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The effect of alpha binaural beat music on orthodontic pain after initial archwire placement: A randomized controlled trial

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ABSTRACT

Objective: The objective of this article was to evaluate the effect of alpha binaural beat music on pain level after initial placement of a maxillary fixed appliance, compared to music without binaural beats (placebo) and no music (control).

Methods: 60 patients undergoing maxillary fixed orthodontic appliance and initial archwire placement were randomly allocated into the three aforementioned groups. The pain level experienced was monitored for the following seven days, using the short-form McGill pain questionnaire (SF-MPQ).

Results / Descriptors: Intensity of both sensory and psychological aspects of pain reduced significantly in the binaural beat music (BBM) group, compared to the control, after the 5th day. Statistically significant lower affective and total pain scores were also found on day 6 for the placebo group, compared to the control. *Present Pain Intensity (PPI):* Statistically significant lower scores were found between the BBM group and the control group from days 3 to 7. Statistically significant lower scores were also found between the placebo and the control groups on days 4, 5 and 6. *Visual Analog Scale (VAS):* Compared to the control group, the placebo group had a lower VAS score on day 4, and the BBM group had lower scores on days 6 and 7.

Conclusions: There was a significant reduction of pain demonstrated in the BBM group, compared to the control, toward the end of the first week of treatment. There was no difference in reported pain between the BBM and placebo groups for any of the scores.

Keywords: Orthodontic treatment. Pain management. Brainwaves.

RESUMO

Objetivo: O objetivo deste artigo foi avaliar o efeito da música alfa com ritmo binaural sobre o nível de dor após a instalação de um aparelho fixo superior com arco inicial, em comparação com a música sem ritmos binaurais (placebo) e sem música (controle).

Métodos: 60 pacientes submetidos a instalação de aparelho ortodôntico fixo superior e do arco inicial foram alocados aleatoriamente nos três grupos acima mencionados. O nível de dor experimentado foi monitorado durante os sete dias seguintes, usando a forma curta do questionário de dor McGill (SF-MPQ).

Resultados: Após o quinto dia, a intensidade dos aspectos sensoriais e psicológicos da dor foi significativamente reduzida no grupo de música com ritmo binaural (BBM), em comparação com o grupo controle. Escores significativamente menores de dor afetiva e total também foram encontrados no dia 6 para o grupo placebo, comparado ao controle. *Intensidade da Dor Presente (PPI)*: escores significativamente menores foram encontrados para o grupo BBM, em comparação ao grupo controle, nos dias 3 a 7. Escores significativamente menores também foram encontrados para o grupo placebo, em comparação ao grupo controle, nos dias 4, 5 e 6. *Escala Visual Analógica (VAS)*: comparado ao grupo controle, o grupo placebo teve um escore VAS menor no dia 4, e o grupo BBM teve escores menores nos dias 6 e 7.

Conclusões: No final da primeira semana de tratamento, houve redução significativa da dor no grupo BBM, em comparação ao grupo controle. Não houve diferença entre a dor relatada nos grupos BBM e placebo para qualquer um dos escores.

Palavras-chave: Tratamento ortodôntico. Manejo da dor. Ondas cerebrais.

INTRODUCTION

Orthodontic patients experience some level of discomfort during treatment, especially in the initial stages of treatment. Pain has been ranked as the worst aspect of orthodontic treatment, and is the most common reason for people wanting to discontinue orthodontic treatment.[1,2] Pain is most frequently reported after bracket bonding and initial archwire insertion. Patients usually experience peak pain after 24 hours, which then decreases after 3 days and declines to baseline levels in the second week.[3,4]

Pharmacological interventions such as non-steroidal anti-inflammatory drugs (NSAIDs) are commonly prescribed to alleviate pain after initial archwire placement. However, multiple doses are usually required to cover the discomfort, and there is a concern regarding the detrimental effect on tooth movement.[2,5] The current trend is directed towards use of preemptive analgesics, which are administered at least one hour before every orthodontic procedure. But the effect of NSAIDs appears to be transient, with only a significant reduction in pain up to two hours after treatment, and with no difference after six hours.[2,6] Non-pharmacological interventions have also been attempted, and found to be beneficial in reducing pain and distress in patients undergoing dental procedures.[7] For orthodontic pain reduction, low-level laser therapy, vibratory devices, chewing adjuncts, brainwave music, cognitive behavioral therapy, and post-treatment text messaging have been attempted.[8-12] Music appears to have various positive effects on the human brain, and helps to soothe and relax.[13] In addition, music therapy was found to be an effective non-pharmacological approach for postoperative pain management.[14-16]

