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Original Article

Effectiveness of Vibration- Assisted Syringe Versus Conventional Syringe on Pain and Anxiety Perception During Local Anesthetic Injection in Children: A Randomized Clinical Trial

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Abstract

Aim: To evaluate the effectiveness of vibration-assisted syringes versus conventional syringes on both pain and anxiety perception during dental local anesthetic injection in children. **Materials and Methods:** Forty-six children ranging in age from 4 to 6 years were randomly allocated to two equal groups. In group (I), children received intraoral injection using vibration-assisted syringes while in group (II), children received intraoral injection using conventional syringes. Children reaction for pain due to needle prick and local anesthetic injection was recorded through visual analogue scale, while the anxiety experienced was evaluated using visual facial anxiety scale. **Results:** Regarding pain score, group II (7.00±2.07) had higher score value than group I (6.52±2.2), but with no statistically significant difference (p=0.484).Although anxiety score in group II (3.78±1.31) had a higher value than in group I (3.57±1.41) , yet the difference was not statistically significant (p=0.551).No significant associations were observed between either gender and pain or gender and anxiety in both groups(p>0.05).A weak negative correlation was found between pain and age which was statistically significant in group II (r_s=-0.480, p=0.019). **Conclusions:** The use of a vibration-assisted syringe didn't provide a significant reduction in dental pain perceived and anxiety expressed by children when compared with the conventional syringe. Further studies are needed to find alternatives to provide less painful local anesthetic injections in children.

KEYWORDS: Local anesthesia, Anxiety, Pain, vibration- assisted syringe, VibraJect.

I. *INTRODUCTION:*

The most prevalent reasons for children avoiding dental visits are dental fear and anxiety. Children who feel severe pain during dental visit usually exhibit worse behavior on subsequent visits, necessitating more restraint and longer procedures. Furthermore, children who are uncomfortable during dental procedures are more likely to avoid necessary dental care in the future. (Cem Ungor et al., 2014).

Injection of local anesthetic agent is considered the main reason of fear and anxiety seen in dental clinics. While the primary goal of local anesthesia administration is to relieve pain during dental procedures, the actual process of anesthetic agent delivery has been shown to be painful

And anxiety rousing due to insertion of the needle and injection of the anesthetic solution. (Appukuttan et al., 2017) .

Since controlling pain and anxiety during local anesthetic injections has a significant clinical benefit. Dental professionals have utilized a variety of techniques to reduce pain associated with dental injections. Topical analgesics, warming and buffering the anesthetic solution, changing the rates of infiltration, and distraction strategies are a few of them. Yet, there is still some debate over how effective these techniques are at managing pain.(Hawker et al., 2011).

According to Melzack and Wall's "gate control" theory, non-noxious stimuli can activate nerve fibers that convey pain signals, thus reducing the intensity of pain perception. The crucial aspect of the hypothesis is that by stimulating large diameter fibers with the proper pressure or vibration, a neural "gate" can be closed, which consequently can reduce pain perception (Caylor et al., 2019).

Taking advantage from the gate control theory in reducing needle insertion pain, a study was conducted to investigate whether vibration affected patient's perceptions of pain during anesthetic injections or not. It was observed that, when compared to non-vibration producing injections, injections with vibration caused less discomfort and a lower pain rating. (AlHareky et al., 2021).

Vibraject is a vibratory, battery assisted, small device which is attached to the conventional dental syringe producing vibrations in a very high frequency on the needle. These vibrations are strong enough for the patients to perceive. When the intensity of vibrations exceeds the intensity of pain, the spinal cord dorsal grey horn blocks pain perception, thus preventing pain sensation during local anesthetic injections (Thilak et al., 2020).

In a single-blind randomized study, 90 children were equally divided to 2 groups. Where control group received conventional injections while experimental group received injections with the VibraJect. Based on patient self-reports, as well as observations of pain associated disruptive behavior and subjective rating scores by the providing dentists, the results showed no difference in pain perception in both groups (Roeber et al., 2011). In another comparative study between conventional syringe and vibration-assisted device, the visual analogue scale and the faces pain rating scale results were significantly different between the two techniques ($p>0.05$).The vibration assisting device provides less pain during local anesthesia injection in comparison with the conventional one(Chaudhry et al., 2015). Moreover, Hamdy et al.,2022 concluded that the applied vibrations from the VibraJect , and the DentalVibe devices can reduce the pain associated with local anesthetic injections in comparison with conventional injection.

