

Needle pain and fear are barriers to health. In 1995, James Hamilton published one of the first needle fear papers. 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. We now know fear correlates the number of injections given on a single day in the 4-6 year window. 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 vaccines relates to preadolescent needle fear and HPV uptake. Vaccine. 2017 Jul 24;35(33):4213-9.

The following references are all unfunded independent investigations of Pain Care Labs' products Buzzy and/or DistrACTION Cards as of 02/03/2022. 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. |BI 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. (81.0% of patients satisfied with Buzzy*; N=184, Reported pain lowest with Buzzy* 33.92 ± 15.59 (p=0.016).)

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, Théroux 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% Cl, -4 to 0) than with vapocoolant (1; 95% Cl, 0-2) Venipuncture success more likely with Buzzy (odds ratio, 3.05; 95% Cl, 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 Buzzy®, 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; 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. International Journal of Applied Research. 2019; 5(6): 404-407 DOI:10.5005/JP-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. 2021 Sep 1;37(9):e512-e516 (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 with Buzzy®, 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

NehadSabry Basiouny. "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 |ournal 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 | 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 signifigant 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

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





<u>Injections</u>

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 - Helfer 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, İnal 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.) (N=60, Ages 10-12.) 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%." (N=40 age 3.5-6.) 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® 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. P(N = 219, age 4-15 years.) 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 with Buzzy® (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/recruiting: Walter C. Davis G. Harrington T, Broder K., CDC, Duke University: **Presyncope** (Syncope) Prevention Study (PS^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

Palagari Lakshmi Prasanna et al (2021). Interpreting the Meaning of Pain Severity Scores in Children Using Buzzy and Distracting Cards- A Randomized Clinical Trial, SAR | Dent Oral Surg Med, 2(2), 22-35.

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 | 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 | Clin Pediatr Dent 2020;13(1):27-30. Conclusion: Buzzy can reduce pain and anxiety during local anesthetic delivery. PMID: 32581474

<u>Dermatology</u>

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





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

<u>Musculoskeletal</u>

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 scare 2.25 95%Cl 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

*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 reatment with Humira or Remicade.** Presentation at ImproveCareNow.

PhD Thesis & Dissertations

Gilcrest, Morgan T., "Does Buzzy® reduce needlestick pain in children between the ages 5 and 12 years old?" (2021). PCOM Physician Assistant Studies Student Scholarship. 594.

Long, Katherine, "Don't Be Such a Buzzy®Kill: Reducing Pain During Vaccinations in College-Age Students" (2021). Evidence-Based Practice Project Reports. 165.

Kim, TK. Implementation and Evaluation of a Nonpharmacological Device to Improve Satisfaction During Immunization. 2021, U Maryland.

Zmrzel, Sara Cortnie, Increasing Healthcare Provider Knowledge About Pediatric Vaccine Administration Pain Mitigation Techniques: A Quality Improvement Project. The University of Arizona. ProQuest Dissertations Publishing, 2018. 13419696.





Distr*ACTION*® Cards

Aydin D, Sahiner NC Effects of music therapy and Distr*ACTION*® cards on pain relief during phlebotomy in children. Appl Nurs Res. 2017 Feb; 33:164-168. (N=200, mean age +/- 2.35 years. All interventions reduced pain.) 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 Distr*ACTION®* cards. J Clin Nurs. 2016 Aug;25(15-16):2328-35. (N = 120, mean age 9.64 +/- 2 years. All interventions reduced pain.) PMID: 27112434

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Mohanasundari SK, Raghu VA et al. Effectiveness of Flippits [Distr*ACTION®* cards] and Virtual Reality Therapy on Pain and Anxiety Among Children Undergoing Painful Procedures, Cureus. 2021 Aug 12;13(8):e17134. (N=105 age 3-12y, pain scores of VRT and card groups were less than the control group (aOR, 95% CI 0.635, 0.504-0.799, P = 0.000 and aOR, 95% CI 0.705, 0.572-0.868, P = 0.001, respectively) and no difference was observed between VRT and Cards group.) PMID: 34548966

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Risaw L, Narang K, Thakur JS, Ghai S, Kaur S, Bharti B. Efficacy of Flippits [Distr*ACTION*® 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 DistrACTION® can significantly relieve the pain associated with blood sampling in children."

