

**Needle pain and fear are barriers to health.** In 1995, James Hamilton published one of the first needle fear papers.<sup>1</sup> At the time, he concluded that 10% of adults and 25% of children feared needles - and that it was a serious health risk. By 2012, research showed 24% of adults and 63% of those born in 2000 feared injections.<sup>2</sup> We now know fear correlates the number of injections given on a single day in the 4-6 year window.<sup>3</sup> At this preschool age, children remember pain and fear, but can't abstract enough to understand why people they trust are hurting them. Before 1985, the number of scheduled preschool injections was zero; by 2000, it was often as high as five. Buzzy is the most proven needle pain reliever and the only intervention proven to reduce fear. Addressing needle pain is a public health priority - Buzzy Helps!

1 Hamilton JG. Needle phobia: a neglected diagnosis. J Fam Pract. 1995 Aug;41(2):169-75. PMID: 7636457

2 Taddio A, Ipp M, Thivakaran S, et al. Survey of the prevalence of immunization non-compliance due to needle fears in children and adults. Vaccine. 2012 Jul 6;30(32):4807-12. PMID: 22617633

3 Baxter AL, Cohen LL, Burton M, Mohammed A, Lawson ML. The number of injected same-day preschool vaccinees relates to preadolescent needle fear and HPV uptake. Vaccine. 2017 Jul 24;35(33):4213-9. PMID: 28647169

The following references are all unfunded independent investigations of Pain Care Labs' products Buzzy and/or DistrACTION Cards as of 8/24/2021. Studies by the inventor (Baxter) were funded by grants from Hope Street Kids and NICHD Grant Number 4R44HD056647-02.

*Adult and All-Age Studies Italicized; Pediatric Studies plain font.*

## Reviews and Meta-Analyses

Ballard A, Khadra C, Adler S, Doyon-Trottier E, Le May S. **Efficacy of the Buzzy Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis.** Clin J Pain. 2019 Jun;35(6):532-543. (N= 1138, pain reduction -1.11; 95% confidence interval [CI]: -1.52 to -0.70; P<0.0001) , anxiety reduction (SMD -1.37; 95% CI: -1.77 to -0.96; P<0.00001.) PMID: 30829735

Su HC, Hsieh CW, Lai NM, Chou PY, Lin PH, Chen KH. **Using vibrating and cold device for pain relieves in children: a systematic review and meta-analysis of randomized controlled trials.** J Pediatr Nurs. 2021 Mar 15;61:23-33. PMID 33735633

Lee VY, Caillaud C, Fong J, Edwards KM. **Improving vaccine-related pain, distress or fear in healthy children and adolescents - a systematic search of patient-focused interventions.** Hum Vaccin Immunother. 2018;14(11):2737 - 2747. PMID: 29792557

## Buzzy is the **Most Proven & Most Effective Solution** for Needle Pain & Fear

"Conclusion: Interventions using coolant and vibration together, as well as a combination of site-specific and patient-led interventions, showed the most consistent effects in reducing self-reported pain, fear or distress."

Lee VY, Caillaud C et al.

Faghihian R, Rastghalam N, Amrollahi N, Tarrahi MJ. **Effect of vibration devices on pain associated with dental injections in children: A systematic review and meta-analysis.** Aust Dent J. 2021 Mar;66(1):4-12. "The findings revealed that use of DentalVibe for Paediatric dental injections was not effective in reducing pain perception. However, use of Buzzy showed promising results." PMID: 33258142.

Ueki S, Yamagami Y, Makimoto K. **Effectiveness of vibratory stimulation on needle-related procedural pain in children: a systematic review.** JBI Database System Rev Implement Rep. 2019 Jul;17(7):1428-1463. Included Buzzy, Dental Vibe, Blaine Labs. "The effect size for the BUZZY tended to be higher than that for the other devices." "Overall, vibratory stimulation was significantly effective: self-rated pain: -0.55, 95% confidence interval [95% CI]: -0.92 to -0.18) observer-rated pain outcomes (SMD: -0.47, 95% CI: -0.76 to -0.18). [With Buzzy] the effect on the child's anxiety (SMD: -1.03, 95% CI: -1.85 to -0.20) was significant." PMID: 31021972



## Venipuncture

Abidin N, Yahya N, Izaham A, Mat W, Zain J, Zainuddin M, Mahdi S. **Assessing the effectiveness of a thermomechanical device (Buzzy®) in reducing venous cannulation pain in adult patients.** *Middle East Journal of Anesthesiology* 2018 Feb 25(1):61-67. (N=184, Reported pain lowest with Buzzy  $33.92 \pm 15.59$  ( $p = 0.016$ ); 81.0% of patients satisfied with Buzzy.)

