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Original Article

ORIGINAL ARTICLE

Effect of music therapy intervention on anxiety and pain during percutaneous renal biopsy: a randomized controlled trial

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ABSTRACT

Background. Percutaneous renal biopsy (PRB) may subject patients to emotional distress and pain before and during the biopsy. The aim of this study was to evaluate the effects of complementary/non-pharmacological interventions such as music therapy (MT) on anxiety, pain and satisfaction in renal patients undergoing PRB.
Methods. A prospective, single-centre, single-blind, randomized controlled two-arm trial was conducted. Patients ≥18 years of age, hospitalized at the Nephrology, Dialysis and Transplantation Unit (Bari, Italy) and scheduled for PRB were screened. Participants were assigned to standard treatment (CG) or to the music therapy (MT) intervention group. Participants in the MT group received standard care and an MT intervention by a certified music therapist qualified in guided imagery and music. The CG patients received the standard of care. MT and CG patients were subjected to identical measurements (pre/post) of the parameters in the State Trait Anxiety Inventory Y1 (STAI-Y1), visual analogue scale for pain (VAS-P) and satisfaction (VAS-S) and heart rate variability.
Results. A statistically significant difference in the anxiety scores after PRB between MT and CG patients (STAI-Y1 35.4 ± 6.2 versus 42.9 ± 9.0) was observed. MT also had strong and significant effects on VAS-P compared with CG (5.0 ± 1.4 versus 6.3 ± 1.3, respectively; $P < .001$) and VAS-S (7.8 ± 1.0 versus 6.0 ± 0.9, respectively; $P < .001$). Decreased activity of the sympathetic nervous system and increased activity of the parasympathetic nervous system was observed after PRB in the MT group.
Conclusion. Our study supports the use of MT to mitigate the psychological anxiety, pain and sympathetic activation associated with PRB.

Keywords: anxiety, heart rate variability, percutaneous renal biopsy, receptive music therapy, stress

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INTRODUCTION

Percutaneous renal biopsy (PRB) is the gold-standard procedure and the *conditio sine qua non* for a correct diagnosis of glomerular kidney diseases and, consequently, for the appropriate treatment options [1, 2]. Over the past 40 years, the use of ultrasonography has helped to better visualize and examine the kidney and to properly guide the biopsy needle (ultrasound-guided biopsy). Thus the adoption of automatic needles has made the kidney biopsy technique much easier to perform and much safer. However, despite these advances, native kidney biopsies are not without risks, with major complications in 5% of cases. PRB is usually performed with the patient awake and under local anaesthesia. However, the patient often experiences anxiety and stress before and during the biopsy and it can generate pain during the procedure and immediately after [3]. Although emotional distress and pain can largely be managed by the administration of anxiolytics, analgesics and anaesthetics [4–6], these drugs may have potential side effects and do not always succeed in reducing emotional stress [7].

Music therapy (MT) is defined as the clinical and evidence-based use of tailored music interventions initiated by a trained and qualified music therapist, which differs from other music interventions, such as 'music medicine', that provide passive pre-recorded music administered by health professionals without experience in MT [8, 9]. MT can be used as a non-pharmacological complementary intervention [10, 11] to prevent emotional distress [12–15] and pain [16, 17] and MT can be effective in enhancing sedation in combination [18–21] with anaesthetic drugs.

Most of the previous studies have been based on the music medicine approach. Due to method and quality control standards shortcomings, results are interesting but heterogeneous. Moreover, no trials have been conducted using MT intervention in renal patients undergoing PRB.

The aim of this study was to assess, in a randomized controlled trial, the effects of MT on anxiety, pain and satisfaction in renal patients undergoing PRB compared with standard care.

MATERIALS AND METHODS

Study design

This was a prospective, single-centre, single-blind, randomized controlled two-arm trial conducted at the Nephrology Unit, University of Bari, Bari, Italy. A patient-centred approach was employed [22]. Using an interactive relational approach of receptive MT [23–25] supplemented by adaptation of the Bonny method of Guided Imagery and Music in the medical setting [26], tailored MT interventions were administered to patients at the time of PRB.

Ethics approval

The study protocol was approved by the Bari Hospital Ethics Committee (6365 protocol 0033297/06/05/2020). The study was performed in accordance with the principles outlined in the Helsinki Declaration. Patients were informed both orally and in writing regarding the study and that the collected data would be recorded anonymously and their personal information would be kept confidential. All patients signed an informed consent form. All PRBs were performed by the same nephrologist and renal resident.

