Original Article

A Phase I Study on the Feasibility and Acceptability of an Acupuncture/Hypnosis Intervention for Chronic Pediatric Pain

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Abstract

The purpose of the present study was to conduct a Phase I investigation examining the feasibility and acceptability of a complementary and alternative medicine (CAM) package combining acupuncture and hypnosis for chronic pediatric pain. Thirty-three sequentially referred children (21 girls) aged 6–18 years were offered 6 weekly sessions consisting of individually tailored acupuncture treatment together with a 20-minute hypnosis session (conducted while the needles were in place). Parent and child ratings of pain and pain-related interferences in functioning, as well as child ratings of anxiety and depression, were obtained at pre- and post-treatment. The treatment was highly acceptable (only 2 patients refused; ≥ 90% completed treatment) and there were no adverse effects. Both parents and children reported significant improvements in children’s pain and interference following treatment. Children’s anticipatory anxiety declined significantly across treatment sessions. Our results support the feasibility and acceptability of a combined acupuncture/hypnosis intervention for chronic pediatric pain.


Key Words

Acupuncture, hypnosis, chronic pain, pediatric patients, complementary medicine, alternative medicine

Introduction

Chronic pain in the pediatric population is a significant problem, affecting 15–20% of children.1 Use of complementary and alternative medicine (CAM) for chronic pain has increased in recent years.2–5 Acupuncture is among the most frequently used CAM treatments for chronic medical conditions6–8, and its effectiveness has been supported for various pain problems in adults (e.g., headaches;9 chronic back pain10). However, there are very few published reports on acupuncture for chronic pediatric pain. By contrast, numerous studies have demonstrated the efficacy of another CAM treatment, hypnosis, for acute pro-
cedural pain, laboratory pain, and chronic pain in children. Despite these encouraging results, controversy persists regarding exact definitions of the interventions utilized, which have been variously labeled hypnosis, hypnotherapy, guided imagery, and the general finding that induction is often redundant for children, given the ease with which they are able to achieve a hypnotic state.

Whereas chronic pain patients across the lifespan have found hypnosis to be well-tolerated and beneficial, many pediatricians hesitate to recommend acupuncture due to concerns regarding its acceptability to parents and children. However, in their qualitative study on children’s experience with acupuncture for chronic pain, Kemper et al. reported that the majority of patients and parents rated the treatment as helpful and pleasant. These findings contradict the conventional view that fear of needles precludes the use of acupuncture in children. On the other hand, most of the patients in this study were adolescents (median age = 16), and the study design was retrospective (i.e., only patients who were referred and actually went to the acupuncturist were interviewed). Because no information was available regarding the percentage of referred patients who refused acupuncture, the authors acknowledge that they may have overestimated the acceptability of treatment. Thus, they recommended further prospective investigations, particularly in younger samples.

In one of the few randomized, controlled studies on acupuncture in children patients aged 7–15 years with migraine headaches received 10 sessions of either true acupuncture, or placebo acupuncture (superficial needling). At post-treatment, the true acupuncture group reported reductions in migraine frequency and severity; panopioid activity in plasma and \( \beta \)-endorphin levels also rose significantly. None of these changes were observed in the placebo group. However, patients receiving medication were excluded from study participation, even though many migraine patients are on regular, prophylactic and/or as needed medications. A recent survey of childhood headache at school entry found that 47% received medication for every headache. Thus, the sample used in this study was not representative of most pediatric migraine patients. Also, no information on refusal rates was reported, so the acceptability of the treatment remains unknown.

Although further randomized, controlled trials are required to establish the efficacy of acupuncture for chronic pediatric pain, additional investigations incorporating clinical practice-based procedures to examine its feasibility and acceptability, particularly in combination with other CAM treatments, are also required. The American Pain Society (APS) recommends a multimodal, multidisciplinary strategy over a single sequential treatment approach for chronic pediatric pain, and in accord, the UCLA Pediatric Pain Clinic employs a variety of CAM and conventional treatments, including a combination of medication, acupuncture, psychotherapy, biofeedback, massage therapy, yoga, physical therapy, and hypnosis, with a number of these treatments often administered simultaneously. Following this multimodal approach, the present study investigated the acceptability of a combined acupuncture/hypnosis treatment for chronic pediatric pain patients from our clinic.

