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ADJUNCT MUSIC THERAPY AND HAEMODYNAMIC BALANCE IN MANDIBULAR THIRD MOLAR SURGERY: A RANDOMIZED CLINICAL STUDY

O.I. Olaopa

Department of Oral and Maxillofacial Surgery, Federal Medical Centre, Ebute-Metta, Lagos

Correspondence:
Dr. O.I. Olaopa
Dept. of Oral and Maxillofacial Surgery,
Federal Medical Centre,
Ebute-Metta, Lagos
Email: segunolaopa@gmail.com

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ABSTRACT

Introduction: **There are conflicting evidences that music can improve psycho-emotional stability and haemodynamic changes during surgeries, as well as improve doctor-patient relationship and the overall clinical outcome. This method is cheaper, devoid of side effects of drugs and provides a memorable experience to patient.**

Aim: **This study sets out to investigate the effect of adjunct music therapy on haemodynamic changes in patients undergoing transalveolar mandibular third molar surgery in a tertiary hospital in southwest Nigeria.**

Methodology: **A total of 146 participants between 21 and 55 years were randomized by balloting into music and non-music groups with equitable gender distribution. For participants in the music group, third molar surgery was performed with selected music tracks played via both external speaker and later headphone while the control group had the stages progress without musical intervention. The blood pressure, pulse rate, respiratory rate were recorded at predetermined interval. Normality of data distribution was tested using Shapiro-Wilk test. Student t-test was used to compare mean for quantitative variables between the groups. The chi-square test was used to compare proportions and to investigate association between categorical variables ($p<0.05$).**

Result and Conclusion: **There was no significant difference in the blood pressure, pulse rate and respiratory rate between participants in this study. This suggests that music therapy confers no significant advantage in stabilizing the blood pressure, respiratory and pulse rates of patient during mandibular third molar surgery.**

INTRODUCTION

Pain is an unpleasant sensory and emotional experience which is associated with actual or potential tissue damage, or described in terms of such damage. This suggests that sometimes, there is no direct relationship between pain and identifiable injury or pathology.[1,2] The biomedical model of pain argues that pain is primarily a sensory neurological experience and pain level correlates predictably with degree of tissue damage. This model has been faulted as there is little evidence to support such systematic relationship especially in patients with chronic pain. Psychological constructs suggest that pain arises out of repression of emotional conflict through conversion where psychic energies are converted into physical symptoms.[1,3]

Patients consider dental treatments to be painful and scary.[4,5] Third molar surgery is considered even more intensely frightening.[6–8] It is an excellent example of a stressful medical or dental reproducible pain model.[9] Fear enhances pain, and both can cause significant haemodynamic imbalance. The anxiety and fear that arise may cause systemic complications and in rare situations, life-threatening complications such as acute heart failure and cerebrovascular accident can occur.[5]

To improve clinical outcomes and ameliorate patient's experience, different methods have been used to reduce anxiety, pain and adverse haemodynamic changes during surgeries, including third molar extraction. These methods are broadly categorized as pharmacologic and non-pharmacologic.[10] The pharmacologic methods carry with it, the risk of systemic complications such as respiratory depression, hypothermia, hypotension and loss of consciousness.[5] To avoid these risks, non-pharmacologic approach provides an effective alternative.

The literature provides conflicting evidences that music can improve psycho-emotional stability and haemodynamic changes during surgeries, as well as improve doctor-patient relationship and the overall

clinical outcome.[8,11] This method is cheaper, devoid of side effects of drugs and provides a memorable experience to patient.[6,12–14]

This study sets out to investigate the effect of adjunct music therapy on haemodynamic changes in patients undergoing transalveolar mandibular third molar surgery in a tertiary hospital in southwest Nigeria. The study objective will compare changes in blood pressure, pulse rate and respiratory rates between participants who received music therapy during third molar surgery and the control group.

METHODOLOGY

Ethical approval was obtained from the institutional ethical board and the study was conducted in line with the Helsinki declaration. This randomized clinical study was carried out at the oral surgery clinic of the University College Hospital, Ibadan, Nigeria among consenting adult participants between the ages of 21 and 55 years who met inclusion criteria for the study. The inclusion criteria for the study include patients with impacted teeth having Pederson Difficulty Index (PDI) ≤6, absence of acute pain, no history of phonophobia or cognitive disorders. A total of 146 participants were randomized by balloting into music and non-music groups with equitable gender distribution. One hundred and forty-six ballot papers were prepared and labelled A (for music) and B (non-music) in equal numbers. For equitable gender distribution, 36 'A' ballots and 37 'B' ballots were place in a concealed box labelled 'Male Box' while 37 'A' ballots and 36 'B' ballots were placed in the second concealed box labelled 'Female Box'. This gave a total of 73 mixed ballots of music and non-music in each of the boxes for male and female. Each participant successively drew from respective gender boxes after tumbling by a trained dental assistant.

