ThemenCheck Medizin

Extract of HTA report

Cancer[1]

Can concomitant music therapy contribute to better treatment results?

Health technology assessment commissioned by IQWiG

IQWiG Reports – Commission No. HT17-02

IQWiG

[1] Translation of the publisher's comment and of Chapters 1 to 9 of the HTA report HT17-02 *Krebs – Kann eine begleitende Musiktherapie zu besseren Behandlungsergebnissen beitragen?* (Version 1.0; Status: 13 June 2019 [German original], 27 May 2020 [English translation]). Please note: This document was translated by an external translator and is provided as a service by IQWiG to English-language readers.

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According to §139b (3) No. 2 of Social Code Book (SGB) V, Statutory Health Insurance, external experts who are involved in the Institute's research commissions must disclose "all connections to interest groups and contract organizations, particularly in the pharmaceutical and medical devices industries, including details on the type and amount of any remuneration received". The Institute received the completed *Form for disclosure of potential conflicts of interest* from each external expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. The information on conflicts of interest provided by the external experts and external reviewers is presented in Chapter A12 of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

Publisher's comment

What is the background of the HTA report?

In "ThemenCheck Medizin" (Topic Check Medicine), statutory health insurance members and other interested people can propose topics for health technology assessment (HTA) reports. According to the legal mandate, the selected topics should potentially supply "additional information and insights for statutory health insurance members and other interested people" and be "especially important for patient care" [1].

From among the first topics suggested, in 2017, the Institute for Quality and Efficiency in Health Care (IQWiG) selected 5, including the topic "Cancer: Can concomitant music therapy contribute to better treatment results?", for the preparation of an HTA report. This was the result of a 2-stage selection process conducted in collaboration with patient representatives.

Why is the HTA report important?

Patients often experience cancer as an existentially threatening life event, and it can be associated with a massive deterioration in quality of life. Cancer and the associated treatment present not only a physical burden but can also give rise to considerable psychological distress. Particularly after inpatient treatment at a hospital, coping with cancer-related anxiety or stabilizing self-esteem presents a challenge for many patients [2, 3].

In recent decades, increasing attention has been paid to cancer-related physical and psychological strains. Since the 1970s, for example, psychooncological care structures in Germany have been continuously expanded.

Music therapy is one treatment option in the psychooncological care of cancer patients. Through the systematic use of music, it aims at restoring, maintaining, and promoting mental and physical health. Irrespective of whether music is listened to or actively made, the verbalization and processing of experiences and emotions together with a therapist are key elements of music therapy.

Music therapy is listed as a service in the relevant classification catalogues for hospitals and rehabilitation facilities. Outpatient music therapy is typically not covered by statutory health insurers, which makes it inaccessible to socioeconomically disadvantaged persons.

The question is whether concomitant music therapy is actually associated with health benefits for cancer patients. These benefits may be in the form of reduced pain or anxiety, better physical functioning, or increased health-related quality of life after music therapy. Proof of

any benefit would require the effect of music therapy to be investigated in well-designed studies.

Against this backdrop, IQWiG selected the topic “music therapy in cancer” for the preparation of an HTA report and commissioned an external working group to prepare it. This working group consisted of methodologists experienced in preparing HTA reports, experts with knowledge and experience in health economic, ethical, social, legal, and organizational issues, an oncological clinician, and a music therapist.

Which questions are answered – and which are not?

The working group found a total of 10 methodologically sound studies that investigated the benefit of music therapy for cancer patients. In summary, on the basis of these findings, the external experts found indications and hints of a short-term effect of music therapy with regard to psychological outcomes such as fatigue, mood swings, anxiety, and health-related quality of life. More simply put: After a music therapy session, attendant psychological symptoms improve in the short term. From the IQWiG perspective, this is a favourable result, particularly in view of patients often being in a very distressing situation.

However, a series of questions were impossible to answer on the basis of the evidence found.

For instance, it would be important to determine whether music therapy helps cancer patients with regard to psychological states such as clinical depression or whether anxiety and fatigue can be favourably influenced over a longer time period. In the identified studies, the external experts did not find any answers to these and other questions.

No results at all are available on other potentially patient-relevant outcomes. These include, for instance, the question whether music therapy can help patients perform activities of daily living within the usual scope or whether social participation and/or coping improve. Furthermore, any potential adverse effects of music therapy were investigated by only one study.

The performance of music therapy can take different forms, as described by the external experts in the report. The way in which a music therapy session is conducted, for instance, depends on the therapist’s training and school of thought. In addition, music therapy offerings can considerably differ depending on indication, treatment goals, and potential patient preferences. This makes it difficult to discuss music therapy as a uniform entity. In addition, this complicates any pooling and interpretation of results of the studies found for this HTA report.

Music therapy is offered in the form of individual and group therapy. At certain points in the cancer disease and therapy, individual music therapy may be preferable since a confrontation

with other patients' experiences may complicate coping with the patient's own difficult situation. However, the external experts point out that in conversations, cancer patients reported group music therapy potentially promoting personal stability and social support. Nonetheless, no studies examining music therapy performed in a group setting were found for this report. This HTA report therefore cannot provide any conclusive results on any patient benefit or harm of group music therapy.

To facilitate a specific assessment of music therapy services, this HTA report was limited to music therapy in the narrow sense. Music medicine, which involves only the passive reception of music with a health-related intention, was excluded. This definition laid out at the beginning of the project means that the HTA report cannot offer any conclusions on any potential benefit or harm of music medicine.

What's the next step?

This HTA report has shown a hint or indication of short-term benefit of music therapy with regard to some psychological outcomes, such as fatigue, mood swings, and stress/tension. Due to the patients' often chronically and acutely distressing disease and life situations, the external experts consider the results to be relevant.

Against the backdrop of the results of this HTA report, the question may be raised whether it is appropriate to include music therapy in Annex 1 of the G-BA's Guideline on Remedies [4], which lists measures whose therapeutic benefit has not been proven according to the G-BA's Rules of Procedure.

The occupational title "music therapist" is not legally protected. Various stakeholders are attempting to address this issue. In 2004, for instance, the Kassel Conference of Music Therapy Societies in Germany [5] defined requirements for the occupational profile of music therapists. Likewise, the German Music Therapy Society (DMtG) has adopted "Certification Guidelines for Using the Professional Title 'Music Therapist DMtG'" [6]. According to the DMtG, this professional title can be used as a "seal of quality". However, this does not change the fact that there are no legally binding qualification requirements for music therapists. A discussion about the statutory health insurance covering the cost of music therapy therefore also requires the specification of binding criteria for the training and professional recognition of music therapists.

Within the framework of this HTA report, it was not possible to examine music medicine alongside music therapy. Nevertheless, a closer look at music medicine and the associated opportunities and risks in the German healthcare context would be desirable.

Likewise, studies should examine in greater detail to what extent music therapy, which was investigated in this HTA report, impacts outcomes such as coping, activities of daily living, and

health-related functioning, including occupational and social participation. The same applies to potential long-term effects of music therapy. Although the authors of this report consider music therapy to be associated with few ethical concerns, future studies should also investigate potential adverse effects of music therapy.

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HTA key statements

Research question of the HTA report

The aims of this investigation are to

– assess the benefit of music therapy (MT) as a therapy accompanying oncological standard therapy by comparing it to no accompanying therapy or other accompanying therapies in adult cancer patients with regard to patient-relevant outcomes,

– determine the costs arising from accompanying MT in comparison with a different or no accompanying therapy in adult cancer patients (intervention costs),

– assess the cost effectiveness of MT accompanying standard therapy in comparison with no accompanying therapy or other accompanying therapies in adult cancer patients as well as

– review ethical, social, legal, and organizational aspects associated with the intervention.

Conclusion of the HTA report

MT as an accompanying therapy in oncology has already been established in the German healthcare system, particularly in the (acute and palliative) inpatient and rehabilitation settings, through service reimbursement as well as its mentions in national guidelines. The present HTA reveals indications and hints of a short-term benefit of MT in comparison with standard care with regard to fatigue, mood swings, anxiety, anxiety & depression, stress/tension, and health-related quality of life as well as, over the course of several sessions, with regard to cancer-related adverse events, fatigue, and mood swings. In comparison with other accompanying therapies (music medicine, mindfulness-based stress reduction), a hint of greater short-term benefit of MT was found with regard to fatigue and subjective well-being. Notably, the available evidence shows a positive effect particularly for comparatively short-term psychological outcomes and, in general, primarily for non-biological outcomes – soon after the intervention. For most biological (clinical) outcomes as well as for persistent psychological conditions such as depression, there is generally a lack of evidence in favour of MT. However, these short-term effects are to be considered in light of the typically precarious, in some cases life-threatening, situation of patients. Furthermore, MT is a non-invasive intervention associated with few ethical concerns and is impossible to conduct without considerable patient motivation and cooperation.

The results on the benefit of MT are transferable to Germany if a consistent professional concept and standardized training and/or certification can be assumed to be in place, which is, however, not entirely the case in view of the current lack of regulation. However, a uniform consensus has been reached on the occupational profile as well as (voluntary) certification.

Due to differences in reimbursement and local availability, access to MT (in general and in oncology) is not uniformly regulated among inpatient care, the rehabilitation sector, and outpatient care.