The development of brainwave entrainment tools proliferated after Oster's article[17] (1973) on the properties of the binaural beat: A sound with a steady intensity and frequency is presented to one ear and another sound with the same intensity but slightly different frequency presented to the other ear. The brain then produces pulsations in the amplitude and localization that is the same with the perceived sounds, which are known as "binaural beat" or "binaural tone". The brain generates several waves with different frequencies. Beta waves (13Hz to 32Hz) are observed while the patient is awake, and are associated with busy thinking, focus and alertness. Alpha waves (8Hz to 12Hz) are the bridge between the conscious and unconscious mind, and helps us to relax. Theta waves (4Hz to 8Hz) are involved in daydreaming, light sleep and deep meditation. Delta waves (1Hz to 4Hz) have the slowest frequencies and are experienced in dreamless sleep.[18] Binaural beats can change the frequency towards a desired state, by synchronizing its own electric cycles to the same rhythm, whether favoring relaxation or alertness.[19]

Preliminary evidence suggests that brainwave entrainment is effective in several cognitive domains and can relieve acute and long-term stress, reduce pain, headaches, migraines and operative anxiety; and improve behavior, mind wandering and creativity.[18,20-25] Only one study[9] using binaural beats was conducted in the orthodontic field, in which the authors utilized customized binaural tones based on an EEG analysis. They concluded that brainwave music was more effective in managing orthodontic pain than cognitive behavioral therapy and a control.

Thus, the aim of this study was to evaluate the effect of alpha binaural beat music on pain after the initial placement of an orthodontic archwire, and to compare the pain level with that of a placebo and a control group. The null hypothesis tested was that there would be no difference in pain relief after listening to an alpha binaural beat music following the initial placement of an orthodontic archwire, compared to the placebo group and the control group.

MATERIAL AND METHODS

SAMPLE

This study was a prospective three-arm randomized controlled trial, with a balanced allocation ratio (1:1:1), and was approved by the Institutional Review Board at the European University College, Dubai. The sample size was calculated with a power analysis using the program G*Power 3.[26]

For a type I error rate of 5% and a power of 80%, a sample of 60 patients was required. The final study sample size consisted of 60 orthodontic patients (23 males, 37 females, with a mean age of 17.7 ± 6.5 years) (Fig 1).

