Needle pain and fear are barriers to health. In 1995, James Hamilton published one of the first needle fear papers.[1] 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.[2] We now know fear correlates the number of injections given on a single day in the 4-6 year window.[3] 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
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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.

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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 ± 15.59 (p = 0.016); 81.0% of patients satisfied with Buzzy.)*

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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

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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/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. 2018 Dec 27 (N=200, Mean age=8, Buzzy = to handheld computer distraction, both statistically significantly less pain than control.) PMID: 30601349

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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

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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*

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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

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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

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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

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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

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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. 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*

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

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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*

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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^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

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

Consistent Lab Values with Buzzy

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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

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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

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Pain Relief Options for IV and Injections

Pain Reliever	Cost/ use $USD	Prep time	Ease of use	Duration	Needle Pain Relief	Stinging Pain Relief†	RCTs for fear/ anxiety*	RCTs IVs*	RCTs for inject-ions*	Meta-analyses	Head to head trials
Buzzy®	$0.20/	1 min	****	60 seconds	****	Y	******* ******	******* ******* ******* ****++X	***** ***** ****+	***	Potts: LMX = Buzzy for IV; Canbulat: Buzzy > Shotblocker IM; Bilgin Buzzy > Shotblocker
Distr*ACTION*® Cards	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
LMX-4®	$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.