Due to a lack of data, some questions cannot be answered at this time: No studies were found on the outcomes of coping or activities of daily living, and no study investigating MT as a group intervention was found. Data are insufficient for performing a comparative analysis of the benefit of MT in different cancer entities or for a comparison of curative versus palliative therapy. In the direct comparison with alternative accompanying therapies, MT in the form defined herein was studied in only 3 out of 10 studies, and no studies investigated it in comparison with “sham treatment”. No data are available on cost-effectiveness, and estimating the intervention costs is hindered by a lack of data on average treatment duration and frequency of sessions. Only 1 out of the 10 studies was conducted in an outpatient setting.

Two ongoing studies on MT from Israel and Germany were found, and their design might potentially produce insights regarding longer-term effects and coping (outcome of “resilience”).

Table of contents

List of tables

List of abbreviations

Abbreviation	Meaning
AE	Adverse event
BAG	Bundesarbeitsgemeinschaft (German Working Committee)
BAG-KT	Bundesarbeitsgemeinschaft Künstlerische Therapien (German Working Committee of Arts Therapies)
BMG	Bundesministerium für Gesundheit (Federal Ministry of Health)
CBMT	Cognitive-behavioural music therapy
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
DMtG	Deutsche Musiktherapeutische Gesellschaft (German Music Therapy Society)
DRG	Diagnosis-Related Groups
EUnetHTA	European Network for Health Technology Assessment
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
GIM	Guided Imagery and Music
GrpMI	Group Music and Imagery
HPG	Heilpraktikergesetz (German Alternative Practitioners Act)
HTA	Health technology assessment
ICD-10-GM	International Classification of Diseases (German Modification)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
MT	Music therapy
OPS	Operationen- und Prozedurenschlüssel (Operation and Procedure Code)
PMR	Progressive muscle relaxation
PTG	Psychotherapeutengesetz (German Psychotherapist Act)
RC	Routine care
RCT	Randomized controlled trial

HTA overview

1 Background

1.1 Health policy background and commission

According to § 139b (5) of the German Social Code Book V, Statutory Health Insurance, the insured and other interested individuals may suggest topics for the scientific assessment of medical interventions and technologies to the Institute for Quality and Efficiency in Health Care (IQWiG). The topics for these health technology assessment (HTA) reports can be submitted on the ThemenCheck Medizin ("topic check medicine") website.

ThemenCheck Medizin aims to promote the involvement of the public in evidence-based medicine and answer questions that are particularly relevant in patient care.

Once yearly, IQWiG, in collaboration with patient representatives, selects up to 5 topics on which HTA reports are to be prepared. IQWiG then commissions external experts to investigate the research question. The results prepared by the external experts together with a publisher's comment from IQWiG are then published in the form of an HTA report.

IQWiG disseminates HTA reports to German institutions, for instance those deciding about health care services and structures. This is done to ensure that the results of HTA reports will impact patient care.

1.2 Medical background

Malignant neoplasms (cancer)

The current "International Statistical Classification of Diseases and Related Health Problems" (ICD-10-GM, version 2018) [1] lists malignant neoplasms, including malignant neoplasms of the lymphatic tissue and leukaemias (neoplasms of the blood or blood-forming organs), in Chapter II, Group C. Malignant neoplasms are characterized by invasive growth, i.e. they invade surrounding tissue and/or spread through the blood and lymphatic systems. In accordance with remarks on ICD-10-GM, version 2018, the term "cancer" is used as an umbrella term for malignant neoplasms.

In Western industrialized nations such as Germany, about 1 in 2 women and 1 in 2 men develop cancer at some point in their lives. Slightly more than half of all cancer cases in Germany affect the lung, mammary gland, prostate, or intestine [2].

According to the German Centre for Cancer Registry Data (ZfKD) [2], about 476,000 initial cancer cases were diagnosed in Germany in 2014. Between 2004 and 2014, the absolute

number of diagnosed new cases rose slightly (by 6% in men and 9% in women). One reason for the rise in incidence is a change in the population's age structure, with the number of older people – especially men – increasing.

Cancer is a leading cause of death in Germany – second only to cardiovascular disease. However, between 2005 and 2015, age-standardized cancer mortality rates in Germany decreased by about 12% in men and about 7% in women; this trend is partially attributed to more effective therapies and early cancer detection [2].

The prognosis of cancer varies greatly by type and stage of disease. For example, 5-year survival rates above 90% have been calculated for malignant melanoma of the skin, testicular cancer, and prostate cancer, while 5-year survival for certain cancers of the lung, liver, or pancreas lies below 20% [2].

The treatment of cancer depends particularly on the type of neoplasm and disease stage. Further, patient-specific factors such as comorbidities and general health status as well as personal treatment goals are taken into account when selecting the specific therapy. As a result, the actual course of therapy can considerably vary from patient to patient. The most common conventional oncological treatment methods (standard therapies) are surgical tumour removal, chemotherapy, and radiotherapy, plus – for leukaemia and certain lymphomas – stem cell transplantation [3]. Lately, more and more new molecular biological therapies (known as targeted therapies) are being developed to target cancer cells even more specifically, lessen harm to healthy body cells, and further reduce side effects. In addition to curative treatment methods, several supportive therapies are available in cancer treatment [4]. For patients with incurable, life-threatening cancer, palliative cancer treatment and palliative care are available. Palliative tumour treatment includes tumour-specific drug-based and non-drug-based interventions that aim to increase life expectancy and/or control symptoms [5]. Palliative medicine (palliative care) is the umbrella term for all activities intended to improve the quality of life of people with incurable, life-threatening diseases (and their families). Adequate palliative medicine or care generally requires an interdisciplinary and multiprofessional approach [5].

Despite proven advances in the efficacy and tolerability of conventional treatment methods, patients typically experience cancer and its therapy as existentially threatening, and it is associated with a massive reduction in quality of life. According to the biopsychological model of illness, the consequences of cancer and adverse effects from cancer treatment present in many different forms, including pain, inability to function in daily life, persistent fatigue, symptom-related burden (including due to severe nausea, vomiting, hair loss, and impaired concentration and memory), body image changes, anxiety, depressive moods, or social withdrawal [6–8].

Music therapy

The German Music Therapy Society (DMtG), under whose auspices representatives of 8 music therapy associations in Germany developed a shared consensus on music therapy (MT), agreed on the following definition of MT:

> "'Music therapy' is a collective term for different music therapy concepts which are psychotherapeutic in nature, in contrast to pharmacological and physical therapy. Music therapy is the systematic use of music within a therapeutic relationship with the goal of restoring, maintaining, and furthering emotional, physical, and mental health. In music therapy, music is the subject matter and thus reference point for the patient and therapist in the material world. On this basis, the individual's perception, experiential, symbolization, and interpersonal skills can develop. Reception, production, and reproduction of music trigger intrapersonal and interpersonal processes and thereby serve both a diagnostic and a therapeutic function. The musical material is suitable for activating resources and substantiating individually meaningful experiential contexts, which are used as a starting point for further exploration. MT methods equally follow depth psychology, behaviour therapy-learning theory, systemic, anthroposophic, and holistic-humanistic approaches."[9]

Therefore, the specific MT treatment process can vary greatly. It is based in particular on the therapist's scientific and theoretical orientation (school of thought) and training background and is aligned with the patient's therapeutic indication, therapeutic objectives, and preferences.

MT with cancer patients

MT is a treatment option in the psycho-oncological care of cancer patients. Psychooncology (also known as "psychosocial oncology") is concerned with the "experience, behaviour, and social resources of cancer patients as they are related to their cancer, its treatment, and its associated problems" [10].

MT in general and specifically MT with cancer patients employs 2 general methods: receptive and active MT. In receptive MT, the central therapeutic approach involves listening to music, followed by processing experiences and feelings in conversation (verbalization). Active MT, in contrast, focuses on creating music, with subsequent verbalization. In this process, music can be made in very different forms: e.g. as improvised music with a wide variety of instruments (from a drum to the piano). Improvisation may be done alone, with the therapist, or with several others in a group. Another important approach in active MT is music reproduction, i.e. the active playing or singing of sheet music or active playing or singing of well-known music titles [11].

The S3 Guideline "Psycho-oncological Diagnostics, Counselling, and Treatment of Adult Cancer Patients" [10] recommends making MT available to cancer patients particularly to reduce anxiety.

The S3 Guideline "Palliative Care for Patients with Incurable Cancer" [5] states the following about MT as a form of creative arts therapy: "Patients with cancer benefit from these interventions through the support of emotional and spiritual expression as well as the promotion of relaxation, pain relief, and well-being."

According to Hillecke 2007 [12], the specific intervention in MT can be understood as the impact of music on emotions, with activating, mobilizing effects as well as calming, stress-reducing effects being conceivable, and overall, the therapeutic effect being initiated, reinforced, and sustained. Other important elements are (nonverbal) communication and social interaction as well as musical expression as a therapeutic alternative to verbal communication [12]. Relationships to the social environment can be addressed by this therapy as well [13].

In the palliative situation, the aspect of nonverbal communication plays a special role, depending on the patient's physical condition and emotional state. In addition, the option of switching from the active to the receptive therapy form is gaining in importance. The linked effect on several levels simultaneously (social, psychological, physical, spiritual) has been described as another strength of MT [14].