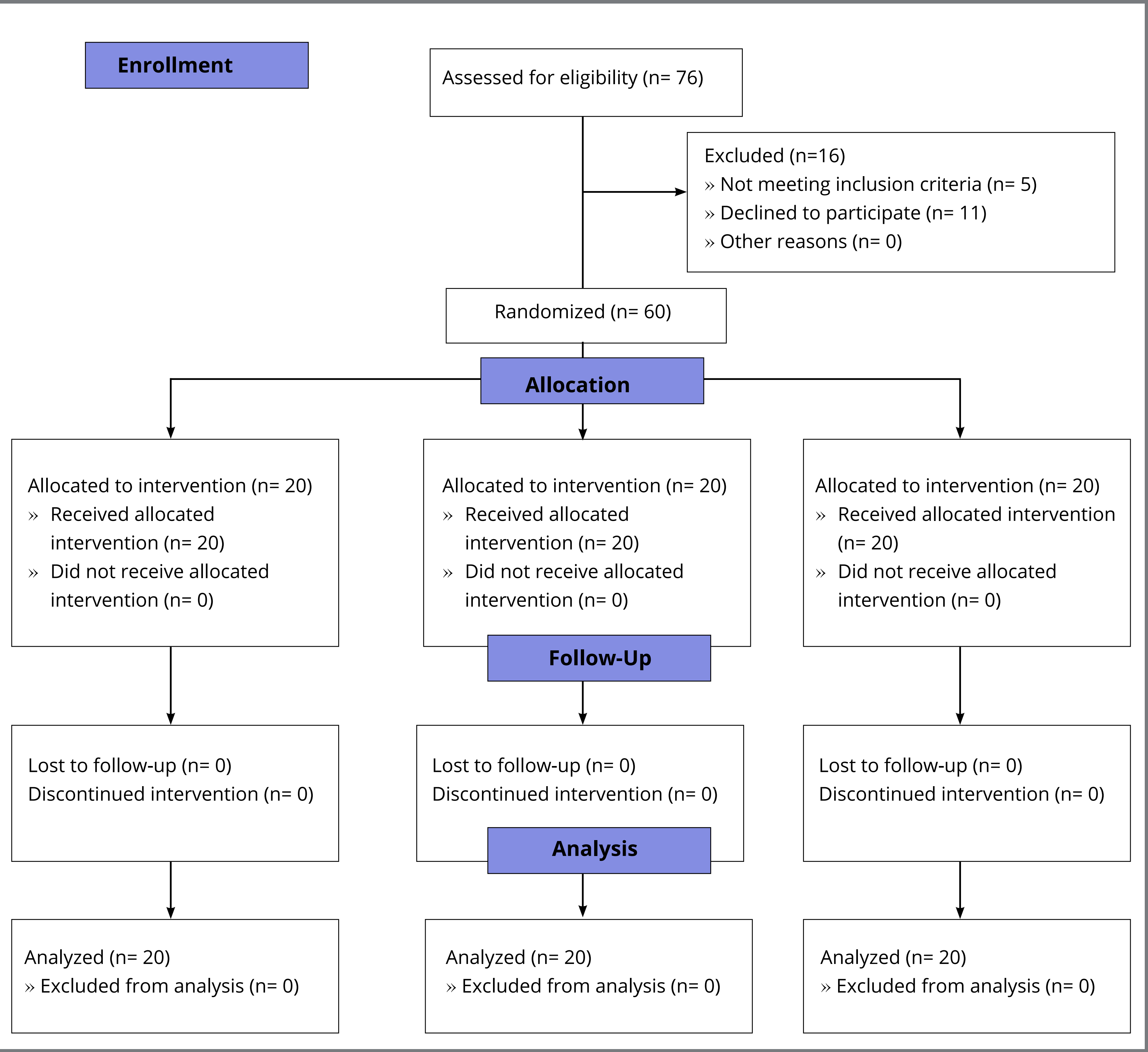

Figure 1: CONSORT diagram.

The patients included in the study were undergoing orthodontic treatment and scheduled for placement of fixed maxillary appliance. Exclusion criteria were as follows: 1) severe maxillary arch crowding (>8mm) or extractions, 2) previous history of orthodontic treatment, 3) oral pathology altering pain perception (pulpitis, periodontitis, oral ulcer), 4) significant medical history (psychological disorders including anxiety or depression, hearing problems, attention disorders) or medication usage affecting pain perception, 5) use of auxiliary appliances (expansion appliances, bite plates). The study period consisted of the first week of orthodontic treatment. The mandibular appliances were placed on completion of the study, or in the following month.

A simple randomization (lots) was used to assign patients upon their arrival, in a 1:1:1 ratio, into one of the three following groups: 1) binaural beat music (BBM) group, 2) plain music placebo group, and 3) no music control group. A total of 60 cards were prepared, each containing the letter B, P, or C. The cards were chosen one by one, and cases allocated to each group as per the letter sequence. The patients received all the information and instructions of the study according to their group allocation, and an informed consent was obtained from each patient. All patients were blinded to their group allocation.

MUSIC FABRICATION

An alpha-wave binaural beat embedded in a lyric-less instrumental music was produced with Audacity® software. An inaudible 10 Hz binaural beat (of the alpha-range) was created with a frequency of 440 Hz in one ear and 450 Hz in the other (the audible range for an adult is between 20 and 20,000 Hz) (Fig 2). The music duration was empirically set to 5 minutes. The placebo group received the same music without the binaural beat frequency, while the control group did not receive any intervention.

PROCEDURES

1. Pre-adjusted Edgewise 0.022-in brackets using MBT prescription was used in all patients, combined with 0.014-in NiTi archwires.
2. Patients in the music groups were asked to listen to the music once a day for 7 days. They were instructed to use earphones or headphones and to listen to the music in the evening (preferably at the same time every day), sitting comfortably in a quiet room, eyes closed with the volume set at their convenience. Thereafter, they completed an online questionnaire.
3. The control group was asked only to complete the questionnaire every day, for 7 days.
4. All patients were instructed not to take any analgesic drug during the study period.

