Original Article

"Adjunctive Effects of a Short Session of Music on Pain, Low-mood and Anxiety Modulation among Cancer Patients" – A Randomized Crossover Clinical Trial

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Abstract

Aims: Pain, a distressing symptom frequently suffered by cancer patients, is inherently associated with anxiety and depression yet often not alleviated with pharmacotherapy alone. This study was aimed at assessing the effect of an instrumental classical music listening session as an adjunct to the ongoing therapies, on pain, anxiety, and mood modulation in cancer patients. **Materials and Methods:** A randomized crossover open clinical trial was designed involving adult resident patients suffering pain at a tertiary cancer care institution. The same group of patients ($n = 24$) were monitored for selected outcomes without (day 1) and then with administration of music (day 2). The primary (subjective) outcomes such as pain, anxiety, and mood levels measured on visual analog scale and surrogate (objective) parameters such as pulse rate, systolic blood pressure, diastolic blood pressure, respiratory rate, and pupillary size monitored were compared utilizing paired-sample *t*-test. **Results:** Statistically significant improvements were noted in all three subjective parameters; pain and anxiety were significantly diminished until the 4th h ($P = 0.007$ and $P = 0.0022$, respectively), while low mood remained alleviated until the 12th h reading point ($P = 0.007$). Statistically significant reductions were present in surrogate end points such as pupillary size ($P = 0.003$ up to 12 h) and respiratory rate ($P = 0.01$ up to 8 h). Declines noted in the heart rate, and blood pressure readings were statistically insignificant. None suffered deterioration of their existing well-being. **Conclusions:** Hence, we conclude that culturally familiar instrumental classical music demonstrates a significant effect in alleviating pain, anxiety, and low mood as an adjunct to on-going therapies in cancer patients.

Keywords: Anxiety, cancer pain, depression, mood, music therapy, palliative care

Introduction

"Pain" is an unpleasant and a distressing feeling that affects humans physically and on occasions psychosocially. Fifty percent of all cancer patients suffer pain, while this proportion rises to 75% among those with advanced cancer.[1] Particularly, in cancer patients, the pain they suffer is closely accompanied by low mood and anxiety,[2] collectively, leading to a poor quality of life.

Cure from cancer is not a realistic goal in all instances. Relieving the patients of their symptoms seems to be a more realistic and feasible task in the majority of cases. Despite the compelling evidence to the fact that pain can be successfully alleviated in 90% of cancer patients,[3] a recent review of published literature estimated that one in every two patients were inadequately treated for cancer-related pain.[1]

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The range of physical and psychological adverse effects of pain relief medications results in impairment of quality of life. This accounts for refusal of those drugs by patients and reluctance of health-care staff to prescribe or administer such medicine.[4-6] Fear of addiction and myriad other

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misconceptions borne by health-care staff and patients about the use of narcotic analgesics in terminal illnesses has also jeopardized prescription rates.[7] The development of tolerance and dependence for analgesics are known to potentially worsen pain with prolonged administration.[8] Weiss *et al*. revealed that 50% of terminal cancer patients experienced moderate-to-severe pain of whom only 30% wanted additional treatment than opioids.[6]

A range of nonpharmacological interventions reports varying degrees of success in cancer pain management, which include breathing and relaxation techniques, distraction therapies, hypnotherapy, imagery, heat or cold application, massage, pressure, vibration, and transcutaneous electrical nerve stimulation.[3,9,10] Included among these is music therapy which has been identified to have a consistent therapeutic benefit on alleviation of pain of all origins.

Music is a universal language and a multifaceted phenomenon that entails physical, emotional, cognitive, and social elements that affects people on an individual basis.[11] Music had been used for its therapeutic effects since millennia ago, of which the earliest references date back to the 5th century BC in the era of the philosophers – Plato, Socrates, and Aristotle.[12,13] They believed in the ability of music to communicate the emotional states of humans. Music has been suggested to stimulate more parts of the brain than any other human function, explaining the magnitude of belief and interest in research on music therapy.