Bahorski JS, Hauber RP, Hanks C, Johnson M, Mundy K, Ranner D, Stoutamire B, Gordon G. **Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study.** *Int J Nurs Stud.* 2015 Oct;52(10):1553-64. [N=173, Buzzy equivalent to LMX4] PMID: 26118441

Ballard A, Khadra C, Adler S3, D Trottier E4, Bailey B4, Poonai N, Thérroux J, Le May S. **External cold and vibration for pain management of children undergoing needle-related procedures in the emergency department: a randomised controlled non-inferiority trial protocol.** *BMJ Open.* 2019 Jan 15;9(1):e023214 (N=346) PMID: 30782698

Baxter AL, Leong T, Mathew B. **External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device.** *Clin J Pain.* 2009 Oct;25(8):705-10. [Buzzy reduced pain > cold spray, adult] (N=31, Reduced Pain (mean 9.9 mm, 95% confidence interval 0.82-19,  $P=0.035$ , SD 16) compared to vapocoolant (mean 7.9 mm, 95% confidence interval -1.8-17.7,  $P=0.1$ , SD 16.9).) PMID: 19920721

Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. **An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department.** *Pediatr Emerg Care.* 2011 Dec;27(12):1151-6. (N=81, Pain scores lower with Buzzy (-2; 95% CI, -4 to 0) than with vapocoolant (1; 95% CI, 0-2) Venipuncture success more likely with Buzzy (odds ratio, 3.05; 95% CI, 1.03-9.02), pediatric] PMID: 22134226

Bergomi P, Scudeller L, Pintaldi S, Dal Molin A. **Efficacy of Non-pharmacological methods of pain management in children undergoing venipuncture in a pediatric outpatient clinic: A randomized controlled trial of audiovisual distraction and External Cold and Vibration.** *J Pediatr Nurs.* 2018 SepOct;42:e66-e72. (N=150, Buzzy significantly effective in children under 9. Reduced anxiety in parents and children.) PMID: 29728296

Binay Ş, Bilsin E, Gerçeker GÖ, Kahraman A, Bal-Yılmaz H. **Comparison of the Effectiveness of Two Different Methods of Decreasing Pain During Phlebotomy in Children: A Randomized Controlled Trial.** *J Perianesth Nurs.* 2019 Feb 20 S1089-9472(18)30414-3 (block randomization, 3-6 y/o, Pain scores were lower in the groups of external cold and vibration, and blowing soap bubbles than the control group.) PMID: 30797673

Bourdier S, Khelif N, Velasquez M, Usclada A, Rochette E et al. **Cold Vibration (Buzzy) Versus Anesthetic Patch (EMLA) for Pain Prevention during cannulation in children: A randomized trial.** *Pediatr Emerg Care.* 2021 Feb 1;37(2):86-91. N=607 children 18 months to 6 years. CHEOPS – Pain relief was not as effective with Buzzy; Time until cannulation was “effectively zero” with Buzzy, versus over one hour with EMLA. The cost of Buzzy for 1000 cannulations was equivalent to the cost of 25 EMLA patches. PMID: 31181022

Canbulat N, Ayhan F, Inal S. **Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients.** *Pain Manag Nurs.* 2015 Feb;16(1):33-9. (N=176, 7-12 y/o, significantly lower anxiety and pain in group using Buzzy.) PMID: 24912740

Chandraleka S. PG - 79: **Effectiveness of Buzzy Technique on Pain During Intravenous Cannulation among Children Admitted in Pediatric ward at Mgmcri, Puducherry.** 2021 Sep 1; 37(9): e512-e516. DOI:10.5005/JIP-JOURNALS-10085-7197

Cozzi G, Crevatin F, Dri V, Bertossa G, Rizzitelli P, Matassi D, Minute M, Ronfani L, Barbi E. **Distraction Using Buzzy or Handheld Computers During Venipuncture.** *Pediatr Emerg Care.* 2018 Dec 27 (N=200, Mean age=8, Buzzy = to handheld computer distraction, both statistically significantly less pain than control.) PMID: 30601349

Erdogan B, Ozdemir AA. **The Effect of Three Different Methods on Venipuncture Pain and Anxiety in Children: Distraction cards, Virtual Reality, and Buzzy.** *J Pediatr Nurs.* May-June 2021;58:e54-e62. 4 groups RCT age 7-12, n=108, Buzzy > VR > Distraction cards and all >> control. PMID: 33485746

