td>Juvenile rheumatoid arthritis</td>
<td>1 (14%)</td>
</tr>
<tr>
<td>High risk for depression</td>
<td>1 (14%)</td>
</tr>
</tbody>
</table>

The most common concerns raised by IRBs were the unnecessary induction of physical pain to children, the level of induced pain, causing unnecessary psychological distress, lack of benefit to the child, and that the CPT was above minimal risk. One researcher reported the requirement of the IRB to have a crash cart nearby or physician to read ECGs. However, almost half of researchers reported no concerns raised by their IRB with only one researcher reportedly failing to receive ethical approval for a CPT study due to IRB concerns. In total, two adverse events were reported by two individual researchers, both instances involving significant distress for the child2. This translates to an adverse event rate of approximately 2/3000 or less than 0.07%. The majority (n = 10; 63%) of researchers reported receiving positive feedback from a family after children completed the CPT. Forty-four percent (n = 7) of researchers received negative feedback from at least one child during the CPT resulting in the withdrawal of data (n = 2; 29%), a complaint immediately following the task (n = 2; 29%), withdrawal from the study (n = 1; 14%), and other complaints (n = 2; 29%). Only one researcher received negative feedback from a parent about the CPT resulting in withdrawal of the child’s data.

As compared to other research protocols involving the same child populations, researchers rated their overall experience conducting studies using the CPT positively (M = 7.4/10, SD = 2.3; range 3–10; scale from 0 ‘very negative’ to 10 ‘very positive’). The majority (n = 12; 75%) of researchers indicated they intend to conduct CPT studies with children in the future.

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1 The midpoints for categorical variables of number of participants (A = <50; B = 50–100; C = 100–250; D = 250–500; E = 500–1,000) were used to estimate the total number of participants from all surveyed researchers’ CPT studies.

2 No operational definition for adverse events was provided to researchers in the survey. Responding researchers reported adverse events based on their own or their approving IRB’s definitions of an adverse event.
Study 2—Children’s and Parents’ Experiences Methods Participants

All children (n = 249) and their parents (n = 289) who participated in one of five CPT studies conducted at the IWK Health Centre, Halifax, Canada (Chambers et al., 2004; Chambers, 2007; Larochette, Chambers, & Craig, 2006; Moon, 2010; Wilby, Chambers, & Perrot-Sinal, 2010) were invited to individually complete a research participation questionnaire after concluding their study participation. In total, 175 children (52% girls; 48% boys) and 194 of their parents (one study required participation of both parents) completed research participation questionnaires. This reflects a response rate of 70.3% for children and 67.1% for parents. Children had a mean age of 11.3 years (SD = 2.5; range 7.5–17 years). Four of the five studies involved only healthy children, whereas one study also included children with recurrent headaches and/or recurrent abdominal pain (Chambers et al., 2004). Two of the five studies required children to undergo two exposures to the CPT, both in a single testing session (Larochette et al., 2006; Moon, 2010). All five CPT studies were conducted between 2003 and 2009 at the Centre for Pediatric Pain Research at the IWK Health Centre in Halifax, Nova Scotia and had received approval from the IWK Health Centre Research Ethics Board.

Table II. Responding Researchers’ Reports of CPT Procedures Used in Research

<table>
<thead>
<tr>
<th>CPT Procedures</th>
<th>Number of Researchers n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of planned CPT exposures in a single study protocol</td>
<td>6 (38%)</td>
</tr>
<tr>
<td>One</td>
<td>10 (62%)</td>
</tr>
<tr>
<td>Multiple</td>
<td></td>
</tr>
<tr>
<td>Multiple CPT exposures in single study conducted in (n = 10 researchers)</td>
<td>5 (50%)</td>
</tr>
<tr>
<td>Same testing session (i.e., on the same day)</td>
<td>5 (50%)</td>
</tr>
<tr>
<td>Subsequent testing session (i.e., on different days)</td>
<td></td>
</tr>
<tr>
<td>Water temperature used</td>
<td>12 (75%)</td>
</tr>
<tr>
<td>10°C (Mode) (Range 5–15°C)</td>
<td></td>
</tr>
<tr>
<td>Maximum allowable immersion time used</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>1 min</td>
<td>3 (19%)</td>
</tr>
<tr>
<td>3 min</td>
<td>4 (25%)</td>
</tr>
<tr>
<td>4 min</td>
<td>6 (38%)</td>
</tr>
<tr>
<td>5 min</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>Child monitored by</td>
<td>16 (100%)</td>
</tr>
<tr>
<td>Researcher/research assistant</td>
<td>4 (25%)</td>
</tr>
<tr>
<td>Researcher/research assistant and parent</td>
<td></td>
</tr>
</tbody>
</table>

