



Received: 19 October 2015
Accepted: 08 March 2016
First Published: 16 March 2016

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ANESTHESIA & ANALGESIA | RESEARCH ARTICLE

Training nurses in basic hypno-analgesia techniques to reduce procedural distress and pain in children: A feasibility trial

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Abstract: *Background:* Children with cancer experience pain and distress due to their illness and frequent medical procedures. Hypno-analgesia techniques effectively prevent and allow pain and distress management in children without any toxicity; however, they remain underutilized because of their cost and the shortage of trained hypnotherapists. We hypothesize that pediatric oncology nurses will change their practice after a four-day training in basic hypno-analgesia techniques, leading to a decrease in procedural distress and pain in their patients. *Methods/Design:* Six nurses from a pediatric hematology-oncology daycare clinic will be enrolled in this interventional pilot study. The intervention will be a four-day training session in basic hypno-analgesia techniques under the supervision of a certified hypnotherapist. Nurses and patients will be video recorded and evaluated during venipunctures

ABOUT THE AUTHORS

Terry Mizrahi, MD, is a clinical fellow in pediatric hematology-oncology. The author designed the research study and wrote the manuscript and also performed the literature review and wrote the protocol.

Serge Sultan, PhD, is a psychologist, associate professor in psychology and pediatrics and participated in designing the research study and revising the manuscript.

Marie-Claude Charest, MPs, is a psychologist, designed the intervention program, and revised the manuscript. The author is a hypno-analgesia training instructor of the study.

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Marie-Claude Charrette, MSc.inf, is a senior nurse and participated in the study design and revised the manuscript.

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PUBLIC INTEREST STATEMENT

Children with cancer are prone to distress and pain due to the illness itself and to the high frequency of medical procedures. Research has shown that hypno-analgesia is an effective and nontoxic method to decrease pain and distress in various pediatric settings. The main barriers to its larger clinical use are costs and the shortage of accredited hypnotherapists. We will train nurses in basic hypno-analgesia techniques to enable them to integrate these techniques in their daily practice. In this pilot study, nurses will receive a four-day training. This will be given by an accredited hypnotherapist. Hypno-analgesia techniques are based on communication techniques, such as suggestions and metaphoric images. They are embedded in nurses' approach and are not expected to delay patient management. In doing so, we will overcome the main barrier to the use of hypno-analgesia: the need for a second health care professional for each procedure.

(pre- and post-intervention). Nurses' mastery of hypno-analgesia techniques will be measured by two external evaluators who quantitatively assess their practice performance on the videotapes. Patients' distress and pain measures will include self- and parent-reported visual analog scale and Faces, Legs, Activity, Cry, Consolability scale's assessments by two external evaluators on video recordings. The primary outcome will be nurses' technique mastery and the main secondary outcome will be the change in patients' self-reported distress after the intervention. *Discussion:* We expect that a four-day training of nurses in basic hypno-analgesia techniques will reduce procedural distress and pain in their patients, thereby opening the way to larger clinical trials in various pediatric settings.

Subjects: Complementary & Alternative Medicine; Oncology; Pediatrics & Child Health

Keywords: hypno-analgesia; procedural distress; procedural pain; pediatric oncology; nurses training

1. Background

Procedure-related pain and distress are major challenges encountered when caring for sick children. Several interventions have been described to prevent or manage these situations, including pharmacological (e.g. local anesthesia, sedation, and/or general anesthesia) or attention-based neuromodulatory treatments (e.g. hypnosis, mindfulness, distraction, and/or imagery) (Jensen, Day, & Miró, 2014; Landier & Tse, 2010; Uman, Chambers, McGrath, & Kisely, 2006). Attention-based neuromodulatory approaches can be used alone or in combination with pharmacological interventions.

The use of hypnosis in adults and children has a longstanding history. For 40 years, it has been used as a treatment for pain under the name of hypno-analgesia (Olness, 1981). This set of techniques is guided by a trained therapist who establishes a collaborative relationship adapted to the patient's age and level of cognitive functioning. Hypno-analgesia techniques are designed to enhance concentration, minimize usual distractions, and heighten responsiveness to suggestions to alter one's thoughts, feelings, or physiological state (Spiegel & Greenleaf, 2005). Children, especially those who are young, are particularly susceptible to hypnotic suggestions (Accardi & Milling, 2009; London & Cooper, 1969).

