

Acute Procedural Pain in Children

Intervention with the Hospital Clown

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ACUTE PROCEDURAL PAIN IN CHILDREN: INTERVENTION WITH THE HOSPITAL CLOWN

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ABSTRACT

Hospitalized children often describe needle-related procedures as the worst pain possible and such procedures may be emotionally traumatic. The use of hospital clowns related to painful medical procedures in children may offer pain relief, but this has not been systematically evaluated. The objective of this study was to assess the effect of a therapeutic clown in comparison to standard care on the experience of pain for children receiving venipuncture. **Methods:** A sample of 116 children aged 4-15 years consecutively admitted to the hospital was allocated to either the experimental (presence of hospital clown) or control group (standard care) prior to venipuncture. Self-reported pain after the procedure was assessed using the FACES Pain Scale combined with a 0-10 Numerical Rating Scale. Separate analysis was done in age groups from 4-6 (N=37) and 7-15 (N=74) years.

Results: Without the clown present, the mean pain score (2.7 ± 2.8) was not significantly different between the two age groups. Children aged 7-15 years had lower pain scores when the clown was present compared to the control group ($P=0.025$). Children aged 4-6 years had higher pain scores with the clown present although the difference is not statistically significant ($P=0.054$). Children with pain (N=49) or previous experiences with venipuncture (N=56) did not score pain significantly differently. **Discussion:** Assessing the pain experience in children receiving venipuncture with the presence of a hospital clown indicates a pain relieving effect for children older than 6 years.

However, future studies should carefully study the effects for younger children where mixed effects may be present.

Keywords: *hospital clown intervention, venipuncture/procedural pain, pain assessment, self-report, children*

1. INTRODUCTION

Hospitalized children experience fear and anxiety due to separation from their family and friends, the unfamiliar environment, and potential painful procedures and treatment (1). Children often describe needle-related procedures as the most painful aspect of the health care experience (2-4). Studies demonstrate that a high frequency of unmanaged pain puts hospitalized children of all ages at risk for both immediate and long-term physiological and behavioral consequences (2,5-9). In cases of acute hospitalization, time to prepare for painful procedures is limited. As a result, the experience is not only more painful for children but it can cause distress to parents (10,11). Painful procedures may not only be immediately traumatic. Indeed, children suffering from untreated procedural pain and children with negative previous procedural experiences have an increased risk of anxiety and distress, with psychological consequences for subsequent procedures and future health care behaviors (9,12,13). Thus, a focus on management of pain is essential in the context of an acute painful procedure (14). To meet this need, the International Guideline in Pediatric Anesthesia (*Good Practice in postoperative and procedural Pain Management*) (10) recommends pain assessment as well as pharmacological and non-pharmacological strategies to prevent and effectively manage acute procedural pain in children.

Pharmacological strategies for intravenous cannulations involve the usage of topical local anesthetics (10,15). However, studies indicate that topical local anesthetics does not guarantee pain relief, and children with anxiety may not be helped by this intervention. Thus, there is a need to reduce anticipatory and procedural anxiety using non-pharmacological strategies (2,10,11,16). Non-pharmacological strategies attempt to shift the child's focus to something more attractive and draw attention away from pain stimuli (7,15,17-19). Stinson et al. reported that acute procedural pain in children was efficiently reduced by distraction and hypnosis (9). Uman et al. had similar results highlighting the effectiveness of distraction, hypnosis, and combined cognitive-behavioral

interventions to reduce the pain and distress that accompany these procedures (19). These findings are in line with other studies focused on the impact of non-pharmacological strategies that involve “moving the focus away from the painful situation” and “guiding the child through the procedure” (14,20).

Hospital clowns are one example of a non-pharmacological distraction strategy (21). The hospital clown is a professional with a specific practical and theoretical education who uses cognitive distraction and imagery to shift attention away from pain or sources of distress and thereby encourage the child to cope (22-25). In the last decade, there has been a rapid growth in the presence of hospital clowns in pediatric hospitals as part of the interdisciplinary teams around the child and family. The hospital clown is still mostly used in the context of entertainment, based on the assumption that humor is associated with increased well-being of the child (21,26,27).