Table III. Self-Reported Researchers’ Experiences with the IRB Process in Obtaining Approval for CPT Studies

<table>
<thead>
<tr>
<th>Experiences with IRBs</th>
<th>Number of Researchers n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRBs</td>
<td>8 (50%)</td>
</tr>
<tr>
<td>University-based</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>Hospital-based</td>
<td>6 (38%)</td>
</tr>
<tr>
<td>Both</td>
<td></td>
</tr>
<tr>
<td>Type of review generally required for CPT studies</td>
<td>13 (81%)</td>
</tr>
<tr>
<td>Full board review</td>
<td>3 (19%)</td>
</tr>
<tr>
<td>Expedited review</td>
<td></td>
</tr>
<tr>
<td>Obtaining IRB approval for CPT studies compared to other pediatric research protocols</td>
<td>10 (63%)</td>
</tr>
<tr>
<td>Comparable</td>
<td>3 (19%)</td>
</tr>
<tr>
<td>Difficult</td>
<td>3 (19%)</td>
</tr>
<tr>
<td>Very easy</td>
<td></td>
</tr>
<tr>
<td>Common concerns raised by IRBs</td>
<td>4 (25%)</td>
</tr>
<tr>
<td>Unnecessary induction of physical pain</td>
<td>3 (19%)</td>
</tr>
<tr>
<td>Level of induced pain</td>
<td>3 (19%)</td>
</tr>
<tr>
<td>Causing unnecessary psychological distress</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>No benefit to the child</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>CPT above minimal risk</td>
<td></td>
</tr>
<tr>
<td>No concerns raised</td>
<td>7 (44%)</td>
</tr>
<tr>
<td>IRB failed to approve a study due to concerns about the CPT</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>Yes</td>
<td>15 (94%)</td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Adverse events</td>
<td></td>
</tr>
<tr>
<td>Significant distress of the child</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>None</td>
<td>14 (87%)</td>
</tr>
</tbody>
</table>

Measure

Child and parent versions of the survey asked individuals to rate their overall research participation experience. Open-ended questions asked children and parents to describe their best and least liked or most difficult aspects of participation. The child version of the survey included questions regarding knowledge about the study prior to participating, questions about enjoyment of participation, and intent to tell others about their experience. The parent version included additional questions about previous research experiences, research recruitment methods, appropriateness of participation reimbursement, suggestions on making participation easier, ease of understanding study information, and intent to participate in the future. Parents rated statements about their reasons for participating in research on a scale from 0 (not important at all) to 5 (extremely important). These statements were based on anecdotal feedback the authors have previously received from families regarding why they participate in research and are consistent with literature regarding parental...
motives for pediatric research participation (Langley, Halperin, Mills, & Eastwood, 1998; Reynolds, 2006). A copy of the research participation questionnaire is available upon request from the first author.

Procedure
The research participation questionnaires were given to participants to complete at home after finishing participation in one of the CPT studies. Participants were provided with a postage-paid envelope to return the questionnaire by mail. Completion of the questionnaire was entirely voluntary and did not influence any compensation the child or parent received for CPT study participation. A content analysis was conducted identifying common themes based on participant responses to the open-ended questions regarding best and least liked/most difficult aspects of participation. A researcher then thematically coded all responses. Multiple theme codings were allowed for a single response with a dichotomous score for each theme. Twenty percent of responses were coded by a second rater with interrater percent agreement of 90.8%.

