ORIGINAL ARTICLE

Music Therapy in Palliative Care

A Randomized Controlled Trial to Evaluate Effects on Relaxation

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SUMMARY

Background: Music therapy has been used successfully for over 30 years as part of palliative care programs for severely ill patients. There is nonetheless a lack of high-quality studies that would enable an evidence-based evaluation of its psychological and physiological effects.

Methods: In a randomized controlled trial, 84 hospitalized patients in palliative care were assigned to one of two treatment arms—music therapy and control. The music therapy intervention consisted of two sessions of live music-based relaxation exercises; the patients in the control group listened to a verbal relaxation exercise. The primary endpoints were self-ratings of relaxation, well-being, and acute pain, assessed using visual analog scales. Heart rate variability and health-related quality of life were considered as secondary outcomes. The primary data analysis was performed according to the intention-to-treat principle.

Results: Analyses of covariance revealed that music therapy was more effective than the control treatment at promoting relaxation ($F = 13.7$; $p < 0.001$) and well-being ($F = 6.41$; $p = 0.01$). This effect was supported by a significantly greater increase in high-frequency oscillations of the heart rate ($F = 8.13$; $p = 0.01$). Music therapy did not differ from control treatment with respect to pain reduction ($F = 0.4$; $p = 0.53$), but it led to a significantly greater reduction in the fatigue score on the quality-of-life scale ($F = 4.74$; $p = 0.03$).

Conclusion: Music therapy is an effective treatment with a low dropout rate for the promotion of relaxation and well-being in terminally ill persons undergoing palliative care.

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Since the first palliative care wards were opened in Canada in the 1970s, music therapists have made an important contribution to the care of seriously ill patients (1). At the same time, review articles indicate that there is a lack of high-quality studies that would make it possible to provide an evidence-based recommendation for the use of music therapy in this field (2, 3).

Music therapy is the “systematic use of music within a therapeutic relationship which aims at restoring, maintaining and furthering emotional, physical and mental health” (4). Music therapy is offered in an extensive range of settings in psychiatric, psychosomatic, neurological, geriatric, pediatric, intensive, and palliative care (5). A distinction is drawn between active techniques, in which the patient takes part in producing music using his or her voice or an instrument, and receptive techniques, which involve only listening attentively to music and sounds (6).

Palliative care aims to support patients with incurable illnesses and their relatives on a physical, psychosocial, and spiritual level (7). The purpose of music therapy—as a creative, complementary approach—in this field is to maintain or improve quality of life. Specific goals are support of symptom management, improvement in regulation of emotions, and enhancement of communication and spiritual experiences (8, 9). These are achieved using interventions involving relaxation and imagery, songs, and improvisation techniques (8).

There are currently five randomized or quasi-randomized controlled trials available on the efficacy of music therapy in palliative care, with levels of evidence Ib to IIa (10–14), as well as other non-randomized or non-controlled pilot studies (level IIb) (15–20). The most powerful evidence exists for pain reduction (10, 14, 16, 20) and improvement in quality of life (11, 13). There is also preliminary evidence of efficacy in terms of a reduction in anxiety (12, 20), improvement in emotional state (13) and communication (15), stress reduction (17), and enhanced spiritual well-being (19). However, systematic reviews reveal that many of these studies have a high risk of methodological bias (2, 3, 8, 21). A recent retrospective data analysis shows that the use of music therapy is associated with increased readiness to discuss spiritual subjects and with a reduction in shortness of breath (22).

As far as is currently known, no randomized controlled trials have yet been conducted in Europe,

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and no controlled trials involving measurement of physiological variables have yet been conducted anywhere. This study therefore examined whether relaxation interventions as part of music therapy could be successfully used to achieve the following endpoints:

- Improvement in self-rated relaxation, well-being, and acute pain (primary endpoints)
- Triggering of a physiological relaxation response
- Improvement in health-related quality of life.

It was expected that there would be improvements in both study groups, and that music therapy would be shown to be superior.

Methods

The study was conducted at the university affiliated Palliative Care Unit at St. Vincentius Hospital, Heidelberg. It was approved by the ethics committee of the Faculty of Medicine of Heidelberg University (approval no. S-406/2012) and entered in the German Clinical Trials Register (DRKS, Deutsches Register Klinischer Studien) under number DRKS00006137.