Owing to the controversial findings between research, the goal of this study was to evaluate the effectiveness of vibration assisted syringes (VibraJect) versus conventional syringes on both pain and anxiety perception during dental local anesthetic injection in children.

II. MATERIALS AND METHODS

Study design:

This is a parallel group, randomized clinical trial with an allocation ratio of 1:1. CONSORT guidelines were followed to ensure proper reporting of study.

Sample calculation:

To apply a two-sided statistical test to the study hypothesis (null hypothesis), that there is no difference in pain and anxiety perception in children during anesthesia administration using the vibration assisted syringe or the conventional syringe, the analysis was created to have adequate power. An effect size (d) of (0.847) was calculated according to the results of Chaudhry et al., 2015. where mean and standard deviation values of the intervention and control groups were (36.50±17.85) and (51.50±17.55) respectively. By adopting alpha (α) level of 0.05 (5%), beta (β) level of 0.20 (20%) i.e. power=80%, and using the calculated effect size (d=0.847); the expected sample size (n) was a total of (46) cases i.e. (23) case per group. G*Power version 3.1.9.2 was used to get proper sample calculation.

Ethical Considerations:

Ethical approval for the trial was obtained prior to its implementation from the Research Ethics Committee, Faculty of Dentistry, Cairo university, with approval number (1 -6 - 20).

The study has been registered on "clinicaltrials.gov "its identifier was NCT04215055.

Study setting and eligibility criteria:

The study was carried out on patients enrolled from the diagnostic clinic of the Pediatric Dentistry, Faculty of Dentistry, Cairo university. Children were carefully assessed for eligibility to participate in the trial.

Inclusion Criteria of participants:

1) Cooperative patients (Rating 3 or 4 based on the Frankl behavior scale).

2) Children ranging in age from four to six years.

3) Children presented with one or more restorable primary molars with deep caries.

Exclusion criteria:

1) Medically compromised children.
2) Children suffering from spontaneous pain, abscess or having any signs or symptoms of irreversible pulpitis.
3) When radiographic examination showed any evidence of necrosis including: abscess, external or internal root resorption, bone loss.
4) Parents or guardians refusing to participate in the study.

Pre-management measures:

1) Patients personal, medical, and past dental history were taken.

2) Clinical examination was done using a dental mirror and a probe to check for the inclusion criteria and proper sample selection.

3) Candidates appropriate for recruitment in the trial were identified based on the pre-specified eligibility criteria.

4) After a thorough explanation of the treatment's procedures, their benefits and possible complications, parents, and legal guardians signed an informed consent form.

Participants' randomization and allocation concealment

Participants were randomly allocated into 2 groups using simple randomization with 1:1 allocation data, according to the type of syringe used in injection. The third author generated the randomization sequence using Random.org., and the allocation concealment by employing shuffled opaque sealed envelopes from which children selected one, to determine which child will be included in which group.

- In group I (Intervention group): children received intraoral injection of local anesthesia using the vibration assisted syringes (VibraJect).
- In group II (Control group): children received intraoral injection of local anesthesia using the conventional syringes.

Blinding

Participating children, their legal guardians and the statistician were all blinded to the type of local anesthetic device.

Management measures:

Each patient was instructed to rinse his mouth properly to remove any gross food debris from his/her mouth. The chair was tilted to a supine position with the head and the heart on the same line parallel to the floor, and the operator sat behind the patient. The patient was instructed to tilt his neck upwards.

The protocol followed for local infiltration using vibration -assisting Syringes (group I):

A cotton pellet was used to dry only the injection area before applying topical anesthesia (20% Benzocaine), another one was needed to apply the topical anesthesia at the injection area for 1 to 2 minutes to provide 2 to 3 mm anesthesia for the soft tissue at the area of penetration, thus reducing the discomfort during the injection.