Setting and participants

Over a 7-month period (from 1 June 2021 to 30 December 2021), 114 patients hospitalized at the Nephrology, Dialysis and Transplantation Unit (Bari, and scheduled for a first PRB were screened. Inclusion criteria were age ≥18 years, undergoing PRB to define a renal pathology diagnosis and without contraindications to perform a PRB (coagulation disorders, uncontrolled blood pressure). Exclusion criteria were age ≤18 years, severe neurological or psychiatric conditions, hearing impairment, concomitant medications including analgesic or anxiolytic drugs to suppress the symptoms of anxiety until 24 h prior to the PRB, refusal to participate and inability to provide a self-assessment.

Randomization and masking

Procedures

On the day of the PRB, participants were assigned to the MT intervention group or to standard treatment (CG) by computer sample randomization. Participants in the MT group received standard care and MT intervention by a certified music therapist qualified in guided imagery and music. The CG group received the standard of care.

The psychologist researcher and statistical analyst did not know the patients' allocation.

The MT intervention consisted of three parts:

- Assessment: 40 minutes before the PRB, patients joined the music therapist in an individual bedside brief conversation (10 min) to identify the preferred musical genres/songs. On the basis of the information collected, the music therapist prepared a customized playlist to listen to during the PRB, tailored to the patient's needs [27].
- After being monitored in the operating room, patients were prepared to listen to the customized playlist with brief guided relaxation or breath entrainment (music matched rhythmically to the rate of breathing then gradually reduced to encourage slower, deeper breathing) [28] to find an image as the focus with a positive outcome.
- The patient then listened to music during the PRB.

Participants listened to music with bone conduction headphone from Ipod headphones and the volume was controlled by the music therapist.

The PRB was mainly performed on the lower pole of the left kidney. In patients with obesity or breathing difficulties, a supine anterolateral left position was preferred. In order to standardize the procedure and for uniform results, the same local anaesthetic drug was used (mepivacaine 20 mg/ml) and injected locally, following the different planes from the skin to the renal capsule in all patients.

Outcomes

All patients were monitored via electrocardiogram, blood pressure and pulse oximetry measurements. Patient anxiety assessment, before and after PRB, was conducted using State Trait Anxiety Inventory Y1 (STAI-Y1) [29]. Subjects were asked to rate the intensity of their anxious feelings for 20 items on a 4-point scale: 'not at all', 'somewhat', 'moderately so' or 'very much so'. STAI-Y values <40 defined the absence of anxiety, 40–50 defined mild anxiety, 51–60 defined moderate anxiety and >60 defined severe anxiety. The STAI-Y1 was administered 30 minutes before the PRB and 45 minutes after the PBR. The patients rated their pain

