Music as a sleep aid in fibromyalgia

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BACKGROUND: Interventions to improve sleep in fibromyalgia may generalize to improvements in multiple symptom domains. Delta-embedded music, pulsating regularly within the 0.25 Hz to 4 Hz frequency band of brain wave activity, has the potential to induce sleep.

OBJECTIVES: To assess the effects of a delta-embedded music program over four weeks for sleep induction in patients with fibromyalgia.

METHODS: The present unblinded, investigator-led pilot study used a within-subject design. Analysis was based on 20 individuals with fibromyalgia who completed the study, of the 24 recruited into the study. The primary outcome variables were the change from baseline in Fibromyalgia Impact Questionnaire (FIQ) and Jenkins Sleep Scale scores. A patient global impression of change was measured on a seven-point Likert scale. Secondary outcome measures, comprised of items 5, 6 and 7 of the FIQ, were used as indicators of pain, tiredness and being tired on awakening.

RESULTS: The FIQ median score of 76.4 (95% CI 61.3 to 82.1) at baseline improved to 60.3 (95% CI 53.1 to 72.0; P=0.004). The Jenkins Sleep Scale median value of 17.5 (95% CI 15.5 to 18.5) at baseline fell to 12.5 (95% CI 8.5 to 14.5; P=0.001) at study completion. The outcomes of the patient global impression of change ratings were mostly positive (P=0.004). Being tired on awakening declined significantly from a median of 9.0 (95% CI 8.0 to 10.0) to 8.0 (95% CI 5.5 to 9.0; P=0.021). However, there was no significant improvement in pain level (baseline median 7.5 [95% CI 7.0 to 8.5] versus study completion median 7.0 [95% CI 6.5 to 8.0]; P=0.335) or tiredness (baseline median 9.0 [95% CI 8.0 to 9.5] versus study completion median 8.0 [95% CI 6.0 to 8.5]; P=0.061). There were no serious adverse events.

CONCLUSIONS: Delta-embedded music is a potential alternative therapy for fibromyalgia.

Key Words: Delta embedded music; Fibromyalgia; Sleep disorders

Fibromyalgia is a common chronic pain disorder. In addition to the defining feature of widespread pain, the range of symptoms is wide (1). Common therapeutic approaches include medications, physical therapies, psychologically based therapies and complementary/alternative modalities (2). Nevertheless, the optimal management of fibromyalgia remains unclear (3).

Morning stiffness, fatigue and nonrestorative sleep were the three most intense symptoms identified in a large Internet survey (2596 respondents). Prescription sleep medications, resting and relaxation/meditation were among the interventions rated as most effective overall for fibromyalgia symptoms (4).

Poor sleep quality is a major feature of fibromyalgia, with >90% of fibromyalgia sufferers affected in some studies (5,6). In addition, sleep disturbances influence fatigue levels and social functioning (5), quality of life (7,8) and mood (9,10).

Sleep is dependent on, and characterized by, an increase in rhythmic oscillatory coherence resulting in a rise in electrocorticogram delta frequency band (0.25 Hz to 4 Hz). A regularly occurring auditory pulse at a frequency of 2 Hz has been shown to increase stimulus-locked oscillatory coherence at 2 Hz and boost delta activity (11). Music with an embedded persistent periodic stimulus at 2 Hz increases delta-band activity and has the potential to decrease sleep onset latency.

Treatment with sodium oxybate, primarily targeted to affect sleep, has been shown to have positive effects on fibromyalgia pain and other symptom domains (12-16). However, nonpharmacological measures could improve sleep quality (17) with fewer potential adverse effects.

A small number of studies have evaluated music in various forms in the treatment of fibromyalgia or chronic widespread pain (18-24). Music had a positive effect on some outcome measures in all of the cited studies, with one exception (20). However, no studies have addressed the use of music as a sleep aid in fibromyalgia.

METHODS

Participants
A total of 24 volunteer subjects recruited from the Wasser Pain Management Centre (Toronto, Ontario) provided written informed consent following approval by the Mount Sinai Hospital Research Ethics Board. The trial was conducted in accordance with the principals set out in the Declaration of Helsinki (25).

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Patients were instructed to complete a compliance calendar tracking the total duration of study (‘exposure days’), number of days on which the program was used (‘usage days’) and total number of applications. The changes from baseline in the FIQ and JSS and GIC-P were the primary end points.

Items 5 (“How bad has your pain been?”), 6 (“How tired have you been?”) and 7 (“How have you felt when you get up in the morning?”) of the FIQ were used as measures of pain, tiredness and being tired on awakening.

Information about medications and other therapeutic interventions were not systematically collected.

Statistical analysis

An open within-subject repeated-measures design was used. The demographic and clinical characteristics of completers versus noncompleters were compared using t-tests for equality of the means except for the sex ratios, which were compared using the χ2 test.

The Wilcoxon matched pairs test was used to compare baseline and completion values for FIQ, JSS and items 5, 6 and 7 of the FIQ. The Wilcoxon matched pairs test was applied to the GIC-P after imputing a baseline level of 4 (ie, ‘no change’). Correlations between selected measures were assessed using Kendal’s Tau-b test.

Outcomes were assessed for study completers using SPSS version 21.0.0.0 (IBM Corporation, USA) for data analysis, taking 5% as the significance threshold. CIs for medians were estimated by bootstrapping.

RESULTS

Principal findings

Compliance calendars were completed by 19 patients. Audio program use is summarized in Table 2.

The FIQ median score of 76.4 (95% CI 61.3 to 82.1) at baseline improved to 60.3 (95% CI 53.1 to 72.0; P=0.004). The JSS median value of 17.5 (95% CI 15.5 to 18.5) at baseline decreased to 12.5 (95% CI 8.5 to 14.5; P=0.001) at study completion.