An aspirating syringe was loaded with a 1.8 ml 4% Articane 1:100000 epinephrine (4%Articane, Artinibsa, Inibsa dental, Spain) and a short beveled 30-gauge side needle (C-k dental, Korea) was inserted into the syringe. The device was attached to the syringe as a small battery-operated attachment. The cheek was retracted, and the injection was applied mesial to the primary molar to be anesthetized, directing the needle to a position between the roots of the molar. The needle was inserted 1-2mm inside the mucosa with the bevel directed toward the bone, then slowly advanced toward the target area. After injection, the needle was gently withdrawn and recapped away from the child's sight.

The protocol followed for local infiltration using conventional syringes (group II):

The same protocol was followed as previously mentioned in group (I), but without the attachment of a small battery.

A 3 to 5 minutes was the waiting time needed to obtain profound anesthesia before starting the treatment procedure planned for the patient. To prevent any variations in the injection technique, local anesthetic was administered to all patients by the same pediatric dentist (the first author).

Outcomes

- The children' reactions to pain were recorded and evaluated through the visual analogue scale (VAS) to rate pain experienced due to the needle prick and anesthesia injection in both techniques. VAS is composed of a line, its length is 10 cm, with verbal anchors at each end. The child applied a sign at a point on the line identical to his rating of pain intensity. A ruler was used to measure the VAS score (the score was represented by the number of millimeters or centimeters for the line end) (Hawker et al., 2011 and Kersten et al., 2014)
- Anxiety experienced during the procedure was evaluated using the visual facial anxiety scale (VFAS). The scale includes categories for different levels of anxiety, including none, mild, mild-moderate, moderate, moderate-high, and highest. These categories were listed on a divided sheet of paper. (Cao et al., 2017).Children were asked to match each face to a corresponding number, ranging from "0"

- to "10" (zero means no anxiety while ten represents the maximum anxiety), and they were asked to select one face to represent their anxiety level. The faces were randomly displayed to avoid any visual bias.

For standardization the second author assessed the study outcomes for all children. Every child was prefaced about the visual analogue scale and visual facial anxiety scale before starting the injection to be sure that they became familiar with it, and verbal guidance was given to make sure that he or she knew what was expected to do. The flowchart throughout the study was presented in Figure (1).

III. RESULTS

A. Statistical analysis:

R statistical analysis software version 4.1.2 was used to conduct the statistical analysis of the study.

Fisher's exact test was used for the analysis of categorical data, which were displayed in the form of frequency and percentage values. Mean and standard deviation values were used to present numerical data. Using an independent t-test, parametric data were analysed. Using the Mann-Whitney U test, non-parametric data were analysed. Spearman's rank-correlation coefficient was used to analyse correlations. For all tests, the significance level was set at p–value ≤ 0.05.

Forty- six children participated in the study, they were equally and randomly allocated to each of the tested groups (23 children each). There were 11(47.8%) boys in group (I) and 12(52.2%) girls. While there were 12(52.2%) boys in group (II) and 11(47.8%) girls. The mean age in group (I) was (5.28±0.64) years, while in group (II) it was (5.15±0.73) years. No significant differences between the two groups were seen regarding gender (p=1) and age (p=0.522). The descriptive statistics for demographic data were shown in **table (1).**

Regarding pain score, group (II) had a higher pain score value (7.00±2.07) than group (I) (6.52±2.2), yet the difference was statistically non-significant (p=0.484).

For pain severity, most of the children in the intervention group 6(26.1%) chose “Hurts little more” to describe the severity of their pain, while in the control group 6(26.1%) either chose “Hurts little more” or “Hurts even more” or “Hurts worst” and the difference between the groups was statistically non-significant (p=0.484). Frequency and percentage values for pain severity in both groups were shown in **table (2)**.

Regarding anxiety score, the control group (3.78±1.31) had a higher anxiety score value than the intervention group (3.57±1.41), but the difference was statistically not significant (p=0.551).

For anxiety severity, most of the children in the intervention group 7(30.4%) chose “Mild” to describe the severity of their anxiety, while in the control group 6(26.1%) chose “Moderate to high” with no significant difference between both groups (p=0.551). Frequency and percentage values for anxiety severity for both groups were shown in **table (3).**

As shown in **table (4)**, no significant association was observed between either gender and pain or gender and anxiety in both groups (p>0.05).

The correlations between pain and age, between anxiety and age, were presented in **figure (2)** and **figure (3)**. A weak negative correlation was found between pain and age , and it was statistically significant in the control group (r_s=-0.480, p=0.019). Other correlations were statistically non- significant (p>0.05).