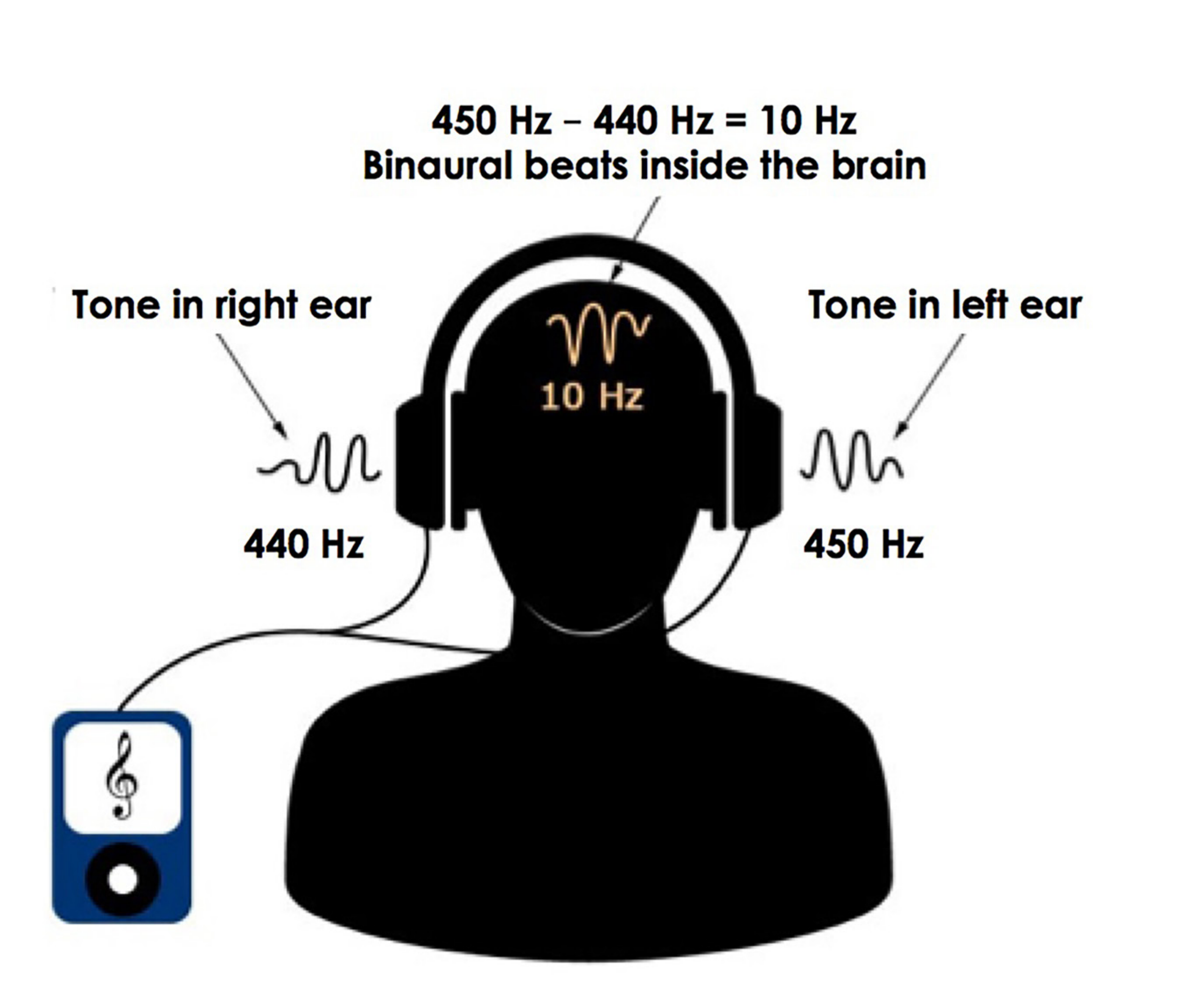

Figure 2: Illustration of the binaural beat fabrication.

A link for an online modified short-form McGill pain questionnaire (SF-MPQ) was sent via email to all participants (Fig 3). The SF-MPQ measures the intensity of sensory and affective aspects of pain, and has been deemed effective for the assessment of pain in adolescent orthodontic patients.[27,28]

The questionnaire had three components.

» Part 1 – patients were asked to consider 7 sensory (pressure, sore, aching, throbbing, tight, pulling, miserable) and 4 affective (uncomfortable, strange, frustrating, annoying) descriptors, and rate each on a 4-point severity response scale (0 = no pain, 1 = mild pain, 2 = moderate pain, and 3 = severe pain). Three pain scores were derived from the sum of the intensity values for the sensory, affective and total descriptors, respectively.