Gahlawat M, Kodi M, Deol R. **Effect of external cold and thermomechanical stimulation on anxiety and pain during intravenous cannulation among children.** *Sudan J Paediatr.* 2021;21(2):01-11. (N=60 age 3-12 Self-reported procedural pain 2.80 ± 1.86 control 7.47 ± 2.40 p<.0001.) DOI:10.24911/SJP.106-1590387019

*García-Aracil N, Ramos-Pichardo J, Castejón-de la Encina ME, José-Alcaide L, Juliá-Sanchís R, SanjuanQuiles. Effectiveness of non-pharmacological measures for reducing pain and fear in children during venipuncture in the emergency department: a vibrating cold devices versus distraction. Emergencias. 2018 Jun;30(3):182-185 (3 study groups: Buzzy reduced pain and fear in adults, Reduced pain in children) PMID: 29687673*

Gerçeker GÖ, Binay Ş, Bilsin E, Kahraman A, Yılmaz HB. **Effects of Virtual Reality and External Cold and Vibration on Pain in 7- to 12-year-old Children During Phlebotomy: A Randomized Controlled trial.** *J Perianesth Nurs.* 2018 Dec;33(6):981-989. (N=121, Buzzy = VR, both statistically significantly less pain than control.) PMID: 29559294

Inal S, Kelleci M. **The Effect of External Thermomechanical Stimulation and Distraction on Reducing Pain Experienced by Children During Blood Drawing.** *Pediatr Emerg Care.* 2020 Feb;36(2):66-69 (N=218, Control, Buzzy, DistrACTION cards, Buzzy + Distraction cards. All groups using Buzzy had significantly reduced pain (P < 0.001), Lowest pain measured with Buzzy in combination with DistrAction Cards.) PMID: 28885392

Inal S, Kelleci M. **Relief of pain during blood specimen collection in pediatric patients.** *MCN Am J Matern Child Nurs.* 2012 Sep;37(5):339-45. [Buzzy v. control, pediatric] (N=120, 6-12y/o, Lower pain (p < .001) and anxiety (p < .001) w/ Buzzy) PMID: 22895207

Kearl YL, Yanger S, Montero S, Morelos-Howard E, Claudius I. **Does Combined Use of the J-tip® and Buzzy® Device Decrease the Pain of Venipuncture in a Pediatric Population?** *J Pediatr Nurs.* 2015 Jul 27 [no significant added benefit putting J-tip with Buzzy] PMID: 26228308

Küçük Alemdar D, Yaman Aktaş Y. **The use of the Buzzy, Jet lidocaine, bubble-blowing and aromatherapy for reducing pediatric pain, stress and fear associated with phlebotomy.** *J Pediatr Nurs.* Mar-Apr 2019;45:e64-e72. (N=195, 5-10 y/o, Significant difference in intervention and control groups, Buzzy made the most impact on reducing 26 fear and pain (p < 0.05).) PMID: 30711327

Mendes-Nato M, Santos SL **Vibration associated with cryotherapy to relieve pain in children** *BrJP.* São Paulo, 2020 jan-mar;3(1):53-7. DOI: 10.5935/2595-0118.20200012

Moadad N, Kozman K, et al. **Distraction Using the BUZZY for Children During an IV Insertion.** *J Pediatr Nurs.* 2016 Jan-Feb;31(1):64-72. (N=48, 4-12 y/o, Buzzy significantly reduced pain.) PMID: 26410385

NehadSabryBasiouny. **"Effect of Thermo-Mechanical Stimulation on Pain Associating Venipuncture among Children with Leukemia."** *IOSR Journal of Nursing and Health Science (IOSR-JNHS),* vol. 8, no. 01 , 2019, pp. 88-98. DOI: 10.9790/1959-0801028898

*Pakiş Çetin S, Çevik K. Effects of Vibration and Cold Application on Pain and Anxiety During Intravenous Catheterization. J Perianesth Nurs. 2019 Aug;34(4):701-709. "Vibration and cold gel pack application is suggested to relive pain during IV catheterization in adults." Pain was less than expected in 44/50 Buzzy patients and 0/50 control, and more than expected in no Buzzy patients and 6/50 control (P<.000), with overall less pain (1.04 v 5.32) and greater satisfaction. (95.3 v 82.12) P<.001. PMID: 30853329*



Potts D, Davis KF, Fein J. **A Vibrating Cold Device to Reduce Pain in the Pediatric Emergency Department: A Randomized Clinical Trial.** *Pediatr Emerg Care.* 2019 Jun;35(6):419-425. (N=224, 4-18y/o, Buzzy equivalent to LMX for pain, satisfaction patients, satisfaction nurses. Time for IV procedure completion significantly shorter in group using Buzzy.) PMID: 28121978