Demographic data, vital signs, weight, height and radiographic difficulty index were collected. Other information such as history of previous third molar surgery and the indication for extraction were recorded. The type and choices of music that relax the participants were identified by asking each participant to provide a list of 10 music tracks (using artiste and/or genres and/or tracks) that relaxes him/her. After the participant selection, each participant was given one-week appointment for surgery. The musical tracks were sourced online from www.tubidy.com before the appointment for surgery.

During the appointment, patient was seated in the dental chair in an isolated and quiet dental office with well-controlled ambience. Written informed consent was obtained. While seated, Contec CMS 6000A multiparameter vital signs monitor cuff was attached to the participants left arm with the 5-lead electrodes to the anterior chest wall, and pulse oximeter to record patient's blood pressure, respiratory rate, and pulse rate, respectively.

For participants in the music group, selected music tracks were played in the background in shuffle mode, soft tone from a MacBook Pro Computer (Apple, Inc) through a HV-SF5626BT external speaker (Havit Inc) while the control group had the stages progress without musical intervention.

After the surgical armamentarium was set, music delivery was switched to Havit Bluetooth Touch headphone (HAVIT 160) from the same MacBook Pro Computer (Apple, Inc) interrupted by a switch tone signal. Local anaesthesia was achieved with 2% Lidocaine 1:100,000 epinephrine based on the 1.8mL cartridge within the 7mg/Kg maximum acceptable dose range. The transalveolar extraction of the index tooth was done by the same surgeon and the procedure progressed adopting the buccal approach technique using rotary instrument. The music administration continued till placement of the last suture (3/0 Vicryl), after which background soft music was recommenced via the external speaker. Postoperative instructions were given in a written note and patient was discharged home on Cap: Amoxil (GlaxoSmithKline) 500mg 8hourly for 5 days, Tab: Flagyl (Sanofi Aventis) 400mg 8hourly for 5 days and Tab: Clofenac (Hovid) 50mg 12hourly for 3 days.

For both groups, blood pressure, pulse rate, respiratory rate were recorded at the following points: at arrival (baseline), one minute after informed consent, at administration of local anaesthetic, after administration of local anaesthetic, two-point record during disto-buccal guttering (DBG, 45 seconds and 90 seconds after commencement of osteotomy), at tooth delivery and at the immediate postoperative period (one minute after the last stitch). The vital signs reading was automated but records of the automated reading were transferred to the proforma by the trained assistant while timing was measured from clock app of an I-phone 6 (Apple Inc.).

The data collected were entered into computer spread sheet using IBM SPSS version 20 software (IBM Inc.). The primary outcome variables are the systolic blood pressure, diastolic blood pressure, pulse rate and respiratory rate of participants, at intervals. Descriptive statistics including means and standard deviation was used to describe age, body mass index, systolic and diastolic blood pressure, pulse rate, respiratory rate and temperature that were analysed in the study.

Normality of data distribution was tested using Shapiro-Wilk test. Student t-test was used to compare mean for quantitative variables between the groups. The chi-square test was used to compare proportions and to investigate association between categorical variables such as depth and type of impaction, difficulty index. Statistical significance was defined at $p<0.05$.

RESULT

Sociodemographic characteristics of participants

Participants in the music and control groups show similar sociodemographic characteristics in terms of age, body mass index, level of education and occupation. The gender was equitably distributed between groups. Details of the sociodemographic characteristics of the participants are described in Table 1.

Baseline features of impacted mandibular third molars under study.

There was a higher proportion of left molar than right molar tooth disimpactions among both groups with 38(52.1%) and 40(54.8%) in the music and non-music groups respectively. Mesioangular impactions were the most common in the two groups accounting for 37% in the music group; 45.2% in the non-music group.

The indication for extraction was pericoronitis in 70(95.9%) of study participants in each of the groups. There was no statistically significant difference between the terms of surgery of the two groups, suggesting that the baseline characteristics of the third molars under study were not different. Details of the distribution of terms of surgery among study participants is shown in Table 2.