Although many pediatric units routinely use them, hospital clowns are rarely asked to interact with children during painful procedures (22). Only a few randomized studies have investigated the usage of hospital clowns related to painful procedures. Felluga et al (28) reported no beneficial effects on pain levels in children aged 4-11 years undergoing five different therapeutic procedures. These results are consistent with Meiri et al. (29) reporting no benefit on pain level in children aged 2-10 years undergoing venipuncture or intravenous cannulation in a comparison with a control group, using topical anesthetics (EMLA). Conversely, their study showed a beneficial effect on anxiety and length of crying with the hospital clown. Another study including children aged 3-16 years undergoing either venipuncture or intravenous cannulation found a pain reduction in 3-7 year old children with the presence of a hospital clown, though no change in 8-16 year olds (25). However, research on the effects of systematic interventions with a hospital clown on children's pain experience undergoing a standardized procedure is limited. Furthermore, major questions

remain as to how different age groups react to the presence of a clown as an intervention and whether the potential effect has any relation to previous experiences of pain.

This study aimed to evaluate the effect of an intervention with the hospital clown on self-reported pain level compared to standard care for children receiving venipuncture in the pediatric admission unit at a hospital. The study specifically focused on examining potential differences in intervention effect based on: 1) age group [4-6 years versus 7-15 years]; and 2) presence of a pain condition prior to venipuncture or previous pain experiences.

2. MATERIALS AND METHODS

2.1 Study design and material

This study is a prospective, non-blinded trial. A parallel design was used that studied children aged 4–15 years who were admitted consecutively at a Danish university hospital over a period of nine months, from April 2016 to January 2017. They were assigned to a hospital clown (HC) intervention or standard care (SC). Children were considered eligible for the study if they were: 1) acutely admitted to the hospital at the admission unit and scheduled for venipuncture procedure, 2) not prepared for the procedure before coming to the hospital (not knowing about having a venipuncture), and 3) accompanied by at least one parent. Children with developmental disorders who could not cooperate with self-reporting of pain or who were unable to speak Danish or English were excluded. The study was approved by the pediatric administration at the University Hospital. Permission was given by the Data Inspectorate (id: 2016-5). The local ethics committee was consulted, and they certified that the study did not require their approval.

Written and oral information were provided to both children and parents. Written informed consent for study participation was obtained from parents.

With expected deviations of pain scores of 10%–20% (estimation for clinical relevance) (30,31,32), a sample size of 52 children in each group was estimated, assuming α -level of 5% and 80% power.

2.2 Allocation

There were specific time frames planned for the study (requiring presence of the hospital clown).

The hospital clown was available on certain days and was scheduled for all day on weekdays and for some evening hours during the study period. This schedule was established for the entire inclusion period before starting child recruitment. When the hospital clown was available, the hospital clown took part in all the venipuncture procedures for the eligible children. Children were considered as assigned to the HC group if they were admitted on days when the hospital clown was available and to the SC group otherwise. Pilot data collection one month prior to the study was conducted to investigate the distribution of age, gender and diagnoses over weekdays. This pilot confirmed that of 173 diagnoses, gender and age were uniformly distributed on all days of the week and hence independent of the presence of the hospital clown. In summary, eligible children were recruited during all weekdays independently of the presence of the hospital clown. Hence, their assignment was considered random and the data were analyzed accordingly. In the SC group, 10 children were included in the summer period, during which the hospital clown was absent for five weeks.

2.3 Intervention

Prior to this study, the hospital clown was not part of the daily routine and practice at the participating unit. Children in the HC group met the clown before venipuncture procedures either in the waiting room or in the examining room. One male hospital clown was used in the study in order to ensure minimal variation in technique. In the HC group, the children and their parents interacted with the hospital clown while waiting for the procedure and during the time needed to complete the venipuncture. Depending on the child's age, emotional state and cognitive development, the

hospital clown used different methods. Overall, the performance of the hospital clown included creating a relationship with the child by using different techniques.

The hospital clown in this study utilized different techniques by building a relationship with the child before the venipuncture, specifically by using music, songs, toys and making agreements for the procedure (ex. looking or not looking at the needle) in collaboration with the child, parents, and healthcare personnel. During the procedure, the hospital clown had a conscious use of distraction techniques such as holding the child's hand, temporary tattoos (a small sticker/label with a picture applied to the skin with water), dream journeys, songs, and storytelling.

Children in the SC group were exposed to the other clinical staff's individual distraction, comfort and care techniques for acutely hospitalized children undergoing painful medical procedures in collaboration with the parents. In the SC group, nurses interacted with the child from the beginning of admission and prepared the child by explaining verbally the venipuncture procedure. Under the procedure, the biomedical laboratory technologist guided and structured the procedure.

Different pediatric nurses and biomedical laboratory technologists assisted with the procedures, and they were randomly distributed in both groups. In both groups of children, the parents, the nurses or the biomedical laboratory technologists were not prepared to use any specific instructions on how to aid the child through the procedure. For both groups, the procedure was performed in two examining rooms of equal size and with the same interior arrangements. The walls were decorated with colorful paintings and characters suitable for children. The procedure was performed on a chair or on the bed.