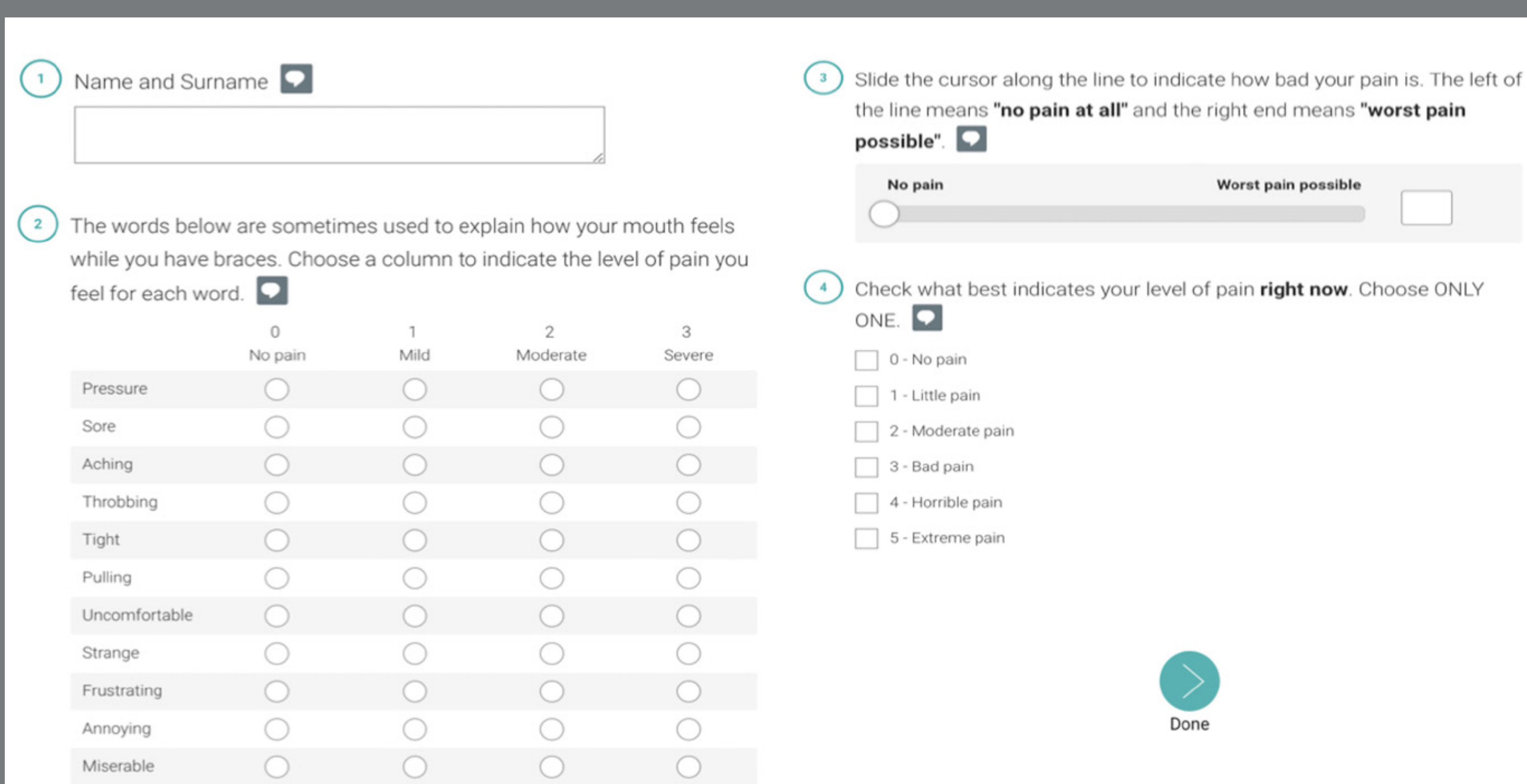

Figure 3: Online modified short-form McGill pain questionnaire (SF-MPQ).

» Part 2 – Visual Analogue Scale (VAS): patients were asked to rate the severity of their pain by sliding the cursor along a line ranging from “no pain” to “worst pain possible” (graduated from 0 mm to 100 mm).

» Part 3 – Present Pain Intensity (PPI): patients were asked to select their current level of pain on a scale of 0 to 5 (0 = no pain, 1 = little pain, 2 = moderate pain, 3 = bad pain, 4 = horrible pain, and 5 = extreme pain).

Upon completion of the survey, an email was automatically generated by the software, to confirm that the task was done. In addition, daily SMS reminders were sent to each patient.

STATISTICAL ANALYSIS

Data were collected and analyzed using the Statistical Package for Social Services (SPSS) software (IMB, Armonk, NY, v. 25.0). A chi-square test was used to examine the differences in patient sex between the three groups, while the distribution of age was compared using ANOVA. Nonparametric methods were applied, as the assumption of normal distribution was rejected by the Shapiro-Wilk test. A probability level of $p < 0.05$ was used to indicate significant differences. Kruskal-Wallis tests were performed to compare the reported scores between the groups. Dunn’s *post-hoc* test with Bonferroni correction was carried out on each pair of groups, to determine intergroup differences throughout the seven time oints. Wilcoxon signed-rank tests were used to evaluate intragroup changes in scores as a function of time.

RESULTS

A total of 60 patients completed the study. No significant differences were observed in sex and age distribution among the three groups (Table 1).

PAIN SCORES BY DESCRIPTORS (TABLE 2)

1. **Sensory pain –** Kruskal-Wallis analysis showed statistically significant differences for the sensory scores between the groups on days 5, 6 and 7 (p = 0.015, p = 0.003 and p = 0.001 respectively). The result of the *post-hoc* test showed significantly lower sensory scores for the BBM group, compared to the control group.

Table 1: Sample demographics.

	Binaural Beat Music (n=20)	Placebo (n=20)	Control (n=20)	*p*
Age (years ± SD)	16.3 ± 5.5	16.5 ± 6.0	20.5 ± 7.4	0.073†
Gender (M:F)	6:14	7:13	10:10	0.400‡

†ANOVA test results; ‡Chi-square test results.

Table 2: SF-MPQ sensory, affective and total pain experience scores over the first 7 days.