1.1. Hypnosis for medical procedures in children

Many studies have demonstrated the effects of hypnosis on pain and anxiety in children or adolescents during medical procedures. In a review of controlled clinical studies, Patterson and Jensen reported that hypno-analgesia was associated with significant reduction in ratings of pain, need for analgesics or sedation, nausea and vomiting, and length of hospital stay (Patterson & Jensen, 2003). Zeltzer and LeBaron randomized children undergoing lumbar punctures and bone marrow aspirations into hypnotic therapy and non-hypnotic behavioral therapy groups and reported less pain and distress in the hypnosis therapy group for both medical procedures (Zeltzer & LeBaron, 1982). Liozzi and Hatira described the use of hypnosis to reduce anxiety and pain during lumbar puncture, bone marrow aspiration, or venipuncture. Cognitive behavioral training and hypnosis both reduced pain, but hypnosis was more effective in relieving anxiety. During venipunctures, children under local anesthetic (lidocaine/prilocaine) plus hypnosis showed less anticipatory anxiety, procedure-related pain, and anxiety than those who received the local anesthetic alone (Liozzi & Hatira, 1999, 2003; Liozzi, White, & Hatira, 2009). Delord observed that hypnosis reduced anticipatory distress in children treated with non-invasive ventilation (Delord et al., 2013). One meta-analysis assessed the effect of hypnosis in reducing emotional distress associated with medical procedures and reported a large effect size of 0.88 (95% confidence interval [CI] = 0.57 – 1.19) in favor of hypnosis. The effect differed significantly with patient age (children benefited more than adults) (Schnur, Kafer, Marcus, & Montgomery, 2008). Hypnosis also significantly reduced preoperative anxiety in adult patients and proved to be effective in managing chemotherapy-related nausea and vomiting or anticipatory vomiting in children (Hawkins et al., 1995; Hockenberry & Cotanch, 1985; Jacknow, Tschann, Link, & Boyce, 1994; LeBaron & Zelter, 1984; Saadat et al., 2006).

Hypnosis also increases procedure ease and reduce duration and cost. Lang et al. demonstrated a significant benefit of hypnosis in decreasing the distress and duration of voiding cystourethrography, an invasive medical procedure. The medical staff reported that the procedure was significantly easier in the hypnosis group (Butler, Symons, Henderson, Shortliffe, & Spiegel, 2005). Shorter procedure duration and lower cost have also been reported for adults who undergo hypnosis (Lang & Rosen, 2002).

Studies of pediatric oncology patients have demonstrated that hypnosis techniques decrease procedure-related pain and distress (Hawkins, Lioffi, Ewart, Hatira, & Kosmidis, 1998; Landier & Tse, 2010; Richardson, Smith, McCall, & Pilkington, 2006). In a review on the contemporary uses of hypnosis in pediatric and adult oncology, hypnosis was reported to be so effective for many symptoms that the authors recommended the integration of hypnosis-derived techniques into usual care (Lioffi, White, & Hatira, 2006).

1.2. Underutilization of hypno-analgesia in clinical practice

Despite strong evidence of its efficacy, hypno-analgesia remains underutilized. This is not due to toxicity as adverse effects (headaches and/or dizziness) are rare, benign, and transient, resolving within hours (Coe & Ryken, 1979; Lynn, Martin, & Frauman, 1996; Orne, 1965). Acute panic attacks or depressive symptoms have been reported with hypnosis, but they are extremely rare (Judd, Burrows, & Dennerstein, 1985). Rather, causes for underutilization include misunderstanding and disbelief of health professionals, as well as the reluctance of some patients to undergo hypnosis (Lang & Berbaum, 1997). The shortage of trained hypnotherapists and the cost (about 30 min of work by a trained hypnotherapist per procedure) are two other major hurdles blocking the wider use of hypnosis. One way to overcome these barriers is training nurses in basic hypno-analgesia techniques and allowing them to incorporate these techniques into their everyday practice. If successful, this approach would decrease patients' pain and distress without additional cost or the need for an additional therapist. However, it remains to be determined whether nurses can master basic hypno-analgesia techniques after basic training and if they can use these techniques to effectively decrease pain and distress in their patients.

1.3. Study aims

The primary aim of this pilot study is to determine if a four-day training session in basic hypno-analgesia techniques would allow pediatric nurses to master these techniques.

The secondary aims are to determine the effects of such training on venipuncture-associated distress and pain in pediatric patients treated at the hematology-oncology clinic. Depending on the results, additional analyses will correlate nurses' practice performance in hypno-analgesia with changes in patients' procedural distress and pain.