2.4 Data collection procedures

Baseline information including age, gender, presence of a current painful condition, and previous experiences with venipunctures was obtained in the examining room.

The primary outcome measure was the child's self-report of pain on an age-appropriate scale. The self-reporting of pain was carried out in the examining room immediately after finishing the venipuncture, during a time interval of between 0–5 minutes. No studies were found, who investigated the specified time interval for self-report of pain after a venipuncture. Thus, this time interval was chosen on basis of a pilot study, which was carried out in the pediatric setting on 11 random selected children in February 2016. This time interval was validated with ethnographic field notes (Ref. HNK *In prep*). No systematic difference was found between the two groups in the pilot study.

Supplementary the number of punctures for each child and duration of each procedure was documented due to their potential relation to the exposure.

2.5. Pain assessment

Self-reported pain assessment is recommended as the primary source for information about pain intensity accounting for differences in age as well as cognitive and communicative abilities. Most children have developed the ability to provide an accurate self-report from 3 years of age (33,34,). Thus, the Numerical Rating Scale (NRS) combined with the Wong-Baker Faces Pain Scale (FPS) was chosen for pain assessment. These two scales are widely used in clinical pediatric practice (35). The NRS is recommended for children aged 8 years and older; the FPS is recommended for ages 4–12 years (10,11,32,34). The NRS ranges from zero on the left side, indicating “no pain,” to 10 on the right side, indicating the “worst pain possible”. The FPS is a horizontal scale of six drawn faces that range from a smiling “no hurt” anchor face on the left side to a crying “hurts worst” anchor on the right. In this study the FPS was coded to a 0–10 scale (34,37). The two scales were depicted on the same laminated paper, with parallel presentation of the numbers and the six faces. This version was chosen to secure a developmentally, cognitively and culturally appropriate pain scale for the age group in the present study (4–15 years) as well as to secure a version easy to use in clinical

practice (12,32). While age is a proxy for developmental level, chronological age is not the sole indicator of a child's capacity to self-report pain. Different children have different assessment needs (10,11,35); thus, independent of age, children were asked to choose either the numbers or the faces on the scale, substantiated by their different cognitive capacities and developmental level. Both scales were well known and routinely used among the nurses in the unit.

2.6. Statistics

Statistical analyses were conducted using STATA version 14 software. Fisher's exact test was used to assess potential differences between the two groups in categorical characteristics of participants. An unadjusted unpaired two-sample *t* test was conducted to compare the pain scores and other respective characteristics of the two groups. Adjusted analysis by multivariable linear regression was performed to capture the effect of potential intermediate variables (local anesthetic, nitrous oxide, time per procedure, number of punctures) (38).

Supplementary analyses were performed, stratified by age group (4-6 and 7-15 years), sex, pain condition and previous venipunctures. By multivariable linear regression, the effects among these strata were compared. In all analyses, the eventual non-normality and variance of in-homogeneity was addressed using bootstrapping with 1000 replications to estimate standard errors.

The cut off for age groups (4-6 and 7-15 years) was based on the literature addressing challenges in providing self-report of pain in younger pre-school children (33,39).

Sensitivity analyses with respect to population heterogeneity due to the summer period, use of nitrous oxide, and 14-15 years of age was done by omitting the few relevant cases from the analyses. Significant findings were found for P-values ≤ 0.05 .

3. RESULTS

A total of 116 children were enrolled in the study. After allocation to either the HC or the SC group, one in each group refused to make the self-report ($n=2$). Furthermore, one child refused to fulfill the

venipuncture and two children had two venipuncture procedures in the same session, thus only the first score was included in the analysis. In total, 111 children were included in the analysis: 49 in the HC group and 62 in the SC group (Fig. 1).

No demographic differences between the children assigned to the HC group (n=49) or the SC group (n=62) were found (Table 1). When comparing the use of local anesthetics, nitrous oxide, number of punctures and duration of procedure, no significant difference between the two groups was found.

The analysis of the entire group (4–15 years) found no statistically significant differences in pain scores between the two groups with or without adjusting for potentially influencing variables (Table 2).

The stratified analysis showed an effect of the hospital clown's presence varying between age groups. Pain scores in the 7–15 years group showed a positive effect of the presence of the hospital clown, with a decrease in the scores (Table 2). When adjusting for the effect of potential intermediate variables, similar effects were identified ($P=0.025$).

