



## A randomized clinical trial of a brief hypnosis intervention to control venepuncture-related pain of paediatric cancer patients

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### ABSTRACT

Venepuncture for blood sampling can be a distressing experience for a considerable number of children. A prospective controlled trial was conducted to compare the efficacy of a local anaesthetic (EMLA) with a combination of EMLA with self-hypnosis in the relief of venepuncture-induced pain and anxiety in 45 paediatric cancer outpatients (age 6–16 years). A secondary aim of the trial was to test whether the intervention will have a beneficial effect on parents' anxiety levels during their child's procedure. Patients were randomized to one of three groups: local anaesthetic, local anaesthetic plus hypnosis, and local anaesthetic plus attention. Results confirmed that patients in the local anaesthetic plus hypnosis group reported less anticipatory anxiety, and less procedure-related pain and anxiety, and were rated as demonstrating less behavioural distress during the procedure than patients in the other two groups. Parents whose children were randomized to the local anaesthetic plus hypnosis condition experienced less anxiety during their child's procedure than parents whose children had been randomized to the other two conditions. The therapeutic benefit of the brief hypnotic intervention was maintained in the follow-up. The present findings are particularly important in that this study was a randomized, controlled trial conducted in a naturalistic medical setting. In this context, convergence of subjective and objective outcomes was reached with large effect sizes that were consistently supportive of the beneficial effects of self-hypnosis, an intervention that can be easily taught to children, is noninvasive and poses minimal risk to young patients and their parents.

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### 1. Introduction

Venepuncture for blood sampling can be a distressing experience for a considerable number of children. In cancer care, between 4% and 17% of school-age children rate venepuncture pain as severe, and 38% of children aged 3–10 years have to be physically restrained during a venepuncture [6].

A variety of psychological and pharmacological interventions are available to reduce the pain and associated anxiety of medical procedures such as venepunctures. A recent meta-analysis of psychological interventions in needle procedures [30] concluded that the largest effect sizes for treatment improvement over control conditions exist for hypnosis—self-reported pain (SMD  $-1.47$ , 95% CI  $-2.67$  to  $-0.27$ ). All studies conducted to date [2,8–12,19,21,31,32] found hypnosis effective in reducing the pain and anxiety of young patients during procedures such as lumbar punctures (LPs), bone marrow aspirations (BMAs), and voiding cystourethrography. In one study [21] in particular, young patients were successfully taught and used self-hypnosis during repeated

LPs. Despite the evidence for its efficacy, however, one of the reasons that prevent the widespread use of hypnosis in clinical settings is the belief that it may take a number of sessions to master hypnotic skills [24].

In terms of pharmacological management of venepunctures, a local anaesthetic frequently used is EMLA cream, a eutectic mixture of lidocaine and prilocaine applied 60 min before the procedure. A number of investigators have evaluated EMLA [14] and combinations of EMLA with distraction in children undergoing venepunctures [4,5,13], and found it effective in significantly reducing subjective pain and distress ratings reported by parents and nurses.

Because EMLA and combinations of EMLA with self-hypnosis (introduced in a single, brief training session) have not yet been compared to one another in a controlled manner in the management of venepuncture-related pain, the primary aim of the present study was to compare the efficacy of EMLA with a combination of EMLA with self-hypnosis in the relief of venepuncture-induced pain and anxiety in paediatric cancer patients.

Recently, Smith and colleagues [28] demonstrated that caregiver's heart rate, blood pressure, and anxiety were affected by witnessing their child undergo IV cannulation in the Emergency

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Department (ED), and these responses were predictive of child distress and pain. The authors concluded that analgesic interventions in the ED should involve caregivers and children. Therefore, a secondary aim of this study was to assess the effect, if any, that a brief hypnotic analgesic intervention administered to children has on parental anxiety during a venepuncture.

More specifically, in the current study the following hypotheses were tested: (1) the combination of self-hypnosis with local anaesthesia will reduce pain, anxiety, and behavioural distress during venepuncture and anticipatory anxiety before the procedure more than local anaesthesia alone, (2) parents whose children have been randomized to the self-hypnosis plus local anaesthetic condition will experience less anxiety during the procedure than parents whose children have been randomized to the local anaesthetic condition alone, (3) the therapeutic benefit of the brief hypnotic intervention will be maintained in the long term follow-up.

