The Effects of Music Intervention in the Management of Chronic Pain

A Single-Blind, Randomized, Controlled Trial

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Objective: A music intervention method in the management of pain was recently developed while taking account of recommendations in the scientific literature. The objective of this study was to assess the usefulness of this music intervention to the management of patients with chronic pain.

Methods: A controlled, single-blind, randomized trial was used. Eighty-seven patients presenting with lumbar pain, fibromyalgia, inflammatory disease, or neurological disease were included in the study. During their hospitalization, the intervention arm (n = 44) received at least 2 daily sessions of music listening between D0 and D10, associated with their standard treatment, and then pursued the music intervention at home until D60 using a multimedia player in which the music listening software program had been installed. The control arm received standard treatment only (n = 43). The end points measured at D0, D10, D60, and D90 were: pain (VAS), anxiety-depression (HAD) and the consumption of medication.

Results: At D60 in the music intervention arm, this technique enabled a more significant reduction ($P < 0.001$) in pain ($6.3 ± 1.7$ at D0 vs. $3 ± 1.7$ at D60) when compared with the arm without music intervention ($6.2 ± 1.5$ at D0 vs. $4.6 ± 1.7$ at D60). In addition, music intervention contributed to significantly reducing both anxiety/depression and the consumption of anxiolytic agents.

Discussion: These results confirm the value of music intervention to the management of chronic pain and anxiety/depression. This music intervention method appears to be useful in managing chronic pain as it enables a significant reduction in the consumption of medication.

Key Words: pain, music therapy, anxiety, depression, stress, non-pharmacological treatment

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Music intervention has been defined as a “controlled method for listening to music, making use of its physiological, psychological, and emotional impact on the individual during treatment for an illness or trauma.”¹ Music intervention is now used in a wide variety of medical settings.² Several meta-analyses can thus be found in psychiatric medicine,³ palliative care,⁴ neurology,⁵ intensive care,⁶ etc. Furthermore, since the 1960s, numerous studies have demonstrated its value in the treatment of pain.⁷ A recent meta-analysis justified its application in this area, but a lack of methodological rigor in the studies performed raised doubts as to its true impact.⁸ The factors for success arising from scientific recommendations have now enabled the modeling of a technique so as to optimize its effects. The principal factors for success identified so far with respect to music therapy sessions are:

- The choice of music, depending on the patient’s tastes and cultural background;⁹–¹⁴
- Listening to instrumental music for 20 to 30 minutes through earphones while wearing an eye mask, in a relaxed position;¹⁵–¹⁷
- The conduct of sessions by care staff, and particularly nurses.¹⁸–²¹

Taking account of all the recommendations in the scientific literature, Montpellier Regional University Hospital Centre (CHRU) and the company Music Care²² have developed a software program that is able to standardize this technique. Using a multimedia player (tablet PC) a 20-minute music intervention session can be chosen by care staff to correspond to the tastes of patients determined using a simplified questionnaire. This technique has already demonstrated its efficacy in models of acute pain²³ and chronic pain.⁵ The results of these controlled and randomized studies highlighted an action of music therapy on heart rate, respiratory rate, and blood pressure. The authors concluded that music intervention contributed to a state of relaxation and a reduction in pain intensity of about 30% to 50%, determined using a visual analog scale (VAS).

It has been shown that music acts on the cognitive component by diverting attention away from pain, according to the “Gate Control” theory.²³ Furthermore, a recent meta-analysis on musical mood-induction procedures revealed that musically induced emotions influences a broad range of cognitive abilities,²⁴ placing music among the most effective inducers of emotion.²⁵ Music chosen as a function of level of the patient’s pleasure enabled a reduction in overall pain sensations.²⁶ The impact of music intervention may also be due to neurophysiological effects specific to pain and to music, acting on the sensory, cognitive, affective, and behavioral components. Psychosocial factors may also intervene in reducing chronic pain phenomena: the expression of emotions by patients after a
At D21, the VAS scores were 3.5 (± 2.3) and 5.3 (± 2.1) in the intervention and control arms, respectively (approximately 30%), patient numbers were increased to 44 per arm.

### Materials and Methods

**Type of Study**

The current study was a randomized single-blind (outcome assessor) controlled trial performed over a total of 18 months, with a 3-month period of patient follow-up.

