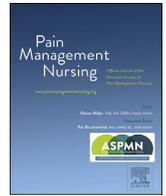




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Original Article

Influencing Vaccinations: A Buzzy Approach to Ease the Discomfort of a Needle Stick—a Prospective, Randomized Controlled Trial



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ABSTRACT

Background: The rate of annual influenza immunization in both the general public and health care workers is less than desirable. Mechanisms to improve compliance with recommendations are needed; prevention of immunization site pain has been suggested as a viable route because fear of pain and needles has been cited as a barrier.

Aims: This study aimed to evaluate the impact of thermomechanical stimulation (Buzzy) on post-procedure pain ratings during vaccination in adults.

Design: This was a randomized controlled trial of Buzzy during immunization.

Settings: Three hospitals and two community health centers which are part of a large, integrated health system.

Participants/Subjects: Employees presenting to employer-sponsored annual influenza vaccination clinics.

Methods: A 10-cm visual analog scale was used to rate preinjection anxiety and expectation of pain as well as postprocedure pain scores; participants also rated their satisfaction with the vaccine injection on a 10-point Likert scale.

Results: In total, 497 employee volunteers were recruited to participate. Preprocedure anxiety was similar between the experimental and control groups (1.53 vs. 1.48, $p = .82$), whereas self-reported postprocedure pain scores were significantly lower in the group that received the Buzzy during injection (0.87 vs. 1.12, $p = .035$). Mean satisfaction scores did not vary between the intervention and control groups (9.11 vs. 9.09, $p = .87$); however, more participants rated their experience as better than previous vaccination experiences in the Buzzy group than control (62.0% vs. 23.9%, $p < .0001$).

Conclusions: These results suggest that Buzzy reduced pain experienced by adults undergoing annual influenza vaccination and may improve overall experience. Buzzy can be used in adult patients to reduce pain during immunization and is especially effective in those with high levels of anxiety.

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Influenza results in more than 300,000 hospitalizations and up to 56,000 deaths annually (Centers for Disease Control and Prevention, 2017). Despite the fact that immunization is both available and efficacious, only a fraction of the population reports receiving annual vaccination (Lu et al., 2017). Research has found reduced nosocomial infection rates in immunocompromised patient populations (Frenzel et al., 2016), lower influenza mortality in long-term care and inpatient settings, fewer overall influenza outbreaks, and decreased rates of absenteeism among staff when

health care workers are immunized against influenza (Chan, 2007; Lemaitre et al., 2009; Maltezou & Poland, 2016). The Joint Commission requires accredited organizations to establish annual employee immunization programs and report rates of immunization. However, the rate of health care worker immunization is still low; during the 2010–2011 influenza season, only 9.9% of included facilities reached the Healthy People 2020 goal of 90% rate of employee vaccination (Lee et al., 2013). A recent study suggested an improvement, with 77% of the health care workers surveyed reporting having been vaccinated and 40% of respondents being required to receive the vaccine (O'Halloran et al., 2017).

Pain has been reported as a significant barrier to vaccination in children and adults. Fear of needles may originate in childhood, particularly if the patient perceives no attempt on behalf of medical

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staff to prevent pain, and may result in avoidance of medical care throughout adulthood (Cook, 2016; McMurtry et al., 2015, 2016). Approximately 24% of adults have a fear of needles (Nir, Paz, Sabo, & Potasman, 2003; Taddio et al., 2012; Wright, Yelland, Heathcote, Ng, & Wright, 2009) and suggest they would be more willing to receive influenza immunization if it could be administered without pain (Taddio et al., 2012). In one report of patients receiving Tdap (tetanus, diphtheria, pertussis) vaccination, 19% of men reported fear of needles or pain and only about half of participants stated they would be willing to receive the influenza vaccine if given free of charge the same day (Rossmann Beel, Rench, Montesinos, & Healy, 2014). Current guidelines state that immunization site pain prevention should become part of the standard of care to help improve patient experience and reduce noncompliance (Gidudu et al., 2012).