*Redfern RE, Micham J, Sievert D, Chen JT. Effects of Thermomechanical Stimulation During Intravenous Catheter Insertion in Adults: A Prospective Randomized Study. J Infus Nurs. 2018 Sept/Oct;41(5):294-300. (N=105 elective surgical adults, no mean pain score difference. "Higher preprocedural anxiety benefitted most.") PMID: 30188451*

Sahar Sedky Faheim. **"Efficacy of Buzzy with Distraction Cards Versus The Traditional Method for Reducing Pain and Parent`s Satisfaction during Venipuncture in healthy Children"** .IOSR Journal of Nursing and Health Science (IOSR-JNHS), vol. 8, no.03 , 2019, pp. 78-89. e-ISSN: 2320-1959.p- ISSN: 2320-1940 DOI:10.11648/J.AJNS.20170601.14

Schreiber S, Cozzi G, Rutigliano R, Assandro P, Tubaro M, Cortellazzo Wiel L, Ronfani L, Barbi E. **Analgesia by cooling vibration during venipuncture in children with cognitive difficulties.** *Acta Paediatr.* 2016 Jan;105(1):e12-6. [N=70, pediatric, severe cognitive impairment, "reported no or mild procedural pain in 32 cases (91.4%) in the Buzzy group and in 22 cases (61.1%) in the no-intervention group (p = 0.003)."] PMID: 26401633

Semerci R, Kocaaslan EN, Kostak MA, Akin N. **[Reduction of pain during intravenous cannulation in children: Buzzy application]** *Agri* 2020 Nov;32(4):177-185. PMID: 33398861 [Article in Turkish]

Susam V, Friedel M, Basile P, Ferri P, Bonetti L. **Efficacy of the Buzzy System for pain relief during venipuncture in children: a randomized controlled trial.** *Acta Biomed.* 2018 Jul 18;89(6-S):6-16. N=72, Buzzy pain 3.65 v. Magic Glove 4.67, p=.039) PMID: 30038198

Tork HM **Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department.** *Am J Nursing Science* 2017 Feb;6(2):26-32 (N=180, Pediatric, Lowest pain scores with Buzzy (1.90±1.34) vs Distracting cards (3.17 ±2.13) vs Balloon inflating (2.83 ±1.41) vs control (4.15±1.29), (p=0.012), Buzzy and distraction card groups had the greatest reduction in anxiety.) DOI: 10.11648

Whelan HM, Kunselman AR, Thomas NJ, Moore J, Tamburro RF . **The impact of a locally applied vibrating device on outpatient venipuncture in children.** *ClinPediatr (Phila).* 2014 Oct;53(12):1189-95. [N=64, historic cohort study, no significant pain difference but 81% phlebotomists said easier with Buzzy, pediatric.] PMID: 24924565

*Yilmaz D., Heper Y., Gözler. Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors. Pain Management Nursing. 2017 Aug;18(4):260-267. [N=90, Pain reduced, satisfaction increased, adult, (p < .05)] PMID: 28601479*

Yılmaz D, Özyazıcıoğlu N, Çıtak Tunç G, Aydın Aİ, Atak M, Duygulu Ş, Demirtaş Z. **Efficacy of Buzzy® on pain and anxiety during catheterization in children.** *Pediatr Int.* 2020 Sep;62(9):1094-1100. PMID: 32311184

*\*In Progress/Recruiting: Clark J. DHHS Buzzy for IV access pain relief in adults with cognitive difficulties.*

*\*In Progress: Ronfani L, Garofolo B, Buzzy versus Virtual Reality during venipuncture. NTC 04853056*



## Injections

*Alshawan M. A Prospective comparison between skin cooling and skin vibration in reducing the pain of local anesthetic injection. J Cosmet Dermatol 2020 Jun; 19(6): 1490-1493. "Skin vibration may be more effective than skin cooling in alleviating the pain caused by local anesthetic infiltration. (Buzzy without ice). PMID: 31556234*

**Baxter AL, Cohen LL, Tzse D. Buzzy versus EMLA: Abstract omits clinical noninferiority and time and cost savings: A commentary on Lescop et al. (2021) Int J Nurs Stud 2021 Sep;121:104011. PMID: 34256940**

**B. Aykanat Girgin ve ark., Let's Prefer the Pain Reducing Intervention, Buzzy or ShotBlocker: A Randomized Controlled Trial İzmir Dr. Behçet Uz Çocuk Hast. Dergisi 2020;10(3):290-8 DOI:10.5222/buchd.2020.13007**