Conversely, in the group aged 4–6 years, we found a *higher* pain score with the presence of the hospital clown (Table 2) although this difference was not statistically significant ($P=0.087$). When adjusting for the effect of potential intermediate variables, the difference was enhanced but still not statistically significant ($P=0.054$).

A statistically significant difference in effect of the hospital clown between the age groups (4-6 and 7-15 years) was found ($P=0.018$) (Table 2). By effect, we mean the difference in score between the exposed and the unexposed children.

There were no differences related to gender found between the two groups ($P=0.997$).

From the stratified analyses, no significant difference was found for children affected by presence of a painful condition and children with previous venipunctures, with or without the presence of the hospital clown (Table 2). However, the estimated effect for children with no previous venipunctures (-1.2 [-2.5, 0.2], $P=0.085$) provides some support for a benefit of the presence of the hospital clown. Conversely, for children with previous venipunctures, the estimated effect was negative (1.0 [-0.7, 2.6], $P=0.248$).

There was no statistically significant difference between the two groups when comparing presence of a painful condition/no presence of a painful condition (1.4 [-1.0, 3.8], $P=0.254$), whereas with respect to previous venipunctures, there was a difference (2.1 [-0.0, 4.3], $P=0.054$). (Table 2)

4. DISCUSSION

For the entire sample (4-15 years), no statistically significant difference in pain scores between the SC and HC groups was found. The literature scarcely reports on the question of hospital clowns' effect on children undergoing venipunctures. Nonetheless, the results of the present study are to some extent in accord with a few other studies assessing pain related to painful procedures with hospital clown intervention (25,28,29). Felluga et al. (28) and Meiri et al. (29) found no significant pain reduction with an intervention of a hospital clown but did find a positive effect on anxiety in children aged 4-11 and 2-10 years respectively. In contrast to the findings from our study, Wolyniez et al. (25) found a tendency for the pain score to be lower with the presence of a hospital clown in children younger than 7 years and unchanged in the older age group (8-16 years). However, these studies have not investigated homogenous painful procedures and have included different age groups and contexts. Thus, the results of our study should be interpreted within the specific context, procedure and age groups.

The overall results may partly be explained by the fact that anxiety and fear may affect the pain level independent of the presence of the hospital clown. The hospital clown intervention can be seen as a non-pharmacological strategy similar to distraction, which seems effective for pain relief associated with painful procedures (7,18,19). Distraction is defined as a cognitive or behavioral strategy that redirects the child's attention or actively involves the child (18). The hospital clown strategy differs from other distraction by tailoring individual child, considering bringing the child's choice and preferences in front (17).

However, a strong correlation exists between perceived pain and affective and cognitive aspects of the pain experience (32). Anxiety, fear and distress can exacerbate children's pain experience (25). Thus, it is preferable to use self-reporting in combination with observational measures of behavior in clinical practice with special attention on younger children (32,34).

Overall, the preferred pain scoring method in both groups was the FPS (Table 1), which is consistent with earlier reviews on self-reporting of pain (34,35). Previous studies on pain assessment in younger children demonstrate challenges in using scales as the children may lack the requisite comprehension level to use measures and to some extent favor the extreme ends of scales (35,40). However, the results of the present study did not show a significantly higher score in the 4-6 year old SC group (2.6 ± 3.8) compared with the score in the 7-15 year old SC group (2.7 ± 2.0), indicating no favoring of the high end of the scale in the 4-6 year group. Thus, these overall results raise questions regarding hospital clown intervention for different age groups.

When conducting the stratified analysis of the data divided into two age groups, an increase in pain score was found in the 4-6 year old group with the presence of the hospital clown although the difference was not statistically significant ($P=0.054$). In contrast, a decrease was found in the 7-15 year old group with the presence of the hospital clown. Adjusting for intermediate variables, the

results showed similar effects, meaning that the observed difference in pain scores cannot be explained by the intermediate variables.

These age-related differences are in contrast with Wolyniez et al. (25), who found improved pain scores in younger children, whereas in older children, pain scores were unchanged. The results are to some degree consistent with Hansen et al. (26), who found gender-specific differences, with a negative effect on boys younger than 8 years.

Thus, the negative effect on younger children in this study may have several different explanations. Firstly, compared to older children, younger children may be especially affected by cognitive, emotional or situational factors (35); such factors may affect the child's collaboration with the hospital clown and thus explain the increase in pain scores in the 4-6 year old group.