IV. DISCUSSION:

One of the key elements influencing child behavior in a dental office is pain management. To ensure patient comfort, cooperation, and dental care compliance,

effective pain management during local dental injections is essential (McDonald, Avery, and Dean, 2004).

In the current study, the Vibraject coupl ed to a standard aspirating syringe was used to evaluate the effectiveness of vibration in reducing pain and anxiety in children receiving local anesthetic injections. VibraJect was selected as the vibration-producing device because it is simple device, it could be easily clipped to the syringe, and requires little to no modification to the standard injection technique. Furthermore, compared to other vibratory devices, it is quite affordable. The barrel of the syringe receives vibrations from the VibraJect, which is then conveyed to the needle. It was claimed that patient perceives these vibrations when the needle is pricked, rendering the nociceptive impulses that result from the prick unnoticeable. (Melzack and Katz, 2004).

The vibraJect effect on pain and anxiety was previously presented with limited and controversially data thus, this study aimed to evaluate vibraJect effectiveness in managing pain and anxiety during local anesthetic injection in children.

This study was conducted considering the infiltration anesthetic technique for maxillary and mandibular teeth. Infiltration was the technique of choice in this study because it's easier, more comfortable for children, non-sensitive technique and a little anesthetic solution was enough to produce profound anesthesia for teeth (Meechan, 2010). This was in harmony with Ogle and Mahjoubi, 2012 who stated that nerve block technique is painful and scary for young age children.

Because pain is a subjective experience, self-report is considered the benchmark method for assessment of pain on children (Merskey and Albe-Fessard, 1979). Furthermore, clinical judgments are more complicated due to each patient's unique characteristics, temperament, culture, prior experience, and family history (N. Stinson et al., 2006, and M. Ranger and M. Campbell-Yeo, 2008). In this study pain was evaluated through a visual analogue scale while anxiety was evaluated through a visual facial anxiety scale both are valid, easily used by children, doesn't require technical knowledge, are quick to fill and are reliable to track patients progress before and after therapy (Cao et al., 2017) .

The baseline characteristics of the children, for instance, age and gender distribution, had no effect on the study's results and conclusion since the baseline variables were evenly distributed amongst the tested groups and revealed the absence of statistically significant difference.

In the current study, group (I) had a lower pain score (6.52) than group (II) (7.00); however, the difference was statistically not significant. According to the findings of the current study, the VibraJect did not provide statistically significant benefits in pain reduction for children when compared to the conventional dental syringe. This agrees with Roeber et al., 2011 who reported that, participants who received conventional injections had an average pain intensity of 31.5 (±34.2), whereas those who received their injections with the VibraJect reported an average pain intensity of 42.0 (±32.1). This difference was statistically non-significant (P>.13). Moreover, Şermet Elbay et al., 2016 studied the efficiency of Dental Vibe in pediatric patients. Similarly, no statistically significant difference was found between groups, and this was attributed to the extremely small vibrations, which didn't stimulate the large nerve fiber in many individuals, also the device design that could have frightened children.

On the other hand, A split mouth study was carried out with sample including 37 patients. A significant difference (p=0.00) was

observed, where 35 patients reported higher pain scores when using the conventional anesthetic technique versus VibraJect technique .VibraJect has reduced the intensity of pain that occurs during needle insertion and solution deposition in comparison with conventional anesthetic technique (Chandrasekaran et al., 2014).

Another contradicting result was reported by Chaudhry et al., 2015 who assessed the efficacy of the Vibraject in decreasing pain during dental local anesthetic injection in twenty patients aged between 8 to 14 years versus the conventional technique through split mouth design. VAS scores for both techniques showed a significant difference ($P < 0.05$). The psychological parameters were conclusive that VibraJect was less significant in pain perception. This was attributed to the nerve impulses evoked by the tactile sensation rather than pain.

Regarding anxiety, the findings of the current study presented that, control group (II) (3.78±1.31) had a higher anxiety score than the intervention group (I) (3.57±1.41) yet the difference was statistically not significant ($p=0.551$). This came in contrast to another study that measured the intensity of the pain and the level of anxiety during an injection whether vibration was present or not. According to the findings, the vibration group experienced much lower levels of anxiety than the group receiving conventional anesthetic injection. Concluding that psychological factors seem to play a significant role in pain perception as dental anxiety increased with the increase of pain duration (Cem Ungor et al., 2014).