Results
Child and Parent Overall Experience Ratings
The majority (54%) of parents reported that either they or their child had previously participated in a research study. Of these individuals, parents had previously participated in an average of 2.75 studies (SD = 2.1; range 1–10) and children in an average of 1.90 studies (SD = 1.1; range 1–6). Both children (M = 8.4/10, SD = 1.6; range 4–10) and parents (M = 9.2/10, SD = 1.2; range 1–10) rated their overall experiences participating in a CPT study very positively. Neither child age nor sex were related to child (r = .06, p = .51; t = 1.34, p = .18) or parent (r = -.03, p = .67; t = .53, p = .59) overall experience ratings. Children participating in studies requiring two CPT exposures (M = 8.8/10, SD = 1.3; n = 48) rated their overall experience significantly more positively than those children participating in studies with one CPT (M = 8.3/10, SD = 1.6; n = 125) (t = −2.29, p < .05).

Parent-reported Reasons for Participation
Parents’ reasons for participating in research are shown in Table IV. Generally, parents endorsed the belief that research is important, that their child wanted to participate, and that participating was educational for their child. Parents also endorsed a desire to help others and a desire to contribute to medical knowledge. Although rated as somewhat less important, parents also indicated deciding to participate because it may benefit their child,

<table>
<thead>
<tr>
<th>Reasons for Participation</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belief that research is important</td>
<td>4.49 (.70)</td>
</tr>
<tr>
<td>Desire to contribute to medical knowledge</td>
<td>4.35 (.82)</td>
</tr>
<tr>
<td>Child wanted to participate</td>
<td>4.18 (.99)</td>
</tr>
<tr>
<td>Desire to help others</td>
<td>4.15 (.89)</td>
</tr>
<tr>
<td>Educational for child</td>
<td>4.11 (.05)</td>
</tr>
<tr>
<td>May benefit my child</td>
<td>3.65 (1.38)</td>
</tr>
<tr>
<td>Want to learn more about health research</td>
<td>3.34 (1.28)</td>
</tr>
<tr>
<td>Reimbursement/incentive offered</td>
<td>2.32 (1.63)</td>
</tr>
</tbody>
</table>

Note. Statements were rated on a Likert scale from 0 (not important at all) to 5 (extremely important).

because they wanted to learn more about health research, and because of the reimbursement or incentive offered (typically monetary). Almost all parents reported they would take part in a research study in the future (99%) and would recommend the experience to a friend (99%).

Child and Parent Enjoyment in the Study and the CPT
All children indicated that they were happy they had participated. Most felt that they had learned something new (n = 129; 75%), helped others (n = 150; 88%), and helped other people learn something new (n = 151; 89%). Almost all children felt that research was important (n = 171; 99%) and would tell a friend to participate (n = 153; 90%).

Children’s and parents’ responses to open-ended questions about the best and least liked/most difficult aspects of their experiences are summarized in Tables V and VI. Given the focus of the current investigation, aspects of each study protocol not related to the CPT were coded together in one category (e.g., sleeping over in the lab, games/playing/watching movies, being videotaped, and answering questions).

Although some children indicated the CPT/cold water was their least liked aspect of study participation (n = 59; 33.5%), they rated their overall experience very positively (M = 8.37/10, SD = 1.5; range 4–10). Furthermore, their overall experience rating was not significantly different from the overall experience ratings of children who indicated the CPT/cold water as being the best aspect of their participation (n = 35; 20%) (M = 8.66/10, SD = 1.4; range 5–10) (t = −.896, ns).

A small number of parents (n = 14; 7.2%) indicated that the CPT or watching their child in pain or discomfort was the most difficult aspect of study participation; however, 100% of these parents indicated they would
participate in another research study in the future. Both these parents and their children rated their overall experience highly (M = 9.07/10 and M = 8.00/10, respectively).