This combination was selected with the rationale that the approach would be more appealing to the younger age group (6+ years) studied (i.e., hypnosis, a mind-focused intervention would increase the initial tolerability of the acupuncture while the needles were in place). Although there were no universally accepted definitions for hypnosis and related interventions (e.g., hypnotherapy, imagery), we followed a consistent procedure that involved progressive muscle relaxation and guided imagery (see Methods: Procedure for detailed description). Previously, we investigated this treatment from a Traditional Chinese Medicine (TCM) perspective using the same sample; this article reports the results of our Phase I study from a Western clinical-practice perspective. Our goal was to collect preliminary data to support future randomized, controlled trials. We expected that our combined acupuncture/hypnosis CAM treatment package would be well-tolerated and acceptable to patients and their families.

**Methods**

**Participants**

Thirty-three children, 6–18 years of age (mean = 13.0, SD = 2.94), sequentially re-
ferred to the UCLA Pediatric Pain Clinic were offered entry into the study; 31 (19 girls; 61.3%) agreed to participate. Ethnic composition of the sample was: 87% Caucasian, 4% African-American, 4% Hispanic, 2% Asian, and 3% other. All participants had chronic pain; half were referred by primary care physicians, and the other half by pediatric subspecialists (e.g., neurologists, gastroenterologists, rheumatologists). Presenting symptoms included myofascial and migraine headaches (46%), abdominal pain associated with irritable bowel syndrome (21%), fibromyalgia (11%), complex regional pain syndrome, type I, of an extremity (11%), juvenile rheumatoid arthritis (4%), myofascial back pain (4%), and myofascial chest pain (4%). All participants gave written informed consent and subject assent, and the study was approved by the UCLA Human Subjects Protection Committee.

**Procedure**

Following an initial medical assessment by a physician (pediatrician, L.Z.), all potential participants and caregivers were given information regarding the multimodal, multidisciplinary approach employed by the clinic, and offered entry to the study. The study was presented as research aimed at helping clinic physicians/researchers gain an understanding of the experiences of children undergoing acupuncture and hypnosis. Potential participants were offered acupuncture and hypnosis outside the study if they wished to receive these treatments without participating in the research. Upon agreeing to participation, patients and their primary caregiver completed baseline questionnaires (all measures are described below). Patients were administered half-hour treatment sessions once every week for 6 weeks (for a total of 6 treatments). Cancellations (e.g., due to car problems) occasionally interfered with the completion of consecutive sessions. In the event of a cancellation, the missed session was made up the following week such that the maximum amount of time between sessions was 2 weeks. All participants maintained their existing treatment regimens (i.e., physician visits and medications) during the study period, with no changes in medication or dosage.

Acupuncture points were individually selected for each patient according to universally recognized Traditional Chinese Medicine (TCM) differential diagnosis criteria. (For details of criteria, diagnoses, and procedure, see Waterhouse et al.\(^\text{23}\)) The licensed acupuncturist (M.W.) who performed the acupuncture treatment had over 25 years of clinical experience, and trained in both Europe and the Peoples Republic of China. Serin acupuncture needles, either #00, 1, or 2 gauge x 30 mm, were used for the treatment. At the initial session, several issues were discussed with the patient. First, the child was assured that he or she would be treated with other modalities if they chose not to have acupuncture treatment. It was made clear that the patient was not obliged to undergo acupuncture if he or she was not comfortable doing so. Patients were informed that acupuncture had helped other children in the past and in our opinion was worth trying. Next, it was acknowledged that everybody, even adults, feel some worry or fear about the idea of having needles inserted and that such concern was very natural. A distinction was made between the experience of having a shot or having blood drawn and the needles used in an acupuncture treatment. It was explained that the former needles were much thicker, hollow, and actually cut the skin and muscle tissue. Acupuncture needles, on the other hand, were so thin as to be like “little hairs,” and that on insertion they pushed aside blood vessels and very rarely caused any bleeding or tissue damage.