In Canada, C. E. Dobek has assessed the effects of music on the pain response in central nervous system using functional magnetic resonance imaging. It is considered a highly accurate means of ascertaining the levels of pain experienced by people in an objective manner. It was confirmed that the emotional valence of music affects neural activity in the brainstem and spinal cord. Subjective pain ratings were significantly lower when painful stimuli were co-administered with music than without music.[11]

A study by SL Beck on the effect of the therapeutic use of music on cancer-related pain and low mood measured these dimensions on visual analog scale (VAS). The effect of music on pain demonstrated significant inter-individual variations. Seventy-five percent showed "some" response of which 47% demonstrated a "moderate" to "great" response.[14]

Aforementioned international literature suggest that music has a significant effect on pain relief. In Sri Lanka, one publication revealed how Indian classical music significantly reduced blood pressure, pulse rate, and respiratory rate in asymptomatic individuals.[15] The same group of researchers in other studies found that Indian classical music has a significant effect in relieving the symptoms and improving exercise tolerance quality of life of patients with stable angina.[16-18]

Aims

Cancer patients experience pain, anxiety, and low mood, together with symptoms of related sympathetic overactivity (such as raised pulse rate, blood pressure, pupillary size, and respiratory rate).[19-23] Our study aimed to fill the gap in knowledge about the potential effect of culturally appropriate instrumental classical music on the alleviation of these symptoms and signs among a cohort of cancer patients in Sri Lanka.

Two related randomized controlled clinical trials conducted by Brazilian and Taiwanese investigators exclusively looked at the immediate effects of music.[24,25] They stressed the importance of determining the longevity of the effects of music on pain. Hence, our study also attempts to establish as to how long do the beneficial effects of music last on each of the subjective and objective parameters, if at all.

Materials and Methods

Study design

This randomized, controlled, open, interventional, crossover clinical trial[26] was conducted to assess the effect of culturally familiar instrumental classical music on pain, anxiety, and low-mood modulation.

Study population

Adult resident cancer patients older than 12 years at a major tertiary care cancer institute of Sri Lanka who essentially suffered basal levels of pain (i.e., at least 1/10 on VAS) for a duration >12 weeks were included in the study.

Those who were subconscious (Glasgow Coma Scale short of 15),[27] confused or irrational, suffering auditory impairment, not able to communicate, not suffering pain, and not on regular analgesics at all were excluded from the trial. Those whose discharge was planned within 48 h of commencement of the study and patients of surgical wards were also excluded.

Of the included patients, those who suffered "incident pain" due to interventions, activity, or mobilization, those who received additional potent analgesics or opioids to manage breakthrough pain, whose analgesic regimens altered during the course of the 48 h concerned and whose mental status deteriorated unexpectedly were planned to be removed from further assessment although the fact that such attrition did not occur.

Randomization and sample size calculation

Calculated sample size was 21 in relation to the primary outcome measures (minimum value = 0, maximum value = 10, minimally significant difference = 2, standard deviation [SD] = 10–0/4 = 2.5 and expected difference/SD = 2/2.5 = 0.8 for a confidence interval (CI) of 95%).[28] We included 24 (21 + 3) patients in the study by simple randomization of which 50% were women.

The researchers took steps to identify all the patients meeting the inclusion criteria in the oncology units who were given a unique identification code. Of the total of 68 patients in the three oncology units on the initial day, 29 patients were deemed ineligible. All the remaining 39 consented participation. Twenty-four patients were selected out of the 39 eligible

patients as illustrated in Chart 1 through computer-assisted simple randomization.

Interventions

There were two arms concerning this study carried out in May 2017. In this open trial, the same group of patients were subjected initially to "control" and subsequently to "intervention" phase, thus conforming to the crossover design.

Duration of assessment

A pilot study on this population involving eight patients revealed that the duration of the effect of music on each measured parameter varied and none persisted beyond 12 h. Hence, it was decided to conduct the study to assess the said parameters periodically over 24 h following exposure to music in an aim to assess the existence of an effect and if so the duration of effect for each parameter.

Depending on the duration of effect on each parameter and the symptomatology of individual patients, the frequency of listening to music was expected to be justified in the future practice.

Measurements

The primary (subjective) parameters such as pain, anxiety and grief were measured on VAS which is an accepted tool with cross-cultural validity[29] augmented with WongBaker Faces Pain Scale.[30] The addition of the latter scale improves the comprehension by individuals with marginal cognitive and mathematical abilities.[31] The VAS is primarily meant to assess the intensity of pain.[32] Nevertheless, there is a wealth of evidence now, for its use in the assessment of the degree of anxiety and low mood for which the tool has been validated.[33]

Since it was required to assess the cohort of patients 4 hourly over 48 h, the assessment tool had to be simple and least disruptive to the patients. Therefore, we did not use exhaustive questionnaires such as Brief Pain Inventory,[34] Hamilton Anxiety Rating Scale,[35] or Beck's Depression Inventory.[36]

The values for objective/surrogate measures, i.e., palpated radial pulse rate, systolic and diastolic brachial arterial blood pressure read by mercury sphygmomanometry, respiratory rate measured visually, and pupillary size observed visually under moderate daylight were also recorded.

