Article

Effectiveness of Auditory Distraction and Brief Relaxation Therapy in Reducing Anxiety in Dental Patients Undergoing Extraction: A Randomized Controlled Trial

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Featured Application: Anxious dental patients are arduous to treat, need more time, and have behavioral issues which lead to a stressful and unpleasant experience for them and the treatment provider. Dentists must take additional measures to make the overall clinical experience more pleasant for their patients. The application of these unintrusive interventions, i.e., auditory distraction and brief relaxation therapy, before a dental treatment is thus encouraged.

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Abstract: Objective: This study compared the effectiveness of auditory distraction and brief relaxation therapy for reducing anxiety in patients undergoing tooth extraction. Methods: A non-blind, three-armed, randomized control trial was carried out. The targeted study population were patients who needed extraction of a non-restorable and non-mobile molar tooth. Eighty-six patients were recruited; the brief relaxation therapy and auditory distraction groups had 32 participants each, while 10 of the 22 participants in the control group were excluded due to missing data. The Hierarchical Anxiety Questionnaire was used to assess the anxiety level. The Mann–Whitney U or Kruskal–Wallis test was performed to compare means between the groups. The before and after comparisons in each group were carried out using the Wilcoxon Signed-Rank test. The alpha value was set at 0.05, and data were analyzed using SPSS version 24. Results: The mean anxiety score after brief relaxation therapy and auditory distraction had significantly decreased ($p < 0.001$). Although not significant ($p = 0.13$), there was a slight increase in the anxiety score of the study participants in the control group just before the extraction procedure. Brief relaxation therapy was significantly effective in reducing anxiety scores in comparison to the control group (MD = 5.87, 95% CI = 2.58, 9.17; $p = 0.001$), but auditory distraction was not ($p = 0.14$). Conclusion: Both auditory distraction and brief relaxation therapy were effective in reducing patient anxiety before a dental procedure. Furthermore, it would be interesting to learn if these findings remain consistent for more complex dental procedures, such as surgical removal of an impacted third molar.

Keywords: dental anxiety; auditory distraction; brief relaxation; randomized control trial; dental procedures; tooth extraction

1. Introduction

Fear/anxiety, stress, and pain/sensitivity should be the three main considerations before any dental procedure is initiated [1–3]. Psychologists present fear and anxiety as two different constructs, whereby the latter is described as a condition experienced by

individuals while preparing themselves for something to happen, usually an abnormal situation; and is expressed as a feeling of apprehension [4]. The anxiety related to dental procedures is considered to be developmentally normative and is prevalent in 54–92% of individuals [5,6]. However, if unaddressed, it may result in long-term fear eventually leading to avoidance of dental visits [7]. Moreover, studies report that the trait of dental anxiety, has a direct effect on the level of pain before a dental procedure. Additionally, highly anxious patients may end up remembering more anxiety-provoking dental experiences [8,9].

Tooth extraction is one of the most feared dental procedures; attributable to the belief that pain will be experienced [1]. Reports suggest that the increased anxiety level in patients undergoing tooth extraction is associated with the use of local anesthetic injections, the oral surgery procedure itself, and the expectation of postoperative pain [10–16]. Despite the fear, anxiety, and apprehension, it is sometimes essential to extract a non-restorable tooth with a deep carious lesion and/or severe periodontitis, when failure to carry out the procedure increases the risk of the infection spreading to surrounding oral tissues, and also potentially increases the risk of systemic disease [17–20]. At times, the extraction procedure becomes more complicated and time-consuming if complex surgical removal is required, thereby increasing the chances of anxiety [21]. Therefore, patient anxiety levels must be assessed and reduced before subjecting them to a tooth extraction procedure. Numerous clinical methods have been proposed and applied to reduce dental anxiety in patients undergoing tooth extractions. In certain clinical situations, general anesthesia is demanded by adult patients to manage their dental anxiety [22]. However, there are chances of post-operative weariness, drowsiness, fever, nausea, constipation, epistaxis, vomiting, and diarrhea associated with the use of general anesthesia [23,24]. Some practitioners prefer carrying out dental extraction after inducing conscious sedation in patients through pharmacological interventions, by prescribing or administering nitrous oxide, benzodiazepines, opioids, barbiturates, and alpha-2-adrenergic receptor agonists [25–27]. A systematic review on the use of conscious sedation to manage dental anxiety found that the evidence was inconclusive and the findings were contradictory [28]. There are also non-invasive and simpler ways of reducing anxiety in patients. A randomized control trial demonstrated a statistically significant reduction in postoperative anxiety levels in a group of patients who were given aromatherapy using lavender oil [29]. Nonetheless, there are adverse reactions related to the use of aromatherapy, such as estrogenic activity, allergic reactions, and cytotoxicity [30,31]. In another trial, the mean anxiety score was substantially reduced post-extraction in patients who were shown a tooth extraction video in comparison to those who received a verbal explanation of the procedure [32]. In this study, the level of anxiety was evaluated after the extraction procedure was completed. It would have been helpful to have information on the anxiety levels before the procedure but after the video, since the objective was to reduce the level of anxiety before the patients were subjected to the extraction procedure.