Regulatory status of MT in the German healthcare system

According to the German Working Committee of Art Therapies (BAG-KT), MT is considered "creative arts therapy", as are art, dance, or theatre therapy [15]. The profession is currently not legally regulated in Germany. The German Working Committee Music Therapy (BAG Music Therapy) and the MT associations under its umbrella are undertaking various efforts towards the standardization of training and occupational profile. On the basis of criteria published in Certification Guidelines [16], for instance, DMtG issues the "Music Therapist DMtG" certificate [17]. According to its website, BAG Music Therapy is developing a universal occupational profile for MT in Germany. In addition, the committee offers a German national directory of music therapists who have MT qualifications that "meet the high quality standards jointly recognized by BAG Music Therapy and its member associations" [18].

MT is offered in outpatient and acute inpatient care as well as in (outpatient and inpatient) rehabilitation, and therapists are can be employed or self-employed. According to a survey published in 2014, among all self-employed persons in the area of creative arts therapies, 43% are licensed to work as alternative non-medical practitioners, three-fourths of which as alternative non-medical practitioners for psychotherapy [19, 20].

In the outpatient sector, MT is currently not included as a standard benefit of statutory health insurers [21]. In inpatient treatment, it is integrated in the Diagnosis Related Groups system through the Operation and Procedure Code (OPS), under the umbrella term “creative arts therapies” [22]. Furthermore, it is listed in the “Classification of Therapeutic Procedures in Medical Rehabilitation” catalogue of the German Pension Insurance, again under the collective term “creative arts therapies”.

2 Research questions

The aims of this investigation are to

- assess the benefit of MT as a therapy accompanying oncological standard therapy by comparing it to no accompanying therapy or other accompanying therapies in adult cancer patients with regard to patient-relevant outcomes,
- determine the costs arising from accompanying MT in comparison with a different or no accompanying therapy in adult cancer patients (intervention costs),
- assess the cost effectiveness of MT accompanying standard therapy in comparison with no accompanying therapy or other accompanying therapies in adult cancer patients as well as
- review ethical, social, legal, and organizational aspects associated with the intervention.

3 Methods

To gain insight into important patient-relevant outcomes as well as ethical, social, legal, and organizational aspects from the perspective of individuals who received music therapy (MT) in the context of cancer, exploratory interviews were conducted with persons affected as part of this HTA.

3.1 Methods of the benefit assessment

The target population of the benefit assessment was adult patients with cancer. The experimental intervention was (active or receptive) MT as a treatment accompanying oncological standard therapy. An essential element of the intervention of MT is the targeted use of music within the framework of a therapeutic relationship. The comparator intervention is either no additional accompanying therapy, accompanying placebo treatment, or another accompanying therapy. Typically, therapy is a process that takes a minimum of several weeks or several therapy units.

The investigation examined the following patient-relevant outcomes[2]:

- Mortality
- Morbidity, including
  - Pain
  - Depressiveness
  - Anxiety
  - Fatigue
  - Physical functioning
  - Stress/tension
- Activities of daily living / everyday functioning
- Health-related social functioning, including occupational and social participation
- Coping
- Subjective well-being
- Health-related quality of life
- (Serious) Adverse events

[2] Outcomes were defined by the team of authors in collaboration with the involved MT experts and in consideration of the results from the interviews with the persons affected.

Only randomized controlled trials (RCTs) were included in the benefit assessment. No limitations were in place regarding study duration other than the one mentioned above (process includes more than one therapy unit).

A systematic search for primary literature was conducted in the MEDLINE, Embase, Cochrane Central Register of Controlled Trials, and PsycInfo databases. In parallel, a search for relevant systematic reviews was conducted in the MEDLINE, Embase, and PsycINFO databases as well as in the Cochrane Database of Systematic Reviews and Health Technology Assessment Database.

The following sources of information and search techniques were additionally used: study registries, systematic reviews, documents made available from commenting procedures, and requests to authors.

Relevant studies were selected by 2 persons independently from one another. Any discrepancies were resolved by discussion between them. Data were extracted into standardized tables. To assess the qualitative certainty of results, the risk of bias was assessed at both study and outcome levels and rated as high or low in either case. The results of the individual studies were organized according to outcomes and described.

To the extent that the studies were comparable in terms of their research questions and relevant characteristics and no meaningful heterogeneity was observed, the results from individual studies were quantitatively combined in meta-analyses.

For each outcome, a conclusion was drawn on the evidence for (greater) benefit and (greater) harm, with 4 levels of certainty of conclusions: proof (highest certainty of conclusions), indication (moderate certainty of conclusions), hint (lowest certainty of conclusions), or neither of the above 3. The latter is the case if no data are available or the available data do not permit classification into one of the 3 other categories. In that case, the conclusion “There is no hint of (greater) benefit or (greater) harm” was drawn.

The results were broken down by time of analysis: short-term effects (immediately after a therapy session or after the last of a series of sessions), effects over the course of several sessions, and measurements during the follow-up period (typically several days, weeks, or months after the intervention phase). Where results were available for several timepoints of analysis within the intervention phase (often consisting of several sessions), preference was given to presenting the measurements after the last session as well as measurements of change over time.

3.2 Methods – health economic assessment

To calculate the intervention costs, the average resources required directly when performing the experimental and comparator intervention were determined. For this purpose, the services directly associated with the intervention in addition to the experimental and comparator interventions were taken into account. The relevant regulated or negotiated prices of these services were used wherever possible. Where a therapy took more than one year, the average annual cost per patient was reported. Reimbursable and non-reimbursable costs were listed separately.

The systematic overview of health economic studies included cost-effectiveness analyses, efficacy analyses, cost-utility analyses, and cost–benefit analyses. Studies were eligible for inclusion if they were conducted in Germany or other high-income economies as defined by the World Bank [23].

In the context of the focused information retrieval, a systematic search for primary literature was conducted in the MEDLINE and Embase databases. In parallel, a search for relevant systematic reviews was conducted in the MEDLINE and Embase databases, and additionally in the Health Technology Assessment Database. Further, the following information sources and search techniques were used: systematic reviews, documents made available from commenting procedures, and requests to authors.

The identified quotes were selected by one reviewer, with quality assurance done by a second person. Standardized tables were used for data extraction, and the criteria of the CHEERS statement [24] and the EUnetHTA's HTA adaptation toolkit [25] were applied in the assessment of the report's quality and transferability. The HTA report aims to include a comparative description of the cost-effectiveness results reported in the studies as well as the authors' conclusions.

3.3 Methods – ethical and social aspects

As part of the scoping search, the ETHMED (Ethics in Medicine), Ethicsweb, and MEDLINE databases were searched. This was complemented by a manual search in Google/Google Scholar and a snowball search for further relevant information sources.

Information from the information sources of the scoping search was screened by one reviewer for statements on ethical and social arguments and aspects of the technology to be investigated. The result underwent quality assurance done by a second person. All arguments and aspects necessary for information processing were extracted into tables.

3.4 Methods – legal and organizational aspects

As part of the scoping search, the MEDLINE database was searched. This was complemented by a manual search in Google/Google Scholar and a snowball search for further relevant information sources.

Information from the information sources of the scoping search was screened by one reviewer for statements on legal and/or organizational arguments and aspects of the technology to be investigated. The result underwent quality assurance done by a second person. All arguments and aspects necessary for information processing were extracted into tables.

4 Results: Benefit assessment

4.1 Results of the comprehensive information retrieval

The information retrieval found 10 randomized controlled studies (10 documents) to be relevant for the research question of this benefit assessment. Two ongoing studies were found. Further, 4 completed studies without reported results were identified as well as 6 studies of unclear completion status.

The search strategies for bibliographic databases and trial registries are found in the appendix. The most recent search was conducted on 25 January 2018.

Table 1: Study pool of the benefit assessment

Study	Available documents (all: full publications in professional journals)
Alcântara-Silva	[26]
Bates	[27]
Bradt	[28]
Cassileth	[29]
Doro	[30]
Hilliard	[31]
Ratcliff	[32]
Rossetti	[33]
Tuinmann	[34]
Warth	[35]

4.2 Characteristics of the studies included in the assessment

A total of 10 studies were included (Alcântara -Silva et al. 2018 [26]; Bates et al. 2017 [27]; Bradt et al. 2015 [28]; Cassileth et al. 2003 [29]; Doro et al. 2017 [30]; Hilliard et al. 2003 [31], Ratcliff et al. 2014 [32]; Rossetti et al. 2017 [33]; Tuinmann et al. 2017 [34]; Warth et al. 2015 [35]). The oldest, by Cassileth, is a multicentric study conducted in the USA and Ireland, while the most recent one was conducted in Brazil by Alcântara-Silva and published in 2018. The Doro study is from Brazil as well, while Tuinmann and Warth were carried out in Germany. Bates, Hilliard, Rossetti, and Bradt were conducted in the USA. Eight RCTs took place in a curative setting. In 5 of them, MT accompanied stem cell transplantation, in 1 RCT, radiation therapy simulation, and in the 2 remaining studies, radiotherapy and chemotherapy. Two studies were done in a palliative setting. Seven studies compare MT with standard care, 2 with music medicine[3] or a mindfulness-based stress reduction programme, and 1 study has

[3] Music medicine is defined herein as an intervention associated with the (passive) listening to music, without a systematic therapeutic process [28].

2 comparator groups (unstructured music listening and standard care). Nine studies took place in an inpatient setting, and 1 (Hilliard), in a hospice setting. The cancer types of the patients who participated in the included studies can be classified into the following 3 general groups: patients with cancer of the blood-forming and lymphatic systems (in studies which included participants on the basis of planned stem cell transplantation), patients with breast cancer (as the major type of cancer, some patients with other gynaecological or other cancers were included as well), and patients with different tumour entities (main selection criterion in this case was a palliative setting or terminal stage of disease).