Study design

This intervention study was conducted as a randomized controlled trial. Patients who met the criteria listed in *Table 1* and were thus eligible to participate in the study were informed of what the study would involve. Those who were willing to participate signed an informed consent form. Both intervention arms (music therapy and control) were presented to the participants as equally effective relaxation exercises throughout the study. The participants were therefore blinded to the study hypotheses. No further blinding methods (of therapists or assessors) could be implemented. Following a baseline assessment of quality of life and previous experience with relaxation techniques, participants were allocated to one of the two study groups using sealed, sequentially numbered envelopes provided by the study assistant. Individuals providing primary treatment were not involved in this process. The allocation sequence was compiled before the beginning of the study, using computerized block randomization (block size: 6). Next, two 30-minute sessions were given two days apart (*eFigure 1*).

Intervention

The relaxation exercise in the experimental group was conducted by trained music therapists according to a standardized procedure, involving voice as well as music played live on a monochord (*eFigure 2*). A monochord is an instrument developed for therapeutic purposes. It has a rectangular wooden body with 24 strings tuned to the same note. When played steadily, it produces a sound rich in overtones and creates a soothing atmosphere. Initial pilot studies show subjective and physiologically detectable relaxation responses in oncology patients as a result of listening to the sounds of a monochord/tambura (23–25).

First, the study assistant took baseline scores on self-assessment scales and began heart rate variability

TABLE 1

Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> – Receiving palliative treatment according to OPS 8–892 or OPS 8–98e – Sufficient comprehension of German or English 	<ul style="list-style-type: none"> – Preterminal/terminal phase of disease – Cognitive limitations (e.g. due to cerebral metastasis, ICD: C71, C72) – Apallic syndrome (ICD-10: G93.80) – Reduced hearing (ICD-10: H90, H91) – Restlessness and agitation (ICD-10: R45.1)

OPS, Classification of Operations and Procedures (the German modification of the International Classification of Procedures in Medicine); ICD, International Classification of Diseases

(HRV) measurement. Five minutes later, he left the room. The music therapist then began a short mindfulness exercise, accompanied by soft monochord sounds. Taking account of the patient's breathing pattern, the volume, dynamics, and intensity of the monochord playing were then increased, and vocal improvisation was begun in Ionian or Mixolydian mode (see [26] for an overview of church modes). Towards the end of the improvisation, which lasted approximately 15 minutes, intensity was gradually reduced. In a five-minute discussion after the procedure, the patient had the opportunity to reflect on his or her experience of listening to the music. The therapist then left the room. The study assistant returned to take post-intervention scores on the self-assessment scales and to measure heart rate variability. This intervention was repeated two days later (*eFigure 3*).

Patients in the control group underwent an intervention of the same duration but with no musical content or therapeutic relationship. This consisted of a 20-minute excerpt from the Mindfulness-Based Stress Reduction (MBSR) Program, played through headphones (27). MBSR is a training program that lasts several weeks and has shown evident health benefits (28). The body-scan meditation exercise used provided an active control condition: a moderately relaxing but not specifically therapeutic effect was expected. The study assistant remained silent in the patient's room during this process in case the patient had any questions or wished to halt the treatment.

Measuring methods

Participants' self-assessments before and after each session served as the primary endpoint. Visual analog scales (VAS) ranging from 0 to 10 were used for subjective assessment of relaxation, general well-being, and acute pain. Previous studies had demonstrated that visual analog scales showed adequate psychometric properties for measurement of acute pain (29).

Throughout the session, intervals in milliseconds between successive heartbeats were continuously recorded using photoplethysmography (Nexus Blood

