Effectiveness of active music therapy for patients suffering from chronic pain

Thomas K. Hillecke³, Anne K. Nickel¹, Alexander F. Wörmit¹, Hans V. Bolay³, Hubert J. Bardenheuer²

¹ German Center for Music Therapy Research (Viktor Dulger Institute) DZM e. V.
² Pain Center of the University Hospital Heidelberg
³ Department of Music Therapy of the University of Applied Sciences Heidelberg

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Address of Author:
Prof. Dr. Thomas K. Hillecke,
Department of Music Therapy
University of Applied Sciences Heidelberg
Maaßstr. 26
69123 Heidelberg
Germany
Tel.: 0043 6221 88 41 50 (54)
Fax: 0043 6221 88 41 52
E-mail: thomas.hillecke@fh-heidelberg.de
Abstract
The purpose of this study was to evaluate the Heidelberg model of adjuvant music therapy for patients suffering from chronic nonmalignant pain. Using a randomized wait-list controlled design parametric analyses and the method of clinical significance were applied. Significant effects of additional music therapy were observed in pain and psychological measures compared to only pharmacologically treated wait-list patients. Results were statistically significant and clinically meaningful. The overall success rate of pharmacologically treated patients could be doubled by additional active music therapy.

Key Words
active music therapy, nonmalignant pain, controlled study, effectiveness

Introduction

Chronic nonmalignant pain is one of the most cost intensive health problems. In Germany Kröner-Herwig (1996) estimates that 10 % of the population suffer from pain syndromes and between 0,8 and 1 % of the German population need treatment by pain specialists. In most cases of severe chronic pain syndromes the single use of drug therapy does not lead to satisfactory results. The difficult management problem of pain disorders needs to be addressed by an interdisciplinary approach (Flor et al. 1992). Psychological cognitive-behavioral interventions became a crucial part of the interdisciplinary paradigm. Modern active music therapy presents an alternative psychosocial intervention to traditional psychological approaches.

The usefulness of music therapy in the treatment of acute pain is well documented in recent studies (e.g. Spintge and Droh 1987; Spintge 2000) and meta-analyses (Standley 1986; Bunt 1997; Dileo 2003). Only few studies exist on music therapy with patients suffering from chronic pain. Schorr (1993) treated rheumatoid arthritis patients with receptive music therapy. While listening to music patients reported less pain. Chesky et al. (1997) treated fibromyalgia patients with vibrotactile stimulation in a prospective, placebo-controlled design. Results showed no significant group differences in pain but in tenderpoint measures.

Over the last decade active music therapeutic approaches for the treatment of nonmalignant chronic pain were developed and evaluated in Germany (Müller-Busch 1997; Müller-Busch and Hoffmann 1997; Hillecke and Bolay 2000; Risch et al. 2001; Hillecke 2002; Nickel et al. 2002). Müller-Busch (1997) found a significant superiority of the experimental group in pain and pain associated measures in a controlled study with muscle related pain syndromes. Risch et al. (2001) used music therapy for headache patients in a group setting. Results
showed no significant changes during the course of treatment but in the follow-up condition. Nickel et al. (2002, 2004) treated children with migraine in a randomized controlled design. They found statistically and clinically significant improvement in headache measures with active music therapy as compared to the drug-placebo condition. The present study evaluates active music therapy with patients suffering from chronic nonmalignant pain (Heidelberg-Model). This model represents a manualized adjuvant treatment specifically designed for patients suffering from severe pain syndromes with long-term chronicification. The study was carried out in order to analyze whether music therapy in addition to pain medication has significant effects on pain parameters and/or psychological symptoms and psychosocial functioning.

**Methods**

**Subjects**
The ethical committee of the University of Applied Sciences Heidelberg approved of the protocol for the study. The analyzed sample consisted of 40 patients randomly assigned to an experimental group (age 51 ± 11 years, 67% female) receiving music therapy in addition to standard pharmacological pain treatment and a waiting group (age 52 ± 10 years, 74% female) receiving pharmacological treatment only. Patients were referred from the Pain Center of the Department of Anesthesiology (University Hospital Heidelberg) if they (1) were older than 18 years, (2) qualified for a diagnosis of one or several chronic nonmalignant pain disorders, (3) suffered from psychological distress but not to a psychiatric extent (except somatoform pain disorder) and (4) did not take part in other psychological intervention programs. Most patients suffered from headache or back pain (figure 1).