4.3 Overview of assessment-relevant outcomes

Data on patient-relevant outcomes were extracted from 10 studies. Table 2 presents an overview of the available data on patient-relevant outcomes from the included studies. None of the studies reported any data on the outcomes of “activities of daily living / everyday functioning”, “health-related social functioning, including occupational and social participation”, and “coping”.

Table 2: Matrix of patient-relevant outcomes

Study	Outcomes																
		Morbidity															
	All-cause mortality / overall survival	Pain	Depression	Anxiety	Anxiety & depression	Fatigue	Physical functioning	Nausea	Mood	Stress/tension	Cancer-related symptoms	Activities of daily living / everyday functioning	Health-related social functioning, including occupational and social participation	Coping	(Serious) AEs / discontinuation due to AEs	Subjective well-being	Health-related quality of life
Comparison with "no accompanying therapy"																	
Alcântara-Silva	-	-	●	-	-	●	-	-	-	-	-	-	-	-	-	-	●
Bates	-	●	●	-	-	●	-	●	●	●	-	-	-	-	-	-	-
Cassileth	-	-	●	●	●	●	-	-	●	●	-	-	-	-	-	-	-
Doro	-	●	-	●	-	-	-	-	●	-	-	-	-	-	-	-	-
Hilliard	●	-	-	-	-	-	●	-	-	-	-	-	-	-	-	-	●
Rossetti	-	-	-	●	-	-	-	-	-	●	-	-	-	-	-	-	-
Tuinmann	-	●	●	●	-	-	-	-	●	-	-	-	-	-	●	-	●

(continued)

Table 2: Matrix of patient-relevant outcomes (continued)

Study	Outcomes																
		Morbidity															
	All-cause mortality / overall survival	Pain	Depression	Anxiety	Anxiety & depression	Fatigue	Physical functioning	Nausea	Mood swings	Stress/tension	Cancer-related symptoms	Activities of daily living / everyday functioning	Health-related social functioning, including occupational and social participation	Coping	(Serious) AEs / discontinuation due to AEs	Subjective well-being	Health-related quality of life
Comparison with different accompanying therapy																	
Bradt	-	●	-	●	-	-	-	-	●	●	-	-	-	-	-	-	-
Ratcliff	-	-	-	-	-	-	-	-	●	-	●	-	-	-	-	-	●
Warth	-	●	-	-	-	●	-	-	-	●	-	-	-	-	-	●	●

● Data were reported and usable.
○ Data were reported but not usable for the benefit assessment.
x Data were not reported despite planned data collection.
- No data were reported (no further information) / The outcome was not surveyed.
AE: adverse events

4.4 Assessment of the risk of bias at study and outcome levels

The risk of bias at study level was rated as high for all studies. In all studies, this was due to a lack of blinding and potential bias caused by subjectively assessed (that is, patient-reported) outcomes. Further reasons for a potential risk of bias were also identified in the individual studies. They included, e.g. missing information on the randomization technique and on participant allocation following randomization as well as high drop-out rates.

4.5 Results on patient-relevant outcomes

Unless stated otherwise, the results below apply to the comparison of MT versus standard care (SC).

Results on all-cause mortality / overall survival

Only 1 study [31] in the hospice setting compares all-cause mortality, finding no significant differences for this outcome. This results in no hint of any benefit of MT in comparison with SC.

Pain

Regarding short-term effects, Tuinmann et al. [34] report prompt success of MT in comparison with SC on the basis of a subscale of the "Quality of Life in palliative cancer care patients" questionnaire from the European Organisation for the Research and Treatment of Cancer (EORTC QLQ-C30). The results from Bates et al. [27] and Doro et al. [30] fail to show an immediate effect: On the basis of visual analogue scales, neither found any significant difference to SC. Bates et al. [27] additionally investigated pain by means of an analogue scale and analgesic drug use over the course of the study – without and with significant results, respectively. In comparison with music medicine or a mindfulness-based stress reduction programme, 2 studies [28, 35] found no significant differences. All things considered, there were therefore no hints of an effect of MT.

Depression

With the exception of one result in favour of an immediate effect of MT [26], the 4 available studies on the outcome of depression [26, 27, 29, 34] found no significant results in favour or against the use of MT. This results in no hint of any benefit of MT in comparison with SC.

Anxiety

Regarding immediate effects of MT versus SC, 3 out of 4 studies [30, 33, 34] found symptom improvement, and in 2 of them [30, 33], the improvement was significant. This results in a hint of an immediate benefit of MT in comparison with SC. In comparison with MM, a promptly measured, non-significant result [28] was found; hence there was no hint of benefit.

Anxiety & depression

One U.S. study used instruments that measure anxiety and depression in combination. Cassileth et al. measured a significant immediate improvement in the MT group. The same study found no significant improvement over the course of multiple sessions. This results in a hint of an immediate benefit of MT in comparison with RC.

Fatigue

In two out of 4 selected studies, a significant positive effect of MT was found immediately after the intervention (phase). This means that there is an indication of (immediate) benefit. Further, (in 1 of the 2 studies [29]), there is a hint of benefit over the course of several sessions. While the comparison of MT versus SC [27] shows no hint of long-term benefit, the comparison of MT with alternative accompanying therapy [35] did result in a hint of long-term effects (follow-up).

Physical functioning

One study [31] reported an immediate, non-significant result for physical functioning. No evidence base is available for long-term effects. Therefore, there is no hint of benefit of MT in comparison with SC.

Nausea

Only 1 study [27] investigated nausea promptly after the intervention phase. While over the course of the stay, the scores initially dropped considerably, seven days after the intervention phase (day “+7”), the authors measured significantly greater nausea in the MT group than in the comparator group. No hint of lesser benefit of MT in comparison with SC was derived despite the presence of a statistically significant effect since the study’s authors reported, as a limitation, antiemetic concomitant medication not having been recorded.

Mood swings

For the outcome of mood swings – occurring shortly after the intervention phase – 2 studies are available showing a significant improvement with MT [29, 30] as well as 1 study with a significant improvement over the course of multiple sessions [29]. Results showing a positive long-term effect [32] as well as immediate improvement in comparison with music medicine [28] (each based on 1 study) are not statistically significant. Hence, for immediate results, there is an indication of benefit, and for measurements over the course of the sessions, a hint of benefit.

Stress/tension

One study [29] shows a significant improvement in immediate effect and hence a hint of benefit. In the comparison of the course over time of the MT sessions, 1 study [29] shows a significant improvement, and another study [27], a non-significant improvement. In

comparison with other accompanying therapies, 2 studies [28, 35] reveal immediate effects, one with a significant improvement [35] and one with non-significant improvement [28]. No evidence is available on long-term effects.

Cancer-related symptoms

One study [32] investigated this outcome and revealed no significant changes. Hence, for this outcome, there is no hint of a benefit.

Activities of daily living / everyday functioning

No studies were found on this outcome.

Health-related social functioning, including occupational and social participation

No studies were found on this outcome.

Coping

No studies were found on this outcome.

(Serious) adverse events (AEs) / discontinuation due to AEs

The selected studies did not analyse MT-related (serious) adverse events as an outcome.

One study [34] counted adverse medical events over the entire hospital stay. With the outcome being operationalized dichotomously, the average number of adverse events was significantly lower in patients with accompanying MT. This results in a hint of benefit of MT.

Subjective well-being

One study [35] is available on this outcome. Comparing the MT group with the comparator group (mindfulness-based stress reduction programme), it shows a significant difference in favour of MT with regard to subjective well-being. Hence, there is a hint of benefit of MT.

Health-related quality of life

The evidence regarding immediate effects is based on 2 studies [26, 31], which both found a significant difference in favour of MT, and 1 study [34] without a significant effect. In the follow-up, neither of the two studies (found for this operationalization) presented a significant result. Comparison with alternative accompanying therapies [35], in contrast, showed (for the short term) only a statistically non-significant benefit for patients receiving MT with regard to health-related quality of life. Therefore, a hint of benefit of MT is found only for immediate measurements of results.

4.6 Evidence map

Table 3 shows the evidence map regarding patient-relevant outcomes. The table breaks down the results of the overall consideration of outcomes by comparator intervention (SC or other accompanying therapy) and time of analysis.

Table 3: Evidence map regarding patient-relevant outcomes

All-cause mortality / overall survival	Morbidity										Activities of daily living / everyday functioning	Health-related social functioning, including occupational and social participation	Coping	(Serious) AEs / discontinuation due to	Subjective well-being	Health-related quality of life
	Pain	Depression	Anxiety	Anxiety & depression	Fatigue	Physical functioning	Nausea	Mood / mood swings	Stress/tension	Cancer-related symptoms						
Comparison with "no accompanying therapy"																
Short term after intervention (phase)																
-	⇑⇓ **Tu,** Ba, Do	⇑⇓ **Al,** Ca, Tu	⇗ **Do, Ro** Tu	⇗ **Ca**	⇑ **Al, Ca**	⇔ Hi	⇔ **Ba**[4]	⇑ **Ca, Do**	⇗ **Ca**	⇔ Ra	-	-		-	-	⇗ **Al, Hi,** Tu
Course over time																
-	⇑⇓ Ba, **Ba**	⇔ Ca	-	⇔ Ca	⇗ **Ca**	-	-	⇗ **Ca**	⇑⇓ **Ca,** Ba	-	-	-	-	⇗ **Tu**	-	-
Follow-up																
⇔ Hi	-	⇔ Ba	-	-	⇔ Ba	-	-	⇔ Ra	-	-	-	-		-	-	⇔ Ra

(continued)

[4] No hint of lesser benefit of MT in comparison with SC was derived despite the presence of a statistically significant effect since the study's authors reported, as a limitation, antiemetic concomitant medication not having been recorded.