Baseline values of outcome variables

The baseline values of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Pulse Rate (PR), Respiratory Rate (RR) and Temperature are within normal clinical range. There is no statistically significant difference in the baseline values of outcome variables in this study as shown in Table 3.

Duration of Surgery

The duration of surgery is comparable between groups both in terms of range and mean. The mean duration from the time of first incision to the time of last stitch was 28.14±12.32minutes for the music group and 29.76±12.31minutes for the non-music group.

Table 1: Distribution of sociodemographic characteristics of study participants

Continuous Variables	Music N=73	Non-music N=73	Total	p-value
Mean age in years (SD)¶	29.1(9.9)	30.8(9.7)	29.87(9.34)	0.288
Age range in years	21.0-55.0	21.0-53.0	21.0-55.0	
Mean BMI* (SD)¶	23.6(4.1)	23.9(4.4)	23.73(4.3)	0.722
Categorical Variables				
Sex (%)†				0.254
Male	36(49.3)	37(50.7)	73(50)	
Female	37(50.7)	36(49.3)	73(50)	
Age range in years (%)†				0.552
21-25	33(45.2)	27(37.0)	60(41.1)	
26-30	18(24.7)	21(28.8)	39(26.7)	
31-35	7(9.6)	6(8.2)	13(8.9)	
36-40	6(8.2)	7(9.6)	13(8.9)	
41-45	2(2.7)	4(5.5)	6(4.1)	
46-50	5(6.8)	2(2.7)	7(4.8)	
51-55	2(2.7)	6(8.2)	8(5.5)	
Level of Education (%)†				0.339
Secondary	3(4.1)	3(4.1)	6(4.1)	
Tertiary	52(71.2)	54(74.0)	108(74.0)	
Postgraduate	18(24.7)	16(21.9)	34(23.3)	

No statistically significant difference between the two groups (p>0.05)

**BMI = Body Mass Index in kg/m^2 ¶ Student t-test analysis † Chi-square analysis*

Table 2: Distribution of baseline features of extracted third molar among study participants

Variables	Group		χ2 test	p-value
	MusicN(%)	No music N(%)		
Oral location of tooth			0.110	0.434
Right Molar	35(47.9)	33(45.2)		
Left Molar	38(52.1)	40(54.8)		
Previous Third Molar Surgery			0.033	0.500
Yes	22(30.1)	21(28.8)		
No	51(69.9)	52(71.2)		
Pederson Difficulty Index			1.161	0.762
3.00	2(2.7)	3(4.1)		
4.00	16(21.9)	15(20.5)		
5.00	26(35.6)	21(28.8)		
6.00	29(39.7)	34(46.6)		
Indication for extraction			6.000	0.999
History of Pericoronitis	70(95.9)	70(95.9)		
History of Pulpitis	0	2(2.7)		
Prophylaxis	0	1(1.4)		
Orthodontics	1(1.4)	0		
History of Dentoalveolar abscess	2(2.7)	0		

Table 3: Outcome variables at baseline

Time interval	Group		t- test	p-value
	Music Mean±SD	No music Mean±SD		
Baseline SBP (mmHg)	131.2±13.3	130.5±20.5	0.235	0.815
Baseline DBP (mmHg)	83.1±10.7	80.6±11.8	1.344	0.181
Baseline PR (beat/min)	84.0±13.6	82.3±12.5	0.790	0.431
Baseline RR (cycles/min)	19.3±4.6	19.2±4.5	0.126	0.900
Baseline Temperature (°C)	36.6±0.7	36.7±0.7	0.057	0.955

No statistically significant difference between study groups at baseline p>0.05
Using Shapiro-Wilk test, baseline data is normally distributed p>0.05