Secondly, the hospital clown represents an additional and unknown person in a challenging situation. Even when the hospital clown met the child and family before the procedure, there may have been some challenges in making an alliance in a situation typically characterized by fear, pain and distress. Although no fear of clowns was registered, Linge (23,24) describe age-related differences in the alliance, pointing out that younger children meet the hospital clown with more caution; as a result, an alliance requires time to develop. Therefore, creating the alliance in an acute situation may be a challenge. Thirdly, the negative effect on children aged 4-6 years may partly be explained by the fact that younger children have a lower perceived level of control to allow them to benefit from a distraction (14). Though the results of the present study did not show a higher score in the 4-6 year old SC group (2.6 ± 3.8) compared with the score in the 7-15 year old SC group (2.7 ± 2.0), the majority of research on rating scales indicate that younger children might experience difficulties using the middle points of scales when rating emotional states (40,41). Their limited cognitive abilities regarding complex abstract thoughts, compared to older children with a more

abstract thinking and logic must be taken into account, when interpreting the results from this study, in particular the results in children aged 4-6 years. Further research is required within this group.

The results revealed by this study showed a non-significant difference between the two groups related to prior venipunctures ($P=0.054$). The estimated effect for children with no previous venipunctures (-1.2) provides some support for a benefit of the presence of the hospital clown that is large enough to be considered clinically important. Although this did not reach statistical significance ($P=0.085$), the confidence interval (CI) leaves open the possibility of a positive effect (-2.5) of the hospital clown intervention. This is large enough to be clinically important, and it provides strong evidence against a substantial negative effect (0.2). Conversely, for children with previous venipunctures, the estimated effect was negative (1.0). Thus, the CI argues against a substantial positive effect (-0.7) but leaves open the possibility of a substantial negative effect (2.6) of the hospital clown intervention. This result supports that earlier experiences (and thus level of distress) are a major factor in children's ability to cope. Earlier negative painful experiences can lead to a current higher pain score (12,26). Comprehensive research on psychological sequelae after unmitigated pain concerning vaccination of children point out the adverse impact these memories may have on fear and pain at future procedures (13). However, in our study, we did not ask if the earlier experience was either negative or positive. Taking into account that children often report pain related to needles as "*the worst pain possible*" (2-4), it may be a plausible explanation that memories of previous painful experiences are characterized by children as negative and therefore seem to have great influence on the child's expectancy of pain, level of distress and efficacy of pain strategies (2,14). Thus, children with previous experiences benefit, to a minor degree, from the intervention.

Strengths and limitations

The results of this study should be considered in the light of the following limitations. First, the results may be somewhat limited by the small sample size, when divided in two age groups (Fig 1). Therefore, the study only demonstrated a tendency in increases and decreases in pain level, respectively. Further research should be undertaken in different age groups with larger samples.

Second, we used self-reported pain as the only pain measurement. Self-reporting of pain reflects different perspectives (32); thus, perfectly reliable and valid measurement is unattainable (34).

Nonetheless, self-reporting of pain is considered as the preferred approach (10).

Although children's self-reporting of pain intensity is a valuable source of information on pain, care must be taken in interpreting pain intensity from standardized pain scores alone. To some extent, we have taken this into consideration by choosing different age-appropriate scales and letting the child choose their preferred scale.

Third, in this study, a pain measurement tool was used which combined the FPS with NRS. This approach could have resulted in response bias, since younger children tend to choose the FPC and have a tendency to use the extremes of the scale (35). However, all children were instructed in both scales, and registration showed a random distribution of choice of scale in both HC and SC groups (Table 1). Furthermore, the results from the SC group for both age groups illustrated no clinically significant differences. Thus, we suggest that there is no response bias regarding this issue in the present study. Despite this finding, it is important to point out that the presence of the hospital clown and other predictors can only explain some of the variances in the children's scores. Thus, these results might also be explained by other factors (e.g., the affective impact, children's control and coping, parental presence and attitude) not taken into account in this study. The parent's role and perspective might be addressed in further studies as well as the nurses' and hospital clown's perspective.

The allocation of children to either the experimental (presence of hospital clown) or control group (SC) depends of the availability of the hospital clown. This limitation is handled by conducting a pilot study prior to the current study. Results from the pilot showed a random distribution of children's diagnosis, age and gender on all days of week, and thereby strengthens the allocation.

A strength of this study is its use of only one hospital clown, validating a uniform hospital clown intervention for all included children. Another strength is that a homogeneous painful procedure, venipuncture, was investigated. A final strength was that usage of the NRS and FPS, depicted on the same laminated paper, was easy, quick, and familiar to all the pediatric nurses in the unit.