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\text{Figure 1: Pain diagnoses of the experimental and wait-list group}
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Socio-demographic data revealed that most patients received higher education, are married and retired or without employment. Employed Patients mostly worked in non-executive positions.

**Procedures**
Different valid measures were used to assess pain including the Visual Analogue Scale (VAS) which measures momentary pain and pain in the last 4 days, and the “Schmerzhinfundungsskala” (SES; Geissner 1996) which is a pain sensation scale, based on the McGill Pain Questionnaire measuring affective and sensory pain components. These
pain measures were chosen because of their wide use for clinical and scientific purposes. To assess psychological and psychosocial outcome the German version of the Outcome Questionnaire (OQ45.2; Lambert et al. 1996), which measures symptom distress, interpersonal relations and social role, has been used. This method is highly sensitive in detecting changes through psychological interventions. Additionally, pain medication was documented by medical staff of the Outpatient Pain Center of the University Hospital Heidelberg.

After admission to the Pain Center, the patients were examined and diagnosed by medical pain specialists and a psychologist. Fulfilling inclusion criteria and after informed consent, patients were invited to the Music Therapy Outpatient Department of the University of Applied Sciences Heidelberg. After inclusion and baseline measurements (VAS, SES, OQ45.2) the patients were randomly assigned to the groups. The control group was offered music therapy after the waiting period. The post-measures were conducted after music therapy and the waiting condition. The intervention consisted of one unit of music therapy each week with a duration of 50 minutes over a time period of 20 weeks.

The individual treatments were carried out according to a therapy manual which had been developed by music therapists, psychologists and pain specialists. The manual was specifically designed for this patient group. According to the phase theory of Lueger (1995) the manual consists of three phases, initially (1) focusing on the re-establishment of well-being (remoralization), then (2) working on pain symptoms (remediation) and finally (3) addressing the psychosocial functioning of the patient (rehabilitation). Well-being was activated by music-assisted imagery and relaxation. Symptoms were addressed by externalization which means musical symbolization and reframing of pain experiences. Psychological functioning was enhanced by emotional activation through music exercises and the implementation of more flexible behavior strategies and broadened experiences by the use of musical role play and ritualized music improvisations. Reliability of the offered music-therapeutic treatment was controlled by supervision and video-documentation.

Statistics and outcome analyses
For data analysis a combination of parametric analyses and the concept of clinical significance was used (Jacobson and Truax 1991; Kordy and Hannöver 2000).

Parametric Analysis
Outcome variables were analyzed with Analysis of Covariance with the baseline measure as covariate variable for group comparisons. This statistical procedure controls for differences in the pre-measurement.
Analysis of clinical significance

The primary aim of the study was to determine how many patients profit clinically from the treatment. For the analysis of clinical significance meaningful positive outcome was defined. The following variables were chosen, because results of a pilot study (including 130 patients suffering from chronic nonmalignant pain) showed that they are less correlated:

- VAS pain in the last 4 days,
- SES affective pain,
- OQ45.2 total score.

Therapy success was defined by the combination of these three scales so that a patient had to improve on at least one of the chosen scales and not deteriorate on any. Variables were analyzed with the method of clinical significance (Jacobson and Truax 1991; Kordy and Hannöver 2000) consisting of two different analytical procedures.

a) The first is called the reliable change and is based on critical differences. This method allows us to make single case evaluations in order to assess if a patient underwent a reliable change respecting the measurement error. For SES and OQ, respectively, the reliable change index (critical differences) can be found in the test manual. In the case of VAS a reliable change was defined by clinical decisions. A reliable change in VAS was defined when a 20% change was measured.