Thus, two points were considered before determining the objective of the current experiment. First, that an unintrusive method of reducing anxiety in patients undergoing dental extractions would make the overall experience more pleasant, and could result in fewer postoperative complications [33]. Second, unlike the earlier randomized control trials [29,32], the anxiety level should be reduced and evaluated before, and not after, the extraction procedure.

The two methods considered for comparison in this study were auditory distraction and brief relaxation therapy. As early as 1981, the effectiveness of music distraction was tested for its effect on pain among selected post-operative gynecologic and/or obstetric patients [34]. In 1990, its effectiveness was tested while performing dental restorations [35]. The mechanism of action involves reducing the perception of pain through distraction and refocusing the attention onto a more acceptable stimulus [34]. This technique has been widely used in a variety of clinical situations; however, its effectiveness is reported to differ in different circumstances [36]. Brief relaxation therapy was first tested in a group of patients requiring treatment for simple dental caries [37], and the method for

implementing the therapy was adapted from an earlier study [38]. Its mechanism of action comprises progressive muscular relaxation inducing a perception of personal control over a situation, which could plausibly lead to a reduction in the anxiety levels of the patients [39]. Brief relaxation therapy is an active phenomenon in contrast to auditory distraction and requires active training of the personnel carrying out the intervention. The objective of this study was to conduct a randomized control trial comparing the effectiveness of auditory distraction, brief relaxation therapy, and no intervention (control group) in reducing anxiety levels in patients undergoing tooth extraction. We hypothesized that study participants in both intervention groups would have significantly lower levels of anxiety compared to those who did not receive an intervention.

2. Materials and Methods

2.1. Ethical Considerations

The current study was carried out in accordance with the Declaration of Helsinki and was approved by the Human Research Ethics Committee at the university (IRB: CODJU-2007I). All the study participants provided written informed consent before the data collection process.

2.2. Study Design and Sample Selection Criteria

The study was a non-blind, three-armed, randomized control trial (Figure 1). The targeted study population were female patients attending the Oral and Maxillofacial Surgery clinics at the university who needed extraction of a non-restorable and non-mobile molar tooth. Only those patients who were older than 18 years, provided signed consent, and had no self-reported mental health issues were included. Patients suffering from somatic or psychiatric disease, using any psychoactive medication (such as an antidepressant or tranquillizer), and needing complex dental treatment which needed more than one treatment session, were excluded. We only selected female patients to reduce the confounding effect of sex on the findings.

Figure 1. CONSORT flow diagram of the study.

2.3. Sample Size Calculation

The sample size, with an equal allocation of study participants in each group (1:1:1), was computed based on the findings from an earlier study [37]. It was assumed that the mean difference before and after intervention in the two treatment groups (excluding the control group) would be 13.0 with a standard deviation of 9.5. The estimated sample size, with 80% power and significance level set at 5% (Type 1 error rate), inclusive of a 10% dropout rate, was 96 (N).