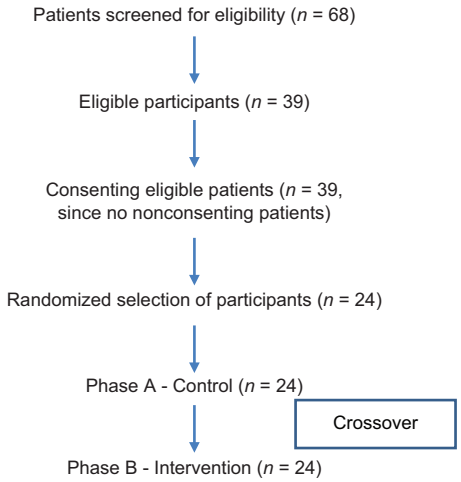

Chart 1: Participant flow

Choice of music

International researchers employed culturally familiar musical compositions for therapy in respective regions for which T. Sathish Kumar in India utilizing Carnatic music and L. Rafer in the USA utilizing Jazz music are examples.[37,38] The music used in our study was composed by two esthetically qualified Sri Lankan composers with Western, South Indian, and Persian influence. This selection was made to ensure the cultural familiarity of the musical styles to the predominant ethnic groups – Sinhalese (74.5%), Tamil (11.15%), and Moor (9.4%) of Sri Lanka. Lyrics were not used in the composition to avoid the potential dimension of "literal meaning" acting as a confounder.

Phases

Phase A

On the 1st day, basal scores for the parameters were recorded at 08:00 AM. From 08:00 to 08:30 AM patients continued to lie in bed with their eyes gently blindfolded while they wore earplugs. After 08:30 AM, they were instructed to engage in their daily routines. The same parameters as above were recorded immediately after the rest (08:30 AM) and 4 hourly thereon.

Phase B

The same group of patients moved onto Phase B the following day, where the parameters were documented at 08:00 AM. From 08:00 to 08:30 h, patients lay in bed with their eyes gently blindfolded while they listened to a 28-min long music clip through an MP3 player with earphones that limited external noise. The volume was adjusted to a level indicated as comfortable by the patient. The parameters as above were recorded at the same time points as the previous day.[31-33]

There was no attrition (fallouts) of study participants. Once 100% of the sample had satisfactorily completed 48 h, further recruitments were deemed unnecessary.

Statistical analysis

Demographic data of the participants were described in terms of percentages. Paired sample *t*-test[39] was used to compare the chronologically corresponding values (16:00 h with 16:00 hrs^{+1Day}) read for individual parameters on the 2 consecutive days. This statistical procedure was intended to determine whether or not there was a mean difference in the values between Phase A (control) and Phase B (intervention). Thereof, it was aimed to assess whether the data provided evidence as for superiority of administration of classical music to conventional therapy alone in terms of symptomatic relief subjectively and the clinical parameters measured objectively. Further, the duration up to which each effect lasted (significantly) was also ascertained.

Ancillary analysis was aimed at assessing the presence of a significant difference in the measured effects, based on

the patients' age, sex, and ethnicity, whether or not enjoyed listening to music and level of baseline pain.

Results

None of the patients discontinued the study owing to administrative reasons, adverse effects, lack of therapeutic efficacy, or their autonomous choice. Once 100% of the sample had satisfactorily completed 48 h, further recruitments were deemed unnecessary.

Patient demographics and baseline characteristics are illustrated in Table 1. The patients represented equal gender compositions, significant range in age, and all majority Sri Lankan races. Patients who suffered different levels of pain, receiving all levels of analgesics, patients who regularly enjoyed listening to music, those who did not, those aversive toward pain killers and those who were not were also included. The leading types of malignancies were gastrointestinal, respiratory, gynecological and endocrine. A third had advanced stage of cancer with distant spread.