The majority of research regarding pain during needle procedures has been completed in pediatric populations. Various approaches to manage pain and anxiety, including psychological, pharmacologic, and physical interventions, have been investigated in adults as well (Hogan, Kikuta, & Taddio, 2010; Shah et al., 2015). In the context of immunization, inexpensive and easily implemented interventions with little necessary training or time investment are needed. Although distraction has been successful in children, music and visual distractions have not been effective in adults, with some populations reporting the techniques as bothersome (Boerner et al., 2015; Kwekkeboom, 2003). Warming vaccines, using frozen needles, and using jet injectors in place of needles have not proven effective (Hogan et al., 2010). Simple physical interventions such as tactile stimulation have been successful but may be difficult to implement consistently (Agarwal, Sinha, Tandon, Dhiraaj, & Singh, 2005; Chung, Ng, & Wong, 2002).

Buzzy (MMJ Labs, Atlanta, GA, USA) is a reusable device that combines external cold and vibration to close the fast pain gate during needle procedures; initial reports suggest its efficacy in pediatric and adult populations (Baxter, Cohen, McElvery, Lawson, & von Baeyer, 2011; Baxter, Leong, & Mathew, 2009; Canbulat, Ayhan, & Inal, 2015; Inal & Kelleci, 2012; Yilmaz, Heper, & Gozler, 2017). Its use can be implemented in fast-paced environments, with minimal cost and no side effects to participants (Baxter et al., 2011). The aim of this study was to investigate the effect of Buzzy on self-reported pain and satisfaction after influenza vaccination during mandatory immunization clinics for employees of a large health system.

Materials and Methods

This study was a prospective randomized controlled trial to investigate the impact of thermomechanical stimulation in adult health care workers 18 years of age and older undergoing annual mandatory influenza vaccination. Participants were required to be Buzzy naïve and were excluded if they had Reynaud syndrome or sickle cell disease with extreme sensitivity to cold (per manufacturer's instructions), a break or abrasion on the skin where the device would be placed, or nerve damage affecting the extremity to be injected. The study was open to enrollment within a large integrated health system in Toledo, OH between October 2016 and December 2016. Employees were recruited at five separate locations, including three hospitals and two standalone clinics; research staff attended a convenience sample of available vaccine clinic times based on location and schedule availability. The local institutional review board approved the study before commencement, and all participants provided written informed consent before study activities.

Buzzy is a plastic vibrating motor with a detachable ice pack that can be sanitized and reused. It is intended for use with needle

procedures including injections, blood draws, and cannulation. In the context of injections, the device is turned on and placed over the injection site for 30 seconds; immediately before injection it is moved approximately 5 cm proximal to the site and held in place throughout the remainder of the procedure. All vaccines were manufactured by GSK (Brentford, UK) and administered via a 1-inch, 23-gauge Covidien Magellan hypodermic safety needle (Medtronic, Minneapolis, MN, USA) into the deltoid muscle of the arm. A 1:1 randomization schedule was created using www.randomizer.org before enrollment began to allocate participants to receive the Buzzy intervention as described (experimental group) or to receive no intervention (control group). Potential participants were approached for consent on presentation to employee health vaccination clinics; participants understood the goal of the study and that the device was meant to prevent pain associated with needle procedures. After provision of consent, group allocation was achieved by opening consecutively numbered, sealed opaque envelopes containing group assignments. Research staff accompanied and observed each consenting participant throughout the vaccination process. Neither research staff nor participants were blinded to the group assignment.

The primary outcome of interest was self-reported post-procedure pain scores immediately after vaccine injection as measured by a 10-cm visual analog scale (VAS). Based on previous reports in the literature, 2.89 ± 1.98 cm was assumed as the mean pain score in the control group (Nahm et al., 2012). To achieve 90% power with a significance level of 0.05, 229 patients per group were required and 458 total (Julious, 2004). We aimed to include 500 total participants to account for expected attrition and incomplete survey responses. The secondary outcome measures of interest were self-reported anxiety levels before injection as measured by VAS and satisfaction with the injection, measured on a 10-point Likert scale. All participants were asked if their experience was the same as, better than, or worse than previous influenza vaccine injections received in the past. Participants who were assigned to receive the intervention were asked to rate discomfort caused by coldness of the ice pack and vibration of the device separately on a 10-point Likert scale (from "Not at all" to "Extremely uncomfortable").