2.4. Study Tool Validation Process

The Hierarchical Anxiety Questionnaire [HAQ] was used to assess the anxiety level of the patients. It was translated into Arabic and subjected to validation tests before administration. In this process, a bilingual dentist (familiar with the English and Arabic languages) was asked to translate the original English version. The translated version was independently reviewed by two oral and maxillofacial surgeons and minor discrepancies regarding the dialect were sorted through mutual consensus. The approved version of the Arabic-HAQ was administered to a sample of 10 adult patients visiting the dental diagnostic clinics at the university. Apart from the responses to the items in the questionnaire, the participants were asked, using a single question, to rate the ease of understanding of the questionnaire on a five-point Likert scale, and were recalled after one week to repeat the response and rating. The intraclass correlation coefficient (ICC) value and the mean difference between the Likert-scale values of both visits were computed. The ICC values within the group of responders were 0.75 and 0.76 in the first and second attempts, respectively. Additionally, there was no significant difference in the mean Likert scale values between the first and second attempts in the same responders ($p > 0.05$). This indicated that the questionnaire yielded the same result on repeat administration and was clearly understood by the responders.

2.5. Data Collection Process

The questionnaires were first distributed to the selected participants in the waiting area of the dental clinics. After questionnaire distribution, these patients were numbered and randomly assigned into the three groups using Randomizer software (<https://www.randomizer.org>; accessed on 12 December 2019). One group did not undergo any intervention (control group), and the participants in the next two groups received either auditory distraction or brief relaxation therapy. The intervention was carried out when each patient was sitting on the dental chair before the tooth extraction procedure. Group 1 (the auditory distraction group) was asked to select their favorite music composition or religious recitation that they would like to hear before and during the tooth extraction procedure. Sanitized ear pods or headphones were provided, and the requested audio was played for at least 15 min using a mobile phone. For group 2 (the brief relaxation therapy group), a trained physiotherapist carried out the process of brief relaxation, as adapted from Loew and colleagues [38,40], which comprised the following instructed steps: (1) Let your lower jaw fall loosely and move it easily from right to left for three to five seconds. (2) Move the joints of your head and neck smoothly so that your head nods slightly from one shoulder to the other for three to five seconds. Let gravity do the work. Do you notice a change in awareness of your neck? (3) For three to five seconds, move your relaxed shoulders in a circular motion in their joints in such a manner that another person would barely see your movements. Let gravity work for you. (4) Pay attention to your awareness of your body. Do you notice any variation? (5) Beginning with your backbone, move your body loosely from side to side and from back to front for three to five seconds. Imagine that your chest is suspended from many flexible small joints. Let your ribs fall with gravity. Feel the flexibility of your chest. Notice the sensation inside your chest. (6) Pay attention to your body and be conscious of your bodily experiences. Notice your flexibility. (7) You do not need to worry about doing something wrong. The brief relaxation therapy process took approximately 15 min.

The final group (control group) did not undergo any intervention and the dental practitioner carried out the extraction in a manner that is commonly practiced in most dental clinics. One oral and maxillofacial surgeon carried out the non-surgical extraction procedures for all the recruited participants at their scheduled appointments. The patient's level of anxiety was assessed again soon after the intervention, and before the procedure, using the same questionnaire. The age and sex of the study participants were also recorded using a self-administered questionnaire. To address any potential confounding related to inter-operator calibration, all extractions were carried out by one specialist oral surgeon following the standard clinical (procedural) and infection control protocols.

2.6. Statistical Analysis

The normality of the data was assessed using the Kolmogorov–Smirnov ($p < 0.001$) and Shapiro–Wilk tests ($p < 0.001$) and the alpha value was set at 0.05. Mean and standard deviation values were used to report the results. Because the data was not normally distributed; the Mann–Whitney U or Kruskal–Wallis tests were performed to compare means between the groups. The before and after comparisons in each group were carried out using the Wilcoxon Signed-Rank test. All the data were analyzed using SPSS version 24 (IBM, New York, NY, USA).

3. Results

The overall sample size was 86 (N); the brief relaxation therapy and auditory distraction groups had 32 participants each, while 10 participants in the control group were excluded due to missing data ($n = 22$). All the study participants were females. The mean age of the overall sample was 33.19 (11.10) years. Age by groups was not significantly different ($p = 0.67$); the mean (SD) age in the brief relaxation therapy, auditory distraction, and control groups were 32.06 (11.97), 33.19 (10.05), and 34.82 (11.10), respectively.