Table 1: Patient demographics, characteristics, baseline pain levels, and analgesics (*n*=24)

Variable	Value(s)
Age, years	
Mean	53.33
Range	38-80
SD	10.11
Sex, *n* (%)	
Male	12 (50)
Female	12 (50)
Ethnicity, *n* (%)	
Sinhalese	17 (70.83)
Muslim	2 (8.33)
Tamil	2 (8.33)
Burgher	1 (4.16)
Level of baseline pain on day 1/arm A (in accordance with VAS pain level categories,[31] *n* (%)	
Mild (1-3/10)	3 (12.5)
Moderate (4-6/10)	8 (33.33)
Severe (7-10/10)	13 (54.16)
Analgesics (levels of analgesia provided according to the WHO analgesic ladder[32]	
WHO analgesic ladder 1	3 (16.66)
WHO analgesic ladder 2	5 (20.83)
WHO analgesic ladder 3	8 (33.33)
Additional use of adjuvants	8 (33.33)
Adjuvants (dexamethasone) alone	8 (33.33)
Patients who usually enjoy listening to music, *n* (%)	20 (83.33)
System involving primary malignancy, *n* (%)	
Hematological	1 (4.17)
Respiratory tract	3 (12.5)
Gastrointestinal	11 (45.83)
Gynecological	3 (12.5)
Endocrine	3 (12.5)
Male reproductive	1 (4.17)
Musculoskeletal	2 (8.33)
Metastatic status	
Metastatic	8 (33.33)
Unknown/not-documented	16 (66.66)
Patients who thought analgesics were harmful overall, *n* (%)	4 (16.66)
Patients who disliked administration of analgesics, *n* (%)	1 (4.17)

WHO: World Health Organization, VAS: Visual analog scale, SD: Standard deviation

Primary end points

Analysis revealed a significant alleviation of all subjective symptoms immediately following administration of music. The levels of pain and anxiety remained significantly diminished until the 4th h reading point (P = 0.007, 95% CI: 3.716 to – 1.534 and P = 0.0022, 95% CI: – 2.465 to – 0.6184, respectively). The effect on depressed mood was significant until the 12th h post-administration (P = 0.007, 95% CI: −2.194 to − 0.3896) and was absent at the 24th h assessment point.

Surrogate end points

The modulation of objective parameters was estimated as secondary end points. The pupillary size was significant up to the 12th-h measurement (P = 0.0166, 95% CI: −0.6752 to – 0.0748) and the respiratory rate was reduced significantly for 8 h following listening to music (P = 0.0098, 95% CI: −0.0645 to − 1.981). The fluctuations observed in hemodynamic parameters (pulse rate and blood pressure) were statistically insignificant [Figure 1].

Ancillary analysis

In the ancillary analysis, it was revealed that the patients' age, sex, ethnic background or level of baseline pain experienced did not have a significant effect on the alleviation of pain, low mood, or anxiety with music. However, anxiolysis achieved in those who did not enjoy listening to music was significantly greater than those who did (P = 0.016).

Discussion

The participants representing the adult cancer patients receiving resident care at this tertiary care institution significantly benefitted from listening to the culturally sensitive, tranquilizing, instrumental classical music half-an-hour a day. The stated benefit was two folds in terms of all subjective parameters (pain, low mood, and anxiety) as well as related objective parameters (pupillary size and respiratory rate). The potential of music to touch the psychosocial elements of "total pain"[40] that the conventional drugs cannot practically reach may have a bearing on this additive effect.

Generalizability and limitations

Importantly, the session did not have any adverse effects attributed to have occurred due to music on the study population which included 4 participants (16.66%) who did not regularly listen to music. The only patient who continued to suffer 10/10 pain in spite of music therapy, having been offered the option to withdraw, opted to continue and did not report additional disturbance due to music or monitoring.