Before injection, participants completed a short demographic form including age, gender, level of education, race, number of previous influenza vaccinations, adverse events after a needle stick, whether his or her job function was clinical or nonclinical, whether the participant considered himself or herself to be more fearful of needles than other adults, and whether the participant had ever avoided addressing a medical issue because of fear of needles. Participants were also asked to rate the level of pain they expected to experience on a 10-cm VAS. These variables were chosen as possible risk factors in a generalized linear model to determine which variables, in addition to group assignment, significantly affected postprocedure pain ratings.

Statistical Analysis

Descriptive statistics detailing frequency of participant characteristics at baseline were completed. To investigate categorical and continuous variables, χ^2 and Student *t* tests were used, respectively. Generalized linear models were performed to examine the significance of potential factors affecting postprocedural pain. SAS Version 9.2 (SAS Institute Inc., Cary, NC, USA) was used for statistical analysis. A *p* value of <.05 was considered significant.

Results

A total of 500 employees presenting for mandatory annual influenza vaccine provided consent to participate in this trial and

Table 1
Baseline Participant Characteristics on Randomization

Characteristic	Buzzy, N = 250	Standard, N = 247	p Value
Age (mean ± SD)	44.4 ± 13.4	41.7 ± 12.9	.03
Gender, n (%)			
Female	206 (82.4)	206 (83.4)	.69
Male	44 (17.6)	40 (16.2)	
Race, n (%)			
African American	15 (6.0)	18 (7.3)	.37
Asian	3 (1.2)	5 (2.0)	
Caucasian	223 (89.2)	210 (85.0)	
Hispanic	3 (1.2)	5 (2.0)	
Mixed race	3 (1.2)	1 (0.4)	
Other	2 (0.8)	7 (2.8)	
Education, n (%)			
High school/GED	13 (5.2)	11 (4.5)	.75
Some college	38 (15.2)	45 (18.2)	
College	126 (50.4)	127 (51.4)	
Advanced degree	71 (28.4)	63 (25.5)	
Number of previous flu shots, n (%)			
Zero	1 (0.4)	4 (1.6)	.39
One to three	63 (25.2)	60 (24.3)	
Four or more	186 (74.4)	183 (74.1)	
Job function, n (%)			
Clinical	117 (46.8)	130 (52.6)	.17
Nonclinical	89 (35.6)	75 (30.4)	
Adverse event after previous flu shot, n (%)			
No	218 (87.2)	230 (93.1)	.03
Yes	32 (12.8)	17 (6.9)	
More fearful of needles than other adults?			
No	226 (90.4)	215 (87.0)	.24
Yes	24 (9.6)	32 (13.0)	
Ever avoided the doctor for fear of needles?			
No	240 (96.0)	242 (98.0)	.20
Yes	10 (4.0)	5 (2.0)	

were randomly assigned to receive Buzzy or no intervention between October 1, 2016, and December 1, 2016. Three participants did not complete or return the research instrument after group allocation and receipt of intervention; therefore 497 total participants were included in analysis, 250 of whom were included in the experimental (Buzzy) group and 247 of whom were allocated to the control group receiving no intervention. Comparison of baseline characteristics of the two groups suggested that those in the control group were significantly younger (Table 1), and a higher proportion of participants in the experimental group reported previously having experienced an adverse event after a needle stick (loss of consciousness, nausea, vomiting, dizziness, weakness, or other) than those in the control group (12.8% vs. 6.9%, Table 1). The remaining characteristics of interest were similarly distributed between groups (Table 1). No adverse events were recorded in either study group.

The mean anxiety reported by participants on VAS before the vaccination did not vary significantly by treatment group (Table 2), nor did the expected amount of pain (2.2 vs. 2.0, $p = .28$). Participants receiving the Buzzy device during injection rated their

postprocedure pain significantly lower than did the control group on average (0.87 ± 0.07 vs. 1.12 ± 0.10 , $p = .035$). Despite the differences in postprocedure pain ratings, mean reported satisfaction did not differ significantly between control and experimental group ($p = .87$). However, when participants were asked to rate whether the injection was the same as, better than, or worse than previous influenza vaccine injections, most in the experimental group reported that the injection was better than previous experiences (62%), whereas the majority of control participants reported it as the same as previous experiences (67.2%). The proportion of those reporting that the current injection was worse than previous injections did not significantly differ between groups (1.2% and 2.0%). Participants receiving the intervention did not report discomfort because of the coldness of the ice pack (median 1.0, interquartile range [IQR] = 1.0) or because of the vibration of the device (median 1.0, IQR = 0).