5. CONCLUSION

The present study contributes to the existing evidence regarding non-pharmacological strategies for acute pain management. Specifically, the study adds new insights regarding the effect of the hospital clown as an individual tailored strategy, and addresses an understudied topic for a non-pharmacological intervention associated for venipunctures in acute hospitalized children.

The results of this investigation show that the usage of the hospital clown had a positive effect on pain relief in children older than 6 years undergoing venipuncture. Furthermore, the findings showed a tendency for children affected by pain and children with previous venipuncture, to a minor degree, to benefit from the hospital clown intervention. Taking into account the difficulties of younger children in responding on scales and the small sample size, further research with a larger sample and on other dimensions of the acute procedural pain experience will be needed to capture the complexity of understanding and managing children's pain experience via hospital clown intervention in different age groups. Furthermore, research will be needed pointing at psychological differences concerning the encounter with the hospital clown in different age groups.

References:

- (1) Sridharan K., Sivaramakrishnan G. Therapeutic clowns in pediatrics: a systematic review and meta-analysis of randomized controlled trials. *Eur J Pediatr* 2016 08 Sep 2016:1-8.
- (2) Friedrichsdorf SJ, Postier A, Eull D, et al. Pain Outcomes in a US Children's Hospital: A Prospective Cross-Sectional Survey. *Hospital Pediatrics* 2015 Jan;5(1):18-26.
- (3) Wilson ME, Megel ME, Enenbach L, et al. The Voices of Children: Stories About Hospitalization. *Journal of Pediatric Health Care* 2010 0;24(2):95-102.
- (4) Walther-Larsen S, Pedersen MT, Friis SM, et al. Pain prevalence in hospitalized children: a prospective cross-sectional survey in four Danish university hospitals. *Acta Anaesthesiol Scand* 2017 Mar;61(3):328-337.
- (5) Harrison D, Joly C, Chretien C, et al. Pain prevalence in a pediatric hospital: Raising awareness during Pain Awareness Week. *Pain Research and Management* 2014;19(1):e24-e30.
- (6) Birnie KA, Chambers CT, Fernandez CV, et al. Hospitalized children continue to report undertreated and preventable pain. *Pain Research and Management* 2014;19(4):198-204.
- (7) Stuber M, Hilber SD, Mintzer LL, et al. Laughter, Humor and Pain Perception in Children: A Pilot Study. *Evidence-based Complementary and Alternative Medicine* 2009;6(2):271-276.
- (8) Taylor EM, Boyer K, Campbell FA. Pain in hospitalized children: A prospective cross-sectional survey of pain prevalence, intensity, assessment and management in a Canadian pediatric teaching hospital. *Pain Research and Management* 2008;13(1):25-32.
- (9) Stinson J, Yamada J, Dickson A, et al. Review of systematic reviews on acute procedural pain in children in the hospital setting. *Pain Research & Management* 2008;13(1):51-57.
- (10) Association of Pediatric Anesthesia. Good practice in postoperative and procedural pain management, 2nd edition. *Pediatric Anesthesia* 2012;22:1-81.
- (11) Center for Kliniske Retningslinjer. Vurdering af smerteintensitet ved akutte smerter hos børn fra 28 dage-18 år, Center for Kliniske retningslinjer - clearing house, 1. Juni 2016. 2016.
- (12) Versloot J, Veerkamp JSJ, Hoogstraten J. Children's self-reported pain at the dentist. *Pain* 2008;137(2):389-394.
- (13) McMurtry CM, Pillai Riddell R, Taddio A, et al. Far From "Just a Poke": Common Painful Needle Procedures and the Development of Needle Fear. *Clin J Pain* 2015 Oct;31(10 Suppl):S3-11.
- (14) Svendsen E.J., Bjork IT. Experienced nurses' use of non-pharmacological approaches comprise more than relief from pain. *J Pediatr Nurs* 2014 01 Jul 2014;29(4):e19-e28.
- (15) Gilboy S, Hollywood E. Helping to alleviate pain for children having venepuncture. *Paediatr Nurs* 2009 10;21(8):14-19.