TABLE 2

Means, standard deviations, and ANCOVA

Endpoints	Music therapy (n = 42)			Control group (n = 42)			ANCOVA	
	Before	After	Δ	Before	After	Δ	F(1.81)	p
Primary								
VAS: relaxation* ¹ (0 to 10)	5.72 (1.97)	7.90 (1.39)	2.17 (1.47)	6.00 (1.54)	6.98 (1.63)	0.99 (1.17)	13.7	<0.001*
VAS: well-being* ¹ (0 to 10)	5.22 (1.85)	7.11 (1.70)	1.88 (1.63)	5.64 (1.54)	6.55 (1.69)	0.91 (1.60)	6.41	0.01*
VAS: pain* ¹ (0 to 10)	2.95 (2.30)	2.45 (2.10)	-0.50 (1.27)	2.89 (2.17)	2.57 (2.16)	-0.31 (1.34)	0.40	0.53
Secondary								
HRV-HF* ^{1,2} (ln [ms ²])	5.50 (1.49)	5.68 (1.47)	0.18 (0.69)	5.40 (1.43)	5.13 (1.48)	-0.26 (0.80)	8.13	0.01*
BVP-A* ^{1,2} (ln [μV])	3.50 (0.76)	3.64 (0.57)	0.13 (0.34)	3.55 (0.69)	3.58 (0.58)	0.02 (0.29)	3.33	0.07
QoL: overall (0 to 100)	29.6 (21.3)	40.4 (20.9)	10.6 (19.6)	23.0 (25.2)	30.6 (24.4)	7.54 (23.0)	2.23	0.14
QoL: fatigue (0 to 100)	87.8 (19.3)	80.4 (23.2)	-7.41 (20.8)	93.7 (13.5)	91.8 (13.9)	-1.85 (15.1)	4.74	0.03*

*¹averaged across sessions; *²log-transformed; *statistically significant
ANCOVA, analysis of covariance (pre-intervention value as covariate); VAS, visual analog scale; HRV, heart rate variability; HF, power in high-frequency spectrum (autoregressive); BVP-A, blood volume pulse amplitude; QoL, quality of life

Volume Pulse Sensor, 128 SPS). Heart rate variability is an indicator of autonomic nervous system function (30). Based on the observation that a healthy heart rhythm has no static phase but rather results from dynamic interaction between ascending and descending neural pathways, heart rate oscillation is used to draw inferences on the cardiovascular activity of the autonomic nervous system (31). Short-term, high-frequency (HF) changes, such as respiratory sinus arrhythmia, are controlled in particular through vagus nerve pathways and can therefore be traced back to parasympathetic activity (30). Low heart rate variability is a risk factor in cardiovascular (32) and oncological diseases (33, 34), and studies have found it to be a predictor of mortality (35). In addition, low heart rate variability as an index of emotional dysregulation is associated with a range of psychiatric and psychosomatic illnesses (36).

For the present analysis, time segments of five minutes before and after the intervention were compared. In addition, the mean amplitude of peripheral blood volume flow (BVP-A) was calculated for the same time frame. High amplitude implies high blood flow in the fingertips and thus lower sympathetic activity (37).

Medium-term effects of the intervention were investigated by gathering information on quality of life using the EORTC QLQ-C15-PAL questionnaire at initial contact and at the end of the second session. EORTC QLQ-C15-PAL consists of 15 items and 10 subscales. It is a short version of QLQ-C30, which is in widespread use in cancer research, adapted and validated for palliative care (38).

Statistical analysis

Descriptive sample statistics included means, standard deviations, and frequencies. The comparability of the two study groups before the beginning of the study was

determined using chi-square tests and *t*-tests for independent samples. Differences between sessions 1 and 2 were analyzed using paired sample *t*-tests. The study hypotheses were tested using analyses of covariance (ANCOVA), with the pre-intervention score as covariate and the post-intervention score as the dependent variable (visual analog scale scores and heart rate variability measurements were averaged across the two sessions if there were no significant differences between sessions). Physiological data that were not normally distributed at baseline were log-transformed for further analysis. For calculation of the number needed to treat (NNT), success was defined as a 30% improvement. For intention-to-treat analysis, incomplete datasets were completed using the last observation carried forward method. Where there was no outcome-relevant data at any time point, the baseline group mean was imputed as a null effect for both pre- and post-intervention scores. The results were then tested for robustness in sensitivity analyses (complete case analysis, CCA). For the three primary endpoints of the study (visual analog scales), the Bonferroni correction was used to account for multiple comparisons, resulting in $\alpha = 0.017$. For further analyses type I error probability was set at $\alpha = 0.05$. The software packages Biotrace+, Kubios 2.1, and IBM SPSS Statistics 20 were used for data analysis. Sample size calculation and other details on the methods described here can be found in the published study protocol (39).