Finally, we will explore important moderators of intervention effects using the results of a descriptive questionnaire of the psychological profile of the child and measures of parental stress and anxiety.

2. Methods/design

2.1. Design overview

This is an interventional non-randomized pilot study that will be carried out in a tertiary care hospital in Canada (CHU Sainte-Justine daycare hematology-oncology clinic, Montreal). We plan to enroll 6 nurses and 36 patients (6 patients per nurse). The intervention will be a four-day training session in hypno-analgesia techniques. Video recordings of venipunctures will be taken at four time points (two pre-intervention and two post-intervention) (Figure 1). The primary outcome will be the nurses' practice performance of hypno-analgesia as assessed by external evaluators. The secondary outcomes will be the changes in patients' pain and distress during venipuncture.

Figure 1. Study timeline.

hypno-analgesia training of nurses by certified psychologist			
Day 1			Day 4
video-recorded sessions			videos are evaluated
Session 1	Session 2	Sessions 3 & 4	Session 5 (optional)
<ul style="list-style-type: none"> ▪ Present basics of hypnosis ▪ Differentiate Ericksonian versus classical hypnosis ▪ Use & usefulness ▪ Ethical challenges <p style="text-align: center;">→ theory</p>	<ul style="list-style-type: none"> ▪ Present methods & techniques of pain control ▪ Elaborate hypnotic trance ▪ Hypno-analgesia techniques based on conversation & hypnotic suggestions <p style="text-align: center;">→ practical exercises</p>	<ul style="list-style-type: none"> ▪ Play roles (nurses) ▪ Supervise acquired techniques ▪ Integrate different techniques in daily work (nurses) <p style="text-align: center;">→ practical exercises</p>	<p style="text-align: center;">Additional session proposed to nurses encountering difficulties in the implementation of hypno-analgesia techniques</p>

2.2. Participants

Six nurses who work in the pediatric hematology-oncology outpatient daycare clinic will take part in the study after providing written informed consent (Figure 1). Each nurse will be assigned six patients for the whole study after obtaining written informed consent of the patients and their legal guardians. For feasibility purposes, we will use a convenience sampling method. Potentially eligible patients will be identified on the hematology-oncology clinic’s computer database by the principal investigator, clinical research assistant, and each participating nurse. For each nurse, the first six eligible patients will be proposed for inclusion and included consecutively. Patients will be approached with a phone call at home and given a basic explanation of the study concept. If interested, they will obtain more detailed information about the study and complete a 10- to 15-min interview with the clinical research assistant on the day of their first appointment. The patients’ parents will provide written consent and a fill out a questionnaire regarding socio-demographic, psychological, and medical data concerning their child. The clinical research assistant will then complete enrollment. The four time points will take place on subsequently planned appointments. The day before each time point, the nurse will call as an appointment reminder.

2.3. Sample size

Six nurses with six patients each will be recruited with a primary objective to describe nurses’ mastery of basic hypno-analgesia techniques after a four-day training. This number of observations will be sufficient to describe the impact of the training and to give insights on its most effective components.

Moreover, we will be able to conclude on the first secondary endpoint with this sample size. Self-reported VAS evaluation of children’s fear for invasive procedures without sedation is 5 ± 2 (mean \pm standard deviation) (Babl, Mandrawa, O’sullivan, & Crellin, 2008), whereas it is 3 ± 2 (mean \pm standard deviation) under sedation. (Dufresne et al., 2010) We expect an effect size of .67 (the same as sedation), reducing the mean VAS from 5 to 3. It is conservatory to expect a standard deviation of 3, larger than the one reported in the literature. Twenty patients will thus be needed to achieve a power of .80 with an alpha level of .05. As 36 patients will be included in the trial, this number will be reached even if we observed a 40% attrition. (Faul, Erdfelder, Buchner, & Lang, 2009; Faul, Erdfelder, Lang, & Buchner, 2007)

2.4. Inclusion and exclusion criteria

Nurses must belong to the hematology-oncology daycare clinic team and be familiar with venipuncture in children. They must have no previous experience in hypno-analgesia. Patients between 5 and 18 years old will be enrolled. Expected follow-up in the hematology-oncology daycare clinic and a good understanding of French are additional inclusion criteria. Patients will be included if needing regular venipunctures (65% direct transcutaneous venipuncture and 35% through veniports). The use of a topical anesthetic cream and distraction methods (bubbles, iPad, and/or other) are allowed,

as long as the same methods are constantly used for the same patient throughout the study. Patients are excluded if they have already had prior exposure to hypno-analgesia or if they are referred to the daycare clinic for an emergency or an unscheduled appointment. Other procedures than venipunctures (lumbar puncture and/or bone marrow aspiration) are not included in the study. Children with a known acute psychiatric disease will also be excluded. To avoid any bias of secondary outcome measures (distress and pain), potential participants should be free of acute infections and pain.