**Patient Consent**

This study was approved by an ethics committee (the Comité de Protection des Personnes (CPP)), as required by French regulations. Before their inclusion in the study, eligible participants were informed about implementation of the study by means of an information leaflet, and were asked to sign an informed consent form to participation in the project. The method, technique, and music sessions were also detailed by the investigator. The nurses followed a 5-day training program in the use of music intervention and the “U technique.” The protocol was submitted for approval by the Commission National Informatique et Libertés (CNIL) (governing the freedom of information) so as to ensure compliance with the need for the confidentiality of personal data.

**Sample Size**

The number of participants necessary was estimated at 34 per arm, based on a first-species risk of 5% and a power of 90% under a bidirectional hypothesis, to anticipate a minimal clinically important difference of 1.8 (± 2.2) at D60 between the intervention and control arms. This estimate was based on the results of the study by Kullich et al. At D21, the VAS scores were 3.5 (± 2.3) and 5.3 (± 2.1) in the intervention and control arms, respectively (P < 0.001). However, in view of the number of patients expected to be lost to follow-up or with missing data (approximately 30%), patient numbers were increased to 44 per arm.

**Randomization**

Randomization was centralized and ensured using a randomization list previously established by the Clinical Research Unit at Montpellier CHRU. Stratification was performed as a function of the source of pain [mechanical (n = 20), inflammatory (n = 20), fibromyalgic (n = 20), and neurological (n = 20)].

**Study End Points**

- The primary study end-point corresponded to the pain experienced at different time points between D0 and D60, measured using a VAS with scores ranging from 0 to 10, where 0 meant no pain and 10 meant maximum pain. The reliability and validity of the VAS had been verified by Gallagher et al.
- The secondary end-points corresponded to the anxiety and depression components, which were assessed using the Hospital Anxiety and Depression scale (HADS) that comprises 7 questions on anxiety and seven on depression, with the answers scoring from 0 to 3. The final scale thus ranges from 0 (mild anxiety-depression) to 21 (severe anxiety-depression) for each of the anxiety and depression components. Assessments were performed at D0, D5, D10, D60, and D90, and were thus able to monitor changes to these components throughout the study period.

**Changes to the consumption of analgesics, anxiolytics, and antidepressants were also evaluated between D0 and D60. At admission (D0), on D5 and at discharge from hospital (D10), consumption rates were recorded by the nurses. At D60 and D90, these rates were evaluated at home by means of a telephone interview with an independent assessor.**

**Inclusion and Follow-up Periods**

All patients were followed-up over a period of 3 months. Assessments were made on the first day of hospitalization (D0), at the end of the first week (D5) and at discharge (D10), and then on D60 and D90 at home. The nurses trained in music intervention were not those who carried out these assessments. All assessments were made by independent assessors (nurses from outside the department who were unaware of the study arms to which patients belonged) until the end of D10. To ensure that the assessor could not guess the arm to which patients belonged (group music intervention or control), the equipment for music sessions (eg, headphones) was stored after use in a closed cupboard in the patient’s room. All patients were clearly informed of the study protocol.

The assessments at D60 and D90 were performed over the telephone using self-questionnaires, the answers being collected by the same assessors at a random moment during the day which depended on the availability of both assessors and patients. For the pain assessments at D60 and D90, a numerical rating scale was used instead of a VAS.

**Authorized/Concomitant Treatments**

All medications and preparations used by patients during the study, including those available over the counter, were recorded in the case report form, which also specified the dosage, indication, and duration of treatments at inclusion and at each follow-up assessment (D0, D5, D10, D60, and D90). All the treatments recorded were coded according to the Anatomical Therapeutic Chemical Classification (ATC) System.

**Intervention**

The 2 groups of patients benefited from standard drug therapy during their 10 days of hospitalization: intravenous therapy (anxiolytics, antidepressants, analgesics) twice a day (morning and evening) for the first 5 days, followed by a switch to oral therapy until they left hospital (doses prescribed and on demand). In all patients, and depending on their needs, other drug therapies were also implemented, such as slow infusion mesotherapy, as well as nonmedicinal treatments: percutaneous neurostimulation, relaxation, massage, psychological support interviews, and health education sessions. As well as receiving this standard therapy, patients in the intervention arm also participated in individual music therapy sessions.
Characteristics of Music Intervention Management

The receptive relaxation music intervention technique was employed. The standardized music session of 20 minutes was broken down into several phases, which gradually caused the patient to relax, according to the new “U” sequence\textsuperscript{11,12,15} (Fig. 1). The effect of this technique is achieved first through a reduction in musical tempo, orchestral size, frequencies, and volume (descending arm of the “U”), reaching a phase of maximum relaxation (bottom of the “U”) before a redynamizing phase (ascending arm of the “U”). All the musical sequences constructed for the “U” technique were specially designed by the music publication company Music Care.\textsuperscript{22}

During these sessions, the patients were lying down in their rooms with their eyes closed under minimum lighting so that they felt at ease. The music was played to them through earphones.