b) The second method was derived from Jacobson and Truax (1991) and defined as the method of clinical significance (in the narrow sense). It is based on cut-off values which define whether a patient is closer to the norm population than to the sick population after treatment. According to the German manual the cut-off value of OQ45.2 (Lambert et al. unpublished) is defined at a score of 58.8. In the SES cut-off-values are not defined but the distribution of a normative pain population is included. Therefore, we applied the concept of Kordy and Hannöver (2000) who define as clinical significant change if a patient changes from the very sick group to the almost healthy group. The cut-off is defined to have lower values than 75% of the sick population after therapy. For the VAS clinically significant changes were defined when the patient improved from severe to light or from medium to light pain, respectively. Thus, the cut-off is defined as 1/3 of the maximum score (33% VAS). For the statistical analysis of reliable and clinical significant change we used the Mantel-Haensel-Chi²-Test.
Results

Patient characteristics
The experimental and waiting list group did not differ significantly in sociodemographic variables, psychological, psychosocial and pain measures as well as in medication. With regard to pain measures, namely the VAS, we found a tendential group differences (t = 1.70; p = .097). The values of the experimental group were lower than the values of the waiting group. Therefore for group comparisons Analysis of Covariance with the pre-measure as covariate variable was used.

The attrition rate of patients amounted to an overall of 25%, analysis revealed no significant group differences. The remaining 40 patients were randomly assigned to 21 patients in the experimental group and 19 patients in the waiting group.

Treatment outcome

Parametric Analysis
Group comparison reveals significant results in the categories VAS (pain in the last 4 days), and total score as well as social role in OQ45.2, respectively. Tendencies towards positive changes were found in VAS (momentary pain) and symptom distress (OQ45.2). Insignificant results were obtained in both affective pain and sensory pain by SES and interpersonal relations (OQ45.2) (table 1).

Analysis of clinical significance
The method of clinical significance includes the possibility to visualize definitions and results using so called Jacobson-plots (figure 2). These figures show that more patients of the experimental group profit from treatment on every outcome criterion. The statistical results presented in figures 3 and 4 are based on the combination of these three outcome criteria.
Figure 2 Jacobson Plots: Experimental group versus wait-list group.
a) Analysis of reliable change shows a tendency of superiority for the experimental group. Patients undergoing music therapy exhibit a positive change rate of 67% in contrast to only 32% of the control group. Additionally we analyzed the groups after controlling for medication, including only the patients with no changes in medication intake (Experimental group (EX): N = 12; Waiting list (WL): N = 11). Data analysis revealed a significant superiority of the music therapy group (figure 3).

Figure 3: Reliable Change.

b) The results of clinical significance are presented in figure 4. The results demonstrate a tendency of superiority for the experimental group. There was no significant difference between the groups with stable medication according to WHO.

Figure 4: Clinical Significant Change.

Discussion

Results of the study indicate that music therapy is an effective adjuvant intervention for patients suffering from chronic nonmalignant pain doubling the effects of pharmacological treatment. Significant results were documented in pain-measures and in psychological measures. Music therapy not only reduces pain but also addresses associated psychological distress in a positive way. It also has the potential to stabilize the social role functioning in contrast to the patients receiving only pharmacological treatment, who on average deteriorate on this scale. Parametric analyses as well as analysis of clinical significance show the superiority of additional music therapy in the treatment of patients suffering from nonmalignant pain. Parametric analyses seem to deliver better results but are less informative in the assessment of the clinical profits of a specific patient so that success rates (e.g. in percent) can not be determined. Additionally, the method of clinical significance controls for meaningless and unreliable changes but has the disadvantage of less variance. The results of the present study support findings concerning the effectiveness of active music therapy with chronic pain patients in an individual setting (e.g. Müller-Busch and Hoffmann 1997, Nickel et al. 2002). These data underscore that active music therapy offers significant
advantages in patients with chronic pain in addition to the well-documented significance of receptive music therapy during acute pain (Standley 1986, Bunt 1997, Dileo 2003). Moreover patients on stable medication profit more from music therapy indicating that this is a prospective factor for more probable success.

In the field of music therapy the number of indication-specific manualized concepts is rather small. However, evidence-based medicine requires such well-documented, scientifically evaluated and transparent approaches. The therapy manual designed for this study is well suited for general clinical use and music therapy staff training. Outcome is readily measurable and easily communicated to patients and treatment partners. Clinical observation from pain therapists indicates that patients with severe non-malignant pain are more compliant to music therapeutic treatment than conventional psychotherapeutic approaches.