2.5. Intervention: training in hypno-analgesia

The nurses will complete four days of training in hypno-analgesia techniques by a certified hypno-therapist with a Master's degree in psychology. The training will be video recorded for supervision purposes. At the end of the training, two qualified therapists will carry out practice performance evaluation using the video recordings. Nurses with a performance assessment <75% will be given a supplementary training session before practicing on patients (Figure 2).

The sessions will provide theoretical and practical training by a psychologist certified in hypnosis. Two days will be devoted to didactic presentations and role-playing between nurses, and two days will be spent practicing under supervision in the usual workplace setting. Unlike conventional hypnosis, hypno-analgesia techniques do not require hypnotic induction. They are based on communication techniques such as suggestions and metaphoric images. They will be embedded in the nurses' approaches and are not expected to delay patient management (Figure 2).

2.6. Assessment time points

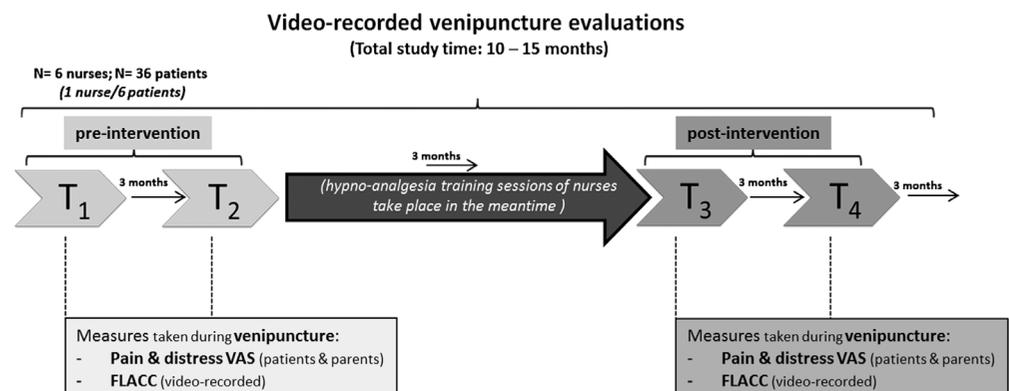
Measurements (see below outcome measures) will be taken during venipunctures, twice before intervention (T1 and T2) to ascertain baseline levels, and then twice after intervention (T3 and T4, Figure 1). Time points will be separated by approximately three months (two–four months), and will occur during regularly scheduled appointments. Self-reported measures will be taken after venipunctures and collected by a research assistant who is not involved in the training, treatments, or procedures. Measures by external raters will be made from the video-recorded venipuncture sessions. Timing from diagnosis to the first time point (T1) will be assessed according to the date of diagnosis and the date of the first time point (T1), and reported in the results.

3. Outcome measures

3.1. Practice performance of hypno-analgesia techniques

There are currently no standardized measures to evaluate hypno-analgesia practice; however, video recordings have been used for teaching and skill evaluation (Wark & Kohen, 1998). Teaching hypnosis with videotapes has also been described (Woody, 1965a, 1965b). Video recording was found to be effective in teaching and evaluating hypno-analgesia performance skills; it resulted in greater improvements in overall performance criteria and helped identify incorrectly acquired skills (Birnbach

Figure 2. Nurse training in basic hypno-analgesia techniques.



et al., 2002). Therefore, we will use a video-based assessment scale to evaluate the practice performance of hypno-analgesia techniques. Recordings will be independently coded by two qualified hypnotherapists for two sets of behaviors: relationship (four items including contact, language, rhythm, and cooperation) and techniques (four items including the use of a multisensory approach, support given to the patient, reassuring language, and establishment of a “hypnotic bubble”). Each item is coded as *positive*, *negative*, or *doubtful*. A nurse will be considered to master the technique if he/she scores at least 75% across all video recordings post-intervention (T3 + T4). The reliability of this assessment will be supported by interrater agreement (intra-class correlation coefficients and kappa values for different cut-points). Disagreements between the two raters will be resolved by discussion.