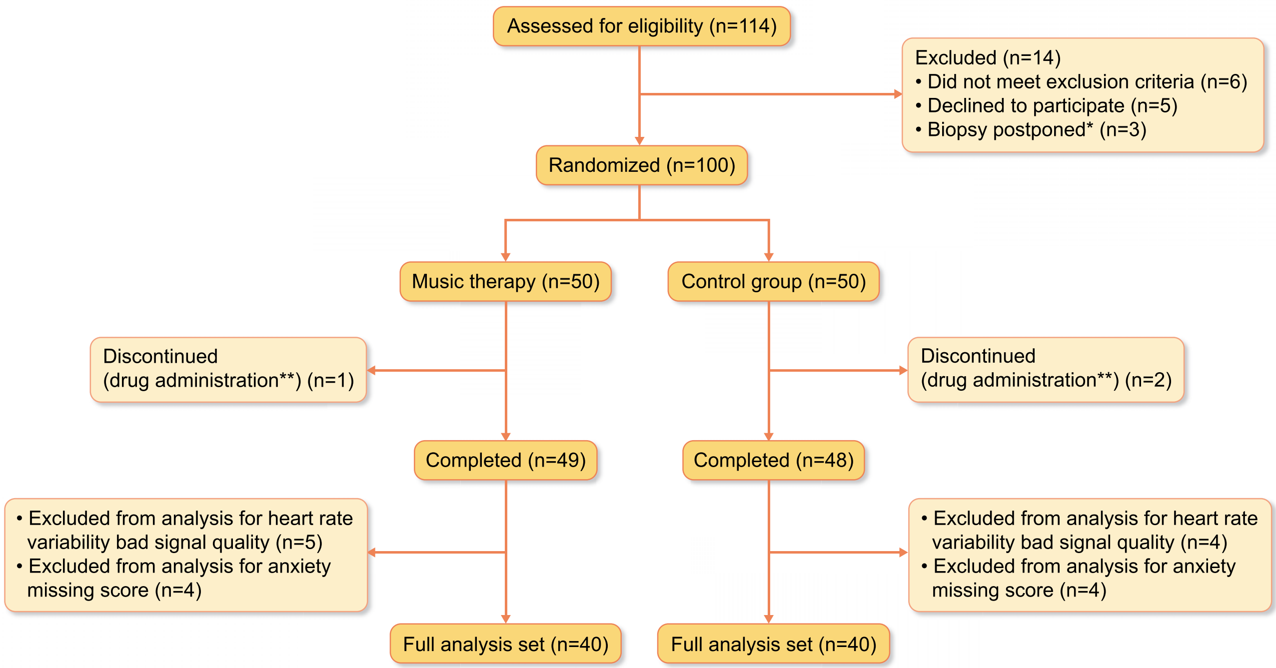

Figure 1: CONSORT flow chart.

and satisfaction levels on a visual analogue scale (VAS-P, VAS-S) scored from 0, meaning no pain/no satisfaction, to 10, meaning maximal pain/satisfaction. Data collection was managed by a psychologist researcher.

The physiological stress level of the participants was assessed by a medical-grade wearable device (E4 wristbands, Empatica, Cambridge, MA, USA). E4 wristbands are validated [30] and approved by the US Food and Drug Administration as a medical device and have been used in a wide range of MT research [31–34]. The E4 includes four sensors: a photoplethysmogram sensor that uses two green and two red LEDs to record blood volume pulse (BVP) from the dorsal wrist (sampling frequency 64 Hz, resolution 0.9 nW/digit); two stainless steel (SUS03) electrodes 8 mm in diameter that use alternating current (8 Hz) to record electrodermal activity from the volar surface of the wrist (sampling frequency 4 Hz, resolution 1 digit ≈900 pS, an optical infrared thermopile to record skin temperature (sampling frequency 4 Hz, resolution 0.02°C) and a three-axis accelerometer that measures acceleration on the x, y and z axes within the ±2 g range (sampling frequency 32 Hz, resolution 8 bits) [35].

The wristband was placed on the patient in the operating room 5 min before starting the PBR procedure and removed 5 min after completion of the PRB [36]. BVP, from which heart rate (HR), interbeat intervals (IBIs) in milliseconds and heart rate variability (HRV) are derived, was recorded in real time [37].

A button placed on the device case was used to mark administration of local anaesthesia on the recording. Raw data obtained from the E4 wristband were imported into Kubios HRV Standard version 3.5.0 software [38].

The data from each session were divided into two segments with a length of 5 minutes, one before administration of the local anaesthetic and one after administration of the local anaesthetic. For each segment, the time domain (SDNN, RMSSD, NN50, pNN50), frequency domain (LH/HF) and geometric HRV metrics (SD1, SD2) were computed.

Statistical analysis

A preliminary exploratory with descriptive statistics and a full statistical data analysis was performed to assess the effect of the MT intervention within the two groups. Differences within groups were tested according to the Mann–Whitney test, with a significance level of 0.01, to check the effectiveness equal median between the two groups. For all the variables, probability distributions were investigated using the Shapiro test with a significance level of 0.01. A power analysis was also performed referring to 40 samples for each group with an effect size of 0.634 at a significance level 0.05 and power of 0.80. All the analyses were developed using R software (R Foundation for Statistical Computing, Vienna, Austria) [39].

RESULTS

A total of 114 participants undergoing renal biopsy at the Nephrology Unit, Policlinic, University of Bari between 1 June 2021 and 30 December 2021 were enrolled (Fig. 1). The median age was 55 years (interquartile range 45–65) and 65 participants (57%) were men. A total of 14 of 114 patients were excluded (6 did not meet inclusion criteria, 5 declined to participate, 3 for postponement of PRB). Due to bad signal quality (MT, $n = 5$; CG, $n = 4$), incomplete data collection (MG, $n = 4$; CG, $n = 4$) and drug administration during the PRB (MT, $n = 1$; CG, $n = 2$), another 20 patients were excluded (Fig. 1). A total of 80 patients (40 in each arm; Table 1) underwent statistical analysis. The variables involved in the analyses between groups were STAI-Y1 in the pre and post segments, VAS and HRV. All patients enrolled had STAI-Y1 scores >40 at baseline (54.59 for females and 47.60 for males; $P = .12$). There was a statistically significant

Table 1: Baseline characteristics.