Discussion

Despite the increasingly popular use of the CPT in pediatric pain research over the past 20 years, potential ethical concerns regarding its use with children continue. IRBs need empirical guidance in applying ethical guidelines, such as assent, risks and benefits (Shah, Whittle, Wilfond, Gensler, & Wendler, 2004; Whittle, Shah, Wilfond, Gensler, & Wendler, 2004) and for methodologies such as the CPT, it is the researcher who is afforded the greatest opportunity and expertise to provide this information. The results of these surveys of researchers, children, and parents indicates that although the CPT requires induction of pain with no direct benefit to the child, the vast majority of researchers, children, and parents report positive experiences with CPT research.

Consistent with previous literature, some variability was noted in the type of review required by IRBs (Shah et al., 2004); however, the majority of researchers indicated that their CPT studies underwent full board review. It appears that most IRBs consider CPT studies with children to involve greater than minimal risk (CIHR, NSERC, & SSHRC, 1998; Enfield & Truwit, 2008), although only a small number of researchers in our study reported that their IRBs had explicitly raised that concern. Minimal risk is generally defined as research in which the probability and magnitude of possible harms is no greater than those encountered by the participant in everyday life (CIHR, NSERC, & SSHRC, 1998; Wendler et al., 2005).

Different interpretations of minimal risk have been used to define daily risks as encountered by a clinical sample in the study (i.e., relative interpretation) or the average healthy child (i.e., absolute interpretation; Wendler, 2009). In this study, both clinical and healthy samples of children were reportedly included in CPT studies. It is possible that sample type or other unreported aspects of study protocols explain studies’ classification above minimal risk. Alternatively, some IRBs may emphasize the increased vulnerability of children generally and require full board review for all pediatric studies. Consistent with this, the majority of researchers reported that obtaining ethics approval for CPT studies was comparable to other pediatric studies. Despite full IRB review, most researchers were not hindered in their ability to obtain ethical approval for CPT use with children. Taken together, this indicates that IRBs consider the CPT to pose an acceptable degree of risk for use in pediatric research.

The requirement for pediatric CPT studies to undergo full IRB review may also reflect concerns by IRBs regarding the lack of direct benefit to the participating child. Indeed, researchers reported the unnecessary induction of harm, the cause of unnecessary psychological distress, and the lack of benefit to the child as common concerns raised by IRBs approving CPT studies. The inclusion of children in research lacking a direct benefit to the participating child is controversial. However, an often neglected, yet important contribution to the debate is the reported experiences.

Table V. Frequencies of Child-Coded Responses to Best and Least-Liked Aspects of CPT Study Participation

<table>
<thead>
<tr>
<th>Percentage (%)</th>
<th>Best thing about experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researchers</td>
<td>25.8</td>
</tr>
<tr>
<td>Child’s enjoyment/participation</td>
<td>24.2</td>
</tr>
<tr>
<td>It was interesting</td>
<td>21.6</td>
</tr>
<tr>
<td>Contributing to research/science</td>
<td>20.1</td>
</tr>
<tr>
<td>Participating together with their child</td>
<td>5.2</td>
</tr>
<tr>
<td>Compensation</td>
<td>3.6</td>
</tr>
<tr>
<td>Other</td>
<td>16.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percentage (%)</th>
<th>Least liked thing about experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>None/nothing</td>
<td>39.7</td>
</tr>
<tr>
<td>Logistics (e.g., timing, parking, scheduling)</td>
<td>22.2</td>
</tr>
<tr>
<td>Answering questions/questionnaires</td>
<td>18.6</td>
</tr>
<tr>
<td>CPT/cold water/watching child in pain/discomfort</td>
<td>7.2</td>
</tr>
<tr>
<td>Sleep and related concerns (i.e., other aspects of study protocol)</td>
<td>6.7</td>
</tr>
<tr>
<td>Other</td>
<td>6.7</td>
</tr>
</tbody>
</table>

Table VI. Frequencies of Parent-Coded Responses to Most Positive and Most Difficult Aspects of Study Participation that Included the Use of the CPT with Children