**Bhattacharya R, Batra B. Comparison of Effect of Various non-pharmacologic Methods on Pain in Infants during Vaccination. Int J Preven Curat Comm Med 2019; 5(4): 7-11** Result: The mean pain score of four groups (G1 - breast feeding, G2 - Buzzy, G3 - Helper technique & G4 - control) were 3.77, 3.80, 4.50 and 4.83. Breast feeding effectively reduces pain score than mechanical stimulation by buzzy device. DOI:10.24321/2454.325x.201922

**Bilgen BS, Balci S. The Effect on pain of Buzzy and Shotblocker during the administration of intramuscular injections to Children: A randomized Controlled Trial. J Korean Acad Nurs 2019 Aug;49(4):486-494.** "The children in the Buzzy group had significantly less pain than the children in both the Shotblocker and control groups  $p < .001$ ." PMID: 31477677

**\*Canbulat Şahiner N, Inal S, Sevim Akbay A. The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. J Perianesth Nurs. 2015 Jun;30(3):228-35. [72-75% TDaP pain reduction, 7 year olds.] PMID: 26003770**

**Canbulat Sahiner N, Turkmen AS, Acikgoz et al. Effectiveness of Two Different Methods for Pain Reduction During Insulin Injection in Children with Type 1 Diabetes: Buzzy and Shotblocker. Worldviews Evid Based Nurs 2018 Oct 11. Epub ahead of print. (N=60, Buzzy and Shotblocker both reduced pain compared to control.) PMID: 30307692**

**Jenkins N, Orsini F, Elia S, Perrett K. Minimising Immunisation Pain of childhood vaccines: The MIP pilot study. J Paediatr Child Health. 2021 Mar;57(3):376-382.** "Buzzy (with cold) was identified as effective by 70% of parents, Coolsense by 64%, Buzzy without cold by 50% and standard care by 60%." PMID: 33099850.

**Lescop K, Joret I, Delbos P, Briend-Godet V, Blanchi S, Brechet C, Galivel-Voisine, Coudol S, Volteau, Riche V, Cartron E. The effectiveness of the Buzzy<sup>®</sup> device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomised, non-inferiority study. Int J Nurs Stud 2021 Jan;113:103803. PMID: 33212328**

**Redfern RE, Chen JT2, Sibrel S3. Effects of Thermomechanical Stimulation during Vaccination on Anxiety, pain, and Satisfaction in Pediatric Patients: A Randomized Controlled Trial. J Pediatr Nurs. 2018 JanFeb;38:1-7 [N=50, pain significantly less (3.56 vs 5.92,  $p=0.015$ ).] PMID: 29167074**

*Redfern RE, Micham J, Seegert S, Chen JT. Influencing Vaccinations: A Buzzy Approach to Ease the Discomfort of a Needle Stick – a Prospective, Randomized Controlled Trial. Pain Management Nursing, 2019 Apr;20(2):164-169. (N=497 pain 0.87 v 1.12  $p=.035$ , better than previous experiences 62% Buzzy 23.9% control  $p<.0001$ .) PMID: 30425014*

**Rundell JD, Sebag JA, Kihm CA, Herpen RW, Vlahovic TC. Use of an external vibratory device as a pain management adjunct for injections to the foot and ankle. The Foot and Ankle Online Journal 2016 9**

(4): 6 (N=108, 31.3% decrease in pain associated w/ injections in treatment vs control group.) DOI: 10.3827

Russell K, Nicholson R, Naidu R. **Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board.** J Paediatr Child Health. 2014 Feb;50(2):112-7. [N=118, Nonadherent group, pain and fear reduced 50%, teens and adults.] PMID: 24134180

*Sahin M. Effect of Buzzy® application on pain and injection satisfaction in adult patients receiving intramuscular injections. Pain Management Nurs 2018 Dec;19(6):645. Diclofenac, (N=65, average age 52, Pain 74% reduced, satisfaction 95 v. 84. P<.001 both.) PMID: 30318424*

Sapçi E, Bilsin Kocamaz E, Gungormus Z. **Effects of applying external cold and vibration to children during vaccination on pain, fear and anxiety.** Complement Ther Med. 2021 May;58:102688. Epub 2021 Feb 26. PMID: 33640458

Taddio A, McMurtry CM, Shah V, Riddell RP, Chambers CT, Noel M, MacDonald NE, Rogers J, Bucci LM, Mousmanis P, Lang E, Halperin SA, Bowles S, Halpert C, Ipp M, Asmundson GJ, Rieder MJ, Robson K, Uleryk E, Antony MM, Dubey V, Hanrahan A, Lockett D, Scott J, Votta Bleeker E; HELPinKids&Adults. **Reducing pain during vaccine injections: clinical practice guideline.** [includes "cold/vibration device"] PMID: 26303247