During an initial pre-therapy interview with a nurse, a questionnaire was completed to obtain a clearer understanding of the patient’s musical tastes. The works chosen were made available as from the first session (classical: piano, violin, flute, etc.; jazz: trumpet, saxophone, trombone, etc.; world music: India, Andes, Africa, etc.). The patients were trained in using the audio equipment, and were asked to note the duration, frequency of listening and type of music chosen. When they returned home, they were given access to a music databank for 50 days (between D10 and D60) using a multimedia system on which the sessions had been pre-recorded. The adherence with home music therapy was assessed by a form completed by the participant after each music session: date, hour, and type of music, to obtain the duration, frequency of listening, and type of music chosen at home.

Each session lasted for 20 minutes, at a rate of at least 2 sessions per day. The assessment at D90 was designed to determine any maintenance of the effects of music intervention for up to 30 days after the discontinuation of sessions.

Patients in the control arm were not trained in the “U” technique program to carry out music sessions at home under the appropriate conditions (lying down with the eyes closed under minimum lighting), but all patients could listen to music under other conditions (radio, television, concert, etc.).

Selection of Participants

To be eligible for the study, patients hospitalized in the Pain Assessment and Treatment Centre at Montpellier CHRU had to have a history of pain for at least 6 months (with a VAS $\geq$ 3 at inclusion), and have mechanical, inflammatory, fibromyalgic, or neurological pain. They were required to be aged 18 years or over, to speak and read French with ease, to sign the written informed consent form and to be receiving standard therapy: intravenous medications (tranquilizers, antidepressants) twice a day (morning and evening) for the first 5 days, followed by a switch to the oral route until their discharge from hospital (doses prescribed and on demand).

Patients excluded from the study were those whose planned period of hospitalization was shorter than 8 days, who had a history of reflex epilepsy or a major hearing deficiency, presented with a strong possibility of nonadherence with the protocol or withdrawal during the study, or could be affected by a life-threatening condition during the scheduled study period. The only reasons for discontinuation of the study were a withdrawal of consent, being lost to follow-up, or death.

Statistical Analysis

All the patients included were taken into account in the intent-to-treat population. Quantitative data were described in terms of population, mean, standard deviation, median, range (minimum and maximum), and the number of missing data. Qualitative data were described by their distribution in terms of populations and percentages by class, and the number of missing data.

A Friedman nonparametric analysis of variance was performed. Variations in scores (for pain, depression and anxiety) between D0 and D60 were compared between the 2 arms using Student t test or, if the conditions of this test...
RESULTS

Eighty-seven patients were randomized to 1 of the 2 treatment arms, with or without music intervention, or 44 and 43 patients per arm, respectively. A description of the sample was made at inclusion. All descriptive analyses, and a comparison of the evolution of scores as described below, were performed on the entire sample of 87 patients. Figure 2 explains the distribution of patients between the arms during the study. The results of this controlled, randomized study are presented in compliance with the guidelines of the consortium on the assessment of non-pharmacological treatments.29,30

Description of Sociodemographic Characteristics at Baseline

At inclusion (D0), the patients in the 2 arms did not differ with respect to all baseline characteristics (Table 1). The history of pain was approximately 6.8 (± 5) years, and the mean age of patients at the onset of pain was 42.1 years. The different types of pain were evenly distributed; that is 25% of patients for each type (Table 2). These 4 types of pain (mechanical, inflammatory, fibromyalgic, and neurological) corresponded to the most common reasons for hospitalization because of chronic pain.

No statistically significant differences were observed between the 2 groups with respect to the pain and HAD scores at baseline. In the music intervention arm, the mean VAS score for pain at D0 was 6.3 (± 1.7), whereas in the control arm it was 6.2 (± 1.5).
Description of the Consumption of Medications at Baseline

The consumption of medications of the 2 groups (with and without music intervention) was tested at inclusion (Table 2). No significant differences between the 2 groups regarding the consumption of antidepressants, anxiolytics, and analgesics were demonstrated at D0. The use of physical medicine was also compared between the arms at D0 and no significant differences were demonstrated: 33 patients in intervention group and 30 in control group were receiving physiotherapy, electrotherapy, relaxation, and/or mesotherapy.