Similarly, Hegde et al., 2019 compared the efficacy of a vibrating device with the conventional technique in controlling pain and anxiety levels. Anxiety was assessed by measuring the pulse rate while pain experience was assessed using VAS scale. The study proved the superiority of vibration injection over conventional injection in terms of lowering pain and anxiety in addition to managing the child's behavior during the procedure.

The results of the present study showed no significant associations between gender and pain, or gender and anxiety for both groups ($p>0.05$). In contrast, Sreenivasagan et al., 2018 assessed dental pain and anxiety prevalence and the efficacy of VibraJect through the evaluation of the dental phobia prevalence. A significant difference was noted in pain scores between conventional and VibraJect anesthetic techniques ($p=0.0001$). Female patients were more anxious by 79% compared to males, due to the phobia of needle prick which is the primary cause of dental anxiety followed by using dental drills. In a similar way to the current study, Şermet Elbay et al., 2016 results revealed that, no significant effect of gender in both Dental Vibe and traditional syringe groups during needle prick and anesthetic injection ($P > 0.05$).

In the current study, a weak negative correlation was found between pain and age , and it was statistically significant in the control group ($rs=-0.480$, $p=0.019$). Other correlations were not statistically significant ($p>0.05$). This was in accordance with Abdellatif et al., 2017 , who explained that the older the child, the greater acceptance, less pain, and less concern he or she shown towards local anesthetic injections. Pain and anxiety associated with vibraject could be due to the voice and vibration sensation produced by Vibraject, device which could be frightening for younger children.

One limitation of this study was that it could have been better if the subjective experience of the child with objective clinical evaluation was supplemented. As some researchers didn't recommend the use of a visual analogue scale with young children less than 5 years old. It was claimed that children in this age range may not be able to report pain perceived and anxiety level obtaining reliable scores.

V. Conclusions

In summary, the present study demonstrated that the vibration-assisted syringe did not provide a significant reduction in dental pain and anxiety levels during needle insertion, and dental local anesthesia administration in children when compared with the conventional syringe. A weak negative correlation was found between pain and age which was statistically significant in the conventional syringe group. No significant associations were observed between either gender and pain, or gender and anxiety in both groups. Further studies are needed to find alternatives to provide less painful dental local anesthesia injections in children.

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Conflict of Interest

The authors declare no conflict of interest.

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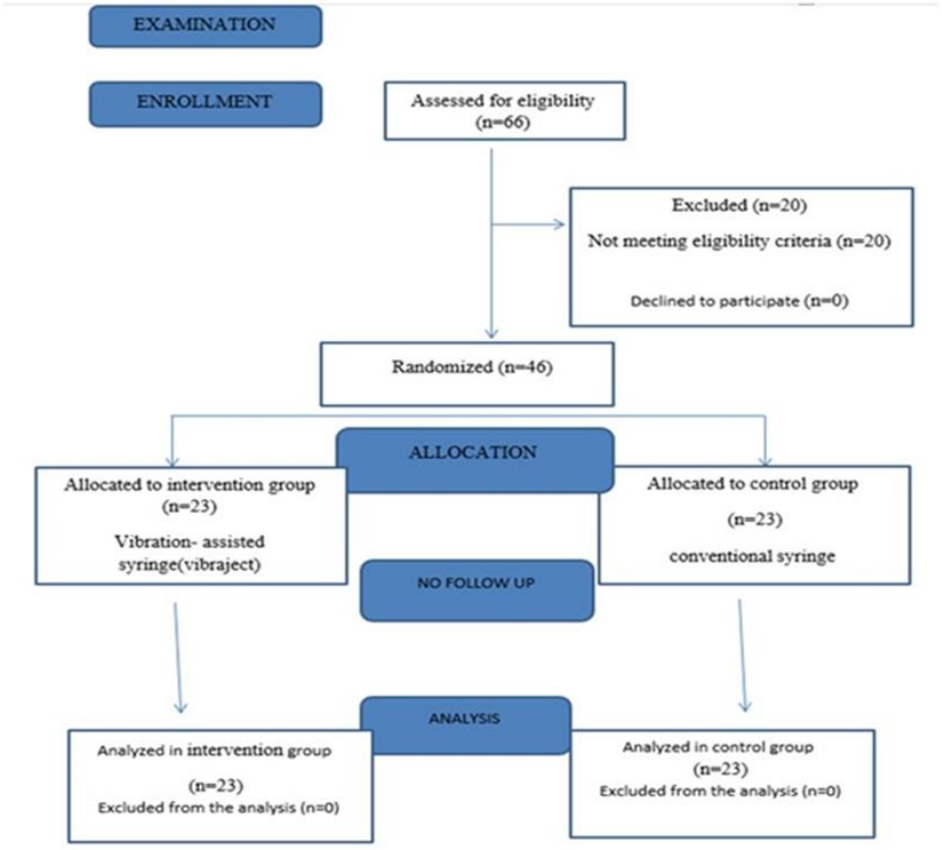