Characteristics	MT (n = 40)	CG (n = 40)
Clinical presentation, n (%)		
Recurrent macrohematuria	6 (15)	2 (5)
Nephrotic syndrome	14 (35)	10 (25)
Chronic renal failure	20 (50)	17 (42.5)
Acute renal failure	7 (17.5)	10 (25)
Comorbidities, n (%)		
Diabetes	5 (12.5)	14 (35)
Hypertension	18 (45)	25 (62.5)
Heart disease	8 (20)	7 (17.5)
Liver disease	6 (15)	6 (15)
Cancer	0 (0)	10 (25)
Laboratory tests, mean ± SD		
Haemoglobin (g/l)	12.6 ± 2.1	12.8 ± 1.9
Haematocrit (%)	37.7 ± 6.9	39.0 ± 5.9
Serum creatinine (μmol/l)	1.9 ± 1.7	1.9 ± 1.2
Platelets ($\times 10^3/mm^3$)	217.7 ± 63.4	206.4 ± 63.2
Prothrombin time (%)	1.0 ± 0.1	1.0 ± 0.1
Partial thromboplastin time (%)	1.0 ± 0.1	1.0 ± 0.1
Fibrinogen (mg/dl)	269.3 ± 56.2	273.8 ± 53.2
Proteinuria (g/24 h)	3.4 ± 8.9	2.4 ± 3.4
Systolic blood pressure (mmHg)	132.4 ± 17.1	138.3 ± 17.9
Diastolic blood pressure (mmHg)	80.8 ± 11.1	82 ± 10.9
Heart rate (bmp)	78.0 ± 10.9	76.2 ± 9
Body weight (kg)	73.4 ± 14	82.7 ± 14.4
DDAVP, n (%)	32 (87.5)	33 (82.5)
Position and biopsy type (SALP/PP)	1/39	4/36

DDAVP: 1-deamino-8-D-arginine vasopressin; SALP: supine anterolateral position; PP: prone position.

Table 2: Outcomes assessed in MT and CG patients undergoing PRB

Outcomes	MT (n = 40)	CG (n = 40)	P-value
VAS-P, mean ± SD	5.0 ± 1.4	6.3 ± 1.3	<.001*
VAS-S, mean ± SD	7.8 ± 1.0	6.0 ± 0.9	<.001*
STAI-Y1 anxiety, mean ± SD	35.4 ± 6.2	42.9 ± 9.0	<.001*
Time domain measures			
SDNN	3.2	2.4	.028*
RMSSD	0.9	0.6	.009*
Non-linear measures			
SD1	0.6	0.4	.018*
SD2	4.6	3.5	.020*
Frequency domain measures			
LF/HF	55.2	84.0	.003*

STAI-Y1: State Trait Anxiety Inventory Questionnaire Y-1; SDNN: standard deviation of all normal to normal intervals; RMSSD: square root of the mean of the sum of the squares of differences between adjacent NN intervals; SD1: Poincaré plot index standard deviation of short-term R-R interval variability; SD2: Poincaré plot index standard deviation of long-term R-R interval variability; LF/HF: ratio of low frequency to high frequency power. *Statistical significance.

difference in the anxiety scores after the PRB between the MT and CG patients (STAI-Y1 35.4 ± 6.2 versus 42.9 ± 9.0). MT had strong and significant effects on VAS-P compared with CG (5.0 ± 1.4 versus 6.3 ± 1.3; $P < .001$) and VAS-S (7.8 ± 1.0 versus 6.0 ± 0.9; $P < .001$) (Table 2). Decreased activity of the SNS and increased activity of the parasympathetic nervous system (PNS) were observed after the PRB in the MT group. Indeed, time domain results analysis in terms of the standard deviation (SD) of the beat-to-beat intervals (SDNN) and root mean square of successive R-R interval differences (RMSSD) showed statistically higher values in the MT compared with the CG patients ($P < .02$ and $P < .009$, respectively). This result was also confirmed by a Poincaré plot index: SD of short-term R-R interval variability (SD1) and SD of long-term R-R interval variability (SD2). Higher significant values of SD1 and SD2 were observed in MT compared with CG patients ($P < .01$ and $P < 0.02$, respectively), confirming that patients treated with MT were more relaxed [40] (Table 2). Finally, the LF:HF ratio was significantly lower at post-test than at pretest in MT compared with CG patients ($P < .003$).