<table>
<thead>
<tr>
<th>Percentage (%)</th>
<th>Most positive aspect of participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researchers</td>
<td>25.8</td>
</tr>
<tr>
<td>Child’s enjoyment/participation</td>
<td>24.2</td>
</tr>
<tr>
<td>It was interesting</td>
<td>21.6</td>
</tr>
<tr>
<td>Contributing to research/science</td>
<td>20.1</td>
</tr>
<tr>
<td>Participating together with their child</td>
<td>5.2</td>
</tr>
<tr>
<td>Compensation</td>
<td>3.6</td>
</tr>
<tr>
<td>Other</td>
<td>16.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percentage (%)</th>
<th>Most difficult aspect of participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>None/nothing</td>
<td>39.7</td>
</tr>
<tr>
<td>Logistics (e.g., timing, parking, scheduling)</td>
<td>22.2</td>
</tr>
<tr>
<td>Answering questions/questionnaires</td>
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</tr>
<tr>
<td>Other</td>
<td>6.7</td>
</tr>
</tbody>
</table>
of research participants themselves. We found that that children and parents reported positive experiences in CPT studies. Furthermore, they would recommend research participation to others, and would take part in research again themselves. Although some children indicated the CPT was their least liked aspect of participation, they still perceived their research experience very positively and no differently than those children who indicated the CPT was their favorite part. Only a small portion of parents reported that watching their child in pain or discomfort while doing the CPT was the most difficult aspect of participation; yet again all of these parents reported having a positive attitude toward the overall study. The higher overall experience ratings given by children who participated in studies requiring two CPT exposures support the acceptability of using such a methodology.

The positive overall experiences reported by children are consistent with the anecdotal reports by LeBaron, Zeltzer, and Fanurik (1989), including their willingness to complete the CPT more than once. A survey of children aged 7–14 years and their parents showed that children and parents were willing to participate in hypothetical research lacking direct benefit to the child, particularly when the research involved minimal risk (Wendler & Jenkins, 2008). Our work provides compelling support for the acceptability of including children in CPT research studies lacking direct benefit, as it is based on actual participation rather than hypothetical consideration. Altogether, this suggests that participation in CPT studies, which lack direct benefit to the child, is acceptable to both children and their parents.

Researchers in the current study reported only two adverse events (out of an estimated total of 3000 participants). Both instances involved significant, but transient, distress of the child during the CPT similarly reported by Trapanotto and colleagues (2009). No physical injury was reported and risk of injury in CPT studies appears to be no more than that posed by everyday life for healthy children (Wendler et al., 2005). Furthermore, the psychological risk posed by the CPT also appears low as children do not report being anxious prior to completing the CPT (Tsao et al., 2004; Wilby et al., 2010). The commonplace nature of mild pain in children’s lives, the frequent experience of immersion in cold water, an extremely low rate of adverse events, and the fact that the majority of children and parents would repeat the experience, all suggest that the CPT fits a classification of minimal risk, or at most, a minor increase over minimal risk. Therefore, the CPT meets the criteria for an intervention to be approved in non-beneficial pediatric research under both Canadian and U.S. regulations (CIHR, NSERC, & SSHRC, 1998; Fisher et al., 2007; Protection of Human Subjects, 2009) and should qualify for expedited ethics review so long as other aspects of the study design do not warrant full board review (e.g., use of deception).

In addition to providing valuable information about the risks and acceptability of the CPT with children, this research also provides a helpful overview of procedural issues related to ethical use of the CPT. As recommended for safety, all researchers reported their participants were monitored by a researcher or research assistant while completing the task. CPT procedures regarding most commonly reported maximum allowable immersion time of 4 min and water temperature of 10°C were generally consistent with standardization guidelines (von Baeyer et al., 2005). The coldest reported water temperature (5°C) is colder than suggested standardization guidelines and more closely approximates early pediatric CPT studies and CPT studies with adults where temperatures between 0 and 5°C are specified (Feuerstein et al., 1982; Hines, 1937; Rubin et al., 1967; von Baeyer et al., 2005). This may reflect a shift by researchers in lowering water temperatures to reduce ceiling effects achieved during the task (Dahlquist et al., 2010) and may suggest that the standardization guidelines published by von Baeyer and colleagues (2005) are too limiting given that no more frequent negative consequences were reported by researchers in the current study at colder temperatures (i.e., 5–7°C).