Results

Sample description

The primary endpoint (completion of a full session, including visual analog scale data) was achieved by 78 of the 84 participants. Complete psychometric datasets (completion of both sessions with complete visual analog scale and quality of life information; *eFigure 4*)

TABLE 3

Effect sizes and confidence intervals

Endpoints	MD (95% CI)	η_p^2	SMD	NNT
Primary				
VAS: relaxation ^{*1}	1.19 (0.50; 1.88)	0.14	0.75	2.80
VAS: well-being ^{*1}	0.98 (0.28; 1.68)	0.07	0.61	5.25
VAS: pain ^{*1}	-0.18 (-0.74; 0.39)	0.01	-0.15	8.40
Secondary				
HRV-HF ^{*1,2}	0.44 (0.12; 0.77)	0.09	0.59	3.50
BVP-A ^{*1,2}	0.11 (-0.03; 0.24)	0.04	0.35	42.00
QoL: overall	3.26 (-5.99; 12.5)	0.03	0.14	7.00
QoL: fatigue	-5.55 (-13.4; 2.33)	0.06	-0.31	8.40

^{*1}averaged across sessions; ^{*2}log-transformed

MD, absolute mean difference between groups; 95% CI, 95% confidence interval; η_p^2 , percentage of variance explained by factor "group"; SMD, standardized mean difference (Cohen's *d*); NNT, number needed to treat (success defined as 30% improvement); VAS, visual analog scale; HRV, heart rate variability; HF, power in high-frequency spectrum (autoregressive); BVP-A, blood volume pulse amplitude; QoL, quality of life

were available in 68 cases. Analysis of physiological variables included the data of 76 patients.

The mean age of patients was 63.0 ($\pm$ 13.4) years, and 71.4% of them were female. The most common primary diagnoses were breast cancer (n = 17), pancreatic cancer (n = 11), ovarian cancer (n = 7), and prostate cancer (n = 6). With two exceptions, all patients were suffering from malignant tumor diseases. Before the beginning of the study there were no significant differences between the groups in terms of age, sex, diagnosis, functional level, or interest in relaxation exercises (*eTable*).

Primary endpoints

Table 2 provides an overview of means, standard deviations, and results of analysis of covariance. Because the effects did not differ significantly between the two sessions (p > 0.05), mean values were used for further analysis. Self-rated relaxation and well-being scores showed significantly greater increases in the music therapy group compared to the control group (p < 0.001 and p = 0.013 respectively). *Figure 1* shows box-and-whisker plots comparing changes in the primary endpoints for the two groups. Number-needed-to-treat analysis revealed that for one person to have a favorable outcome it was necessary to administer music therapy to 2.80 and 5.25 patients (for relaxation and well-being respectively). There were no significant differences in pain perception between the groups (p = 0.53). *Table 3* shows mean between-group differences and effect sizes.

Secondary endpoints

Analysis of physiological data showed a significantly greater increase in high-frequency (HF) changes in heart rate variability in the music therapy group (p = 0.01). In terms of peripheral blood volume flow

(BVP-A), there was an insignificant trend towards greater vasodilation in the experimental group (p = 0.07) (*Figure 2*).

Additional analyses investigated differences in the subscales of the quality of life questionnaire. *eFigure 5* shows that between the beginning and end of the study there were improvements on the overall quality of life scale in both study groups. The improvements were greater in the experimental group, but the difference between the groups was not significant (p = 0.14). Music therapy was found to be superior in terms of the fatigue subscale (p = 0.03). Further descriptive trends in the expected direction were found for the constipation (p = 0.13) and physical function (p = 0.14) scales. There were no further effects in other areas.

According to CCA sensitivity analyses, the effect on fatigue failed to reach statistical significance (p = 0.07). All other test decisions were robust in terms of variations related to missing data analysis.

Discussion

The primary hypothesis of this study is supported by the results: music therapy improved subjective assessment of relaxation and well-being in terminally ill patients receiving palliative care. The effect sizes between the groups were medium to high (*Table 3*). This finding is supported by both the significant increase in high-frequency (HF) variations in heart rate and a trend towards greater peripheral blood flow, which suggests increased parasympathetic modulation and reduced sympathetic modulation of cardiovascular activity of the autonomic nervous system. Because physiological data varied greatly between individuals, additional growth curve modeling is planned.

The hypothesis that music therapy contributes to pain reduction was not confirmed. Examination of

Box-and-whisker plots showing changes in VAS (before and after)
middle line (bold), median; colored rectangle, 25th to 75th percentile; whiskers, upper/lower quartile; points, outliers; asterisks, extremes. MT, music therapy; CG, control group; VAS, visual analog scale

FIGURE 1

Box-and-whisker plots showing changes in physiological data (before and after)
middle line (bold), median; colored rectangle, 25th to 75th percentile; whiskers, upper/lower quartile; points, outliers; asterisks, extremes. HRV, Heart rate variability; MT, music therapy; CG, control group; HF, power in high-frequency spectrum (autoregressive); BVP-A, blood volume pulse amplitude

FIGURE 2

baseline values shows that many participants were already being treated well for pain before the beginning of the study. In other studies that did find evidence of an analgesic effect for music therapy, recruitment was targeted at patients with acute symptoms of pain (10).