DISCUSSION

This study aimed to investigate the effects of MT intervention on anxiety, pain and satisfaction in patients undergoing PRB. Our data suggest that music therapy significantly reduces pre-operative anxiety and pain management, especially in cases of an STAI-Y1 moderate/high baseline (54.59 for females and 47.60 for males; $P = .12$) compared with the mean state anxiety for normal working adults (35.20 for females and 35.72 for males) [41] and improves satisfaction in patients who underwent PRB, supporting previously reported data in different clinical settings [8, 19, 22, 42].

To our knowledge, this is the first study testing the effect of MT in patients undergoing PRB. On a neurophysiological level, the anxiety- and pain-relieving effects were supported by a change in HRV parameters. Physiological response of an organism to anxiety is characterized by increased activity of the SNS and a decreased activity of the PNS. Overactivation of the SNS affects numerous adverse responses, such as arterial and venous constriction, leading to myocardial stimulation, bronchoconstriction and both psychological and behavioural impairment. In contrast, the PNS promotes relaxation and triggers acetylcholine release, influencing the heart through the vagus nerve. The vagus nerve plays a central role in conducting the relaxation response for the body, leading to a decrease in oxygen consumption, R-R, BP and HR, with an overall increase in well-being. Low HRV is associated with impaired regulatory and homeostatic autonomic nervous system functions, which reduce the body's ability to cope with internal and external stressors.

When an individual feels anxiety or emotive pressure, SDNN and RMSSD decrease [41, 43]. SDNN is considered an index of physiological resilience against stress, while RMSSD refers to activity of the PNS. Our results confirmed that during MT, HRV indexes significantly increase. Moreover, frequency domain analysis (LF/HF) for short-term measurements (i.e. 5 minutes) [36] were also analysed and supported the relaxing role played by MT. The HF component of HRV represents parasympathetic regulation of the heart and is strongly correlated with pain intensity [44], the LF component is jointly contributed by both sympathetic and parasympathetic nerves and the LF:HF ratio is considered to reflect SNS activity [45]. In this study, the LF:HF ratio results strongly support the effects of MT on anxiety and pain. The greater reduction in LF led to a reduction in the LF:HF ratio and demonstrated that MT increases PNS activity and consequently induces relaxation. At a cognitive level, studies suggest that the anxiolytic effect of music derives from its distracting ability. However, in moderately/highly anxious patients, using music for distraction may not be sufficient to reduce the anxiety and pain caused by an impending procedure [15]. It is also necessary to consider that the wait time before the procedure may cause even more anxiety than the procedure itself [21, 46], so patients needed additional guidance to actively refocus their attention on the music. This was achieved because the music therapist was present during the PBR [15].

Unlike other music-based interventions, in which patients undergo passive listening to pre-recorded music provided by nurses or other medical staff, the presence of a certified music therapist made it possible to customize the listening experience based on the needs of each patient in that moment, offer verbal instructions for refocusing and change or stop the music if necessary [13].

A customized play list was developed by the music therapist using specific music elements such as pulse, mood, melodic line, dynamic change, bass line, volume, timbre, rhythm and form. Thus our intervention was made up of three closely related steps.

The brief guided relaxation or breath entrainment to find an image as a focus with a positive outcome helped patients promote more active engagement with the music. Music listening may also activate imagery. This played an important role in anxiety management, as it offers a temporary escape from the stressful reality [19], focusing the patient's attention away from negative stimuli present in the operating room towards something pleasant and encouraging. Finally, the active engagement of the patient in preparing and listening to music gave them a certain feeling of control over the situation [21]. Patients listened to music with bone conduction headphones. Using over-ear or on-ear headphones, patients would not have been able to monitor the progress in the operating room, hampering communication with the nephrologist, and thus they would have been deprived of any information from the environment. This perceived sense of control plays an important role in the management of anxiety and pain [15].

On a psychosocial level, MT provided a positive and comfortable experience before, during and after the procedure, with high satisfaction scores. Moreover, lower VAS-P and higher VAS-S scores observed in the MT group, regardless of whether they were reflected in the physiological variables, can be interpreted as a qualitatively better experience associated with PRB. Furthermore, listening to music has shown better efficacy in reducing preoperative anxiety with shorter interventions (15 minutes) than other complementary medicine modalities such as hypnosis and acupuncture (30 minutes) [21].