## 2. Method

### 2.1. Participants

The study received Ethics approval and was conducted in the outpatient Haematology/Oncology clinics of a Children's Hospital in Athens, Greece. Eligible participants included Greek-speaking patients with cancer, between the ages of 7 and 16 years who were off active treatment, were undergoing regular venepunctures as part of their disease status monitoring and had one of their parents in attendance. Exclusion criteria for the children were (1) previous hypnosis treatment; (2) concurrent treatment during the project with analgesic or psychotropic medication; (3) a major affective disorder or other psychiatric diagnosis; (4) no clearly visible veins as judged by the nurse who was going to perform the venepuncture. The exclusion criterion for the parents was diagnosis of an anxiety or mood disorder or other psychiatric diagnosis within the past 5 years. Fifty-nine consecutive children/parent dyads were evaluated for possible inclusion to the study; three children were excluded because they had previous experience with hypnosis, three adolescent boys declined participation on the grounds that they could cope with the pain on their own, three further patients were excluded because they had not clearly visible veins, two parents were excluded because they were not fluent in Greek, three parents were excluded because they were suffering from a long-standing anxiety disorder. Hence, the final sample for the study was 45 children/parent dyads [20 boys, 25 girls, mean age: 8.5, standard deviation (SD): 2.21 and their parents (33 mothers and 12 fathers; mean age: 37.8, SD: 3.42)]. Flow of patients through the trial is presented in Fig. 1.

### 2.2. Design

Forty-five children with cancer who were undergoing VPs were randomly allocated (1:1:1) to one of three treatment groups using computer-generated random positive integers [26]: (a) the EMLA group (EMLA) was treated with EMLA cream applied to intact skin for approximately 60 min before the procedure; (b) the EMLA plus self-hypnosis group (EMLA + Hypnosis) was administered EMLA cream and was also taught self-hypnosis; (c) in the EMLA plus Attention group (EMLA + Attention) patients were administered EMLA cream and met the therapist for the same amount of time as those in the EMLA + Hypnosis group.

### 2.3. Outcome measures

#### 2.3.1. Patients

**2.3.1.1. Pain.** Child self-report of procedure-related pain was obtained by a 100 mm Visual Analog Scale (VAS). The anchors “no

pain” and “worst possible pain” were used at either end of a 10 cm line. VAS scores can range from 0 to 10 on the basis of how many centimeters from the left to the mark made by the research participants indicate level of pain. Assessment of pain in paediatric populations by VAS from the age of 7 onwards has received strong empirical support in the literature [27].

**2.3.1.2. Procedure-related distress.** Two additional measures of children's procedure related distress were obtained, that is, self-report of procedure-related anxiety and observed behavioural distress.

**2.3.1.2.1. Anxiety.** Child self-report of procedure-related anxiety was obtained by a 100 mm VAS with the anchors “no anxiety” and “worst possible anxiety” at either end.

**2.3.1.2.2. Procedure behaviour checklist [15].** This structured behaviour observation instrument requires observers to document the presence, and rate the intensity (on a 1–5 scale) of 10 operationally defined behaviours that indicate anxiety and pain (e.g. pain verbalized, screams, anxiety verbalized, physical resistance) during three time periods of an invasive procedure (ie, preparation, needle insertion, and post procedure). It is appropriate for use with children between 6 and 18 years, and correlates significantly (Pearson's  $r=0.26-0.53$ ) with patient ratings of anxiety and pain before and during cancer procedures [15]. Scores can range from 0 to 24. For the present study, three observers (psychology graduates) received 3 h of training in the completion of the Procedure Behaviour Checklist (PBCL). During the training phase, interrater reliability among coders was 0.85. During the course of the actual study, interrater reliability was evaluated by having a second observer unrelated to the study present in the treatment room to independently complete the PBCL for 30 procedures (22.22%), randomly distributed throughout the course of the trial.

#### 2.3.2. Parents

**2.3.2.1. Anxiety.** Parental self-report of anxiety was obtained by a 100 mm VAS with the anchors “no anxiety” and “worst possible anxiety” at either end.

### 2.4. Procedure

On arrival to the outpatient clinic all children received 2.5 g of EMLA 5% (1 ml) and were informed about the study. Cream was applied over a prominent vein, in a thick layer, and covered with occlusive dressing (tegaderm 3M). After 60 min the dressing was removed and the cream wiped off with sterile gauze.

Once a child was deemed eligible and his or her parent agreed to participate, the child was randomized to a group by consulting a printout of the computer-generated randomization sequence.

After randomization, the study involved three procedural steps: (a) interventions (Time T1); (b) b1, assessment of the patient's degree of anticipatory anxiety and procedure-related pain and anxiety during a venepuncture immediately following interventions (Time T1); b2, assessment of the patient's parent degree of anxiety during their child's venepuncture (Time 1); (c) c1, assessment of the patient's degree of anticipatory anxiety and procedure-related pain and anxiety during two follow-up venepunctures (Times T2, T3); c2, assessment of the patient's parent degree of anxiety during their child's second follow-up venepuncture (Time T3); these are discussed in turn and are presented graphically in Fig. 2.

#### 2.4.1. Interventions

Both the hypnosis and attention control sessions were delivered to patients individually by the same therapist according to the study protocol manual and were standardized to last 15 min. The hypnosis protocol manual was modified from previous studies

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