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Specific Music Therapy Techniques in the Treatment of Primary Headache Disorders in Adolescents: A Randomized Attention-Placebo-Controlled Trial

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Abstract: Migraine and tension-type headache have a high prevalence in children and adolescents. In addition to common pharmacologic and nonpharmacologic interventions, music therapy has been shown to be efficient in the prophylaxis of pediatric migraine. This study aimed to assess the efficacy of specific music therapy techniques in the treatment of adolescents with primary headache (tension-type headache and migraine). A prospective, randomized, attention-placebo-controlled parallel group trial was conducted. Following an 8-week baseline, patients were randomized to either music therapy (n = 40) or a rhythm pedagogic program (n = 38) designed as an "attention placebo" over 6 sessions within 8 weeks. Reduction of both headache frequency and intensity after treatment (8-week postline) as well as 6 months after treatment were taken as the efficacy variables. Treatments were delivered in equal dose and frequency by the same group of therapists. Data analysis of subjects completing the protocol showed that neither treatment was superior to the other at any point of measurement (posttreatment and follow-up). Intention-to-treat analysis revealed no impact of drop-out on these results. Both groups showed a moderate mean reduction of headache frequency posttreatment of about 20%, but only small numbers of responders (50% frequency reduction). Follow-up data showed no significant deteriorations or improvements.

***Perspective:** This article presents a randomized placebo-controlled trial on music therapy in the treatment of adolescents with frequent primary headache. Music therapy is not superior to an attention placebo within this study. These results draw attention to the need of providing adequate controls within therapeutic trials in the treatment of pain.*

***Key words:** Music therapy, primary headache, adolescents, attention placebo, randomized controlled trial.*

Music therapy is a psychology-based complementary therapy integrating listening to music (receptive music therapy), making music (active or interactive), or composing music (eg, song writing) into the therapeutic process. Music therapists aim to improve or sustain health in a large variety of domains (eg, emotional and affective development, cognitive functioning, and motor skills), settings (eg, clinical care, rehabilitation, and outpatient treatment), and clients (eg, children, adults, the elderly) with different health issues, predominantly with psychiatric or psychosomatic disorders. Despite a wide qualitative and quantitative research literature base, knowledge about the efficacy of specific music therapy techniques and underlying mechanisms is limited. With this study, we aimed to investigate the specific effectiveness of music therapeutic techniques—that have previously been evaluated within different designs—compared to a nontherapeutic music program in the treatment of primary headache disorders in adolescents.

Primary headaches such as migraine and tension-type headache (TTH) are of high prevalence in children and

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increase in frequency during adolescence, particularly in females.[1,43] For the acute treatment of migraine and TTH, ibuprofen for children (>6 years) and paracetamol and sumatriptan nasal spray for adolescents (>12 years of age) are effective and considered first choice.[14,42] Magnesium, beta-blocker, or flunarizine are recommend for an appropriate prophylactic treatment, but there is a lack of evidence for a clinical problem so prevalent.[42] Previous meta-analyses have revealed that psychological approaches (principally relaxation and cognitive-behavioral therapy) are effective in pain control[13] and lead to improvement of symptoms (especially headache frequency) in children and adolescents.[12,52,61]

Music therapy shows moderate effect sizes as an intervention for children and adolescents with heterogeneous psychopathology.[18] However, evidence that music therapy might be effective in the treatment of adults with headache[57] and children with migraine[49] comes from 2 studies, 1 of which was a randomized controlled trial. In the last-mentioned study, music therapy has been shown to be equally efficient to butterbur root extract (Petadolex; Weber & Weber, Biologische Arzneimittel, Inning, Germany) and superior to a drug placebo in reducing headache in children with migraine.[49] However, its specific treatment effect remains unclear since the nonspecific effect of psychotherapeutic treatments (eg, expectancy, relationship to therapist) accounted for about half of the total response in this study. Further evaluation in contrast to a psychological "placebo" (attention-placebo control) and research on the indicated specific components of music therapy interventions[19] is needed.[49] Furthermore, music therapy has not been evaluated in the treatment of other primary headaches (eg, TTH). Our group has recently developed manualized music therapy for adolescent primary headache disorders and published promising pilot data.[35] The aim of this study was to investigate the efficacy of specific music therapy techniques in adolescents with primary headache disorders (migraine or TTH) in a prospective, randomized, attention-placebo-controlled parallel group trial.

Methods

Study Design

A 32-week randomized, attention-placebo-controlled, 2-arm parallel-group study comprising a psychotherapeutic treatment (music therapy) and an equally dosed attention-placebo treatment (rhythm pedagogic program) was conducted at the School of Therapeutic Sciences in Heidelberg, Germany. The study consisted of 4 phases: an 8-week baseline assessment phase, an 8-week treatment phase (6 sessions of 90 minutes each), an 8-week posttreatment assessment phase (postline), and an 8-week follow-up assessment phase 6 months after the end of the treatment phase. The detailed study procedure is described in Fig 1. The study was performed in compliance with good clinical practice and followed the recommendations of the Declaration of Helsinki on biomedical research involving human subjects and the International Association for the Study of Pain's guidelines for pain research in humans.[9] The protocol was approved by the University of Heidelberg Ethical Committee and regulatory authorities. Because of imprecise effect sizes (large confidence intervals) within the pilot study,[35] the sample size was not determined by power analysis. According to a previous study on music therapy in the treatment of migraine[49] and funding possibilities, a sample size of a maximum of 100 participants within 5 blocks was determined. Periods of recruitment were scheduled 6 weeks ahead of the initial baseline assessment. Baseline assessment (6-week headache diary) for the blocks started on Monday as follows: block 1, January 11, 2010; block 2, March 22, 2010; block 3, May 17, 2010; block 4, September 13, 2010; block 5, January 24, 2011. Follow-up assessment (6-week headache diary) for the blocks started as follows: block 1, November 22, 2010; block 2, January 31, 2011; block 3, April 25, 2011; block 4, July 18, 2011; block 5, October 24, 2011. The trial was stopped as planned after the fifth block. Written informed consent was obtained from all patients and their parents before enrollment. Patients were allocated to 1 of the 2 treatment groups after baseline by computerized randomization (permuted block randomization) with 5 blocks. A maximum block size of 20 per block with an allocation ratio of 1:1 was set in consequence of the number of therapists available. All therapists were conducting both interventions. Randomization was accomplished by the fourth author (not involved in patient contacts or enrollment), who assigned the subjects that qualified for randomization to the treatment groups and therapists. Patients were enrolled by the first author (not involved in randomization or treatment of participants). Participants within 1 block that qualified for inclusion in the trial according to the predefined inclusion criteria were reported by the first author to the fourth author. Based on the total number of subjects eligible for inclusion within 1 block (block size), subjects were allocated equally (allocation ratio 1:1) by permuted block randomization using a random sequence generator to 1 of the groups and to a therapist depending on the therapist's workload at the time of randomization. Participants and their parents were informed that 2 variations of a music therapeutic treatment were compared within the study and that the researchers had no knowledge of their group assignment. Outcome assessors and statisticians were masked to group assignment. Treatment was offered free of charge for every participant. Participants were rewarded €5 for each week of keeping the diary (€40 for 8 weeks) and a bonus of €80 at the end of the study when completed questionnaires and diaries were submitted.

Participants

Patients were recruited within 5 cohorts (maximum of 20 each) through newspaper advertisements. To be eligible for the study, adolescents had to be between the ages of 12 and 17 years, with 1 or multiple diagnoses according to the International Headache Classification