Participant characteristics influencing postprocedure pain rating were investigated individually in Table 3. Without considering group assignment, women in the cohort rated pain significantly higher than did men (1.05 vs. 0.71, $p = .006$). Those who reported

Table 2
Procedural Ratings

	Buzzy, mean ± SEM	Standard, mean ± SEM	p
Prevaccine anxiety	1.53 ± 0.13	1.48 ± 0.15	.82
How much do you think it will hurt?	2.20 ± 0.13	2.00 ± 0.13	.28
Postprocedure pain rating	0.87 ± 0.07	1.12 ± 0.10	.035
Satisfaction	9.11 ± 0.11	9.09 ± 0.12	.87
Better than, same as, or worse than previous flu shots? n (%)			
Better	155 (62.0)	59 (23.9)	<.0001
Same	78 (31.2)	166 (67.2)	
Worse	3 (1.2)	5 (2.0)	

SEM = standard error of the mean.

Table 3
Postprocedure Pain Ratings as a Function of Baseline Characteristics

	Postprocedure Pain (mean ± SEM)	<i>p</i>
Gender		
Female	1.05 ± 0.07	.006
Male	0.71 ± 0.10	
Race		
African American	1.18 ± 0.28	.50
Asian	0.49 ± 0.14	
Caucasian	1.01 ± 0.06	
Hispanic	0.53 ± 0.34	
Mixed race	0.15 ± 0.05	
Other	1.07 ± 0.44	
Education		
High school/GED	0.65 ± 0.31	.38
Some college	1.17 ± 0.17	
College	1.0 ± 0.08	
Advanced degree	0.96 ± 0.12	
Number of previous flu shots		
Zero	0.59 ± 0.36	.57
One to three	1.09 ± 0.13	
Four or more	0.97 ± 0.07	
Job function		
Clinical	1.01 ± 0.09	.40
Non-clinical	0.91 ± 0.09	
Adverse event after previous flu shot		
No	0.91 ± 0.06	<.001
Yes	1.83 ± 0.24	
More fearful of needles than other adults?		
No	0.91 ± 0.06	.001
Yes	1.67 ± 0.22	
Ever avoided the doctor for fear of needles?		
No	0.98 ± 0.06	.16
Yes	1.56 ± 0.38	

SEM = standard error of the mean.

having experienced an adverse event after a previous needle stick and those who considered themselves more afraid of needles than other adults rated their pain significantly higher than those who did not (Table 3). There were no differences in pain scores as a function of race, education, number of previous influenza vaccinations, job function, or self-report of avoidance of medical treatment as a result of needle fear.

A generalized linear model was created to investigate the impact of multiple demographic factors, including education, gender, race, age, job function, and preprocedure anxiety (Table 4). The overall model was significant; however, with this combination of variables, only preprocedure anxiety was significantly associated with pain rating, whereas higher anxiety correlated with higher postprocedure pain scores ($p < .001$). For this reason, we completed exploratory post hoc investigation into the impact of Buzzy between low- and high-anxiety participants, by separating all patients into <50th quartile anxiety and >50th quartile anxiety ratings. Figure 1 illustrates that although the postprocedure pain ratings for those who reported low anxiety was not affected by the use of the Buzzy device, a significant reduction in pain could be appreciated for those in the high (>50th quartile) preprocedure anxiety group.

Discussion

Recent reports suggest that vaccine coverage is less than satisfactory, even among health care workers. Fear of needles and fear of pain have been identified as barriers to vaccine receipt in both children and adults. The American Society for Pain Management Nursing endorses pain control before and during painful procedures (Czarnecki et al., 2011), and immunization guidelines also suggest that site pain should be prevented, such that easy-to-implement, inexpensive interventions need to be available (Gidudu et al., 2012).