3.2. Evaluation of procedural distress by patients and parents

We will use the visual analog scale (VAS), a well-validated, appropriate, efficient, and easy-to-use scale in children from 5 to 18 years old (Babl et al., 2008; Crandall, Lammers, Senders, Savedra, & Braun, 2007; Ortiz, López-Zarco, & Arreola-Bautista, 2012). As the concept of distress is not expected to be understood by the younger children in our sample, we will use a self-report with anchor terms referring to levels of fear as described by Nilsson, Finnström, and Kokinsky (Dufresne et al., 2010). After the procedure, the child will be asked “How much did you fear the venipuncture?” and rate their feeling from 0 to 10 corresponding to “no fear at all” and “a lot of fear,” respectively. The parent will be asked “How much do you think your child feared the venipuncture?” At each time point, events that might have distressed the child between time points will be assessed by questioning the child or parent (“Has anything stressful happened to the child since the last meeting?” or “Has the child needed emergency venipunctures since the last time?”).

3.3. Evaluation of procedural pain by patients and parents

The VAS is validated for self-evaluation of pain (Babl et al., 2008; Ortiz et al., 2012). After the procedure, the patient will be asked “How much pain did you feel during the venipuncture?” with 0 being “no pain at all” and 10 indicating “extreme pain.” The parent will be asked “How much pain do you think your child felt during the venipuncture?”

3.4. Evaluation of procedural distress and pain by external evaluators

Distress will be assessed on the video recordings by an external evaluator using the Faces-Legs-Activity-Cry-Consolability (FLACC) scale, which is validated for measuring procedural pain and distress in children (Blount & Loiselle, 2009; Nilsson, Finnström, & Kokinsky, 2008; Willis, Merkel, Voepel-Lewis, & Malviya, 2003). It is easy to use in subjects aged 0–18 years, including children with cognitive impairment. It has been used to measure pain and distress in pediatric patients during procedures in an emergency department (Babl et al., 2012). The FLACC scale will be independently coded by two raters who view the video recordings, and inter-judge reliability will be documented.

3.5. Moderators of intervention effects

Socio-demographic and psychological descriptors of children and their parents will be collected at the beginning of the study. We will use validated and widely used parent-reported questionnaires to describe the children’s psychological status, Child Behavior Checklist, Achenbach (CBCL) (Achenbach & Ruffle, 2000), and their parent’s baseline stress and anxiety levels, State Trait Anxiety Inventory (STAI, Spielberger (Iwata et al., 1998); Parental Stress Inventory-Short Form (PSI-SF)).

Additionally, procedure time will be calculated based on video records, with and without the use of hypno-analgesia. Time will be added as a supplementary outcome. Analyses will be also performed to evaluate the costs and benefits (time saved) associated with the intervention.

4. Success criteria and statistical analysis

4.1. Primary endpoint and success criteria

The hypno-analgesia training will be considered effective if knowledge is correctly translated into practice. Practice performance $\geq 75\%$ will be considered as the success threshold for each nurse. The trial will be considered successful if at least four out of the six nurses reach this level. Additionally, changes in practice performance before and after the intervention will be assessed by Wilcoxon signed-rank non-parametric tests ($n = 6$). At the end of time point 4 (T4), a questionnaire will be provided to the nurse to assess the completion of their training, the effectiveness of the intervention, the impact on success of venipuncture, and the nursing anxiety related to additional demands to provide the hypno-analgesia.

4.2. Secondary endpoints

Repeated measures models will be used to compare pre- versus post-intervention changes. We will use a repeated measure analysis of variance to compare outcomes among patients (VAS distress, VAS pain, and FLACC distress). To measure anticipatory issues occurring between T3 and T4, we will separately compare anticipatory distress and procedural distress across time points. To ascertain baseline levels, we will examine the absolute and relative stabilities of T1 and T2 (pre-intervention) measures. These will set a baseline to which post-intervention measures will be compared. We will compute the percent changes with confidence intervals in anticipatory and procedural distress between T3/T4 and the aggregated baseline measure. Using recommendations from Barlow and Hersen (Hersen, 2009) on multiple baselines across subjects design, we will graphically explore the inter-individual consistency of intra-individual pre-post changes (Cohen, Feinstein, Masuda, & Vowles, 2014). In additional analyses, we will compare the means of outcome measures between nurses for each time point and examine evolution trends. This will be done both statistically at each time point (non-parametric Kruskal-Wallis tests for small samples) and graphically. Finally, additional analyses will identify the conditions for which the effects of the hypno-analgesic training are maximized in patients. We will compare contrasted groups according to measures of internalized vs. externalized difficulties in children (CBCL) and parental anxiety (STAI) to formulate further hypotheses on potential moderators to account for in future trials.