Figure 2 presents the mean anxiety score (HAQ) of the study participants in each of the three groups before the interventions were implemented. The lowest score was recorded in the control group (mean = 16.0; SD = 3.32), followed by the auditory distraction (mean = 24.94; SD = 9.02) and brief relaxation therapy (mean = 28.75; SD = 8.49) groups. There was a significant mean difference in the overall anxiety level between the three groups before ($p < 0.001$) and after ($p = 0.01$) the intervention (Table 1).

Figure 2. Mean Hierarchical Anxiety Questionnaire scores at the baseline.

Table 1. Difference in the anxiety level between the three groups before and after the interventions.

	Group	N	Mean Rank	Mean (SD)	Range	<i>p</i> -Value
Before Intervention	Brief Relaxation	32	36.94	24.07 (9.17)	12–50	<0.001 ^a
	Audible distraction	32	28.06			
	Control group	22	19.05			
After Intervention	Brief Relaxation	32	35.88	20.30 (6.44)	12–37	0.01 ^a
	Audible distraction	32	29.13			
	Control group	22	31.59			

^a Significant *p*-Value using the Kruskal-Wallis test.

Table 2 presents the effectiveness of brief relaxation therapy and auditory distraction in reducing the level of anxiety among the study participants, and also checks the changes in the control group. The mean anxiety score after brief relaxation therapy and auditory distraction had significantly decreased ($p < 0.001$). Although not significant ($p = 0.13$), there was a slight increase in the anxiety score of the study participants in the control group before the tooth extraction procedure (Table 2). Figure 3 graphically demonstrates the effect of the interventions in reducing the anxiety level of the study participants.

Table 2. Effectiveness of the intervention by pre-and post- intervention mean anxiety scores.

Type of Intervention	Before Mean (SD)	After Mean (SD)	<i>p</i> -Value
Brief Relaxation Therapy group	28.75 (8.49)	22.88 (7.21)	<0.001 ^a
Audible Distraction group	24.94 (9.02)	20.0 (6.34)	<0.001 ^a
Control group	16.0 (3.32)	17.0 (3.21)	0.13

^a Significant *p*-Value using the Wilcoxon Signed-Rank test. **Figure 3.** Graphical representation of the change in the mean anxiety scores before and after the interventions.

Table 3 presents the findings from a series of comparisons between the groups to show the effectiveness of brief relaxation therapy and auditory distraction in reducing the anxiety scores (HAQ). Brief relaxation therapy was significantly effective in reducing the anxiety scores in comparison to the control group (MD = 5.87, 95% CI = 2.58, 9.17; $p = 0.001$). No significant difference was observed in the reduction of anxiety levels between the brief relaxation therapy and the auditory distraction interventions ($p = 0.15$). Additionally, the auditory distraction intervention did not significantly reduce the anxiety score in comparison to the control group ($p = 0.14$).

Table 3. Series of comparisons to demonstrate the effectiveness of brief relaxation therapy and audible distraction in reducing anxiety levels.

Group	N	Mean Rank	Mean (SD)	Mean Difference (95% CI)	<i>p</i> -Value
Brief Relaxation	32	35.88	22.88 (7.21)	2.87 (−0.52, 6.27)	0.14
Audible distraction	32	29.13	20.00 (6.34)		
Brief Relaxation	32	33.13	22.88 (7.21)	5.87 (2.58, 9.17)	0.001 ^a
Control group	22	19.32	17.00 (3.21)		
Audible Distraction	32	30.06	20.00 (6.34)	3.0 (0.05, 5.95)	0.15
Control group	22	23.77	17.00 (3.21)		

^a Significant *p*-Value determined using the Mann Whitney U test.