The observed improvement in overall quality of life in both groups may be explained by effective palliative care in general. The effects are greater in the music therapy group, but the difference is not statistically significant. Broader interventions may be needed in order to describe effects on a global variable such as quality of life. In some previous studies standardized description of specific interventions was not used, and active as well as receptive techniques were performed (11, 13).

On the fatigue subscale the observed differences were statistically significant; this is concordant with the findings of a recent pilot study involving breast cancer patients (40). Because evaluation of individual quality-of-life scales was explorative (with no alpha adjustment for multiple testing), this provides a useful basis for research addressing the effects of music therapy on fatigue in confirmatory studies.

No treatment-as-usual study arm was included in the design of the present study, as it was considered more ethical to use an active control (21). The selected design means that both study arms share factors that affect personal care and relaxation. The observed differences were therefore caused by the two factors that were not common to both groups: music and the therapeutic relationship. According to the definition given above (4), these two aspects form the identity of music therapy as a health-care profession; the study results presented here may thus be considered evidence of the efficacy of genuine music therapy treatment. Long-term treatment effects are difficult to measure, as patients typically spend only a short time (sometimes only a few days) in palliative care units.

Because study patients were not informed as to which of the two interventions was the experimental condition and which the control, they were blind with regard to the study hypotheses. For organizational reasons, no further blinding procedures (for the music therapist or study assistant) were possible. In a total of 78 music therapy sessions, only one (1.3%) was halted due to pain/anxiety on the part of the patient (*eFigure 4*). This fact suggests high acceptance and low levels of side effects.

This study is the first randomized controlled trial to examine objective data for evidence that receptive music therapy has an effect on well-being and relaxation in patients receiving palliative care. The tested relaxation exercise can be used effectively by music therapy practitioners in their work with seriously and terminally ill patients. Because more data has become available in recent years (10, 20), review articles should re-examine the available evidence on the efficacy of music therapy (2, 3).

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Conflict of interest statement

The authors declare that no conflict of interest exists.

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KEY MESSAGES

- Receptive music therapy can effectively enhance relaxation and well-being in seriously and terminally ill patients.
- The relaxing effect of the music therapy intervention was detected on the basis of both patients' self-assessments and evaluation of physiological data.
- The recorded reduction in fatigue resulting from music therapy should be further investigated in future studies.
- Long-term effects of the intervention were not recorded and are difficult to measure in the investigated population.
- A total of 78 music therapy sessions were conducted. Only one patient (1.3%) required treatment to be halted due to pain/anxiety.

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Supplementary material to:

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Study design

VAS, visual analog scale; HRV, heart rate variability, T, time

eFigure 2: Music therapy session involving a monochord

eFIGURE 3

Session procedure

EG, experimental group; CG, control group;
VAS, visual analog scale; HRV, heart rate
variability

eTABLE

Group comparison at time T0 (baseline)

Variable	MT (n = 42)	CG (n = 42)	p ^{*4}
Sex (female) ^{*1}	28 (66.7%)	32 (76.2%)	0.33
Diagnosis (tumor disease) ^{*1}	41 (97.6%)	41 (97.6%)	1.00
Age ^{*2}	63.8 (14.1)	62.2 (12.8)	0.59
Karnofsky scale ^{*2}	38.6 (11.7)	40.0 (10.6)	0.57
Interest in relaxation exercise (scale 1 to 4) ^{*2,3}	3.39 (0.70)	3.42 (0.70)	0.82

MT, music therapy; CG, control group

^{*1}absolute and relative frequencies, chi-square test

^{*2}means, standard deviations, t-test

^{*3}4 = great interest

^{*4}statistically significant if p < 0.05

eFIGURE 4

Box-and-whisker plots showing changes in quality of life (before and after)

middle line (bold), median; colored rectangle, 25th to 75th percentile; whiskers, upper/lower quartile; points, outliers; asterisks, extremes.

MT, music therapy; CG, control group;

QL, overall quality of life; FA, fatigue