Sahiner NC, Turkmen AS. The effect of Distr*ACTION®* Cards on reducing pain and anxiety during intramuscular injection in children. Worldviews on Evidence-Based Nursing 2019;1-6. (N=120, selfreported 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







Buzzy® Reduces Impact of Prolonged Tourniquet Application for Hematology:

In a study by Dr. Lima-Olivieri et al., it was found that leaving a tourniquet in place 120 seconds caused the largest derangement of hematology lab values compared to free flowing blood collection. (1) Dr. Lima-Olivieri et al. then tested Buzzy®, leaving it in place between 90 and 180 seconds and comparing results to free-flowing blood.(2)

The changes from leaving a tourniquet in place for 2 minutes were greater than the changes from leaving Buzzy® in place 2 minutes. Dr. Lima-Olivieri did not reference his earlier work, or discuss his labs funding by the maker of the free-flow unit. The Journal solicited an opinion.

Table 1 - Both Buzzy and a tourniquet were left on 90 – 180 seconds and compared to a transilluminating free flowing collection device where blood was collected without a tourniquet. Comparison numbers between free-flow versus Buzzy® and free-flow versus Tourniquet with percentage Mean Difference between paired results. Buzzy® caused less difference after two minutes than a standard tourniquet for all outcomes except lymphocytes: prolonged tourniquet +2.6%, prolonged Buzzy-3.9%. The greatest clinical concern is overestimating WBC and neutrophils, failing to recognize immunocompromise.

	Units	Free-Flow	Buzzy®	%Diff	Free-Flow	Tourniquet	%Diff
				Buzzy			Tourniquet
RBC	(10 ₁₂ /L)	4.80±0.55	4.90±0.55	2.0	4.68(0.45	4.81(0.46)	2.8
Hb	(g/L)	137.9±12.7	141.4±13.2	2.5	14.1(1.4)	14.6(1.4)	2.6
Het	(%)	40.6±4.0	41.5±4.0	2.2	41.7(4)	42.9(4)	2.9
MCV	(fL)	84.4	84.6	0.2	88(5)	89(5)	1.1
		(81.8-88.3)	(81.9-88.1)				
RDW	(%)	12.7±0.5	12.7±0.6	0			
WBC	(109/L)	7.35±1.94	7.10±1.89	-3.5	6.59(1.87)	6.9(2.02)	4.8
Neu	(106/L)	4.27±1.57	4.15±1.49	-2.9	3.72(1.31)	3.87 (1.4)	4.2
Lymp	(10 ₆ /L)	2.41±0.80	2.32±0.80	-3.9	2.23(0.73)	2.29(0.75)	2.6
Mono	(10 ₆ /L)	0.29±0.08	0.28±0.05	-3.6	0.33(0.11)	0.34(0.13)	3.9
Eos	(10 ₆ /L)	0.16±008	0.16±0.07	0	0.30(.34)	0.37(0.36)	24.1
Baso	(106/L)	0.046±0.02	0.041±0.02	-12.2	0.026(0.02)	0.021(0.02)	23.8
Plt	(109/L)	274±66	272±66	-0.7	200(46)	208(46)	3.6
MPV	(fL)	9.12±0.81	9.09±0.71	-0.3			

- 1. 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. PMID: 21412480
- 2. 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
- 3. 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





Buzzy® Reduces Impact of Prolonged Tourniquet Application for Chemistry:

In one study by Dr. Lima-Olivieri et al., it was found that leaving a tourniquet in place 2 minutes caused the largest derangement of chemistry lab values from free flowing blood using a device made by a manufacturer in his town.(4)

Dr. Lima-Olivieri et al. then tested Buzzy®, leaving it in place also for 2 minutes and comparing to free-flowing blood.(5) The changes from leaving a tourniquet in place for 2 minutes were greater than the changes from leaving Buzzy® in place, and in neither case was there a derangement in potassium from lysed cells that was clinically significant.