Table 3: Evidence map regarding patient-relevant outcomes (continued)

All-cause mortality / overall survival	Morbidity										Activities of daily living / everyday functioning	Health-related social functioning, including occupational and social participation	Coping	(Serious) AEs / discontinuation due to	Subjective well-being	Health-related quality of life
	Pain	Depression	Anxiety	Anxiety & depression	Fatigue	Physical functioning	Nausea	Mood / mood swings	Stress/tension	Cancer-related symptoms						
Comparison with different accompanying therapy																
Short term after intervention (phase)																
-	⇔ Br, Wa	-	⇔ Br	-	⇗ **Wa**	-	-	⇔ Br	⇑⇓ **Wa**, Br	-	-	-	-	-	⇗ **Wa**	⇔ Wa
Course over time: no results																
Follow-up: no results																

⇑⇑: proof of (greater) benefit or proof of lesser harm
⇓⇓: proof of lesser benefit or proof of (greater) harm
⇑: indication of (greater) benefit or indication of lesser harm
⇓: indication of lesser benefit or indication of (greater) harm
⇗ hint of (greater) benefit or hint of lesser harm
⇘: hint of lesser benefit or hint of (greater) harm
⇔: no hint, indication, or proof, homogeneous result
(⇔): no hint, indication or proof, homogeneous result; the 95% confidence interval for relative effect is so imprecise that neither halving nor doubling of the effect can be ruled out
⇑⇓: no hint, indication or proof, heterogeneous result
-: no data reported

Al: Alcantara-Silva et al. 2018; Ba: Bates et al. 2017; Br: Bradt et al. 2015; Ca: Cassileth et al. 2003; Do: Doro et al. 2017; Hi: Hilliard et al. 2003; Ra: Ratcliff et al. 2014; Ro: Rossetti et al. 2017; Tu: Tuinmann et al. 2017; Wa: Warth et al. 2015

Note: Study name codes shown in bold indicate significant results.

4.7 Discussion

Hints and indications of efficacy are mostly found soon after MT interventions and tend to apply to psychological outcomes, but not to biological (clinical) outcomes. Regarding the psychological outcomes, it is notable that evidence in favour of MT is available for comparatively short-term mental states, such as mood (swings), anxiety, anxiety & depression, fatigue, and stress/tension, whereas there is a lack of evidence in favour of MT for persistent mental states such as depression. For biological outcomes (such as survival, pain, nausea, cancer-related symptoms), there are no hints or indications of any superiority of MT. An exception on the basis of 1 study are cancer-related clinical adverse events (e.g. infection, anaemia, or diarrhoea) measured over time (1 study found superiority in the MT group). Furthermore, there are hints of MT having a positive effect on quality of life and subjective well-being. No results are available on coping or for activities of daily living.

The effect of MT strongly depends on the therapeutic relationship and requires working with emotions as well as direct interpersonal interaction at the time of the treatment session. For this reason – and in view of cancer and its treatment often causing considerable acute distress – this report's team of authors and scientific advisers took into account short-term or immediate effects despite their potentially limited patient relevance. In a palliative setting and in any situation associated with a shorter life expectancy, the importance of rapid-onset effects cannot be overstated.

Conversely, in patients where MT accompanies curative therapy, the preponderance of data on short-term versus long-term effects is considered a lack of evidence. This particularly applies to outcomes such as pathological mental states or coping, which per se require a long-term effect or are impossible to meaningfully measure in the short term (alone). Hence, several study authors mention too short a time horizon as a limitation.

Many results of the included studies that show numerical superiority of MT are not statistically significant. The fact that the authors frequently list an insufficient number of participants as a limitation might be a sign of the rather low power of many studies. In a large number of them, interpretation was also somewhat hindered by the fact that they did not collect one clear-cut outcome but many individual (partial) results at different times and for different outcomes by means of different measuring instruments. In many cases, a focus on a single operationalization as the primary outcome would have facilitated interpretation.

Pooling studies was not possible or meaningful due to the differences in measuring instruments, times of analysis, and comparator interventions.

5 Results: Health economic evaluation

5.1 Intervention costs

In the acute inpatient and rehabilitation setting, MT is found in the corresponding classifications as a creative arts therapy (Classification of Therapeutic Procedures in Medical Rehabilitation (KTL) [36], Operation and Procedure Code (OPS) [37]). Hence, the costs are covered as part of treatment, but a direct determination of costs is not possible. The cost of MT provided in freelance practice, in contrast, is covered by statutory and private health insurers only on a case-by-case basis. As a first step in estimating costs, it is therefore possible to try to determine the average professional fees per unit of time in freelance practice and multiply it with the average number of necessary treatment units.

The average billed practitioner fees can be gleaned from various sources: on the one hand, from the 2013 "Analysis of the professional field of creative arts therapists" questionnaire [19, 20, 38] and a DMtG publication [39] and on the other hand – in view of music therapists in private practice being subject to licensing in accordance with PTG or HPG – from the German fee schedule for alternative non-medical practitioners [40], the German Fee Schedule for Physicians providing care outside the Statutory Health Insurance Scheme [41], and the Uniform Value Scale [42]. Combining this information with survey results reveals figures slightly below €30 on the lower end and over €100 on the upper end of the range; most practitioner fees are likely between €40 and €60. Most of these figures are based on individual therapy; the cost of group therapy is likely around €20 per participant and treatment unit. Session duration varies greatly as well, but cost and rates are often standardized to 50 or 60 minutes.

A look at the other creative arts therapists covered by the analysis of the professional field (dance, eurhythmics, and theatre therapists as well as other creative arts therapists) overall reveals no signs of considerable differences in average practitioner fees.

The duration of MT can in principle be either shorter or longer than one year and – according to the analysis of the professional field [38] – is on average apparently shorter for employed music therapists than for those who are self-employed. However, a duration of only "1 day to 1 week" was by far the least common answer given by both groups. In combination with information on the number of sessions per week, it can be concluded that therapies in the inpatient area are characterized by shorter duration but possibly greater session density – in part due to the setting. No further information is available, particularly on the specific average duration and number of sessions in (outpatient or inpatient) MT accompanying cancer treatment. All but one study included in the benefit assessment stem from individual therapy in an inpatient setting, and the analyses typically used the results of (only) a few sessions (although in some studies, therapy was certainly continued).

The Federal Joint Committee's guideline on the performance of psychotherapy [43] differentiates short-term and long-term therapy and defines a maximum of 12 sessions for short-term therapy. At an estimated mean cost of €50 for one MT unit provided in private practice, costs of €600 would arise in a fictitious case with 12 sessions of individual therapy. In light of the results of the analysis of the professional field, costs can range from a total of €100 to €200 for a few sessions to figures in the four-digit range for "long-term therapy" (for instance €2600 for once-weekly therapy for 52 weeks).

5.2 Cost effectiveness

5.2.1 Results of the information retrieval

The focused information retrieval did not reveal any relevant health economic evaluations.

The search strategies for bibliographic databases are found in the appendix. The most recent search was conducted on 25/01/2018.

5.2.2 Discussion

No health economic evaluation is available (yet), apparently because the available data and evidence on efficacy are inconsistent and mixed. In the context of MT, it is furthermore difficult to differentiate between the effect of the music itself and (potentially independently therefrom) that of interpersonal interaction and empathy. From a cost perspective, it might be of interest to compare MT with a form of "sham treatment" (insofar as ethically justifiable) offering no MT but interpersonal attention and potentially requiring fewer resources, since it would not necessitate any MT equipment or qualifications. However, the majority of the studies included in the benefit assessment compared MT with standard care without any further intervention. From a cost perspective, a comparison of individual versus group therapy would also be of interest. No RCT was found on this topic, either. A further difficulty in an economic assessment is the lack of standardization – or standardizability (particularly in palliative care [44]) – of the number of necessary sessions. Conceivably, the use of MT might shift costs in other areas or for other health services. If MT as an accompanying therapy has a positive effect, otherwise required symptom-relief measures (e.g. pain therapy) may be eliminated, or therapy might be improved due to better treatment adherence.

6 Results: Ethical, social, legal and organizational aspects

6.1 Results on ethical aspects

Although MT as an accompanying therapy in cancer is a non-invasive form of intervention [45], ethically and socially relevant questions exist in this context. This is in part due to complex and invasive cancer treatment causing great symptomatic distress, everyday and occupational activities often having to be given up, and the disease frequently being associated with existential worries. The scoping search of the ethical implications of MT with regard to the research question to be examined was based on ethical principles developed by Beauchamp and Childress. The relevant search criteria did not reveal any studies that explicitly investigate ethical aspects of MT or the mentioned ethical principles in this context or address ethical problems. However, the results of the 3 guided, exploratory interviews with affected persons, which were conducted in the context of the HTA, and the overall results of the search permit drawing conclusions on aspects that are ethically relevant from the authors' perspective. These aspects were additionally systematized on the basis of selected questions from Hofmann's checklist [46], which were developed for ethical reflection as part of "pragmatic HTA".