During this discussion, it was never claimed that the patient would feel nothing. Rather, it was stated that often nothing would be felt and sometimes the child might feel a little pinch or prick that might last a second. It was also explained that, if any needle should cause pain for more than a second or two, then the acupuncturist would either adjust or remove the needle so there would be no pain. After this explanation, the acupuncturist would ask the child if he or she would like to see the needle. If the child said yes, then the acupuncturist would show the needle and insert it into his own hand to demonstrate how relatively innocuous this experience was. A few of the children were squeamish about seeing the needle and sometimes this step was avoided, at the patient’s request. Next, children were told that they would be lying face up or down on the treatment table, that the acupuncturist would
like at their tongue, feel their pulse, and then insert 4 to 6 needles in relevant locations. Following needle insertion, children would be asked to lie still for 20 minutes. During this time, they would experience the guided imagery (hypnosis) administered by another practitioner (S.L.), after which the needles would be removed. The child was also told how acupuncture enables the brain to release natural painkillers, which make the patient feel relaxed and pleasant and that most patients really enjoy the feelings of the treatment and actually look forward to it. It at any time during these explanations the child appeared hesitant, then the acupuncturist would recommend inserting only one needle and, depending on the child’s reaction, either continue with the full treatment or not. Only one child did not have the full complement of needles during the first session, and the number of needles to be used was re-negotiated at the second session. After the first session, all of the children became comfortable with a full treatment of between 6 and 15 needles.

A clinical psychologist (S.L.) conducted the hypnosis sessions. A consistent procedure was followed across patients, while allowing some flexibility within the techniques that worked most effectively for each individual child. First, each patient was guided through a progressive muscle relaxation. This was accomplished either by focusing on each muscle group and “softening” it or by imagining the entire body as a wax candle and having each muscle group progressively warm and melt. Typically, each of the two progressive muscle relaxation techniques was done with each child during the first two sessions. Before the third session, the child was asked which technique was most helpful in achieving relaxation, and that technique was used for the following four sessions. Lastly, each child was guided through an imagery process designed to strengthen the child’s sense of mastery over the physical pain. This part of the hypnosis was identical for each child. The child was asked to imagine his or her brain like the cockpit of an airplane, where each of the knobs and switches controlled the feeling to a different part of the body. The child was told to find the dial that controlled the feeling to the painful part of the body. Then, the child was told to turn the dial in his or her imagination until the feeling to that part of the body was at the correct level. The child was then given the suggestion that this process could be done any time to control feelings to any parts of the body. The word “pain” was never used, so as not to focus the child’s attention on his or her pain. The word “feeling” to that part of the body was always used, which also made sense given that numb limbs needed more feeling and painful limbs needed less. Each of the three parts of the hypnosis process described above were used during each hypnosis session. The total hypnosis session lasted for the length of time required for the acupuncture needles to stay in place (approximately 20 minutes).

Just prior to and following each treatment, children were administered an in-session rating form to evaluate their present pain. Anticipatory anxiety ratings were also obtained immediately prior to needle insertion. After the final (sixth) session, participants and their caregivers completed post-treatment questionnaire. All measures were administered by research assistants.

Measures

The Holistic Health Questionnaire. This measure, completed by parents at pre-treatment, was developed for this study to determine which CAM modalities had been previously tried for the child’s pain. Parent’s expectations about the efficacy of acupuncture (AC) and hypnosis (HY) to reduce the child’s pain were also assessed using a 1–10 scale (1 = not at all helpful; 10 = extremely helpful).