- (16) Lal MK, McClelland J, Phillips J, et al. Comparison of EMLA cream versus placebo in children receiving distraction therapy for venepuncture. *Acta Paediatr Int J Paediatr* 2001;90(2):154-159.
- (17) Koller D, Goldman RD. Distraction Techniques for Children Undergoing Procedures: A Critical Review of Pediatric Research. *J Pediatr Nurs* 2012 12;27(6):652-681.
- (18) Kleiber C, Harper DC. Effects of distraction on children's pain and distress during medical procedures: A meta-analysis. *Nurs Res* 1999;48(1):44-49.
- (19) Uman LS, Chambers CT, McGrath PJ, et al. A systematic review of randomized controlled trials examining psychological interventions for needle-related procedural pain and distress in children and adolescents: An abbreviated cochrane review. *J Pediatr Psychol* 2008;33(8):842-854.
- (20) Karlsson K, Dalheim Englund AC, Enskar K, et al. Experiencing Support During Needle-Related Medical Procedures: A Hermeneutic Study With Young Children (3-7Years). *J Pediatr Nurs* 2016 Nov - Dec;31(6):667-677.
- (21) Dionigi A, Sangiorgi D, Flangini R. Clown intervention to reduce preoperative anxiety in children and parents: a randomized controlled trial. *J Health Psychol* 2013 Jan 29.
- (22) Barkmann C, Siem AK, Wessolowski N, et al. Clowning as a supportive measure in paediatrics - a survey of clowns, parents and nursing staff. *BMC Pediatrics* 2013;13(1) (pagination):Arte Number: 166. ate of Pubaton: 10 Ot 2013.
- (23) Linge L. Magical attachment: Children in magical relations with hospital clowns. *Int J Qual Stud Health Well-being* 2012;7:10.3402/qhw.v7i0.11862. Epub 2012 Feb 24.
- (24) Linge L. Joyful and serious intentions in the work of hospital clowns: a meta-analysis based on a 7-year research project conducted in three parts. *Int J Qual Stud Health Well-being* 2013 Jan 4;8:1-8.
- (25) Wolyniez I, Rimón A, Scolnik D, et al. The effect of a medical clown on pain during intravenous access in the pediatric emergency department: a randomized prospective pilot study. *Clin Pediatr (Phila)* 2013 Dec;52(12):1168-1172.
- (26) Hansen LK, Kibaek M, Martinussen T, et al. Effect of a clown's presence at botulinum toxin injections in children: a randomized, prospective study. *J Pain Res* 2011;4:297-300.
- (27) Pinquart M, Skolaude D, Zaplinski K, et al. Do clown visits improve psychological and sense of physical well-being of hospitalized pediatric patients? A randomized-controlled trial. *Klin Padiatr* 2011 Mar;223(2):74-78.
- (28) Felluga M, Rabach I, Minute M, et al. A quasi randomized-controlled trial to evaluate the effectiveness of clowntherapy on children's anxiety and pain levels in emergency department. *Eur J Pediatr* 2016 May;175(5):645-650.

- (29) Meiri N, Ankri A, Hamad-Saied M, et al. The effect of medical clowning on reducing pain, crying, and anxiety in children aged 2-10 years old undergoing venous blood drawing - a randomized controlled study. *Eur J Pediatr* (2016) 175: 373-379.
- (30) Kelly A. Does the Clinically Significant Difference in Visual Analog Scale Pain Scores Vary with Gender, Age, or Cause of Pain? *Acad Emerg Med* 1998;5(11):1086-1090.
- (31) Powell CV, Kelly A, Williams A. Determining the minimum clinically significant difference in visual analog pain score for children. *Annals of Emergency Medicine* 2001 January 2001;37(1):28-31.
- (32) von Baeyer CL. Children's self-reports of pain intensity: scale selection, limitations and interpretation. *Pain Res Manag* 2006;11(1203-6765; 1203-6765; 3):157-162.
- (33) von Baeyer CL, Uman LS, Chambers CT, et al. Can we screen young children for their ability to provide accurate self-reports of pain? *Pain* 2011 Jun;152(6):1327-1333.
- (34) Tomlinson D, von Baeyer CL, Stinson JN, et al. Systematic Review of Faces Scales for the Self-report of Pain Intensity in Children. *Pediatrics* 2010 11;126(5):999-999.
- (35) Stinson JN, Kavanagh T, Yamada J, et al. Systematic review of the psychometric properties, interpretability and feasibility of self-report pain intensity measures for use in clinical trials in children and adolescents. *Pain* 2006 11;125(1-2):143-157.
- (36) Emmott AS, West N, Zhou G, et al. Validity of Simplified Versus Standard Self-Report Measures of Pain Intensity in Preschool-Aged Children Undergoing Venipuncture. *J Pain* 2017 Jan 6.
- (37) Kozlowski LJ, Kost-Byerly S, Colantuoni E, et al. Pain Prevalence, Intensity, Assessment and Management in a Hospitalized Pediatric Population. *PAIN MANAGE NURS* 2014 03;15(1):22-35.
- (38) Kirkwood BR, Sterne JAC. *Essential medical statistics*. 2. edition ed. Malden, Mass.: Blackwell Science; 2003.
- (39) von Baeyer CL, Forsyth SJ, Stanford EA, et al. Response biases in preschool children's ratings of pain in hypothetical situations. *Eur J Pain* 2009 Feb;13(2):209-213.
- (40) Chambers CT, Johnston C. Developmental differences in children's use of rating scales. *J Pediatr Psychol* 2002 Jan-Feb;27(1):27-36.
- (41) Noel M, Chambers CT, Petter M, et al. Pain is not over when the needle ends: a review and preliminary model of acute pain memory development in childhood. *Pain Manag* 2012 Sep;2(5):487-497.