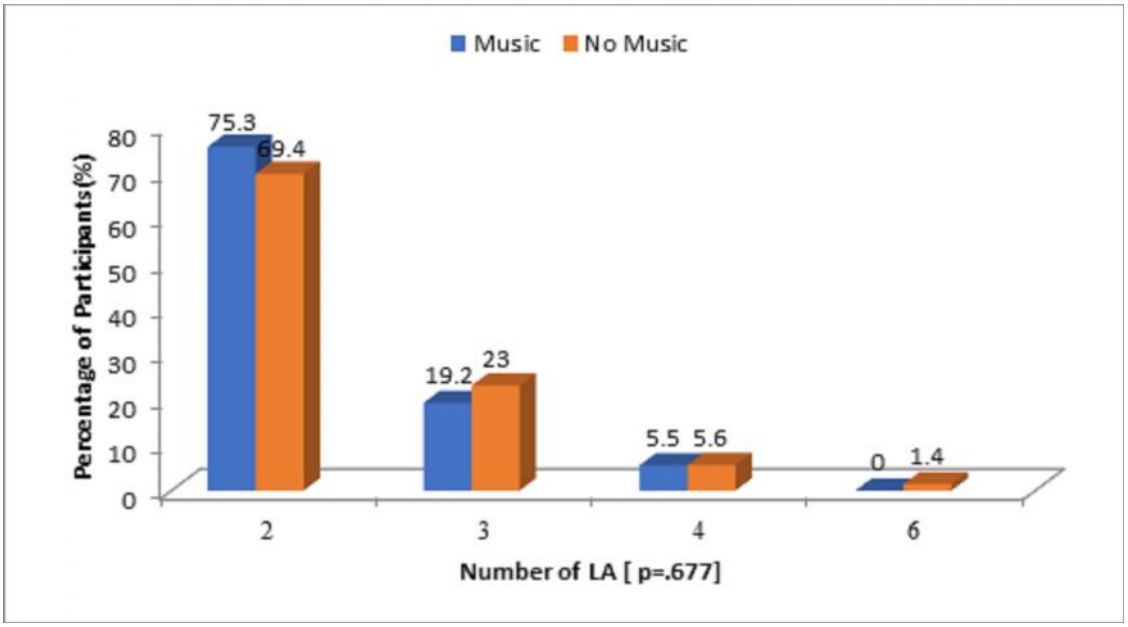

Figure 1: Distribution of number of Local Anaesthetic (LA) used among the two groups

Table 4: SBP at different time intervals among study participants.

Time interval	Group		t- test	p-value
	Music Mean±SD (mmHg)	No music Mean±SD (mmHg)		
At arrival (baseline)	131.2±13.3	130.5±20.5	0.235	0.815
1-minute after consent	131± 13.9	131.5±15.3	0.181	0.857
During LA admin	134.4±16.6	134.3±17.3	0.018	0.986
After LA admin	134.4±15.7	135.2±17.3	0.291	0.772
45 seconds intra-DBG	142.3±17.7	140.4±17.9	0.672	0.503
90 seconds intra-DBG	136.2±27.0	138.2±17.3	0.545	0.586
At tooth delivery	137.9±17.67	139.8±16.6	0.666	0.506
1-minute after last stitch	132.8±14.8	134.0±15.7	0.448	0.655

Table 5: DBP readings at different time among study participants.

Time interval (Diastolic BP)	Group		t- test	p-value
	Music Mean±SD (mmHg)	No music Mean±SD (mmHg)		
At arrival (baseline)	83.1±10.7	80.6±11.8	1.344	0.181
1-minute after consent	82.6± 10.7	79.9±11.6	1.538	0.126
During LA admin	83.3±14.7	81.5±11.1	0.836	0.404
After LA admin	83.4±11.6	80.0±13.6	1.584	0.115
45 seconds intra-DBG	87.2±12.3	84.8±10.5	1.299	0.196
90 seconds intra-DBG	84.6±16.0	83.9±10.6	0.341	0.734
At tooth delivery	86.3±13.6	85.4±12.3	0.412	0.681
1-minute after last stitch	83.9±11.5	84.1±11.8	-0.100	0.920

Table 6: Pulse rates (in beats per minutes) at different time intervals among study participants

Time interval	Group		t- test	p-value
	Music Mean±SD	Non-music Mean±SD		
At arrival (baseline)	84.0±13.6	82.3±12.5	0.790	0.431
1-minute after consent	82.8± 13.0	80.7±12.6	0.973	0.332
During LA admin	85.9±14.4	83.3±15.2	1.064	0.289
After LA admin	85.9±13.8	84.8±14.4	0.457	0.649
45 seconds intra-DBG	86.6±14.2	84.1±13.0	1.120	0.264
90 seconds intra-DBG	83.2±19.5	81.9±13.9	0.464	0.643
At tooth delivery	82.2±11.9	79.9±12.4	1.121	0.264
1-minute after last stitch	80.3±12.0	78.2±11.3	1.075	0.284

Amount of local anaesthetic agent used

Lasting anaesthesia was achieved with two cartridges of 2% Lidocaine 1:100,000 Epinephrine (1.8mL) in 75.3% and 69.4% of music and non-music groups respectively. On the other hand, minority of participants in both music and non-music groups required additional top up doses for maintenance of anaesthesia through the procedure as shown in Figure 1. The difference in the number of local anaesthetic cartridges used was not statistically significant (p=0.677).