Table 4
Generalized Linear Model Investigating Demographic Factors and Use of Buzzy on Postprocedure Pain Rating

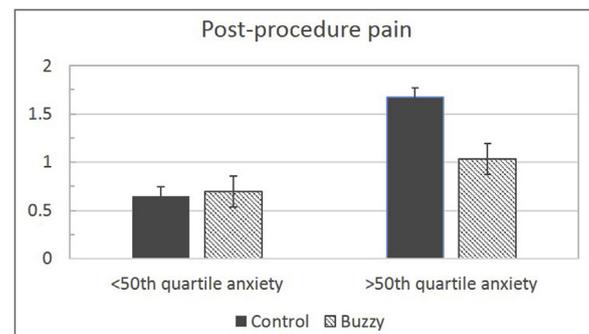
Source	<i>df</i>	Type III SS	Mean Square	F Value	<i>p</i>
Group	1	2.77	2.77	1.97	.16
Education	3	9.64	3.21	2.29	.08
Gender	1	3.42	3.42	2.43	.12
Race	5	7.12	1.42	1.01	.41
Age	1	1.88	1.88	1.34	.25
Job function	2	1.62	0.81	0.58	.56
Preprocedure anxiety	1	61.39	61.39	43.71	<.0001

df = degrees of freedom; SS = sum of squares.

The results of this study suggest that Buzzy, which combines application of cold and vibration to the site before and during an injection, can significantly reduce the level of self-reported pain after immunization in a group of health care workers undergoing mandatory annual influenza vaccination. Although preprocedure anxiety did not vary between groups, the impact on pain in those who reported higher anxiety was greater than that found in those reporting low anxiety before injection. Even though mean satisfaction was very similar between those randomly assigned to intervention and control, a significantly greater proportion of those receiving Buzzy stated that their experience was better than previous influenza vaccine injections.

Many studies have investigated the effectiveness of Buzzy in both pediatric and adult populations; however, most of these reports have focused on patients undergoing venous access for blood draws or intravenous cannulation. Researchers have reported that Buzzy significantly reduced postprocedure pain in pediatric populations (Baxter et al., 2011; Inal & Kelleci, 2012, 2017), though few studies focused on the use of Buzzy during injections. In one group of pediatric patients undergoing routine immunization, Benjamin, Hendrix, and Woody (2016) reported that the device was not effective in reducing postprocedure pain. Although the group was homogeneous, with all participants being the same age and undergoing the same injection, the investigators did not use the ice pack with the device, applying only vibration during the needle procedure, which may account for the lack of efficacy reported in that study compared with our results (Benjamin et al., 2016). Importantly, all the participants included in the present investigation underwent the same procedure, receiving the same injection with the same needle gauge for all participants.

Russell, Nicholson, and Naidu (2014) investigated the use of Buzzy in a group of pediatric and adult patients required to undergo at-home intramuscular injections for the treatment of rheumatic fever. Patients were allowed to choose to use lidocaine and/or Buzzy and served as their own controls because the injections occurred on a monthly basis. Although the youngest group

**Figure 1.** Comparison of effects of Buzzy in subjects as a function of self-reported preprocedure anxiety.

(<13 years of age) in that study reported a significant improvement with the addition of Buzzy to lidocaine, the adolescent and adult groups did not appreciate the same benefit. The authors acknowledged that benzathine penicillin injections are known to be quite painful, which may account for the difference in efficacy compared with our results; however, in those subgroup analyses, only 14 of 34 adults and 24 of included adolescents (65%) chose to use the Buzzy device with lidocaine during injections, such that analyses may not have been adequately powered to detect possible differences.

Adult studies have also focused mostly on the use of Buzzy in venous access, which has also been associated with significantly reduced self-reported pain. Two studies of healthy volunteers have been reported; in that by [Baxter et al. \(2009\)](#), the participants reported lower pain with Buzzy compared with vapocoolant sprays; importantly, the participants served as their own controls, minimizing bias and variability associated with pain perception. Volunteers who were included in an investigation of the impact of this device on the pain experienced by healthy blood donors also reported that pain was significantly lower with Buzzy than placebo (the device in place without freezing the ice pack or turning on the vibrating motor) or no intervention ([Yilmaz et al., 2017](#)). The pain levels reported in those studies were higher than in the present investigation; however, the impact should be somewhat similar because the participants included in the present report were also healthy adults. Moreover, [Yilmaz et al. \(2017\)](#) and [Baxter et al. \(2009\)](#) recruited participants who volunteered to undergo needle procedures; it was unlikely that preprocedure anxiety or incidence of needle fear would be high in those groups. In the present cohort, 56 of all participants (11.3%) stated that they considered themselves more fearful of needles than other adults. Moreover, the results of our study suggest that preprocedure anxiety was strongly tied to postprocedure pain scores. Previous research has suggested that fear of pain may affect the amount of pain experienced and modulate the impact of intervention, specifically distraction (which is one of the modes of action of the device used in the present investigation), to prevent pain ([Roelofs, Peters, van der Zijden, & Vlaeyen, 2004](#)).