Yilmaz G, Alemdar DK. **Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear caused by intramuscular injection. A Randomized Controlled Trial.** J Emerg Nurs. 2019 Sep;45(5):502-511. "Pain and fear were notably less in the group of children receiving the Buzzy intervention. DISCUSSION: The Buzzy intervention should be used when children are undergoing IM injections to reduce their levels of pain and fear." PMID: 31257044

Walter EB (Duke) Harrington T. (CDC) **Preventing presyncope and syncope in adolescents using simple, clinic-based interventions: A pilot study.** Duke/CDC NCT03533829 results: N=30. No presyncope or syncope in Buzzy or Buzzy + Music intervention. 1 syncope in Music only group.

\*In progress/recruiting: Büşra Güliz Yıldırım **Effect Of Distraction Methods On Procedure-Related Fear, Anxiety, And Pain During Intramuscular Injection** N=30 5-12 NCT04847934

\*In Progress: Marcio Boniatti, Hospital Nossa Senhora da Conceicao Rio Grande Do Sul, Brazil, **Minimizing pain during childhood vaccination. Infants, outcome crying in seconds** NCT03540589

\*In Progress: Mesterman R. **Pain Perception of Children and Youth Receiving Non-sedated Botulinum Toxin-A Injections Using the Buzzy®.** NCT02273284

\*Recruitment Complete: **Feasibility, Acceptability and Satisfaction of a New Device (Buzzy®) for Pediatric Procedural Pain and Anxiety Management During SQ, IV, and IM Needle-Related Procedures: A Pilot Study.** NCT02771600

\*In progress: Ricardo JW, Lipner SR. Weill Medical College of Cornell University. **The Evaluation of External Thermomechanical Stimulation for Pain Reduction in Patients Undergoing Nail Injection** NCT04422795 est. completion 2/2024

\*In Progress: Ryan Cobb MD: **Thermomechanical distraction and social anesthesia in interventional radiology** Temple University, Philadelphia. NTC04236674

\*Recruitment Complete: Seda CEVHEROĞLU: **The Effect of Three Different Local Cold Applications on Pain and Ecchymosis in Subcutaneous Heparin Injections:** NCT04235244

\*In Progress/Completed: Stein K. **Buzzy Use for IV access in Dentistry.** University of Iowa College of Dentistry. NCT03619135

\*In progress/recruiting: Walter C. Davis G. Harrington T, Broder K. , CDC, Duke University: **Presyncope (Syncope) Prevention Study (PS<sup>^</sup>2) n=340 NCT04772755**

## Dental Injections

Alanazi KJ, Pani S, AlGhanim N. **Efficacy of external cold and a vibrating device in reducing discomfort of dental injections in children: A split mouth randomised crossover study.** Eur Arch Paediatr Dent. 2019 Apr;20(2):79-84. (N=60 FLACC and Wong-Baker both p<.001 favor Buzzy.) PMID: 30519955

AlHareky M, AlHumaid J, Bedi S, Tantawi M, AlGahtani M, AlYousef Y, **Effect of a Vibration System on Pain Reduction during Injection of Dental Anesthesia in Children: A Randomized Clinical Trial** Int J Dent. 2021 Jan 30;2021:8896408. doi: 10.1155/2021/8896408. PMID: 33564311

Bilsin E, Gungormus Z, Gungormus M. **Efficacy of external cooling and vibration on decreasing the pain of local anesthesia injections during dental treatment in children: A randomized controlled study.** J Perianesth Nurs 2020 Feb;35(1):44-47. External cooling and vibration had a significant effect on reducing injection pain during dental treatment. PMID: 31564620

Cox J., Salama F, Lancaster B.. **Effect of Vibration-Cold on Behavior of Children Receiving Local Anesthesia.** University of Nebraska College of Dentistry. New York: AAD 2012:A

Mai Gamal Eldeen Hassan Sabra, Cairo University. **Effect of External Cold and Vibration (Buzzy Device) Versus the Conventional Technique on Pain Perception During Local Anesthesia Injection in Children.** NCT05067218

Sahithi V., Saikiran KV, Nunna M, Elicherla SR, Challa RR, Nuvvula S. **Comparative evaluation of efficacy of external vibrating device and counterstimulation on child's dental anxiety and pain perception during local anesthetic administration: a clinical trial** J Dent Anesth Pain Med. 2021 Aug; 21(4): 345-355. PMID: 34395902