With respect to the GIC-P ratings, one subject reported worsening while five reported no change and 14 reported varying degrees of improvement. Thus, the subjective responses were mostly favourable (P<0.001); Figures 1 to 3 illustrate the principal findings.

Secondary results

The pain level, measured on the Likert scale comprising question 5 of the FIQ, was not significantly altered (baseline median 7.5 [95% CI 7.0 to 8.5]) compared with the level at study completion (median 7.0 [95% CI 6.5 to 8.0]; P=0.335).

To be eligible, the subjects had to meet recently revised criteria for fibromyalgia (26). Subjects were required to attend both a baseline and a postcompletion data gathering session, read and write English adequately, have satisfactory hearing bilaterally (by self-report) for the appreciation of music and have the ability to operate the supplied listening device. Recruits were subject to exclusion if there was any objection of sleep/bed partner or family members to study participation or if there was a history of a seizure disorder.

No compensation was provided. However, participants were permitted to keep one copy of the supplied music program. Four participants did not attend the final assessment and were not included in the final analysis. None of the recruits were disqualified by the exclusion criteria. Table 1 details the demographic and clinical characteristics of the recruits.

Intervention

The study was of four weeks’ duration. Patients continued to receive usual care, which could vary through the course of the study. Participants were given a music program (‘Music to Promote Sleep’ on the Sonic Aid label by Somerset Entertainment) on an MP3 player. The program material was chosen specifically for its embedded content of mostly 2 Hz binaural beats. All participants received the same device and earbuds (Coby MP620-4GBLK, Coby Electronics Corporation, USA).

Subjects were instructed to initiate the audio selection at bedtime and continue at their individual discretion. Program repetition, ad libitum, in the event of awakening was permitted. Playback volume was adjusted to match the participant’s comfort level.

In the event of adverse reactions patients were advised to discontinue the intervention and report to one of the investigators.

Assessments and outcome measures

Demographic data comprising patient age, sex and fibromyalgia duration were collected for descriptive purposes. The Fibromyalgia Impact Questionnaire (FIQ) (27) and Jenkins Sleep Scale (JSS) (28) were administered at study initiation and as close as practicable to the end of week 4.

A patient global impression of change (GIC-P) was rated on a seven-point Likert scale (ranging from 1 [much worse] to 7 [much better]) at the final assessment.
Tiredness, as measured by question 6 of the FIQ, declined from a median of 9.0 (95% CI 8.0 to 9.5) to 8.0 (95% CI 6.0 to 8.5), but this change was not statistically significant (P=0.061).

Awakening tired versus rested, as measured on the Likert scale comprising question 7 of the FIQ declined significantly from a median of 9.0 (95% CI 8.0 to 10.0) to 8.0 (95% CI 5.5 to 9.0; P=0.021).

Table 3 summarizes the two-way correlations between selected study variables. There were particularly strong correlations between the change in FIQ and changes in tiredness, awakening tired versus refreshed and GIC-P (Kendal’s Tau-b correlation coefficients 0.557, 0.551 and 0.556; P=0.001, P=0.001 and P=0.002, respectively). Patients averaged 31.7±4.0 days on treatment (range 21 to 41 days).

Adverse events
No serious adverse events were reported. Two patients reported discomfort from the earbuds.

DISCUSSION
The present open-label study evaluated the impact of a tailored music program for sleep induction in individuals with fibromyalgia over a four-week period.

Self-reported, subjective sleep quality, as assessed by the JSS, showed a significant improvement. There were also significant improvements in the FIQ and GIC-P. However, there was no significant effect on pain, possibly reflecting both small effect and small sample sizes. Also, while being tired on awakening improved, there was no effect on overall tiredness.

No serious side effects were reported. Two participants (10%) reported discomfort from the earbuds. This was not anticipated and, hence, not evaluated systematically. The true numbers may have been higher.

Because of methodological differences, direct comparisons with other studies are not possible. However, the FIQ change from baseline in the

![Figure 2) Jenkins Sleep Scale (JSS), baseline and final values (box and whisker plot). Lower scores indicate better sleep quality.](image1)

![Figure 3) Response counts for patient global impression of change (GIC-P). Scores: 1 = Very much worse; 2 = Much worse; 3 = Slightly worse; 4 = No change; 5 = Slightly better; 6 = Much better; 7 = Very much better.](image2)
Deficient inhibitory pain modulation may play a role in fibromyalgia (49). Sleep quality, in turn, influences pain inhibition (50). Nevertheless, our findings suggest that improving sleep quality does not reduce the clinical pain of fibromyalgia. Our results are at variance with the findings of others (51) and may simply reflect inadequate statistical power to demonstrate a small effect. However, sleep quality may not be closely linked to pain intensity in fibromyalgia (52).

CONCLUSION
The present open-label pilot study supports a potential benefit of delta-embedded music in the treatment of fibromyalgia and fibromyalgia-associated sleep disturbances. The treatment appears to be safe and well tolerated.

Further research is needed to rule out a purely placebo effect, optimize the audio program, determine the best means of program delivery and integrate this potential therapy with other modalities, as well as assess the durability of the effect.

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DISCLOSURES: Dr Lee Bartel serves as a paid consultant for the scientific design of music recordings to Mood (formerly Somerset) Entertainment including Fisher Price recordings for children, the Solitudes ‘Music for Your Health’ series and the Sonic Aid series. He is not a composer or performer on these recordings. He receives no royalties for the Music for Your Health series. He receives limited (noncomposer or performer) royalties for Fisher Price recordings and the Sonic Aid series.


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