Music Intervention Characteristics

All the patients in the experimental group received music intervention sessions twice a day until D60. At all end-points, the mean duration of music sessions was 20 minutes, and all patients in the music intervention arm stopped the music sessions on D60. No patients in the control group received a music intervention session.

Effects of Music Intervention on Pain (VAS)

Figure 3 shows the evolution of pain scores over time in each group. The reduction in the pain score at D60 in comparison with D0 was significantly greater in the music intervention group (-3.4 ± 2.3) and -1.6 ± 2.2, P < 0.001), which corresponded to a relative improvement of 54%, as opposed to 25.8% in the control arm. At D90, the mean score was 3.4 ± 1.7 in the music intervention group versus 4.7 ± 1.8 in the control group (P < 0.001). The evolution between D0 and D90 was also significantly in favor of the music intervention group (-6.0 ± 4.3) and -0.5 ± 3.1, P < 0.001).

Secondary End Points

Effect of Music Intervention on Depression

Figure 4 reports the values and variations in depression scores during follow-up. The evolution between D0 and D60 differed significantly between the 2 treatment groups (an absolute variation of 7.3 ± 3.4 and 0.7 ± 4, respectively; P < 0.001). At D60, the relative improvement in the score was 53%, versus an improvement of 5% in the control group. A D90, the mean score was 7.4 ± 3.8 in the music intervention group versus 13.1 ± 3.1 in the control group (P < 0.001). The difference between D0 and D90 was also significantly in favor of the music intervention group (-6.6 ± 3.9 versus 0.4 ± 4.1, P < 0.001).

Effect of Music Intervention on Anxiety

Figure 5 reports the values and variations in anxiety scores between D0 and D90. At D60, the relative improvement was 50% in the music intervention arm versus 6.5% in the control arm at that time point. A D90, the mean score was 7.8 ± 3.4 for the music intervention group versus 13.5 ± 4.3 in the control group (P < 0.001). The improvement between D0 and D90 remained greater in the music intervention group (-6.0 ± 4.3) and -0.5 ± 3.1, P < 0.001).

Effect of Music Intervention on the Consumption of Medications

With respect to anxiolytics, a significant difference appeared in favor of the music intervention group at D60 (42.9% versus 66.7% in the control group, P = 0.028; Fig. 6). At D90, no significant difference was observed (55.0% vs. 52.5%).
As for the consumption of antidepressants and analgesics, no significant difference was observed, despite a trend in favor of the music intervention group as from D60 (antidepressants: 42.9% vs. 59.5% at D60, and 52.5% vs. 57.5% at D90; analgesics: 42.9% vs. 57.1% at D60, and 37.5% vs. 47.5% at D90).

Furthermore, regarding the different types of physical medicine, no difference was significant at D60. Only 21 patients (vs. 63 at D0), 9 in the intervention group, and 12 in the control group, received other therapy.

**DISCUSSION**

This music intervention technique using a “U” sequence can modify the experience of pain through its sensory, cognitive, affective, and behavioral effects, and can

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**FIGURE 3.** Evolution of pain over time.

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**TABLE 2.** Description of Clinical Data at D0

<table>
<thead>
<tr>
<th>Variable</th>
<th>Music Intervention</th>
<th>Control</th>
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<td>Description of Groups</td>
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<td>%</td>
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<td>Type of pain</td>
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<td></td>
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<tr>
<td>Inflammatory</td>
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<td>Lower limbs</td>
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<table>
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<th>Mean (SD)</th>
<th>Min/max</th>
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<th>Mean (SD)</th>
<th>Min/max</th>
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<td>43</td>
<td>6.7 ± 5</td>
<td>1/23</td>
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<td>Age at onset of pain</td>
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<td>17/68</td>
<td>43</td>
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<td>43</td>
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<td>13.8 ± 2.4</td>
<td>8/19</td>
<td>43</td>
<td>12.9 ± 2.5</td>
<td>5/17</td>
</tr>
<tr>
<td>Anxiety (HADS)</td>
<td>44</td>
<td>13.8 ± 3.1</td>
<td>5/19</td>
<td>43</td>
<td>13.9 ± 2.4</td>
<td>9/19</td>
</tr>
</tbody>
</table>

HADS indicates Hospital Anxiety and Depression Scale; SD, standard deviation; VAS, Visual Analog Scale.