Score	Day	Binaural Beat Music (n=20)	Placebo (n=20)	Control (n=20)	*p* [a]	Significance between groups [†]
Sensory (7 items)	1	4 (2-17)	5 (0-11)	4.5 (0-16)	NS	
	2	6 (2-13)	5.5 (0-16)	9 (1-19	NS	
	3	4 (0-13)	4.5 (0-14)	7 (1-17)	NS	
	4	2 (0-10)	2.5 (0-9)	5.5 (0-19)	NS	
	5	1 (0-7)	1 (0-9)	4 (0-16)	0.015	Binaural Beat * < Control
	6	0 (0-7)	1.5 (0-6)	4.5 (0-11)	0.003	Binaural Beat ** < Control
	7	0 (0-3)	0.5 (0-9)	2.5 (0-7)	0.001	Binaural Beat *** < Control
Affective (4 items)	1	5.5 (0-10)	4 (0-12)	5 (0-12)	NS	
	2	5 (0-9)	4 (0-12)	6 (0-12)	NS	
	3	2.5 (0-8)	2 (0-12)	5 (0-10)	NS	
	4	1.5 (0-5)	1 (0-8)	3 (0-12)	NS	
	5	1 (0-4)	1.5 (0-12)	3.5 (0-8)	0.038	Binaural Beat * < Control
	6	0 (0-4)	0.5 (0-8)	4 (0-7)	0.004	Binaural Beat ** < Control Placebo * < Control
	7	0 (0-4)	0 (0-6)	2.5 (0-4)	0.017	Binaural Beat * < Control
Total (11 items)	1	10 (3-27)	9 (0-21)	9.5 (0-28)	NS	
	2	12.5 (2-21)	8.5 (0-24)	16 (3-31)	NS	
	3	6.5 (1-21)	7 (0-24)	12.5 (2-27)	NS	
	4	3 (0-14)	4 (0-14)	9 (0-31)	NS	
	5	1.5 (0-11)	4 (0-19)	8 (0-24)	0.014	Binaural Beat * < Control
	6	0.5 (0-11)	2 (0-12)	8 (0-16)	0.001	Binaural Beat *** < Control Placebo * < Control
	7	0 (0-7)	1 (0-13)	4.5 (0-11)	0.001	Binaural Beat *** < Control

Scores are represented as median (range).

[a]Kruskal-Wallis test, performed to compare the scores between the groups.

NS=not significant; [†]Dunn's test with Bonferroni correction, for multiple comparisons between the groups; *p < 0.05. **p < 0.01. ***p < 0.001.

2. **Affective pain –** Statistically significant differences were found between the groups on days 5, 6 and 7 ($p = 0.038$, $p = 0.004$ and $p = 0.017$ respectively). Compared to the control group, statistically lower affective scores were found for the BBM group on these days, and a statistically significant lower affective score was found on day 6 for the placebo group.
3. **Total pain experience –** Statistically significant differences were found for the total pain scores between the groups on days 5, 6 and 7 ($p = 0.014$, $p = 0.001$ and $p = 0.001$ respectively). Compared to the control group, statistically lower total pain scores were found for the BBM group on these days, and a statistically significant lower total pain score was found on day 6 for the placebo group.

PRESENT PAIN INTENSITY (PPI) SCORES (TABLE 3)

The PPI scores were lower for the test and placebo groups compared to the control group. Statistically significant lower scores were found between the BBM group and the control group on days 3, 4, 5, 6 and 7, whereas statistically significant lower scores were also found between the placebo and the control groups on days 4, 5 and 6.

Table 3: Present Pain Intensity (PPI) score over the first 7 days.

Day	Binaural Beat Music (n=20)	Placebo (n=20)	Control (n=20)	p^a	Significance between groups[†]
1	1 (0-3)	1 (0-2)	1 (0-3)	NS	
2	1.5 (0-3)	1 (0-5)	2 (1-4)	NS	
3	1 (0-2)	1 (0-3)	2 (0-5)	0.007	Binaural Beat ** < Control
4	1 (0-2)	1 (0-2)	2 (0-4)	0.002	Binaural Beat ** < Control Placebo * < Control
5	0 (0-1)	0.5 (0-3)	1 (0-3)	0.001	Binaural Beat *** < Control Placebo * < Control
6	0 (0-1)	0 (0-1)	1 (0-2)	0.001	Binaural Beat *** < Control Placebo * < Control
7	0 (0)	0 (0-1)	1 (0-2)	0.001	Binaural Beat *** < Control

PPI scores are presented as median (range). [a]Kruskal-Wallis test, to compare the scores between the groups. NS=not significant. [†]Dunn's test with Bonferroni correction, for multiple comparisons between the groups. *$p < 0.05$. **$p < 0.01$. ***$p < 0.001$.

Table 4: Visual Analog Scale (VAS) values over the first 7 days.

Day	Binaural Beat Music (n=20)	Placebo (n=20)	Control (n=20)	p^a	Significance between groups[†]
1	32.7 ± 24.9	18.7 ± 16.4	25.8 ± 25.3	NS	
2	33.7 ± 21.5	32 ± 26.9	39.2 ± 24.4	NS	
3	25.9 ± 20.4	21.9 ± 21.5	37.4 ± 25.3	NS	
4	15.9 ± 14.5	13.2 ± 14.7	29.1 ± 20.1	0,023	Placebo * < Control
5	9.4 ± 10.1	11.9 ± 14.2	21.3 ± 18.9	NS	
6	4.5 ± 7.8	9.1 ± 11.3	20.9 ± 19.9	0,005	Binaural Beat ** < Control
7	0.8 ± 2.1	6.7 ± 8.5	14.8 ± 15.4	0,001	Binaural Beat *** < Control

VAS values are presented as mean ± standard deviation.

[a] Kruskal-Wallis test result, comparing scores between groups.