After internal discussion the integration of a follow-up measurement into the study design was rejected because a wait-list design would only allow for uncontrolled follow-up measurements. Added to the fact that it is nearly impossible to control for post-study interventions in the field of chronic pain, uncontrolled follow-up measures seem to produce invalid data and can not strictly be interpreted as music therapy effects.

The question about the working factors of music therapy is still unanswered. Often the emotional / affective power of music is discussed as to be the effective tool of music therapy (Müller-Busch 1997). The results of the present study do not underline emotional / affective power of music as a major factor because the affective pain component does not significantly differentiate between the experimental and the control group, respectively. To describe the role of music therapy in greater detail, a more complex working model can be proposed integrating the following factors: (i) Distraction of attention by music, (ii) broadening of emotional experience by music improvisation, (iii) change of dysfunctional cognitions, (iv) activation of motor behavior by musical activities and (iv) training of nonverbal interpersonal communication (Hillecke 2002).

On the basis of these clinical data the Heidelberg music therapy approach is a valuable tool in outpatient pain management. This therapeutic concept offers a new effective dimension to the complex field of chronic pain treatment. Further methodological sound research is needed to test differential effects in relation to other psychological treatments.
References


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Figures and tables

Figure 1: Pain diagnoses of the experimental and wait-list group

<table>
<thead>
<tr>
<th>Measure</th>
<th>Scale</th>
<th>EX</th>
<th>WL</th>
<th>p-value</th>
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<tbody>
<tr>
<td><strong>Pain intensity score (VAS)</strong></td>
<td>Momentary pain</td>
<td>21</td>
<td>19</td>
<td>.092 n.s.</td>
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<td>Pain in the last 4 days including today</td>
<td>21</td>
<td>19</td>
<td>.014 *</td>
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<tr>
<td><strong>Pain sensation scores (SES)</strong></td>
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<td>21</td>
<td>19</td>
<td>.355 n.s.</td>
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<tr>
<td></td>
<td>Sensory Pain</td>
<td>19</td>
<td>19</td>
<td>.832 n.s.</td>
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<tr>
<td><strong>Psychotherapeutic Outcome</strong></td>
<td>Total score</td>
<td>21</td>
<td>19</td>
<td>.042 *</td>
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<tr>
<td>(OQ45.2)</td>
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<td>19</td>
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<tr>
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<td>Interpersonal Relations</td>
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</tr>
<tr>
<td></td>
<td>Social Role</td>
<td>21</td>
<td>19</td>
<td>.027 *</td>
</tr>
</tbody>
</table>

Table 1: Results of the post-group comparison (Analysis of Covariance) (pre-measure = covariate; F-value = Influence of group). The figure shows means (m) and standard deviations (sd) after therapy. EX = Experimental group; WL = Wait-list; n.s. not significant; * = significant (p < .05).
Figure 2 Jacobson Plots: Experimental group versus waitlist group. The Figure presents pre-post changes of the patients on the chosen variables. Experimental group = top-up triangles, waitlist group = top down triangles. The horizontal and vertical lines represent the defined cut-off-values. The diagonals and their parallels contain the areas where no reliable changes can be found. The additional horizontal and vertical broken gray lines in the VAS graph are based on the definition of severe, medium and light pain. The additional gray lines in the SES-graph represent the average of pain patients in the test-manual. The broken lines parallel to the diagonal show average changes of the experimental group (line, dot) and the wait-list group.

**Reliable change**: triangles lie outside the area defined by the parallels of the diagonal (reliable improvement = underneath, reliable deterioration = above).

**Clinical significance**: Field I: clinically significant improvement, Field II: clinically irrelevant change, Field III: clinical change is not sufficient, Field IV: clinically significant deterioration.
Figure 3: Percent of Reliable Change. Reliable improvement = reliable improvement in at least one of the defined criteria and no change in the others; no change = no reliable change in all criteria or mixed reliable positive and negative changes; reliable deterioration = reliable deterioration in at least one of the defined criteria and no change in the others.

Figure 4: Percent of Clinically Significant Change. clin. sig. improvement = clinically significant improvement in at least one of the defined criteria and no change in the others; no change = no clinically significant change in all criteria or mixed clinically significant positive and negative changes; clin. sig. deterioration = clinically significant deterioration in at least one of the defined criteria and no change in the others.