In this study the results of univariate analyses suggested that self-reported pain varied significantly according to gender, with women reporting higher pain scores than men, similar to previous reports ([Nahm et al., 2012](#)). In addition, those who reported having experienced an adverse reaction after a previous flu shot, which included loss of consciousness, nausea, vomiting, dizziness, weakness, or other) and those who reported being more fearful of needles than other adults reported higher levels of postprocedure pain, irrespective of group assignment. In analyses not reported herein, we found that these individuals also reported a higher expectation of pain before the procedure. On multivariate analyses, the level of anxiety reported before the procedure was more strongly associated with postprocedure pain rating than any other characteristic, including group assignment. Comparing the entire cohort's postprocedure pain ratings, the Buzzy device seemed to significantly improve pain scores. However, this reduction was only -0.25 cm on the VAS scale, which may not be clinically important ([Cepeda, Africano, Polo, Alcalá, & Carr, 2003](#)). Considering the multivariate analysis, it seems that anxiety is the strongest predictor of pain. Previous authors have suggested that treatment for prevention of pain during needle procedures should be tailored to the individual ([Boerner et al., 2015](#)). Our results support this; although efficacy was appreciated in the entire cohort, it may not be valuable to use such an intervention in all adults undergoing needle procedures such as routine immunizations. Rather, having interventions such as this one available to offer to those who may be more anxious than the majority of patients is likely to have the greatest impact. Furthermore, some patients may not wish to have any intervention

and may find these efforts bothersome. Our results suggest that the intervention is tolerable in this population because the majority rated discomfort as a result of both coldness and vibration to be "not at all."

Limitations

This study and its results are subject to a number of limitations. First, participants were not blinded to the group allocation, nor was there any attempt to provide a placebo intervention to reduce bias. All participants understood the goal of the study and that the study device was meant to prevent pain, which may have affected the results via a placebo effect. Moreover, participants were accompanied and observed by a research staff member throughout the vaccination process, which could have affected postprocedure reports. Additionally, the population included in this investigation may not be representative of the general population as a result of the nature of the study, because all participants were employees of a health care system, whether serving in a clinical or nonclinical job function. The majority of participants were Caucasian women with high levels of education; most had a college degree or advanced degree, which may also limit the generalizability of the results. Furthermore, the nature of the study relied on self-report of all information, including the incidence of adverse events after a previous influenza vaccination. Needle phobia was assessed by self-report and did not use a validated instrument or question. The respondents' assessment of whether their fear was equal to or greater than that of other adults was subjective, such that the incidence of needle phobia may have been under- or overestimated in this cohort. It is difficult to interpret the effects of the device on satisfaction; participants' knowledge of the study goal to help prevent pain may have affected their satisfaction with the experience. Furthermore, satisfaction estimates could be biased because all the injections were provided by coworkers employed in the Employee Health department of the institution or may have been interpreted to relate to the entire process rather than just the injection itself. Finally, it was not possible to determine whether this intervention may affect future compliance with immunization recommendations; further research is warranted.

Conclusion

Use of Buzzy was associated with a significant reduction in pain in this large group of employees undergoing mandatory annual influenza vaccination. The intervention was feasible to implement in a large, fast-paced immunization clinic setting at a low cost and with minimal required training. The reduction in self-reported pain over the entire cohort may not be clinically significant but was more pronounced in participants reporting higher preprocedure anxiety after random group allocation. The Buzzy device is a valuable intervention that should be included in a clinician's arsenal to offer to patients who may wish to receive pain prevention before a needle procedure.

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