Along with the feasibility of MT in an operating room setting, our study seems to suggest that MT does not impact the total length of stay of the patient in the operating room and is greatly appreciated by patients.

Considering all the physiological and psychological effects related to the PRB procedure, MT has been shown to be useful in supporting and containing the numerous stressful factors to which these patients are commonly subjected.

LIMITATIONS

The main biases of the study are correlated to the lack of blinding and/or a placebo for the control patients. However, we tried to overcome this bias by using standardized outcomes such as VAS and HRV. Furthermore, participants did not know the aim of this study. Moreover, the psychologist researcher and statistical analyst did not know the patients' allocations. A long-term effect of our receptive MT intervention was not evaluated. Furthermore, all the participants were enrolled from the same hospital. Due to this, their demographic characteristics might be somewhat similar and might not reflect the characteristics of the broader population. In the CG patients, we found an increased by chance incidence of malignancy. Many patients often associated PRB with investigation for malignant disease. Due to this, the incidence of malignancy in the CG patients could have altered their anxiety perception when undergoing PRB. This finding may be worthy of future investigation.

The costs of MT should be also considered, but this study was not designed to specifically address this issue. It is also possible that patients' responses could have been biased due to unilateral attention by MT personnel. Reports of better performance during and after intervention could have been biased and the Hawthorne effect cannot be excluded. However, we used an adaptation of a specific approach of receptive MT—Guided Imagery and Music—in which music, imagery and breathing are closely involved. Therefore we wish to highlight that MT is not the same as simply playing music in the operating room when performing a biopsy, a feature we consider a strength of our study.

CONCLUSION

PRB represents the canonical method used to properly establish a diagnosis in patients affected by renal disease. Despite its common practice, it is an invasive procedure that may generate emotional distress and potential complications in patients. Sometimes this can be the reason why the patient rejects having a PRB, making determining clinical management and treatment plans difficult. In patients undergoing kidney transplant or those affected by complex conditions such as lupus nephritis, or those involved in clinical trials, a second biopsy may be important to monitor the evolution of the disease and the validity of the personalized and selected therapy. Emotional engagement can explain the difficult scheduling of a second 'protocol biopsy', reducing clinical and therapeutic surveillance.

Our study demonstrates how the application of MT in a cohort of patients undergoing an invasive procedure such as a PRB may ameliorate patient's stress and anxiety.

SUPPLEMENTARY DATA

Supplementary data are available at *ckj* online.

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DATA AVAILABILITY STATEMENT

The data underlying this article are available in the article and in its online supplementary material.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

REFERENCES

1. Muñoz AT, Valdez-Ortiz R, González-Parra C *et al*. Percutaneous renal biopsy of native kidneys: efficiency, safety and