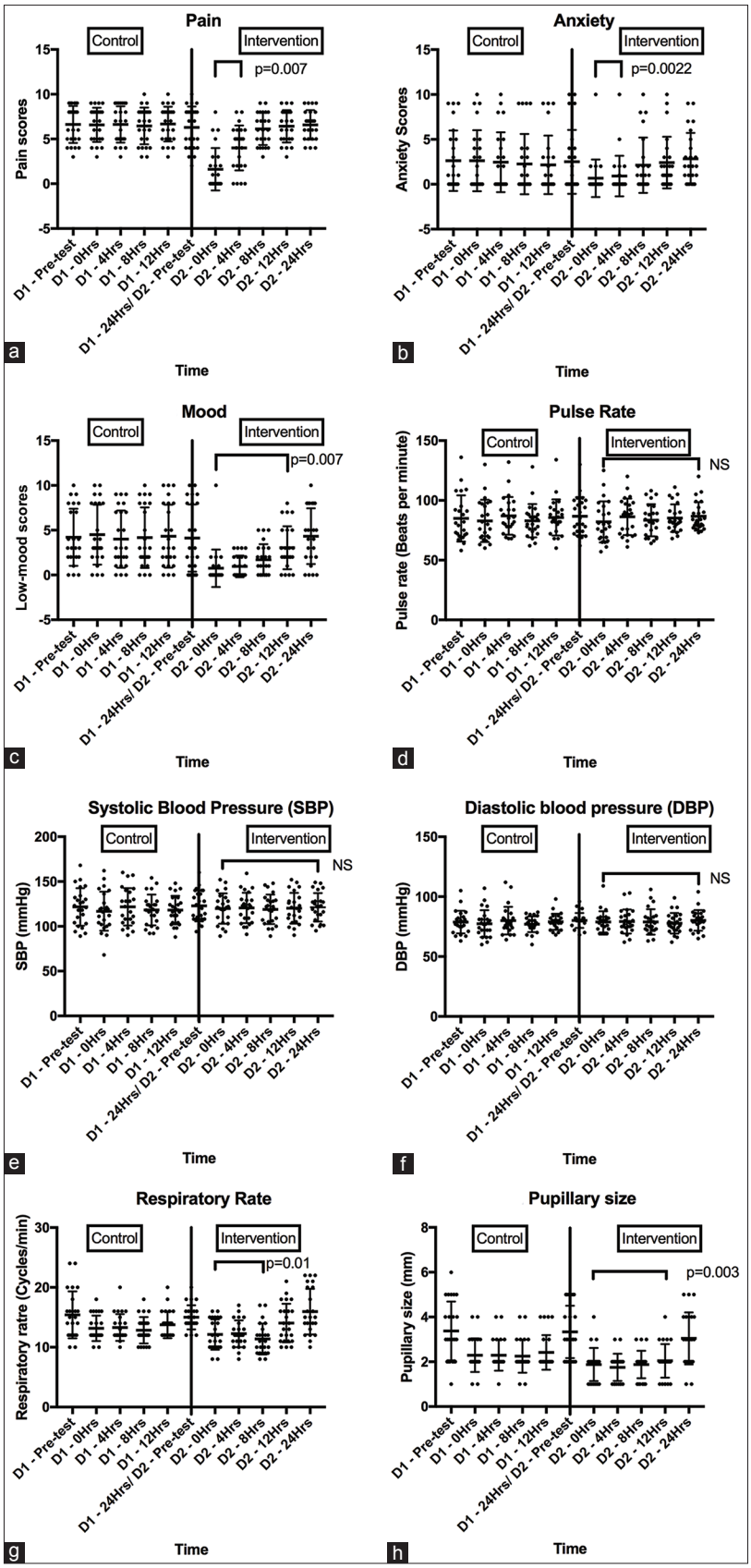

Figure 1: Variation of subjective and objective parameters along phase 1 (a) Intensity of pain (b) Degree of anxiety (c) Low-mood (d) Pulse rate (e) SBP (f) DBP (g) Respiratory rate (h) Pupillary size

Hence, music therapy can be justified to be safely applied to complement conventional symptomatic treatment of adult cancer patients through a common sound system.

As mentioned before, the musical composition was deemed culturally appropriate and tranquilizing by two qualified musicians, thus enhancing the generalizability to the Sri Lankan setting.

The investigators were careful to select equal numbers of patients from the two sexes. The aforesaid exclusions were made through consensus among the investigators that the primary outcomes (involving measurement of subjective parameters on VAS) will be an area poorly comprehended by those groups. The patients in the surgical wards were not included as the chance of occurrence of incident pain (e.g., due to wound dressings, mobilization, and procedures) was expected to be higher among them.

The patients could ideally have been assessed at all 4-hourly intervals following the control and intervention. However, it was decided not to monitor them at midnight and 04:00 AM with the intention of not disturbing their sleep. A statistically significant alleviation was noted both in low mood and pupillary size at 8 PM, and the effect had disappeared by 8 AM in the following morning. Hence, the duration of persistence of these effects which fell in between 8 PM and 8 AM could not be ascertained with precision.

Another perceived limitation was the Colombo (commercial capital of Sri Lanka)-based study setting. Nevertheless, patients from all regions of the island belonging to all educational and social strata receive care in this principle tertiary care state-operated cancer institution.

Conclusions

This study was able to demonstrate that a short session of culturally familiar, instrumental classical music is capable of alleviating pain, anxiety, and low mood in institutionalized cancer patients, complementing conventional symptomatic therapies.

There would be a scope to explore in the future studies, the degree to which symptom-relieving medications can be cut down with co-administration of music while achieving the same level of symptomatic relief. The effects of longer term periodical exposure to music and sensitivities of Sri Lankan population to different genres of music are other potential areas for future investigation.

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Conflicts of interest

There are no conflicts of interest.

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