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As for the consumption of antidepressants and analgesics, no significant difference was observed, despite a trend in favor of the music intervention group as from D60 (antidepressants: 42.9% vs. 59.5% at D60, and 52.5% vs. 57.5% at D90; analgesics: 42.9% vs. 57.1% at D60, and 37.5% vs. 47.5% at D90).

Furthermore, regarding the different types of physical medicine, no difference was significant at D60. Only 21 patients (vs. 63 at D0), 9 in the intervention group, and 12 in the control group, received other therapy.
play a valuable role in multidisciplinary and global patient management. This controlled, randomized study involving a blinded assessment of its results thus confirmed the efficacy of this new music intervention technique in the management of pain, anxiety, and depression, in that it enabled a significant reduction in the consumption of medications.

The results of this study showed that patients who underwent music intervention sessions experienced an improvement in their pain level that was double that seen in the control arm. This effect on pain was sustained for up to 1 month after discontinuing the sessions. By comparison with the control group, music intervention also exerted a significant impact on anxiety, depression, and the consumption of medications. At D60, nearly 50% of the patients in the music intervention group were no longer taking any anxiolytics, versus 10% in the control group.

Our results confirmed those already observed during a controlled, randomized study in patients with chronic back pain (n = 65), which demonstrated significant differences between the 2 groups (with and without music intervention) regarding pain severity.27 Another controlled, randomized study (n = 66) had also demonstrated a significant reduction in arthritic pain in patients who participated in music intervention sessions for 14 days.31 Our results also confirmed that the music intervention effect was sustained for up to 2 weeks after the discontinuation of sessions; similar results had also been obtained in a study on open hernia repair.16

Our study achieved more positive results, especially regarding the prolonged effect (for 30 days) of previous music therapy, than previous studies.32–34 This was probably due to the therapeutic quality of the relationship between patients and nurses until the end of hospitalization,
similar to that which has been observed during the use of hypnoanalgesia. It is important to note that we are the first group to use this “U” technique, and our patients benefited from a total of 120 music intervention sessions.

This new music intervention technique can be compared with sophrology or hypnosis, but in our case oral suggestion is replaced by musical induction. Indeed, our technique is similar to the autogenic training relaxation technique developed by the German psychiatrist Johannes Schultz, in the sense that the patient is trained to relax by himself. Our technique has several advantages: music intervention is an effective means of allowing patients to express themselves after the session regarding the emotions they are experiencing. It can also be applied individually if patients do not wish to attend group sessions. Finally, a therapeutic music intervention session does not require the presence of care staff during the period of listening but only at the start (installation of the patient) and end (expression of feelings), thus enabling better time management for care staff.

One methodological problem that cannot be solved with respect to randomized controlled trials on music intervention is that patients in the intervention group cannot be blinded for the music intervention, so that bias may be introduced in terms of a positive outcome (placebo effect). Indeed, it would have been interesting to compare our findings with the results in a third group of patients participating under the same conditions in another type of musical intervention, such as listening to standard relaxation music (where the patient has no choice regarding the style of music) or without the “U” scheme. Another limitation to our study concerned the attitude of participants in music therapy sessions, which was assessed using a self-questionnaire at home. Finally, the inclusion of patients presenting with different types of pain (mechanical, inflammatory, fibromyalgic, or neurological pain) also constituted a methodological bias of the study.

Nevertheless, this study respected the strict methodological criteria of a controlled, randomized and blinded study involving the independence of the therapist and assessor, thus enabling a rigorous assessment of this new music intervention technique in the context of pain management.

Although the effects of music intervention in pain management appear to have been established, this research was able to validate specific parameters for its success, assess its efficacy over the longer term and develop a music databank adapted to the tastes of different patients. In view of the availability, simplicity and low cost of musical interventions, combined with the absence of any side effects, this therapeutic technique appears to be of particular interest in the context of pain management.

This new music intervention technique, already available via the internet in high-dependency units (intensive care, coronary angiography, recovery rooms, etc.) and in the rooms of hospitalized patients (oncology, palliative care, pediatrics, etc.), enables the conduct of multicenter studies in different types of pain. This standardized and reproducible tool also means that the pursuit of patient management can be envisaged over the longer term at home. The statistical data collected during the study made it possible to verify the number of times patients listened to music sequences, the types of music they chose and clinical assessment parameters. This music intervention technique is now applied in many hospitals by care staff who has received specific training in its use.

REFERENCES