Dr. Lima-Olivieri did not reference his earlier study or note funding from the free flowing unit, and the journal solicited an editorial.(6)

	Units	Free-flowing	Buzzy	%Diff	Free-flowing	Tourniquet	%Diff
Glucose	mmol/L	4.66 (4.33–5.11)	4.66 (4.27–5.11)	0	4.77±1.0	4.83±1.0	1.2
Total Protein	g/L	78.9 ± 3.6	80.1 ± 4.4	1.5	76.0±6.0	79.0±6.0	3.8
Albumin	g/L	47.9 ± 3.4	48.9 ± 3.7	2	46.0±4.0	48.0±5.0	4.2
AlkPhos	μkat/L	1.14 ± 0.3	1.19 ± 0.3	4.2	1.53±0.37	1.56±0.39	1.9
Triglyceride	mmol/L	78.9 ± 3.6	80.1 ± 4.4	1.5	1.63±0.95	1.68±0.96	3.0
Potassium	mmol/L	4.0 ± 0.3	4.0 ± 0.4	0	4.2±0.2	4.3±0.4	2.3
Sodium	mmol/L	144.3 ± 1.8	144.3 ± 1.9	0	142.2±3.2	142.7±3.2	0.4
Phosphate	mmol/L	1.32 ± 0.2	1.30 ± 0.2	-1.5	1.17±0.16	1.18±0.19	0.8
Calcium	mmol/L	2.36 ± 0.1	2.37 ± 0.1	0.4	2.35±0.12	2.40±0.12	2.1
Magnesium	mmol/L	0.81 ± 0.06	0.81 ± 0.07	0	0.810±0.08	0.827±0.08	2.0

- 4. 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. PMID: 2213855
- 5. 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):235-4. PMID: 24426217
- 6. Baxter AL, Lawson ML. Methodological concerns comparing Buzzy® to transilluminator device. Indian | Clin Biochem. 2014 |an;29(1):114-5. PMID: 24478562





Prep Eas time u	Ease of Dur use	Duration Pa Rel	Pain RCTs Relief IVs*	RCTs for injections*	Head to head
1 min **** 1 min	Ē	.****	*****	* * * * * * * * * * * * * * * * * * *	Potts: LMX = Buzzy® for IV; Canbulat: Buzzy® > Shotblocker IM
10 sec ***** n/a	n/a	**	******	n/a	97% say better phlebotomy experience(11)
60 min * 2 hours	nour	***	******* ****** ****** ****** ***	* * * * *	Vasoconstricts until 90 min; Emla> Buzzy® for IV <6 year olds
20 min ** 20 min	mim	**	*****		Try Glad Press- n-Seal instead of Tegaderm for comfort(13)
1 min *** 30 seconds	30 conds	*	*	E	
1 min *** 0 seconds	0 Sonds		**	***	SB = Buzzy® for insulin; SB < Buzzy® vaccines

Buzzy meta-analyses, systematic reviews

* Reduced Peds' Pain

* Reduced Adults' Pain

* Reduced Dental Pain

* Reduced Fear/Anxiety

X Negative Study Peds

X Negative Study Adults + Equivalent Study rd A et al. Clin J Pain. 2019 June;35(6):532-543 1138, **pain -1.11**; 95% [Cl]: -1.52 to -0.70; P<0.0001) **ety -1.37**; 95% Cl: -1.77 to -0.96; P<0.00001) 2747 "coolant and vibration together... most consistent effects in reducing self-reported pain, fear or distress." W, et al Hum Vaccin Immunother. 2018;14(11):2737-