The Varni-Thompson Pediatric Pain Questionnaire (V-T PPQ). This instrument, completed by parents and children at pre- and post-treat-
ment, assessed pain and pain-related interference in functioning. Ratings for average pain in the previous week and current pain were made on a 0–6 scale (0 = no pain; 6 = worst pain imaginable). Pain-related disruption in functioning (interference) was measured in the following areas: 1) general physical activity, 2) ability to concentrate on schoolwork, 3) sleep, 4) activities with friends, 5) activities at home, 6) eating/appetite, 7) anger, 8) sadness, 9) nervous/upset. Each area was assessed by a single item asking to what extent pain interfered in the past week. The first 6 items were rated on a 0–6 scale (0 = pain did not interfere; 6 = pain interfered a lot). For the last 3 items, ratings were made on the extent to which pain influenced the child’s feelings (0 = pain did not influence; 6 = pain influenced a lot). Total interference scores were calculated by summing responses to all 9 items. On the child version, interference items were modified by adding neutral and sad faces as anchors at each end of the scales to enhance comprehension. This measure has shown adequate validity and stability.\(^{25}\)

The Children’s Depression Inventory (CDI).\(^{26}\) This 27-item instrument with a 3-point scale (0 = absence of symptom; 1 = mild symptom; 2 = definite symptom) was completed by children at pre- and post-treatment to measure symptoms of depression. The CDI has been shown to have good reliability and validity.\(^{27}\)

The State-Trait Anxiety Inventory for Children (STAIC) – State Version.\(^{28}\) The state version of this measure, a 20-item instrument rated on a 4-point scale, was completed by children at pre- and post-treatment to assess anxiety. Participants rated items (e.g., “I feel nervous”) according to how they felt “right now” (1 = not at all; 4 = very much so). The STAIC has demonstrated adequate validity and reliability.\(^{28}\)

In-Session Rating Forms. Children’s self-reported pain levels were measured using a 1–10 scale (1 = no pain; 10 = worst pain imaginable) just prior to and following each treatment session using a form designed for this study. Children’s self-reported anticipatory anxiety levels were also rated using a similar form, on a 1–5 scale (1 = not at all anxious; 3 = moderately anxious; 5 = very anxious) at the start of each session, just prior to needling.

**Analytic Approach**

Pre-treatment differences in parental expectations and baseline child variables were examined using independent \(t\)-tests. Predictive relationships between expectations and treatment outcome (i.e., pre–post changes in pain ratings) were elevated using multiple regression analyses. Pre- to post-treatment changes in pain ratings, pain-related interference in functioning, depression, and anxiety were examined using paired \(t\)-tests. For these tests, a Bonferroni correction was used to lower the risk of Type I error for the three classes of outcome data (pain, interference, and mood ratings) (\(\alpha = 0.017\)); a trend was accepted for 0.018 < \(P < 0.05\). For all other tests, \(P < 0.05\) (2-tailed) was considered significant. To evaluate relationships between parent and child ratings, Pearson correlation coefficients were calculated. Anticipatory anxiety ratings were examined using a repeated-measures ANOVA, followed by contrast analyses comparing the mean for each session to the previous mean. Trend analysis was used to describe the function for in-session pain ratings across treatment sessions, according to procedures outlined by Keppel,\(^{29}\) as follows. A repeated-measures ANOVA on in-session pain ratings was conducted. In the event of an omnibus significant F, testing of trend components was done sequentially, proceeding from linear to quadratic, to cubic, and so on. At each step, a nonsignificant finding resulted in termination of further testing for higher-order trend components. All analyses were performed using the SPSS statistical program (SPSS, Chicago, IL).

**Results**

**Feasibility**

Of the 33 patients invited to participate, 31 accepted (93.9%) and 2 declined (6.1%). One refused due to severe needle phobia; the other feared the questionnaires would cause distress (the latter patient received AC outside the study). Nearly all participants completed the study (\(n = 28\); 90.3%); only 3 did not (9.7%). Drop-outs did not differ from completers on pain ratings, pain-related interference, anxiety, or depression. The following reasons were given for dropping-out: one child reported a complete reduction in pain such that her mother felt treatment was no longer needed;
one child was hospitalized for anorexia during the study period; and one child improved to the extent that his mother wanted him to attend school, which he did not want to do. Thus, this participant declined further treatment because he indicated that he was ambivalent about getting better. No adverse side effects of treatment were reported.