Subramaniam P, Ghai SK. **Reducing Discomfort during Local Anesthesia Administration in Children: A Clinical Study.** Int J Clin Pediatr Dent 2021; 14 (3):353-356. DOI: 10.5005/jp-journals-10005-1948

Suohu T, Sharma S, Marwah N, et al. **A Comparative Evaluation of Pain Perception and Comfort of a Patient Using Conventional Syringe and Buzzy System.** Int J Clin Pediatr Dent 2020;13(1):27-30. Conclusion: Buzzy can reduce pain and anxiety during local anesthetic delivery. PMID: 32581474

## Dermatology

*Alshawan M. A Prospective comparison between skin cooling and skin vibration in reducing the pain of local anesthetic injection. J Cosmet Dermatol 2019 Sept 26 e pub ahead of print. "Skin vibration may be more effective than skin cooling in alleviating the pain caused by local anesthetic infiltration. (Buzzy without ice)." PMID: 31556234*

## Itching

Troger, A. Robinson H et al. **Helping Children Cope with Discomfort Associated with Skin Prick Testing in a Pediatric Setting: A Quality Improvement Report.** J Allergy Clin Immunol 133 (2) 2014:A

## Musculoskeletal

Marovino T., Baxter AL. **Crossover Trial of Novel Mechanical Oscillatory Vibration Frequency Device Versus TENS for Musculoskeletal Pain.** AAPMR&R Annual Meeting 2019;A.

Marovino T., Majewski M. **Pain Therapy Options for Home.** Practical Pain Management 2019 Jan-Feb; 19(1):56-59. (pooled OR of reducing pain by 3 on a 10 pt scale 2.25 95%CI 1.34-3.77 p=.0021)

## Misc.

Bisht P. **Effectiveness of self-instructional module on knowledge of Buzzy technique among staff nurses working in paediatric ward in Shri Mahant Indresh Hospital, Patel Nagaer, Dehradun Uttarakhand.** Gal Int J Health Sci Res. 2020; 5(2): 10-15.

Hwang LK Nash DW, Yedlin A, Greige N, Larios-Valencia J, Choice C, Pothula A. **The Effect of Vibration on Pain During Intravenous Injection of Propofol: A Randomized Controlled Trial** Ann Plast Surg. 2021 Jul 1;87(1s Suppl 1):S36-S39. PMID: 33833179

JEN Editor-in-Chief's Choice: Gamze Yilmaz, PhD, RN, and Dilek Küçük Alemdar, PhD, RN, for their article **"Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear Caused by Intramuscular Injection: A Randomized Controlled Trial."** Published in the journal's September 2019 issue, the article describes the authors' test of a low-cost device that applies cold and vibration to the intramuscular injection site. The evidence showed the device reduced a child's pain and fear associated with the injection, providing a promising nursing intervention for this pediatric procedure.

"Our award-winning authors and reviewers demonstrate an impressive and consistent commitment to excellence in practice, research, education, leadership and mentorship," said JEN Editor-in-Chief Jessica Castner, PhD, RN, CEN, AE-C, FAEN, FAAN. "They are trailblazing emergency nursing practice innovations and improvements while illuminating the path to continuously elevate the specialty of emergency nursing." ~Amy Baxter MD FAAP FACEP CEO + Chief Medical Officer

*\*In progress: University of Madison, Wisconsin: Neuman H. Pain Control for Breast Cancer Patients Receiving Injection of Radioactive Tracer NCT04822597*

*\*In Progress: Steiner SJ, Riley Children's Hospital. Buzzy for patients with IBD – improvement of treatment with Humira or Remicade. Presentation at ImproveCareNow.*

## Consistent Lab Values with Buzzy

Lima-Oliveira G, Lippi G, Salvagno GL, et al. **Transillumination: a new tool to eliminate the impact of venous stasis during the procedure for the collection of diagnostic blood specimens for routine haematological testing.** International journal of laboratory hematology. 2011 Oct;33(5):457-62. \

Lima-Oliveira G, Lippi G, Salvagno GL et al. **Quality impact on diagnostic blood specimen collection using a new device to relieve venipuncture pain.** Indian J Clin Biochem. 2013 Jul;28(3):235-41 PMID: 24426217

Baxter AL, Lawson ML. **Concerns with the methodology, analysis and discussion of the Buzzy® and transillumination comparison article Blood Transfus.** 2014 Jan; 12(Suppl 1): s3-s5 PMID: 24599904

Lima-Oliveira G, Lippi G, Salvagno GL, et al. **New ways to deal with known preanalytical issues: use**



**of transilluminator instead of tourniquet for easing vein access and eliminating stasis on clinical biochemistry.** *Biochemia medica.* 2011;21(2):152-9.