Pattern and Distribution of Vital Signs Changes

Systolic blood pressure (SBP) readings were obtained from all study participants in the two randomized groups and at different time intervals. At arrival, the mean systolic blood pressure (SBP) of participants in the music group was 131.2±13.3mmHg versus 130.5±20.5 mmHg in the non-music group. The difference between groups at every interval was marginal and not statistically significant Table 4. Peak reading was obtained at 45 seconds intra-DBG for

the music group and at tooth delivery for the non-music group. (Table 5).

The mean pulse rate of participants is shown in Table 6. Changes in the mean pulse rate between groups was marginal and no statistically significant difference was observed between the two groups. The mean respiratory rate in the music and non-music group only shows minimal changes across intervals within each group (Table 7).

It was observed that SBP increased gradually in this study and reached a peak at 45 seconds after commencement of distobuccal guttering (osteotomy) after which the value decreased till placement of last stitch, in the two groups. Similar to the finding in this study the mean values of SBP in the study by Kim *et al.*[6] increased gradually and reached a peak. The difference however is that the SBP reached a peak at the time of injection of local anaesthetic and the beginning of incision in the study by Kim *et al.*[6] contrary

Table 7: Comparison of mean respiratory rates (in cycles per minute) at different time intervals among study participants

Time interval	Group		t- test	p-value
	Music Mean±SD	No music Mean±SD		
At arrival (baseline)	19.3±4.6	19.2±4.5	0.126	0.900
1-minute after consent	18.5± 4.7	18.6±5.3	-0.111	0.912
During LA admin	18.7±5.3	18.7±5.3	0.036	0.971
After LA admin	18.5±4.3	19.0±5.1	-0.613	0.541
45 seconds intra-DBG	19.3±5.5	18.0±4.2	1.592	0.114
90 seconds intra-DBG	20.2±4.5	18.2±3.8	1.490	0.139
At tooth delivery	19.4±3.0	18.3±4.5	0.828	0.409
1-minute after last stitch	19.2±3.9	18.0±5.3	0.711	0.478

DISCUSSION

This study sets out to evaluate the effect of music administration on blood pressure, pulse rate and respiratory rate during impacted mandibular third molar surgery. The study showed that relaxing music has no significant impact on haemodynamic changes during third molar surgery. Music therapy is used in different fields of medicine and its use has been compared with control groups at various stages of surgical treatment.[15] The literature reported conflicting outcomes on the effect of music in lowering blood pressure and heart rate.[16]

Dental treatment evokes pain, anxiety and nervousness which can cause acute autonomic nervous activities and these acute fluctuations affect circulatory dynamics resulting in complications and vagal reflex.[17] Different studies have attempted to investigate the effect of music as adjunct to routine preparation on haemodynamic changes in various types of surgeries including third molar surgery.[6,18–21] Some studies suggest that music may have some effect on systolic blood pressure (SBP) without having significant effect on diastolic blood pressure (DBP) and vice versa.[6,16,20] Other studies have highlighted separately or jointly the effects of music on other vital parameters like the heart rate and respiratory rate in patients with conflicting results.[18,22]

to the peak mean SBP values reached 45 seconds after commencement of distobuccal guttering in the current study. Anxiety may result from sudden experience of deep vibration of the rotary handpiece used for the procedure. Furthermore, the SBP declined gradually after a peak till placement of last stitch in the current study unlike the study by Kim *et al.*[6], where the SBP plateaued until time of suturing. There was no statistically significant difference in the SBP at the various stages of the third molar surgery, from commencement of procedure to placement of last stitch in this study suggesting that music administration has no effect on systolic blood pressure changes during third molar surgeries. This supports earlier finding by Kim *et al.*[6]

For some patients, 'anticipation syndrome' cause fear of dental needles and burs with subsequent acute haemodynamic changes which stabilizes with time.[23] Brand and Abraham-Inpijn[24] noted that cardiovascular system continuously adapts to internal and external stimuli thus explaining the pattern of SBP changes in this study. It was reported that a visit to the dental surgery induces an increase in SBP of about +13mmHg and DBP of about +5mmHg higher than in the outpatient medical clinic or when compared with the day after receiving dental treatment.[24] This

underscores the body's physiologic ability to adapt after initial haemodynamic changes associated with dental treatment, with or without music intervention.[24] As in SBP, there was no significant difference in DBP between the experimental and control groups at all stages of surgical procedure ($p>0.05$) in agreement with other similar studies.[6,17,18] There was similar sharp rise in the DBP at 45 seconds after commencement of distobuccal guttering followed by a gentle tapering till the end of procedure. This study established that music confers no advantage on participants' SBP and DBP.