Previous Experience with CAM

Prior experience with acupuncture \( (n = 9; 29\%) \) was more common than with hypnosis \( (n = 5; 16\%) \). Over half the sample \( (n = 17; 55\%) \) reported previous experience with other CAM modalities (e.g., herbs, biofeedback, chiropractic). Nineteen percent \( (n = 6) \) had no prior CAM experience. All three drop-outs endorsed previous CAM use, with one reporting prior acupuncture, and one reporting previous hypnosis. The two study refusers reported no prior CAM experience. Parents with previous acupuncture experience expected the treatment to be less effective \( (\text{mean} = 4.67, \text{SD} = 1.73) \), compared to those without previous acupuncture experience \( (\text{mean} = 5.95, \text{SD} = 1.23) \), \( (t(27) = -2.28, P < 0.05) \). Parent expectations of effectiveness for hypnosis did not differ between those with prior hypnosis experience \( (\text{mean} = 5.20, \text{SD} = 1.30) \), and those without \( (\text{mean} = 5.17, \text{SD} = 1.37) \). Neither previous experience, nor effectiveness ratings were significantly related to treatment outcome.

Pre/Post Study Pain

Table 1 presents means and standard deviations for child and parent ratings. Child ratings of current pain were significantly reduced from pre- to post-treatment \( (t(27) = 4.38, P < 0.001) \), and there was a trend \( (P = 0.02) \) for child ratings of average pain for the week following treatment to be lower than the week before treatment. Parent ratings of current pain were significantly reduced by post-treatment \( (t(25) = 3.36, P < 0.01) \), although there was no change in average pain ratings. Relationships between parent and child pain ratings were examined at both time points. At pre-treatment, parent and child ratings of average pain were moderately, significantly correlated \( (r = 0.39, P < 0.05) \), whereas ratings of current pain were not correlated \( (r = 0.33, \text{ns}) \). At post-treatment, high correlations were found between parent and child ratings of both average pain \( (r = 0.70, P < 0.01) \) and current pain \( (r = 0.27, P < 0.01) \).

The clinical significance of these findings was explored by calculating the number of children who experienced at least a 50% reduction in their current pain ratings following treatment—14 children \( (45.2\%) \) reported such a reduction at treatment’s end.

Pre/Post Study Pain-Related Interference

There was a significant reduction in child ratings of total pain-related interference in functioning from pre- to post-treatment \( (t(27) = 2.62, P = 0.014) \) (see Table 1 for means and standard deviations). Parent ratings also indicated a significant decrease in overall pain-related interference following treatment \( (t(25) = 3.10, P < 0.01) \). Total interference ratings for...
parents and children were significantly correlated at both pre- \( r = .75, P < 0.01 \) and post- \( r = 0.90, P < 0.001 \). In addition, 10 children (32.3%) reported at least a 50% reduction in their total interference scores by the end of the treatment.

Additional analyses were conducted on each of the 9 items comprising the total interference score (Table 1 shows means and standard deviations). By post-treatment, both parent and child endorsed significantly reduced interference in general physical activity (parent: \( t(25) = 2.78, P = 0.01 \); child: \( t(27) = 2.93, P < 0.01 \)), and in activities with friends (parent: \( t(21) = 4.01, P < 0.01 \); child: \( t(27) = 2.59, P = 0.015 \)). Only parents indicated decreased interference in children’s ability to concentrate on schoolwork (parent: \( t(24) = 3.29, P < 0.01 \)), and activities at home (parent: \( t(25) = 3.24, P < 0.01 \)), whereas only children endorsed a reduction in interference with eating/appetite (\( t(27) = 3.07, P < 0.01 \)). Ratings of interference with sleep, pain-related anger, sadness/unhappiness, and nervousness/upset were unchanged for both parents and children across the study period.