One relevant aspect is the issue of non-harm: This principle includes recognizing risks and preventing them. A legal basis for and regulation of the profession of music therapist substantially contributes to patient safety in this (expanded) sense. In Germany, however, these conditions are not currently met [47].

Concerning the question of an equitable distribution of health services, it must be noted that access to MT is limited insofar as statutory health insurers typically do not cover its costs in the outpatient setting [48]. Hence, socio-economically disadvantaged persons are potentially excluded from this service.

From the authors' perspective, morally relevant questions associated with outcome selection arise insofar as coping is an important potential outcome of MT but has not been investigated in the literature found. As another aspect related to research ethics, it must be noted that MT targets facets of (subjective) well-being that are, by their nature, usually more difficult to measure objectively than physiological outcomes, for instance. Morally relevant aspects in terms of the degree of generalization arise from the fact that music is part of daily life for many people and is practised and received in a variety of ways. Therefore, it is conceivable for patient acceptance to be affected by the individual's biography and cultural background, particularly since active cooperation (and motivation) are an essential part of therapy.

Several comments submitted in the course of the commenting procedure characterized MT as a research field that is typically equipped with few resources.

6.2 Results on social aspects

Since ethical and social aspects overlap, the scoping search was done for these two aspects in combination. The employed search criteria did not return any study explicitly investigating social aspects. However, conclusions on social aspects can be drawn on the basis of the results of the 3 guided interviews with affected persons, which were conducted as part of the HTA. They reveal that group MT can promote social contacts and strengthen the sense of belonging, and the group itself is considered a “safe space” which can provide support. These are important aspects when considering the fact that cancer treatment can be associated with severe symptom-related distress and the disease itself can force affected persons to abandon everyday and occupational activities and face existential worries.

Some level of patient acceptance of psychotherapeutic treatment forms is necessary for MT since it is classified and defined as a psychotherapeutic form of therapy [49].

6.3 Results on legal aspects

The scoping search returned 25 documents and other sources on legal aspects of the use of MT in adult patients in Germany. These documents were found exclusively through the manual search in sources outside of MEDLINE.

In Germany, there is no legal basis or regulation of the profession of music therapist [47]. Its practice on a self-employed basis requires a license to practice in accordance with the German Psychotherapist Act (Psychotherapeutengesetz, PTG) or a limited license as an alternative non-medical practitioner in accordance with §1 of the German Alternative Practitioners Act (Heilpraktikergesetz, HPG). If practising within an employment relationship, clinical responsibility lies with the medical supervisor, which means that licensing in accordance with PTG or a limited license as an alternative non-medical practitioner in accordance with §1 HPG is not necessary, although it is increasingly called for. Hence, the profession of music therapist is not practised within a harmonized framework. Training is available at public as well as private institutions [50]. In Germany, MT has been established as an academic discipline since 1979 [51].

According to the Guideline on Remedies (Heilmittelrichtlinie), Annex 1, MT is classified as a non-prescribable remedy [52] and therefore not reimbursable by the statutory health insurance. MT is not explicitly listed in the DRG catalogue but is included in the OPS as a psychosocial intervention under the umbrella term “creative arts therapies” and mentioned as a measure in the areas of early rehabilitation, pain therapy, palliative medicine, and psychological and psychosomatic disorders [37, 53]. In the German Pension Insurance’s Classification of Therapeutic Procedures in Medical Rehabilitation, MT is listed under clinical psychology and neuropsychology [36].

Voluntary certification conferring the title “Music Therapist DMtG” is available to members of the German Music Therapy Society (DMtG) [16]. Voluntarily certified music therapists are listed in the national registry of the German Working Group on Music Therapy (BAG MT) [18]. The voluntary certification is predicated on an equivalent quality of different MT training options and therefore serves quality assurance purposes. Furthermore, it requires advanced training. Recommendations and certificates issued by DMtG are not legally binding.

MT is mentioned (explicitly or under the umbrella term of creative arts or creative therapies) in the Guideline Program in Oncology [54–59] and in the Rehabilitation Therapy Standard for Breast Cancer [60].

6.4 Results on organizational aspects

The scoping search revealed 8 documents and other sources on organizational aspects of the use of MT in adult patients in Germany. These documents were found exclusively through the manual search in sources outside of MEDLINE.

MT is delivered in accordance with patient needs in various settings, for instance in acute care hospitals, rehabilitation centres, outpatient therapy centres, oncology practices and hospices, and in the form of individual and group therapy [39, 61]. Some outreach programmes are available as well. Performing MT requires infrastructure that is dependent on and adapted to the setting, such as designated rooms, musical instruments, and technical equipment [19, 39].

In terms of (potential changes in) provider qualification requirements, the authors of the professional field analysis [19] generally identify a need for standardizing the training of creative arts therapists. Two associations for MT training exist, the working group of MT training in public tertiary education and the standing conference of supervisors in private MT training institutions, which, together with the MT societies in Germany, have defined uniform standards as part of consensus building on the occupational profile [62]. On the basis of the sources of information found, no conclusions can be drawn about further organizational aspects – such as changes in staffing needs, structural quality, or effects on the degree of utilization of other technologies or resources.

Due to a lack of legal regulations, professional associations of music therapists are highly relevant. Other interest groups that are potentially relevant in this context are professional societies in the fields of oncology, psychooncology, psychotherapy, palliative care, or pain therapy.

7 Summary of results

As a therapy accompanying oncological standard therapy, MT concerns patients who are often in both chronically and acutely distressing situations in terms of their lives and illnesses or in palliative care after all curative options have been exhausted. For many patient-relevant outcomes, the highly heterogeneous studies on the benefit of MT show no hint, indication, or proof of benefit in comparison with SC or other accompanying therapies (music medicine, mindfulness-based stress reduction). However, **for some psychological outcomes** (anxiety, anxiety & depression, fatigue, mood swings, stress/tension) as well as for subjective well-being and health-related quality of life, the evidence reveals an **indication or hint of benefit of MT, but usually limited to short-term effects**. For cancer-related adverse events, the evidence shows a hint of benefit of MT (only) over the course of several sessions.

On the basis of the available data, no conclusions can be drawn regarding any effect on **coping, activities of daily living**, and **health-related social functioning, including occupational and social participation**; likewise, no studies were found from which it was possible to draw any conclusions on the efficacy of MT in a **group therapy** format. However, the interviews conducted with affected persons show, among other things, that coping in its various facets is an outcome that can be positively influenced by MT, and it was shown that MT in a group therapy format can bolster inner reassurance and social support. MT exhibited particular strengths in areas which, by their very nature, are typically more difficult to objectively measure – such as subjective well-being – than, e.g., physiological outcomes.

At the same time, MT is a non-invasive **intervention associated with few ethical concerns** and is impossible to perform without considerable **motivation and cooperation on the part of the patient**. The cultural background or musical socialization of patients as well as therapists is of importance and can affect the performance of MT. The “constants” in this therapy are the management of the patient’s specific reactions on the basis of MT training and the use of music relevant to the (patient’s) biography. Some reservations regarding the **quality of therapy provision** are conceivable because in Germany, while statements from DMtG are available, there is currently a lack of **legal regulation of the profession** – as in a standardization of the professional concept and activities – or of training and/or certification. Under these conditions, the **transferability of the results found in the benefit assessment to the German context** is limited. Yet, general transferability of the positive effects of MT can be assumed in comparable settings in Germany (MT performed by qualified therapists and for at least 2 sessions), not least because 2 studies from Germany have contributed to the available evidence.

In German **inpatient and rehabilitation settings**, **access** to MT is available even to socioeconomically disadvantaged patients since the intervention is included in the relevant classification catalogues; however, it is subject to actual local availability. Conversely, in the

outpatient setting, access is limited for socioeconomically disadvantaged people because health insurers cover the cost only on a case-to-case basis.

On the basis of the **available evidence**, it is not possible to differentiate conclusions about the benefit of MT by **setting**, by **cancer entity,** or in terms of **curative versus palliative** treatment.

Beyond MT, various **alternative accompanying therapies** are available for cancer treatment, such as other creative arts therapies, music medicine (music listening only, without any therapeutic relationship), mindfulness training techniques, and many more. Two studies that compare MT with music medicine or mindfulness-based stress reduction reveal a hint of greater short-term benefit of MT for 2 outcomes, while no hint of any difference was found for 4 other outcomes. Concerning the comparison with the other creative arts therapies, the studies found do not permit drawing any conclusions.

In an outpatient setting, the **cost per unit** is likely to be based on comparable average practitioner fees for MT as for other creative arts therapies. On average, this practitioner fee is lower than for a psychotherapy unit, for instance. However, **estimating the cost** of the intervention as a whole is complicated by the fact that treatment duration and frequency of sessions of therapy accompanying oncological standard care can be difficult to predict in some cases, and there is a **lack of available evidence**.

The routine use of MT as a **therapeutic discipline separate from the practice of medicine or nursing** would add a quasi “new” profession to the respective healthcare setting as well as the associated requirements in terms of professional law, professional ethics, and organization, and involves a greater potential for interprofessional interaction and exchange (communication, delimitation of responsibilities).