Consistent with previous reviews (von Baeyer et al., 2005), CPT studies were reported to include healthy and clinical samples of children across a wide age range. Surprisingly, one researcher reported using the CPT with children as young as one year of age. Given the anonymity of the survey, no additional details were obtained, making it impossible to determine whether its use was warranted in this age range (i.e., the only means of obtaining important information). This age range is younger than previously reported. Taken together with previous research indicating that slight changes in water temperature (±2°C) can impact perceived pain intensity (Mitchell, MacDonald, & Brodie, 2004), it suggests that ethical appropriateness of the CPT is perhaps dependent on the interplay of sample characteristics (i.e., healthy versus clinical, child age) and CPT procedures (i.e., water temperature and immersion time). Further reflection and empirical investigation is needed to examine if water temperature or CPT procedures should differ with sample age with continued consideration of consistent methodology across researchers.

Children and parents endorsed a variety of motives for research participation in these CPT studies. Although the majority of children endorsed feeling that they had helped
others and had helped others learn something new, only a small number of children indicated altruistic motives (e.g., research contribution/helping others) as the best thing about their participation experience. Most children referred to activities involved in study participation (e.g., aspects of the study protocol, CPT) as the best part. Of note, the current sample includes children of a wide age range, including those considered incapable of altruistic intentions in research (Wendler, 2006). Parents rated motives about others (e.g., contribute to knowledge, desire to help others) and their child (e.g., child wanted to participate, participating was educational for their child) as important reasons for participating. They were less motivated by benefit to their child, compensation, or for their own learning. Parents’ indications of the most positive aspects of participation generally corresponded with their motives with their child’s enjoyment/participation, contributing to research/science, and finding participation interesting as common responses.

Strengths of the current study’s approach include the large child and parent sample from CPT studies of varied methodology and the international representation of researchers who have used the CPT with children. Together, these provide a comprehensive picture of children’s, researchers’, and parents’ perspectives on the CPT. A limitation to the design of the online survey of researchers was that it was created to maximize anonymity in responding through the use of a generic survey url, thus limiting our ability to obtain additional information about researchers beyond what was asked in the survey. The current report would also have been strengthened by including the experience of children and parents with the CPT in other lab settings, as other aspects of the study environment may influence the positive or negative experience with the CPT. It is important to note that our study included the perspectives of children 7 years and older; the extent to which our findings apply to children under the age of 7 is not known. Additionally, the research participation questionnaires did not specifically include questions about the CPT, but rather asked children and parents to report on their research experience more broadly. More specific questions around the CPT would be helpful in confirming our findings. It is possible that through the use of an open-ended format to ask parents and children about their least liked/most difficult aspects of participation, respondents may have felt obligated to report on something they did not like. Lastly, an important area for future research not adequately addressed by the current study is the accurate assessment of child assent to participation and assessment of the child’s understanding of their control over the CPT process. This is especially relevant if use of the CPT is extended to younger children who may not have the same capacity to understand the research process as older children.

This study provides an empirical basis for consideration of ethical issues associated with the CPT and provides information that is useful for researchers as well as IRBs. This research demonstrates that the CPT is judged by researchers, children, and parents to be an acceptable research method in pediatric research. Our findings support that the CPT can be classified as a procedure that carries minimal risk or, at most, a minor increase over minimal risk. As such, pediatric CPT research should qualify for expedited IRB review unless full board review is warranted by other aspects of a specific study protocol or sample characteristics. We conclude that the CPT is ethically permissible in pediatric research with appropriate study safeguards. Although future research is needed and the use of colder water may prove useful, previously published standardization guidelines (von Baeyer et al., 2005) should in the main continue to guide use of the CPT in pediatric pain research.

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