**Pre/Post Study Depression and Anxiety**

Child-reported depression symptoms remained unchanged from pre- (z-score range = \(-1.42 \) to \(+2.38 \)) to post-treatment (z-score range = \(-1.15 \) to \(+2.05 \)). T-scores greater than 65 (i.e., z-scores greater than \(+1.5 \)) are generally considered clinically significant.\(^{26}\) Because over 90% \((n = 28)\) of patients were below this cut-off prior to treatment start, the sample was not significantly depressed at baseline. For child anxiety levels, there was a trend \((P = .019)\) toward a reduction from pre-treatment (mean = 34.03, SD = 6.39) to post-treatment (mean = 30.39, SD = 7.48). Mean scores at pre-treatment were consistent with those reported in emotionally disturbed children,\(^{30}\) falling in the 77th percentile. At post-treatment mean scores were within the normal range (i.e., 53rd percentile).\(^{28}\)

**In-Session Ratings**

Anticipatory anxiety ratings, taken at the start of each session, differed significantly across treatment sessions \((F(3, 80) = 3.72, P < 0.05)\). As illustrated in Figure 1, anticipatory anxiety levels declined from the first to the last session. Contrast analyses indicated that anticipatory anxiety ratings declined significantly from session 1 to session 2 \((F(1, 16) = 6.94, P < 0.05)\), and from session 3 to session 4 \((F(1, 16) = 9.33, P < 0.01)\).

In-session pain ratings also differed significantly across treatment sessions \((F(11, 209) = 3.96, P < 0.001)\) (see Figure 2). Analysis of trend components indicated a significant, negative linear trend \((F(1, 19) = 8.28, P = 0.01)\). Because sequential testing did not reveal a significant quadratic trend, no further testing of higher-order trend components was conducted. As shown in Figure 2, pain ratings declined by the end of each session, although there was some return in pain between sessions 3 and 4.

**Discussion**

A combined package of acupuncture and hypnosis was highly acceptable to children with
chronic pain treated at the UCLA Pediatric Pain Clinic, including patients as young as 6 years of age. Of the 33 families approached, 31 accepted (93.9%) and only 2 declined (only one because of fear of needles; the other refuser had acupuncture outside the study, but feared the questionnaires). The tolerability of the intervention was also demonstrated, with 28 children completing the study (90.3%). Notably, no adverse side effects were reported (e.g., no incidence of infection or injury), and no patients withdrew from the study due to negative effects of treatment. Contrary to conventional wisdom, only one child refused, and no children prematurely terminated participation, due to fear of, or discomfort from, the needles. Although our findings should be interpreted with caution due to the lack of a control group, our preliminary results showed that both children and their parents reported improvements in children’s pain and functioning by the end of treatment.

The results of this study, together with those of Kemper et al., support the feasibility of acupuncture in pediatric pain populations. Even those parents with previous acupuncture experience did not expect our treatment package to be as effective as those without such experience, those negative expectations did not impact treatment outcome. Parental expectations for the effectiveness of hypnosis did not differ depending on prior experience and also did not affect treatment outcome. Kemper et al. reported that perceptions of treatment among parents and children tended to become more positive over the course of therapy and we also found that, despite some initial hesitation in a few children at the start of the first treatment session, all children subsequently became comfortable with the full complement of needles.

An interesting finding was greater agreement between parent and child ratings of pain by the end of treatment. Whereas correlations between parent and child ratings of pain were modest at baseline, by treatment end, these correlations were very high. Our findings are consistent with an earlier report of increased parent–child agreement for ratings of headache pain following relaxation/biofeedback for migraine headaches. It appears that as a consequence of these CAM interventions, parent’s perception of their child’s pain more closely matched the child’s own. The reason(s) for this increased agreement are unknown, although one possibility is greater parent–child communication about treatment (e.g., due to its novelty), or the child’s symptoms.