8 Discussion

8.1 HTA report compared with other publications

In 2016, Bradt et al. published a comprehensive Cochrane Review on music interventions in cancer patients [63]. Since it also includes the intervention of music medicine, its scope exceeds that of the current report. On MT, a total of 23 studies were included. Some of them were excluded from this HTA since the target population (e.g. paediatric population) or the intervention (e.g. music imagery) did not meet the inclusion criteria defined in the research question. In addition, the present report defined the development of a therapeutic relationship as an element of MT and consequently specified a treatment duration of at least 2 sessions. A notable difference was found for the outcome of pain, for which Bradt et al. report a strong effect on standardized mean differences. A closer examination revealed, however, this was based on music interventions other than MT.

8.2 HTA report compared with guidelines

In slight deviation from the results of this report, the S3 Guideline “Psychooncological Diagnostics, Counselling, and Treatment of Adult Cancer Patients” [55] recommends allowing MT to be offered to cancer patients, particularly to reduce anxiety. This recommendation is based on the Cochrane Review cited in the section above, which was first published in 2011 (in its 2011 version [64]).

8.3 Critical reflection on the approach used

For the purposes of this HTA, an intentionally narrow definition of the intervention “music therapy” was used to ensure clear differentiation and certainty of conclusions. This definition reflects the consensus defined by DMtG, which calls MT an essentially psychotherapeutic therapy and requires the systematic use of music within a therapeutic relationship that aims at restoring, maintaining, and furthering emotional, physical, and mental health [9]. On the basis of this definition, a relatively narrow range of studies was available. However, this allows drawing more specific and concrete conclusions on benefit as well as on economic, social, ethical, organizational, and legal aspects of MT with regard to the professional policy context and general professional policy concept in Germany.

Irrespective of the narrow focus on the intervention of “MT” (which is inherent in the research questions underlying this HTA), a series of related research questions might be considered. For instance, the focus could be shifted to MT as part of a meaningfully defined bundle of therapies, which might, e.g., also include different “creative arts therapies”. In this manner, empirical research might potentially do greater justice to individual patient preferences (for instance, those favouring painting rather than music).

Further, one might question whether in the palliative care context, it is even appropriate to use a study design with a measure taking several sessions or weeks since high drop-out rates are possible. After conducting a pilot RCT, Porter et al. 2018 [65] concluded that an RCT on the outcome of improvement of quality of life is feasible in palliative care patients, although they recommend limiting the study duration to 1 week – with a 2-week follow-up accompanied by qualitative surveys.

8.4 Excursus: Bonny method of Guided Imagery and Music (GIM) and cognitive behavioural therapy-based MT forms in combination with psychotherapeutic elements, which were excluded as hybrids

Systematic reviews require, from the outset, strictly defined inclusion and exclusion criteria for study selection. The narrower the criteria for the intervention, the clearer a comparison can be drawn with alternative forms of therapy. Hybrids that combine MT methods with other methods were therefore excluded. However, two comments on the basic preliminary report suggested reconsidering the exclusion of studies using "music imagery" or a cognitive behavioural therapy-based MT intervention. The comments stated that GIM was used by music therapists with advanced training in this area, including to perform MT with cancer patients. Both interventions are MT methods and simultaneously contain elements from research theoretical areas of depth psychology, psychodynamics, and cognitive behavioural therapy. The comment specifically mentioned 2 studies that were excluded from this report on the basis of the inclusion criteria as well as 1 doctoral thesis that was not found in the literature search.

In an effort to provide a supplementary overview of the potential of these hybrids, the results of the three studies are described below. In summary, all studies included relatively few participants, and the results largely match the picture of this HTA report.

Guided Imagery and Music (GIM)

In GIM, music is used for the imagination of images as well as sounds, smells, tastes, body sensations, thoughts, memories, or intuitions and thereby supports the mobilization, structuring, stimulation, and limitation of corresponding mental processes. The Bonny method of GIM is typically used in depth-psychology-oriented, analytical, humanistic, and transpersonal psychotherapy as well as in MT and other creative art therapies [66].

In 2001, **Burns et al.** [67] applied the Bonny method of GIM (in the form of 10 weekly sessions) in 4 out of 8 cancer patients to determine how it favourably affected mood swings and quality of life. All participants completed the Profile of Mood States (POMS) and Quality of Life-Cancer (QOL-CA) questionnaires as pretests and posttests and at a 6-week follow-up appointment. As a result, it was found that the 4 participants who took part in GIM sessions showed better results for mood and quality of life than the 4 participants of the control group. Further, mood

and quality of life of the experimental group continued to improve even after the sessions were completed. These results suggest that GIM improved mood and quality of life in these patients.

Another comprehensive research project (**Hertrampf 2017** [68]) investigated the evaluation of the Bonny method of GIM. This doctoral thesis is a mixed-methods study that triangulates a randomized controlled study and a qualitative study.

In the introduction, the author describes her experiences working with cancer patients before conducting the study. In her opinion, the use of GIM in individual sessions in the clinical context has shown that this method facilitates the activation of internal iconic images and the (re)activation of internal resources. She states that these internal processes help people with cancer find new sense in life and develop new coping strategies to better handle the medical treatment. She continues that they help prepare for death, find peace with unresolved personal or interpersonal issues, and escape the physical limitations posed by the disease [68].

In her study project, Hertrampf compares GIM-based group MT (GrpMI) with progressive muscle relaxation (PMR) in cancer patients. The part of the study project that was designed as an RCT compares the change in both groups with regard to the outcomes of anxiety, depression, and quality of life (QoL). Well-being was examined as well, but only in the GrpMI group. GrpMI (16 patients) and PMR (12 patients) were each performed in 6 small-group sessions for 6 weeks.

Viewed separately, both groups showed a positive trend towards before–after success (some results being significantly positive) in the interval from study start, through the 6 individual sessions, and up to 4 months in the follow-up. For anxiety, only the GrpMI group showed a distinct positive effect; no such effect was found in the PMR group. Depression and QoL (total score) were reported to have improved about equally. Well-being (Basel Scale of Well-Being) increased considerably after each individual GrpMI session, but also considerably dropped between sessions; across sessions, only a relatively small improvement was therefore noticeable. No significant differences in results were found for any of the described comparisons between the intervention group (GrpMI) and comparator group (PMR).

Cognitive behavioural forms of MT

In 2014, a pilot study by **Fredenburg et al.** [69] included 11 patients to investigate whether cognitive behavioural MT can reduce cancer-related fatigue. Further, the authors tried to explain the underlying mechanisms of action. Patients were randomly allocated to the intervention group “cognitive-behavioural music therapy” (CBMT) or a control group receiving standard care. The mean fatigue scores in the 7 patients with CBMT did not significantly differ from those of the control group (5 patients). Unlike in the control group, however, short-term improvements over baseline taken before the session were recorded after each of the CBMT

sessions. The authors commented their work by stating that the results should be interpreted with caution due to the small sample size.

9 Conclusion

MT as an accompanying therapy in oncology has already been established in the German healthcare system, particularly in the (acute and palliative) inpatient and rehabilitation settings, through service reimbursement as well as its mentions in national guidelines. The present HTA reveals indications and hints of a short-term benefit of MT in comparison with standard care with regard to fatigue, mood swings, anxiety, anxiety & depression, stress/tension, and health-related quality of life as well as, over the course of several sessions, with regard to cancer-related adverse events, fatigue, and mood swings. In comparison with other accompanying therapies (music medicine, mindfulness-based stress reduction), a hint of greater short-term benefit of MT was found with regard to fatigue and subjective well-being. Notably, the available evidence shows a positive effect particularly for comparatively short-term psychological outcomes and, in general, primarily for non-biological outcomes – soon after the intervention. For most biological (clinical) outcomes as well as for persistent psychological conditions such as depression, there is generally a lack of evidence in favour of MT. However, these short-term effects are to be considered in light of the typically precarious, in some cases life-threatening, situation of patients. Furthermore, MT is a non-invasive intervention associated with few ethical concerns and is impossible to conduct without considerable patient motivation and cooperation.

The results on the benefit of MT are transferable to Germany if a consistent professional concept and standardized training and/or certification can be assumed to be in place, which is, however, not entirely the case in view of the current lack of regulation. However, a uniform consensus has been reached on the occupational profile as well as (voluntary) certification. Due to differences in reimbursement and local availability, access to MT (in general and in oncology) is not uniformly regulated among inpatient care, the rehabilitation sector, and outpatient care.

Due to a lack of data, some questions cannot be answered at this time: No studies were found on the outcomes of coping or activities of daily living, and no study investigating MT as a group intervention was found. Data are insufficient for performing a comparative analysis of the benefit of MT in different cancer entities or for a comparison of curative versus palliative therapy. In the direct comparison with alternative accompanying therapies, MT in the form defined herein was studied in only 3 out of 10 studies, and no studies investigated it in comparison with “sham treatment”. No data are available on cost-effectiveness, and estimating the intervention costs is hindered by a lack of data on average treatment duration and frequency of sessions. Only 1 out of the 10 studies was conducted in an outpatient setting.

Two ongoing studies on MT from Israel and Germany were found, and their design might potentially produce insights regarding longer-term effects and coping (outcome of “resilience”).

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Please see full HTA report for the full reference list.

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The full HTA report (German version) is published under
https://www.themencheck-medizin.iqwig.de/de/hta-berichte/26-ht17-02-krebs-kann-eine-begleitende-musiktherapie-zu-besseren-behandlungsergebnissen-beitragen.143.html

Appendix A – Topics of the EUnetHTA Core Model

The European Network for Health Technology Assessment (EUnetHTA) is a network of European HTA agencies. EUnetHTA promotes the exchange of HTA information between its members and developed the core model [70] for this purpose. IQWiG is also a member of the network.