Table 1. Homogeneity in general characteristics of participants (n=111)

Characteristic	Hospital clown (n=49)	Standard care (n=62)	<i>p</i>
Gender			
Boy, n (%)	27 (55.1)	36 (58.1)	0.848
Girl, n (%)	22 (44.9)	26 (41.9)	
Age (years)			
4-6, n (%)	15 (40.5)	22 (59.5)	0.686
7-15, n (%)	34 (46.0)	40 (54.0)	
Age (years) mean \pm SD	9.1 \pm 3.4	8.6 \pm 3.4	0.396
Local anesthetic, n (%)			
Yes	32 (65.3)	38 (61.3)	0.396
No	17 (34.7)	24 (38.7)	
Nitrous Oxide, n (%)			
Yes	2 (4.1)	1 (1.6)	0.582
No	47 (95.9)	61 (98.4)	
Previous VP, n (%)			
Yes	27 (55.1)	29 (46.8)	0.446
No	22 (44.9)	33 (53.2)	
Pain, n (%)			
Yes	18 (36.7)	31 (50.0)	0.182
No	31 (63.3)	31 (50.0)	
Duration, (minute) mean \pm SD	5.2 \pm 2.4	5.7 \pm 3.8	0.316
Number of punctures, n (%)			
1	44 (89.8)	56 (90.3)	1.000
> 1	5 (10.2)	6 (9.7)	
Pain score n (%)			
NRS	14 (28.6)	26 (41.9)	0.167
FPS	35 (71.4)	36 (58.1)	

Table 2. Crude and adjusted¹ analysis

Variable	Control group mean±SD	Hospital Clown mean±SD	Crude Difference SE/CI	<i>p</i>	Adjusted Difference ¹ SE/CI	<i>p</i>
Total	2.7±2.8	2.5±3.2	-0.1 [-1.3,1.0]	0.819	-0.1 [-1.2,1.0]	0.920
Age						
4-6 years	2.6±3.8	4.9±4.1	2.2[-0.3,4.8]	0.087	2.6[-0.1,5.2]	0.054
7-15 years	2.7±2.0	1.5±2.0	-1.2[-2.1,-0.3]	0.010	-1.0[-1.9,-0.1]	0.025
<i>Diff</i> (4-6/7-15)			3.4[0.6,6.8]	0.016	3.6[0.6,6.5]	0.018
Sex						
Boys	2.4±2.5	2.2±2.9	-0.2[-1.5,1.2]	0.837	-0.03[-1.4,1.3]	0.960
Girls	3.0±3.1	2.9±3.5	-0.2[-2.0,1.7]	0.867	-0.3[-2.0,1.5]	0.754
<i>Diff</i> (boys/girls)			0.0[-2.3,2.3]	0.997	0.2[-2.1,2.6]	0.838
Pain						
Yes	3.0±3.2	3.9±3.7	0.9[-1.1,2.8]	0.389	0.8[-1.3,2.8]	0.466
No	2.3±2.3	1.7±2.6	-0.6[-1.8,0.7]	0.371	-0.4[-1.6,0.8]	0.535
<i>Diff</i> (yes/no)			1.4[-1.0,3.8]	0.254	1.1[-1.1,3.4]	0.332
Previous Venipunctures						
Yes	1.9±2.4	2.8±3.8	1.0[-0.7,2.6]	0.248	1.1[-0.4,2.6]	0.163
No	3.4±2.9	2.2±2.2	-1.2[-2.5,0.2]	0.085	-0.9[-2.4,0.5]	0.202
<i>Diff</i> yes/no			2.1[-0.0,4.3]	0.054	2.0[-0.0,4.0]	0.053

¹Adjusted for baseline variables related to the procedure: Local anesthetic, Nitrous Oxide, Time per procedure, Number of Punctures

Figure 1. CONSORT flow diagram of sampling