Lima-Oliveira G, Lippi G, Salvagno GL et al. **A new device to relieve venipuncture pain can affect haematology test results.** *Blood Transfus.* 2014 Jan; 12(Suppl 1): s6–s10 PMID: 24120583

Baxter AL, Lawson ML. **Methodological concerns comparing Buzzy to transilluminator device.** *Indian J Clin Biochem.* 2014 Jan;29(1):114-5. PMID: 24478562

## DistrACTION Cards

Aydin D, Sahiner NC **Effects of music therapy and DistrACTION cards on pain relief during phlebotomy in children.** *Appl Nurs Res.* 2017 Feb; 33:164-168. PMID: 28096012

Aydin D, Sahiner NC, Ciftici EK. **Comparison of the effectiveness of three different methods in decreasing pain during venipuncture in children: ball squeezing, balloon inflating, and DistrACTION cards.** *J Clin Nurs.* 2016 Aug;25(15-16):2328-35. PMID: 27112434

Canbulat N, Inal S, Sönmezer H. **Efficacy of distraction methods on procedural pain and anxiety by applying distraction cards and kaleidoscope in children.** *Asian Nurs Res (Korean Soc Nurs Sci).* 2014 Mar;8(1):23-8. PMID: 25030489

Inal S, Kelleci M. **Distracting children during blood draw: looking through distraction cards is effective in pain relief of children during blood draw.** *Int J Nurs Pract.* 2012 Apr;18(2):210-9. PMID: 22435986

Risaw L, Narang K, Thakur JS, Ghai S, Kaur S, Bharti B. **Efficacy of Flippits [DistrACTION cards] to Reduce Pain in Children during Venipuncture - A Randomized Controlled Trial.** *Indian J Pediatr.* 2017 Aug;84(8):597-600. PMID: 28378139 “Odds of severe pain/discomfort (total pain score 7-10) were 2.5 times higher in controls as compared to the intervention group (OR 2.5; 95% CI: 1.40-4.45) (P 0.002). Conclusions: The use of simple distraction technique using flippits can significantly relieve the pain associated with blood sampling in children.”

Sahiner NC, Turkmen AS. **The effect of DistrACTION Cards on reducing pain and anxiety during intramuscular injection in children.** *Worldviews on Evidence-Based Nursing* 2019;1-6. (N=120, self-reported pain cards 5.67+/-3.5 v. control 7.65 +/- 2.77, p=.001. Anxiety Parent-reported cards 1.73 v. control 2.53 p=.003.) PMID: 30997744

Sahiner NC, Bal MD. **The effects of three different distraction methods on pain and anxiety in children.** *J Child Health Care.* 2016 Sep;20(3):277-85. Distraction cards had lower pain with venipuncture. PMID: 26040282

### Pain Relief Options for IV and Injections

Pain Reliever	Cost/ use \$USD	Prep time	Ease of use	Duration	Needle Pain Relief	Stinging Pain Relieft	RCTs for fear/ anxiety*	RCTs IVs*	RCTs for injection*	Meta- analyses	Head to head trials
<u>Buzzy®</u>	\$0.20/	1 min	****	60 seconds	****	Y	***** *****	***** ***** *****+ *****+X	***** ***** *****+	***	Potts: LMX = Buzzy for IV; Canbulat: Buzzy > Shotblocker IM; Bilgin Buzzy > Shotblocker
<u>DistrACTION®</u> <u>Cards</u>	0.01	10 sec	*****	n/a	***	Y	***	***	*		97% say better phlebotomy experience
EMLA®	\$6.00	60 min	*	2 hours	***	N	X	***** ***** ***** **+	X*	***X	Emla> Buzzy for IV <6 year olds; not effective injections >1 year
<u>LMX-4®</u>	\$4.00	20 min	**	20 min	***	N		***** ***++			Bahorski, Potts: Buzzy = for IV
Ice	\$.10	1 min	***	30 seconds	**	N			***		
Shotblocker®	\$.05	1 min	*****	0 seconds	**	N			*+XXX		SB = Buzzy for insulin; SB < Buzzy vaccines

Each \* indicates one peer reviewed publication for the procedure indicated with statistically improved outcomes compared to control. X is trials **without** improvement compared to no intervention, + is each trial with equivalent outcome compared to another proven intervention. Injections are defined as delivery of medication into soft tissue, thus studies evaluating microneedling, dermatologic scalp steroid injections, lumbar punctures etc. are not included. Adult only or adult + pediatric studies indicated in **BOLD**

†Buzzy is FDA 510K indicated for control of needle pain from injections, lab draws, and temporary relief of stinging among other indications.