In order to make it easier for readers of this HTA report to find information on the superordinate domains of the EUnetHTA Core Model, Table 4 indicates where the relevant information can be found. The original names of the domains of the core model are used to describe the topics.

Table 4: Domains of the EUnetHTA Core Model

EUnetHTA domain	**Information in chapters and sections of the HTA report**
Health problem and current use of the technology (CUR)	**Background** Chapter 1
Description and technical characteristics of technology (TEC)	
Safety (SAF)	**Benefit assessment** Section 3.1; Chapter 4
Clinical effectiveness (EFF)	
Costs and economic evaluation (ECO)	**Health economic evaluation** Section 3.2; Chapter 5
Ethical analysis (ETH)	**Ethical aspects** Section 3.3; Section 6.1
Patients and social aspects (SOC)	**Social aspects** Section 3.4; Section 6.2
Legal aspects (LEG)	**Legal aspects** Section 3.4; Section 6.3
Organizational aspects (ORG)	**Organizational aspects** Section 3.4; Section 6.4

Appendix B – Search strategies

B.1 – Search strategies for benefit assessment and economic evaluation

B.1.1 – Searches in bibliographic databases

1. MEDLINE

Search interface: Ovid

- Ovid MEDLINE(R) 1946 to January Week 3 2018
- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations January 24, 2018
- Ovid MEDLINE(R) Daily Update January 24, 2018
- Ovid MEDLINE(R) Epub Ahead of Print January 24, 2018

The following filters were adopted for the benefit assessment:

- Systematic review: Wong [71] – High specificity strategy
- RCT: Lefebvre [72] – Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity-maximizing version (2008 revision)

The following filters were adopted for the economic evaluation:

- Glanville [73] – Emory University (Grady)

#	Searches
1	exp Neoplasms/
2	Radiotherapy/
3	exp Stem Cell Transplantation/
4	Bone Marrow Transplantation/
5	(cancer* or tumor* or tumour* or oncolog* or malignan*).ti,ab.
6	(radiotherap* or radiation* or stem cell transplantation* or chemotherap* or bone marrow transplant*).ti,ab.
7	or/1-6
8	Music Therapy/
9	music*.ti,ab.
10	or/8-9
11	7 and 10
12	randomized controlled trial.pt.
13	controlled clinical trial.pt.
14	(randomized or placebo or randomly or trial or groups).ab.

#	Searches
15	drug therapy.fs.
16	or/12-15
17	exp animals/ not humans.sh.
18	16 not 17
19	cochrane database of systematic reviews.jn.
20	(search or MEDLINE or systematic review).tw.
21	meta analysis.pt.
22	or/19-21
23	or/16,22
24	and/11,23
25	24 not (comment or editorial).pt.
26	(economic* or cost*).ti.
27	cost benefit analysis/
28	treatment outcome/ and ec.fs.
29	or/26-28
30	animals/ not humans/
31	letter.pt.
32	or/30-31
33	29 not 32
34	and/11,33
35	34 not (comment or editorial).pt.

2. PubMed

Search interface: NLM

- PubMed – as supplied by publisher
- PubMed – in process
- PubMed – pubmednotmedline

Search	Query
#1	Search (cancer* [TIAB] OR tumor* [TIAB] OR tumour* [TIAB] OR oncolog* [TIAB] OR malignan* [TIAB])
#2	Search (radiotherap* [TIAB] OR radiation* [TIAB] OR stem cell transplantation* [TIAB] OR chemotherap* [TIAB]OR bone marrow transplant*[TIAB])
#3	Search (#1 OR #2)

Search	Query
#4	Search music*[TIAB]
#5	Search (#3 AND #4)
#6	Search (clinical trial*[TIAB] OR random*[TIAB] OR placebo[TIAB] OR trial[TI])
#7	Search (search[TIAB] OR meta analysis[TIAB] OR MEDLINE[TIAB] OR systematic review[TIAB])
#8	Search (#6 OR #7)
#9	Search (#5 AND #8)
#10	Search (#9 NOT medline[SB])
#11	Search (economic*[tiab] OR cost*[tiab])
#12	Search (#5 AND #11)
#13	Search (#12 NOT Medline[SB])

3. Embase

Search interface: Ovid

- Embase 1974 to 2018 January 24

The following filters were adopted for the benefit assessment:

- Systematic review: Wong [71] – High specificity strategy
- RCT: Wong [71] – Strategy minimizing difference between sensitivity and specificity

The following filters were adopted for the economic evaluation:

- Glanville [73] – Embase G

#	Searches
1	exp neoplasm/
2	exp cancer therapy/
3	cancer patient/
4	radiotherapy/
5	exp stem cell transplantation/
6	bone marrow transplantation/
7	(cancer* or tumor* or tumour* or oncolog* or malignan*).ti,ab.
8	(radiotherap* or radiation* or stem cell transplantation* or chemotherap* or bone marrow transplant*).ti,ab.
9	or/1-8

#	Searches
10	music therapy/
11	music*.ti,ab.
12	or/10-11
13	(random* or double-blind*).tw.
14	placebo*.mp.
15	or/13-14
16	(meta analysis or systematic review or MEDLINE).tw.
17	or/15-16
18	and/9,12,17
19	18 not medline.cr.
20	19 not (exp animal/ not exp humans/)
21	20 not (Conference Abstract or Conference Review or Editorial).pt.
22	(Cost adj effectiveness).ab.
23	(Cost adj effectiveness).ti.
24	(Life adj years).ab.
25	(Life adj year).ab.
26	Qaly.ab.
27	(Cost or costs).ab. and Controlled Study/
28	(Cost and costs).ab.
29	or/22-28
30	and/9,12,29
31	30 not medline.cr.
32	31 not (exp animal/ not exp humans/)
33	32 not (Conference Abstract or Conference Review or Editorial).pt.

4. The Cochrane Library

Search interface: Wiley

- Cochrane Database of Systematic Reviews: Issue 1 of 12, January 2018
- Cochrane Central Register of Controlled Trials: Issue 12 of 12, December 2017

ID	Search
#1	[mh Neoplasms]
#2	[mh ^Radiotherapy]

ID	Search
#3	[mh "Stem Cell Transplantation "]
#4	[mh ^"Bone Marrow Transplantation"]
#5	(cancer* or tumor* or tumour* or oncolog* or malignan*):ti,ab
#6	(radiotherap* or radiation* or stem cell transplantation* or chemotherap* or bone marrow transplant*):ti,ab
#7	#1 or #2 or #3 or #4 or #5 or #6
#8	[mh ^"Music Therapy "]
#9	music*:ti,ab
#10	#8 or #9
#11	#7 and #10 in Cochrane Reviews (Reviews and Protocols) and Trials

5. PsycINFO

Search interface: Ovid

- PsycINFO 1806 to January Week 3 2018

The following filters were adopted for the benefit assessment:

- Systematic review: Eady [74] – Best Specificity;
- RCT: Eady [74] – Best Optimization of Sensitivity and Specificity

#	Searches
1	exp NEOPLASMS/
2	*ONCOLOGY/
3	*RADIATION THERAPY/
4	*CHEMOTHERAPY/
5	*STEM CELLs/
6	(cancer* or tumor* or tumour* or oncolog* or malignan*).ti,ab.
7	(radiotherap* or radiation* or stem cell transplantation* or chemotherap* or bone marrow transplant*).ti,ab.
8	or/1-7
9	MUSIC THERAPY/
10	music*.ti,ab.
11	or/9-10
12	8 and 11
13	(double-blind or random* assigned or control).tw.

#	Searches
14	(meta-analysis or search*).tw.
15	or/13-14
16	12 and 15

6. Health Technology Assessment Database

Search interface: Centre for Reviews and Dissemination

Line	Search
1	MeSH DESCRIPTOR Neoplasms EXPLODE ALL TREES
2	MeSH DESCRIPTOR Radiotherapy
3	MeSH DESCRIPTOR Stem Cell Transplantation EXPLODE ALL TREES
4	MeSH DESCRIPTOR Bone Marrow Transplantation
5	(cancer* or tumor* or tumour* or oncolog* or malignan*)
6	(radiotherap* or radiation* or stem cell transplantation* or chemotherap* or bone marrow transplant*)
7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
8	MeSH DESCRIPTOR Music Therapy
9	(music*)
10	#8 OR #9
11	(#7 AND #10) IN HTA

B.1.2 – Searches in study registries

1. ClinicalTrials.gov

Provider: U.S. National Institutes of Health

- URL: http://www.clinicaltrials.gov
- Type of search: Basic Search

Search strategy
music AND (cancer OR tumor OR tumour OR oncology OR malignant OR malignancy OR radiotherapy OR radiation OR stem cell transplantation OR chemotherapy OR bone marrow transplantation)

2. International Clinical Trials Registry Platform Search Portal

Provider: World Health Organization

- URL: http://apps.who.int/trialsearch/
- Type of search: Standard Search

Search strategies
music AND cancer OR music AND tumor OR music AND tumour OR music AND oncology OR music AND malignant OR music AND malignancy
music AND radiotherapy OR music AND radiation OR music AND stem OR music AND chemotherapy OR music AND marrow