Figure 1: Flow chart of patients through the study

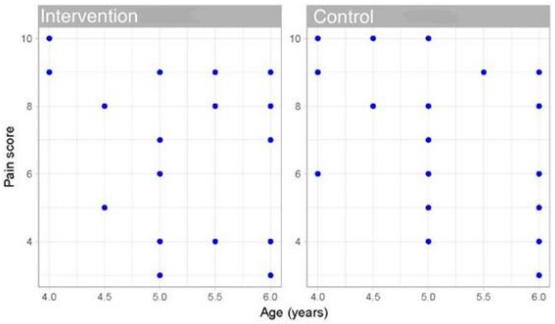

Figure (2): Scatter plot showing the correlation between age and pain

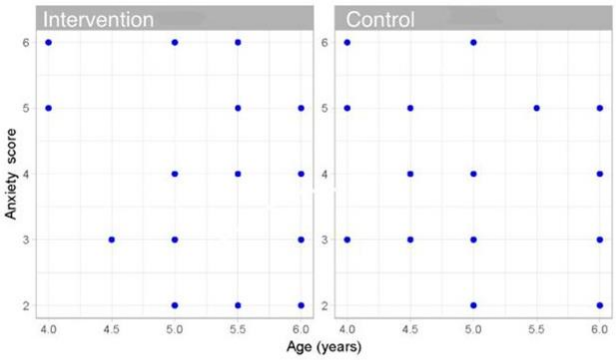

Figure (3): Scatter plot showing the correlation between age and anxiety

Table (1): The descriptive statistics for demographic data for both groups

Parameter			Intervention	Control	p-value
Sex	Boy	n	11	12	1
		%	47.8%	52.2%	
	Girl	n	12	11	
		%	52.2%	47.8%	
Age	Mean±SD		5.28±0.64	5.15±0.73	0.522

Table (2): Frequency and percentage values for pain severity in different groups

Pain severity		Intervention	Control	***p-value***
Hurts little bit	n	2	1	***0.484***
	%	8.7%	4.3%	
Hurts little more	n	6	6	
	%	26.1%	26.1%	
Hurts even more	n	5	6	
	%	21.7%	26.1%	
Hurts whole lot	n	5	4	
	%	21.7%	17.4%	
Hurts worst	n	5	6	
	%	21.7%	26.1%	

; significant (p ≤ 0.05

Table (3): Frequency and percentage values for anxiety severity in different groups

Anxiety severity		Intervention	Control	p-value
Mild	**n**	7	5	**0.551**
	%	30.4%	21.7%	
Mild-Moderate	**n**	5	5	
	%	21.7%	21.7%	
Moderate	**n**	5	5	
	%	21.7%	21.7%	
Moderate-High	**n**	3	6	
	%	13.0%	26.1%	
Highest	**n**	3	2	
	%	13.0%	8.7%	

*; significant ($p \leq 0.05$)

Table (4): Associations between gender, pain, and anxiety

Parameter	Group	(Mean±SD)		p-value
		Male	**Female**	
Pain	**Intervention**	6.09±2.02	6.92±2.39	**0.289**
	Control	6.92±2.15	7.09±2.07	**0.926**
Anxiety	**Intervention**	3.27±1.27	3.83±1.53	**0.394**
	Control	3.75±1.36	3.82±1.33	**0.925**

*; significant ($p \leq 0.05$)

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