NS=not significant; [†]Dunn's test with Bonferroni correction, for multiple comparisons between the groups; *$p < 0.05$. **$p < 0.01$. ***$p < 0.001$.

VISUAL ANALOG SCALE (VAS) PAIN SCORES (TABLE 4)

The VAS scores significantly differed between the three groups on days 4 ($p = 0.023$), 6 ($p = 0.005$) and 7 ($p = 0.001$). Pairwise comparisons revealed that, compared to the control group, the BBM group had lower scores on days 6 ($p < 0.01$) and 7 ($p = 0.001$) and the placebo group had a lower VAS score on day 4 ($p < 0.05$).

INTRAGROUP VAS PAIN SCORE CHANGES (FIG 4)

The pain intensity tended to increase between the first and the second day after initial archwire placement, and then decreased until the end of the week. The three groups followed the same trend, with differences patterns (Fig 4). From day 1 to day 2, a statistically significant increase in the VAS score was noted only in the control group ($p < 0.05$). From day 2 onwards, the scores started decreasing in all groups. In the BBM group, the pain intensity decreased progressively from day 2 to day 7 with significant differences ($p < 0.05$) between the time points.

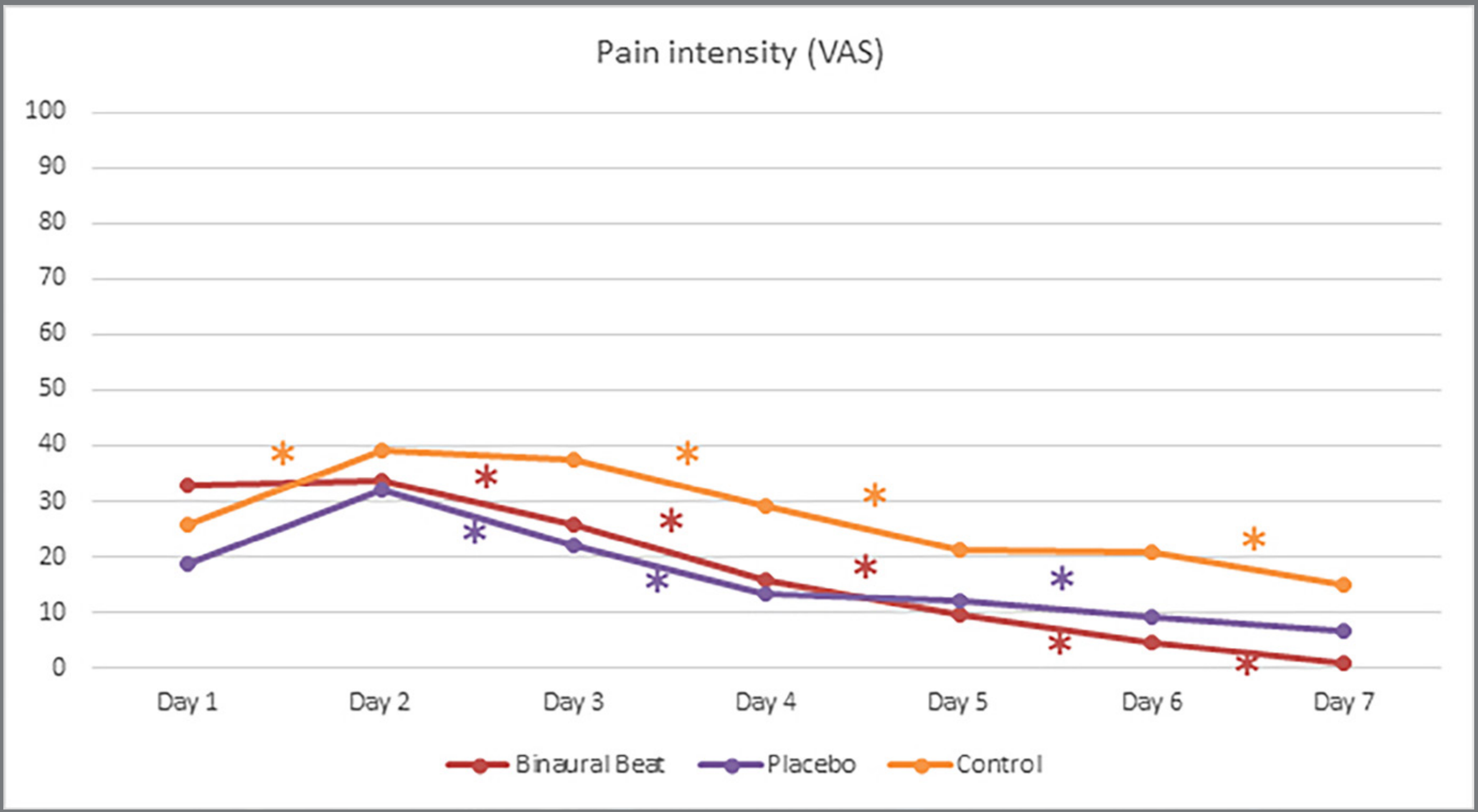

Figure 4: Intragroup VAS score changes between the time points. * $p < 0.05$, based on the Wilcoxon signed-rank test.