risk factors associated with major complications. *Arch Med Sci* 2011;**5**:823–31. https://doi.org/10.5114/aoms.2011.25557
2. Granata A, Distefano G, Pesce F *et al.* Performing an ultrasound-guided percutaneous needle kidney biopsy: an up-to-date procedural review. *Diagnostics* 2021;**11**:2186. https://doi.org/10.3390/diagnostics11122186
3. Bakdash K, Schramm KM, Annam A *et al.* Complications of percutaneous renal biopsy. *Semin Intervent Radiol* 2019;**36**:97–103.
4. Koelsch S, Fuermetz J, Sack U *et al.* Effects of music listening on cortisol levels and propofol consumption during spinal anesthesia. *Front Psychol* 2011;**2**:58. http://journal.frontiersin.org/article/10.3389/fpsyg.2011.00058/abstract
5. Cao X, Elvir-Lazo OL, White PF *et al.* An update on pain management for elderly patients undergoing ambulatory surgery. *Curr Opin Anaesthesiol* 2016;**29**:674–82. https://doi.org/10.1097/ACO.0000000000000396
6. Brandt J, Leong C. Benzodiazepines and Z-drugs: an updated review of major adverse outcomes reported on in epidemiologic research. *Drugs R D* 2017;**17**:493–507.
7. Conway A, Rolley J, Sutherland JR. Midazolam for sedation before procedures. *Cochrane Database Syst Rev* 2016;**2016**:5. http://doi.wiley.com/10.1002/14651858.CD009491.pub2
8. Bradt J, Dileo C. Music interventions for mechanically ventilated patients. *Cochrane Database Syst Rev* 2014;**2014**:CD006902.
9. American Music Therapy Association. What is Music Therapy? https://www.musictherapy.org/about/musictherapy/
10. Stegemann T, Geretsegger M, Phan Quoc E *et al.* Music therapy and other music-based interventions in pediatric health care: an overview. *Medicines (Basel)* 2019;**6**:25.
11. Giordano F, Zanchi B, Leonardis FD *et al.* The influence of music therapy on preoperative anxiety in pediatric oncology patients undergoing invasive procedures. *Arts Psychother* 2020;**68**:101649.
12. Fachner JC, Maidhof C, Grocke D *et al.* "Telling me not to worry…" Hyperscanning and neural dynamics of emotion processing during guided imagery and music. *Front Psychol* 2019;**10**:1561. https://doi.org/10.3389/fpsyg.2019.01561
13. Giordano F, Losurdo A, Quaranta VN *et al.* Effect of single session receptive music therapy on anxiety and vital parameters in hospitalized Covid-19 patients: a randomized controlled trial. *Sci Rep* 2022;**12**:3154. https://doi.org/10.1038/s41598-022-07085-8
14. Giordano F, Messina R, Riefolo A *et al.* Music therapy in children affected by brain tumors. *World J Pediatr Surg* 2021;**4**:e000307. https://wjps.bmj.com/content/4/3/e000307
15. Bradt J, Teague A. Music interventions for dental anxiety. *Oral Dis* 2018;**24**:300–6. https://doi.org/10.1111/odi.12615
16. Lee JH. The effects of music on pain: a meta-analysis. *J Music Ther* 2016;**53**:430–77. https://doi.org/10.1093/jmt/thw012
17. Short A, Gibb H, Fildes J *et al.* Exploring the role of music therapy in cardiac rehabilitation after cardiothoracic surgery: a qualitative study using the bonny method of guided imagery and music. *J Cardiovasc Nurs* 2013;**28**:E74–81. https://doi.org/10.1097/JCN.0b013e31825bc9c9
18. Giordano F, Rutigliano C, De Leonardis F *et al.* Covid-19 and absence of music therapy: impact on mother-child dyad during invasive procedures in pediatric oncology. *Arts Psychother* 2021;**75**:101839. https://doi.org/10.1016/j.aip.2021.101839
19. Bradt J, Dileo C, Shim M. Music interventions for preoperative anxiety. *Cochrane Database Syst Rev* 2013;**2013**:CD006908.
20. Chlan LL, Heiderscheit A, Skaar DJ *et al.* Economic evaluation of a patient-directed music intervention for ICU patients receiving mechanical ventilatory support. *Crit Care Med* 2018;**46**:1430–5. https://doi.org/10.1097/CCM.0000000000003199
21. Palmer JB, Lane D, Mayo D *et al.* Effects of music therapy on anesthesia requirements and anxiety in women undergoing ambulatory breast surgery for cancer diagnosis and treatment: a randomized controlled trial. *J Clin Oncol* 2015;**33**:3162–8.
22. Bradt J, Dileo C, Magill L *et al.* Music interventions for improving psychological and physical outcomes in cancer patients. *Cochrane Database Syst Rev* 2016;**8**:CD006911. https://doi.wiley.com/10.1002/14651858.CD006911.pub3
23. Bruscia KE. *Defining Music Therapy*. 2nd ed. Gilsum, NH: Barcelona Publishers, 1998.
24. Bruscia KE, Grocke DE. *Guided Imagery and Music: the Bonny Method and beyond*. Gilsum, NH: Barcelona Publishers, 2002.
25. Grocke DE, Wigram T. *Receptive Methods in Music Therapy: Techniques and Clinical Applications for Music Therapy Clinicians, Educators and Students*. 1st paperback ed. Philadelphia: Jessica Kingsley, 2007.
26. Grocke DE, Moe T, eds. *Guided Imagery & Music (GIM) and Music Imagery Methods for Individual and Group Therapy*. Philadelphia: Jessica Kingsley, 2015.
27. Robb SL, Burns DS, Carpenter JS. Reporting guidelines for music-based interventions. *J Health Psychol* 2011;**16**:342–52. https://doi.org/10.1177/1359105310374781
28. Fallek R, Corey K, Qamar A *et al.* Soothing the heart with music: a feasibility study of a bedside music therapy intervention for critically ill patients in an urban hospital setting. *Palliat Support Care* 2020;**18**:47–54. https://doi.org/10.1017/S1478951519000294
29. *State-Trait Anxiety Inventory: Bibliography*. 2nd ed. Palo Alto, CA: Consulting Psychologists Press, 1989.
30. McCarthy C, Pradhan N, Redpath C *et al.* Validation of the Empatica E4 wristband. In: *2016 IEEE EMBS International Student Conference (ISC)*. Ottawa, ON, Canada, 2016. http://ieeexplore.ieee.org/document/7508621/
31. Kowash M, Al-Halabi M, Hussein I *et al.* A single-centre investigator-blinded randomised parallel-group study protocol to investigate the influence of an acclimatisation appointment on children's behaviour during N2O/O2 sedation as measured by psychological, behavioural and real-time physiological parameters. *BDJ Open* 2020;**6**:5.
32. Ragot M, Martin N, Em S *et al.* Emotion recognition using physiological signals: laboratory vs. wearable sensors. In: Ahram T, Falcão C, eds. *Advances in Human Factors in Wearable Technologies and Game Design*. Cham: Springer International, 2018:15–22. http://link.springer.com/10.1007/978-3-319-60639-2_2
33. Kaczor E, Carreiro S, Stapp J *et al.* Objective measurement of physician stress in the emergency department using a wearable sensor. *Proc Annu Hawaii Int Conf Syst Sci* 2020;**2020**:3729–38. https://hdl.handle.net/10125/64198
34. Zanetti M, Faes L, Nollo G *et al.* Information dynamics of the brain, cardiovascular and respiratory network during different levels of mental stress. *Entropy* 2019;**21**:275. https://doi.org/10.3390/e21030275
35. Menghini L, Gianfranchi E, Cellini N *et al.* Stressing the accuracy: wrist-worn wearable sensor validation over different conditions. *Psychophysiology* 2019;**56**:e13441. https://onlinelibrary.wiley.com/doi/10.1111/psyp.13441
36. Kim H-G, Cheon E-J, Bai D-S *et al.* Stress and heart rate variability: a meta-analysis and review of the literature.