4.3. Sample size

The study's primary endpoint is translation of the training into practice. The trial will be considered successful if at least four of the six nurses master the technique (practice performance score $\geq 75\%$). Secondary endpoints are changes in patients' distress and pain. Among these endpoints, changes in self-reported distress (fear) is the main secondary endpoint. The self-reported VAS evaluation of children's fear for invasive procedures without sedation is 5 ± 2 (mean \pm standard deviation) (Babl et al., 2008), compared to 3 ± 2 under sedation (Dufresne et al., 2010). This equals an effect size of .67. Expecting the same for hypno-analgesia, we anticipate the mean VAS score to be reduced from 5 to 3 with an assumed conservatory standard deviation of 3 (due to the possibility of high variability in responses to hypno-analgesia techniques). Twenty patients will thus be needed to achieve a power of .80 with an alpha level of .05. We expect the attrition to be less than 40% of the planned sample ($n = 36$) (Faul et al., 2007, 2009).

4.4. Ethics

This study will be conducted in accordance with the Declaration of Helsinki. The protocol and the consent forms have been approved by the CHU Sainte-Justine Research Ethics Committee (NCT02421562).

5. Discussion

In Canada, there are 1,500 new diagnosis of cancer per year in children. Most of them (95%) need CVLs for their treatments (two-thirds picclines and one-third veniports) and about 1,000 patient per year necessitate 50–100 venipunctures per year in hemato-oncology settings under treatment.

This trial is the first step of a strategy aimed at providing every child in pain the proven benefits of hypno-analgesia, despite the shortage and cost of certified hypnotherapists. This new strategy is based on training nurses in basic hypno-analgesia techniques so they can incorporate them in their everyday practice. As a first step, this trial will determine if such training allows nurses to master basic techniques (primary outcome) and if this mastery translates into changes in their patients' self-reported distress during venipuncture (main secondary outcome). Changes in distress and pain reported by parents and external evaluators will also be measured, as will moderators of the intervention effect (e.g. child psychological profiles and parental stress and anxiety levels).

This trial will not provide a definitive answer on the efficacy of nurse-provided hypno-analgesia. However, it will provide the first insight into the feasibility of this strategy. If the primary endpoint is met (at least four out of the six nurses with a performance score $\geq 75\%$), we will be able to verify if nurses' mastery of such basic techniques can decrease their patients' distress and pain. If so, the way will be open for a larger trial enrolling children in various settings. Correlations analyses of nurses' practice, patients' distress, and pain improvement, and the identification of moderators of the intervention effect will be useful in designing this larger trial.

On the other hand, if the primary endpoint is not met, secondary analyses of the video recordings will be carried out to understand how the training could be modified to provide nurses with techniques they can master and incorporate in their everyday practice. Finally, nurses might master the techniques but fail to decrease patients' distress and pain. In this case, correlations analyses of nurses' practice and patients' improvement and study of moderators of the intervention effect will be useful for designing a more powerful intervention or defining patient subgroups that may benefit more.

In conclusion, this pilot trial will provide insight into the feasibility of this new nurse-based hypno-analgesia strategy. It will allow for the refinement of nurse training and establish a foundation for larger clinical studies designed to provide the benefits of hypno-analgesia to every child in pain. To date, there are no publications relating to the transferability of hypno-analgesia techniques to nurses. This attests for the originality and purpose of our study. Future studies may access the use of these techniques by nurses for other painful procedures in hemato-oncology clinics, such as lumbar puncture and bone marrow aspirations.

List of Abbreviations

CBCL	Child Behavior Checklist
FLACC	Faces, Legs, Activity, Cry, Consolability
STAI	State Trait Anxiety Inventory
VAS	Visual Analog Scale

Acknowledgments

This study received support from the Saint-Justine and Family Rossey Foundations granted to Serge Sultan (Centre d'excellence en oncologie psychosociale). Terry Mizrahi is a Fellow of the Fondation Centre de cancérologie Charles-Bruneau.

Funding

The authors received no direct funding for this research.

Competing Interests

The authors declare no competing interests.

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Citation information

Cite this article as: Training nurses in basic hypno-analgesia techniques to reduce procedural distress and pain in children: A feasibility trial, Terry Mizrahi, Serge Sultan, Marie-Claude Charest, Jennifer Aramideh, Marie-Claude Charrette, Anouk Streff, Caroline Plante & Michel Duval, *Cogent Medicine* (2016), 3: 1165083.

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