In the placebo group, significant differences ($p < 0.05$) were noted from day 2 to day 4, and between days 5 and 6 only. In the control group, significant decreases ($p < 0.05$) in pain intensity were noted from day 3 to day 5, then the pain intensity plateaued before reaching again a significant decrease at the end of the week, between days 6 and 7 ($p < 0.05$).

DISCUSSION

Over the years, many non-pharmacological means were used in the attempt to reduce the orthodontic discomfort.

Sensory, affective and total pain scores were significantly lower in the BBM group, compared to the control group, from days 5 to 7, thus rejecting the null hypothesis (Table 2). By exploring the pain ratings with respect to affective and sensory dimensions, a decrease in both aspects with time can be seen in all groups: the BBM group displaying the higher improvement, followed by the placebo and control groups. This shows how pain is subjective and can be altered by both physiological processes and psychological factors.[3,5,29] The affective aspect of pain is noteworthy, as it describes the perception of an experience rather than a pure pain feeling, raising the importance on patient education about what they can expect, and may consequently help in pain management.

The reduction in pain between the BBM and control groups was noted only during the second half of the week (Tables 2 and 4). This is in disagreement with the study of Huang et al.[9] in which significant differences were found during the first four days after the appliance placement. This difference may be due to their use of customized frequency ranges of binaural beats based on the patients' electroencephalogram (EEG). The present study used a relaxing music in which only an alpha binaural beat of 10 Hz frequency was embedded.

The PPI scores showed earlier significant decrease of pain intensity in both the BBM group (from day 3 to 7) and the placebo group (from day 4 to 6) (Table 3). However, the peak pain (on day 2) was not reduced significantly, although lower scores were recorded in both music groups. It is interesting to note that by the end of the week, patients in the control group reported some amount of pain (median score of 1 on days 6 and 7), while patients in both the BBM and placebo groups felt no pain (median score of 0 on days 6 and 7). This gives an insight on how music in its broad sense could affect pain.

Orthodontic pain peaks at 24h and then gradually decreases to baseline levels.[3,5] All three groups followed this trend, albeit slightly differently. As seen by the VAS scores, only the control group showed a significant increase in pain intensity on the first day, and significant decreases started to be noted not sooner than the third day. Interestingly, the BBM group showed a significant gradual decrease from day 2 onwards between the time points, unlike the two other groups, which showed periods of stagnation. This finding implies that the BBM may have some additional effect on pain relief, although statistically insignificant (Tables 2 to 4, Fig 4). Indeed, the soothing effect of music on the human brain can be observed from the changes in the alpha brainwave activity, since the alpha brainwave is related to the relaxed mental state. Alpha waves were selected in the BBM group and this may have enhanced the alpha activity of the brain, leading to better results.

Many studies have used auditory alpha range stimulation and have demonstrated positive effects (mainly on anxiety, pain and mood enhancement) accompanied by an increase in alpha power.[13,24,30,31] Nevertheless, the extent to which a simple auditory stimulus modulates the brain response is still unknown, and the phenomenon of brain entrainment remains controversial. While some studies found entrainment effects within short durations of stimulation, others denied binaural beats as a potential brainwave entrainment.[19,32,33] A recent meta-analysis,[34] conducted in 2019, suggested that binaural beat exposure is an effective way to affect cognition, anxiety levels and pain perception, but relies highly on the exposure time, the moment of exposure (i.e., before, during and before, and during the task), and the type of sound used to mask the binaural beat.

During the whole study period, the placebo and the BBM group were similar for the most part, and no significant differences between the two groups was noted, indicating that music alone could help reduce discomfort and that the BBM used in this study might have played a limited role in pain reduction.

LIMITATIONS

It was not possible to control the compliance of the patients in listening to the music as requested, which may have influenced the results. The duration of the exposure of the binaural beat may have been too short (5 minutes), and longer exposure could have improved results, although patient compliance could then be reduced. The incorporation of the binaural beat into the music may have also reduced its effectiveness, as the frequencies present in the music might have introduced some interferences with the binaural beat. Lastly, the lack of blinding of the clinician and statistician may have introduced some bias.

CONCLUSIONS

1. There was a significant reduction of pain reported in the binaural beat music group, compared to the control group, toward the end of the first week of treatment.
2. There was no difference in any reported pain scores between the binaural beat music and placebo groups.

AUTHORS' CONTRIBUTIONS

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Donald J. Ferguson (DJF)

Nikhilesh R. Vaid (NRV)

Conception or design of the study:

AEA, NRV

Data acquisition, analysis or interpretation:

AEA, IH, DJF, NRV

Writing the article:

AEA, DJF

Critical revision of the article:

AEA, IH, DJF, NRV

Final approval of the article:

AEA, IH, DJF, NRV

Overall responsibility:

AEA, NRV

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