Our findings indicate that the observed reductions in pain were accompanied by reported decreases in pain-related interference in functioning across a broad range of activities including general physical activity, and activities with friends, as assessed by both parent and child. We also found general agreement between parent and child interference ratings at both pre- and post-treatment. Consistent with prior research, parent–child assessments of interference in functioning were more closely aligned than parent–child pain ratings and the findings that may be due to the fact that functioning ratings are, to a greater extent than pain ratings, based on observable behaviors (e.g. the number of times the child goes out to play). Future studies may focus on how parent–child agreement across response domains might vary as a function of treatment response.

Nevertheless, pain-related anger, sadness, and nervousness/upset were unchanged according to both parent and child ratings. Similarly, depression scores were not reduced following treatment, although our sample did not score in the clinically severe range on this measure at baseline. In fact, anticipatory anxiety was the only mood variable that evidence a reduction following treatment (see Figure 1). This finding suggests that children were not unduly anxious about being needled, and our results have potentially important clinical implications because many pediatricians hesitate to recommend acupuncture due to concerns that children are afraid of needles. The fact that no patients dropped out due to fear/anxiety over the acupuncture, together with the low anticipatory anxiety ratings, suggest that patients found the treatment to be acceptable and not anxiety-provoking. We found the greatest declines in anticipatory anxiety between sessions 1 and 2, and sessions 3 and 4 (see Figure 1). By session 4, mean anticipatory anxiety ratings were very near their minimum (i.e., mean = 1.12; SD = 0.49, on a 1–5 scale), indicating that patients had been comfortable with the intervention.

In-session pain ratings also declined across treatment (see figure 2). Not only were pain
ratings lowered by the end of each session, the most significant decreases occurred during the first two sessions. However, pain also returned between sessions—the most pronounced return occurred between sessions 3 and 4. In fact, at the start of session 4, pain ratings were at about the same level as the end of the first session. Thus, it appears there was some rebound in pain that was gradually reduced by the sixth session. These results suggest that although pain may sometimes return between sessions, continued treatment may eventually lead to its reduction over time. Future studies may examine the optimal number and timing of treatment sessions to achieve the most rapid and cost-efficient results in pain reduction.

There are several limitations to our findings. The main limitation is the lack of control group, a design factor that is necessary to determine whether our findings were due to non-specific effects of treatment (e.g., increased time/attention from clinicians). However, our aim was to conduct a Phase I study on the feasibility and acceptability of our intervention from a clinical perspective, as a precursor to larger, randomized controlled trials. A second limitation concerned the use of a combined treatment package, which prohibited us from determining whether both components are necessary for beneficial effects. Future dismantling studies may examine whether acupuncture or hypnosis alone leads to better outcome, compared to their combined use. This, we did not include a rating scale to assess hypnotizability, or to determine whether patients entered a hypnotic state, and the extent of hypnotic induction. However, the focus of our hypnosis intervention was on achieving a relaxed state using imagery, and thus, we did not include a measure of the depth of hypnosis achieved. Nevertheless, use of such measures would have strengthened the study, despite the fact that such scales have not been validated in children, and there are no data indicating that for children, such measures are correlated with depth or ease of entering a hypnotic state.

Fourth, we relied solely on self-report measures as outcome data, although we did include reports from both children and parents. A further limitation concerns the large number of statistical comparisons conducted due to the many outcome variables of interest. Despite the use of a Bonferroni correction for the main outcome variables, our findings must be interpreted with caution. Finally, we did not include a follow-up assessment to examine the longer-term effects of our treatment. Few CAM studies have included such assessments and these are required to delineate the time period over which treatment effects persist and the optimal timing of “booster” sessions to maintain pain reduction.

In sum, the high patient acceptance and low dropout rate, as well as preliminary evidence of symptom reduction in our study, support the feasibility of incorporating acupuncture and hypnosis into a major university-based pediatric setting. Our findings also emphasize the need for continued, controlled studies of CAM treatments for chronic pain in children.

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References