Psychiatry Investig 2018;**15**:235–45. https://doi.org/10.30773/pi.2017.08.17

37. Milstein N, Gordon I. Validating measures of electrodermal activity and heart rate variability derived from the Empatica E4 utilized in research settings that involve interactive dyadic states. *Front Behav Neurosci* 2020;**14**:148. https://doi.org/10.3389/fnbeh.2020.00148
38. Tarvainen MP, Niskanen J-P, Lipponen JA *et al*. Kubios HRV—heart rate variability analysis software. *Comput Methods Programs Biomed* 2014;**113**:210–20. https://doi.org/10.1016/j.cmpb.2013.07.024
39. R Foundation. The R Project for Statistical Computing. https://www.r-project.org/
40. Melillo P, Bracale M, Pecchia L. Nonlinear heart rate variability features for real-life stress detection. Case study: students under stress due to university examination. *Biomed Eng Online* 2011;**10**:96. https://doi.org/10.1186/1475-925X-10-96.
41. Chang H-K, Peng T-C, Wang J-H *et al*. Psychophysiological responses to sedative music in patients awaiting cardiac catheterization examination: a randomized controlled trial. *J Cardiovasc Nurs* 2011;**26**:E11–8. https://doi.org/10.1097/JCN.0b013e3181fb711b
42. Bradt J, Dileo C, Potvin N. Music for stress and anxiety reduction in coronary heart disease patients. *Cochrane Database Syst Rev* 2013;**2013**:CD006577. http://doi.wiley.com/10.1002/14651858.CD006577.pub3
43. Taelman J, Vandeput S, Vlemincx E *et al*. Instantaneous changes in heart rate regulation due to mental load in simulated office work. *Eur J Appl Physiol* 2011;**111**:1497–505. https://doi.org/10.1007/s00421-010-1776-0
44. Boselli E, Daniela-Ionescu M, Bégou G *et al*. Prospective observational study of the non-invasive assessment of immediate postoperative pain using the analgesia/nociception index (ANI). *Br J Anaesth* 2013;**111**:453–9. https://doi.org/10.1093/bja/aet110
45. Chuang C-Y, Han W-R, Li P-C *et al*. Effects of music therapy on subjective sensations and heart rate variability in treated cancer survivors: a pilot study. *Complement Ther Med* 2010;**18**:224–6. https://doi.org/10.1016/j.ctim.2010.08.003
46. Thompson WF. *Music, Thought, and Feeling: Understanding the Psychology of Music*. New York: Oxford University Press, 2009.

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