Kim *et al.*[6] explained some possible aetiologies for the rise in the blood pressure at the early intraoperative phase which may have no bearing on the environment of surgery. First, it was proposed that increases in the blood pressure, heart rate and respiratory rate may be caused by the anaesthetic solution which often contains a vasoconstrictor.[6,25] Brand and Abraham-Inpijn[24] confirmed this theory by showing that DBP decreased after injection of local anaesthetic without constrictor whether or not music was administered. This agrees with an earlier study by Salonen *et al.*[26] who evaluated the effect of the adrenaline in lidocaine mixture on plasma catecholamines, heart rates and blood pressure. It was further postulated that endogenous adrenalin release caused by pain reflex to injection could be responsible for the sudden rise in the blood pressure at this stage.[6] A combined effect of the sharp pain of injection and decreased pain threshold associated with stress and fear induced by rotary instrument may explain the rise of participants' blood pressure in the early phase of the surgery. The finding in this study agrees with Kim *et al.*[6], Salonen *et al.*[26] and Huang.[18] Huang[18] conducted a clinical study on music intervention in the extraction of mandibular impacted third molar among 53 patients who were randomly assigned into music and non-music groups. The author found no significant differences in blood pressure between the two groups as in this study. The current study also agrees with an earlier report on SBP, DBP and heart rate during total knee arthroplasty.[27]

In contrast, Liu and Petrini[28] reported statistically significant reduction in the systolic blood pressure after thoracic surgery between music and non-music group. The type of surgery and extent of bone removal may therefore have significant effect as previously highlighted on haemodynamic changes observable when music is used as a form of therapy in surgery.

In recent studies, heart rate (or pulse rate) variability has been reported to be a useful calibrator for monitoring autonomic changes during dental treatments.[17,29–31] This study however showed that there was no statistically significant difference in the pulse rate between the music group and control in agreement with studies conducted by Yamashita *et al.*[17] and Huang.[18] Yamashita *et al.*[17] conducted a randomised clinical trial with a study population of forty women between 20 and 40 years of age. The study participants were randomised into music and non-music groups. Yamashita *et al.*[17] found that there were no relevant intra- and inter-group differences in the heart rate of both music and control groups notwithstanding same sex study population. Kim *et al.*[6] also found no statistically significant difference in patient's heart rate at rest, and during extraction of third molar in a study population of 219 comprising 59 male and 47 female participants in the music group; 63 male and 50 female participants in the control group. This study therefore further adds to existing evidences that music has no effect on patient heart rate or pulse rate during third molar surgery. An earlier study demonstrated that the technique of achieving anaesthesia could influence amount of changes in the heart rate during dental treatment with infiltration achieving more optimal changes than block analgesia.[24]

Respiratory rates at various stages of surgery in this study do not appear to be affected by music intervention as in other vital signs ($p>0.05$). This finding supports a previous study by Huang.[18] The mean values of respiratory rate in studies that assessed respiratory changes in third molar surgery showed that values were still within normal limits. When Kim *et al.*[6] adjusted for changes in respiratory rates from baseline, however, the study showed significant changes between the experimental and control groups ($p=0.012$). It is difficult to make inferences on the result of the study by Kim *et al.*[6] as the method of analysis failed to compare the mean values of respiratory rates at each stage of the study. In contrast, the study participants in this study had similar baseline values for vital signs and other outcome variables. Due to the limited number of studies in the literature that assessed effect of music on respiratory rate during third molar surgery, further comparison was difficult. Yamashita *et al.*[17] in a study to evaluate the effects of music listening during third molar surgery on autonomic nervous system and psychological state did not assess the effect of music on respiratory rate.

CONCLUSION

From the findings of this study, music therapy does not have significant effect on changes in blood pressure, respiratory and pulse rates of patient during mandibular third molar surgery.

CONFLICT

There is no conflict to declare.

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