4. Discussion

Anxious dental patients are arduous to treat, need more time, and have behavioral issues which lead to a stressful and unpleasant experience for them and the treatment provider [12,41]. The current experiment delivers evidence to support the hypothesis that auditory distraction and brief relaxation therapy are effective in reducing anxiety among patients undergoing dental extractions. However, between the two interventions, brief relaxation therapy had better outcomes when compared to the control group. This is in accordance with a similar study carried out earlier; wherein brief relaxation therapy was shown to be more effective in reducing the anxiety level of patients when compared to musical distraction and control groups [37]. Because the current study presents the findings for patients undergoing tooth extraction, in contrast to tooth restoration in the previous study [37], it is evident that brief relaxation therapy is applicable for simple and complex dental treatments.

Most earlier experimental studies assessed the anxiety level of the patients after the dental treatments were performed and compared it to the baseline readings [30–32,37]. This type of approach has two issues. First, any treatment provider intends to have a less anxious patient on a dental chair before the dental treatment is provided and therefore the effectiveness of an intervention to reduce the level of anxiety should be measured before the dental treatment and not after. Second, it is obvious that the patient will be less anxious after the dental treatment is completed because the dental treatment is the anxiety-provoking stimulus. Thus, this may have led to biased results in the earlier investigations. In the current study, the level of anxiety was measured before and after the intervention, and before the dental treatment. This design allowed us to measure the effectiveness of auditory distraction and brief relaxation therapy in reducing anxiety more accurately. Moreover, the current study showed that patients in the control group i.e., those not receiving any intervention, had a higher level of anxiety just before dental treatment (mean = 17; SD = 3.21) in comparison to their level at baseline (mean = 16; SD = 3.32). Thus, the current study provides a more accurate measurement of the effectiveness of the interventions compared to the earlier investigations.

The finding that brief relaxation therapy is more effective in reducing anxiety in comparison to auditory/musical distraction is confirmed by the current study and an earlier report [37]. This can be attributed to the functional characteristics of the former therapy. It is suggested that ‘*brief relaxation is a euphemism for hypnosis*’ and is a progressive relaxation

hypnotic technique [42]. Moreover, it is plausible that the interaction between the treatment provider and the patient during the therapy and the use of sentences such as ‘*you do not need to worry . . .*’ (Step 7; see in the Section 2) may have enhanced treatment acceptability in the patients by exhibiting the dentist’s compassion for the patient, thereby reducing their anxiety. This, however, should be further established using qualitative analysis. In contrast, the auditory distraction process is passive and lacks such interaction between the treatment provider and the patient, which may have contributed to inferior findings when compared to brief relaxation therapy. In an experimental study, musical distraction was not effective in reducing the anxiety level in younger populations [43]. Although inferior to brief relaxation therapy, this study demonstrated that auditory distraction does effectively reduce the anxiety level of patients undergoing tooth extraction. The mechanism of action could be through the diversion of attention from a self-perceived unpleasant dental treatment. It is suggested that music influences the brain, leading to relaxation by distraction, operating across the neuroendocrine and sympathetic nervous systems [44].

The results of the current study should be interpreted in accordance with the weaknesses. Only female participants were included and therefore the findings may not be reproducible in male patients. It has been shown in earlier studies that female patients are more apprehensive of dental extractions than males [45,46], so the level of change in anxiety before and after the intervention in male patients may not be similar to female patients. However, because the interventions have worked on the more anxious female participants, it is highly plausible that they may also work with the comparatively less anxious male patients. Additionally, having only female patients contributed to the homogeneity of the study sample, thus adding to the robustness of the results. The findings on the anxiety level of the participants also rely on the validity of the Hierarchical Anxiety Questionnaire, and future studies may use other assessment scales to evaluate the results.

5. Conclusions

In conclusion, it is essential that dentists take additional measures to make the overall clinical experience of their patients more pleasant. The current study provides evidence that auditory distraction and brief relaxation therapy are effective in reducing the anxiety level among patients before a dental procedure; therefore, application of these unintrusive interventions is encouraged. Furthermore, it would be interesting to learn if these findings remain consistent for more complex dental procedures, such as surgical removal of an impacted third molar, and also if the findings are applicable in patients of different age groups.

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Informed Consent Statement: Written informed consent has been obtained from the patient(s) to publish this paper.

Data Availability Statement: The data for this study could be achieved on a reasonable request made to the corresponding author.

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