Effect of Music Therapy on Pain, Physical and Cognitive Function, and Mood of Patients with Knee Osteoarthritis After Total Knee Arthroplasty: Protocol for A Randomized Controlled Trial

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Study protocol

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Abstract

Background

Total knee arthroplasty (TKA) is the major treatment to decreases pain and improves function for end-stage knee osteoarthritis. Although clinical studies proved the effect of music therapy on physical/cognitive function, mood, or wellbeing, little is known about the effectiveness of music therapy in TKA. This study aims to investigate whether music therapy is a valid treatment for elderly with knee osteoarthritis who underwent TKA.

Methods

This study will apply randomized control trail (RCT) among 120 senior citizens with knee osteoarthritis after undergoing TKA. These participants would be randomly assigned to either the music therapy group or the controlled group, with a 1:1 allocation. Patients will be monitored for long-term effects over a 40-week period.

Results

The primary outcomes include numerical rating scale (NRS)-the maximum pain, NRS-the average pain, and Knees Injury and Osteoarthritis Outcome Score. Secondary outcomes included four areas: cognitive assessment, physical assessment, mood assessment, and others. We will apply an intention-to-treat analysis for the withdrawals and missing data.

Conclusions

This work will be the first RCT and large sample size trial on the use of music therapy for pain after TRK surgery for elderly patients. We will also explore the numbers of primary and secondary outcomes to conduct an in-depth analysis of the possible mechanisms of music therapy on pain, physical function, cognitive function, and mood for elderly patients after TKR.

Trial registration:

Chinese clinical trial registry, ChiCTR2200062469

1 Background

Knee osteoarthritis (KOA) has been noticed as the most popular diseases that cause disability among elderly adults [1]. According to a nationwide population-based clinical study in China, the rate of
symptomatic KOA is 8.1%; the prevalence of KOA increases with age [1, 2]. To relieve KOA pain, total knee arthroplasty (TKA) is routinely performed [3]. TKA's success is based on the success of “surgical technique and implant longevity” [4]. In addition, besides the observe typical complications and mortality rates among elder patients after TKA, an increasing amount of attention is being given to post-operative functional outcomes, such as physical function, cognitive function, and quality of life [5, 6]. The lack of clear treatments or strategies for elder KOA patients after TKA may contribute to the inadequate recovery of physical function and cognitive function [7].

The goals of the regular rehabilitation courses are to enhance knee strength, knee range of movement, and the tempo of TKA patients [8]. Although TKA patients have completed the regular rehabilitation treatments, they have a lower walking pace and have difficulty climbing [9]. TKA surgery patients continue to have knee functional limitations; thus, non-surgery rehabilitation strategies need to be identified. Music therapy as a non-pharmacological intervention with tremendous benefits for elderly patients after TKA surgery, such as low-budget, less physiological and psychological side-effects, and healing improvement [10]. The American Music Therapy Association (2019) uses the terms “music medicine” or “music therapy” to refer to the use of therapeutic music. Music medicine involves providing pre-recorded music to patients by healthcare staff [11]. Music therapy is provided by credentialed music therapists who usually employ music and its relationships to develop a systematic treatment and to improve patients’ health status [12]. With effective music stimulus, TKA patients experience the following: relief from pain; a decrease in blood pressures [13]; declined depression [14]; and increased range of motion of joints [10].

Recently, only three studies on the effectiveness of music therapy on pain degree of elderly patients after TKA surgery [14–16]. However, there are a few gaps within this domain. First, the small sample size cannot determine whether the study was adequately powered to detect clinically meaningful differences. Second, no follow-up observation was performed, and no long-term outcomes were obtained from these studies, because pain scores of participants were assessed immediately. Thus, this protocol is to investigate whether TKA followed by music therapy intervention offers better pain relief rates and enhancement in physical function, cognitive function, and mood than regular treatment alone. Also, the difference between this protocol and those described in previous clinical studies is that the outcomes of the post-operative acute stage are also considered. We hypothesize that music therapy has longer-term effects.

2 Methods/design

Purpose

This purpose of protocol is to explore the use of music therapy to improve the pain relief, cognitive function and physical function of elderly patients with KOA who underwent TKR. We hypothesize that participants in music therapy group will have (1) reduced pain, (2) improved physical function, (3) improved cognitive function, (4) improved mood, and (5) enhanced overall health and well-being.
compared with the control group. This study aims to recruit 120 elder TKA patients in Shanghai Shangti Orthopedic Hospital, Shanghai City, China. The detailed process is shown in Fig. 1.

Participants

Participants will be divided into a 1:1 ratio. One researcher will use a program to generate random numbers for these participants. This researcher will not be involved in either recruitment or intervention session during this study. After randomly grouping 120 patients, the patients will be grouped into either a controlled group to receive regular treatments or a music therapy group to receive music therapy treatment with regular treatments. In the music therapy group, participants will receive regular healthcare and extra 20 min of music therapy intervention. In the control group, participants will only receive the regular treatment. Both groups’ participants will undergo the intervention for a total of 8 weeks. After 8 weeks, patients will be observed during the follow-up period of 24–48 weeks without intervention.

Eligibility criteria

The study populations will be mainly elderly adults living in Shanghai with KOA who underwent TKA. The following approaches will be used to recruit as many participants as possible: (a) distribution of recruitment flyer in Shanghai Shangti Orthopedic Hospital with permission; (b) asking nurses at Shanghai Shangti Orthopedic Hospital to introduce the study and present the introduction part to potential participants; and (c) posting of the recruitment information via social media or electronic communication. Anyone interested can contact the recruiter via telephone.

Participants will be included if they (1) are patients with KOA who underwent TKA; (2) are aged 50–80 years old persons who are fluent in Chinese (speaking and reading) and can complete the questionnaire; (3) can participate in a standardized rehabilitation program following surgery (Bade et al., 2010); (4) can comprehend the whole trial and accomplish all the courses; (5) can participate in the trial as a volunteer and willing to sign the informed consent; (6) can participate in intervention sessions for 8 weeks and attend and finish the follow-up study; (7) can function independently; and (8) have NRS (in the range of 0–10) average scores of 3 and 8.

The exclusion criteria for recruiting the population are as follows: (1) do not meet the inclusion criteria; (2) have practiced music therapy within the past 6 months or attended music activities for approximately half of the year as treatment for postoperative orthopedic rehabilitation; (3) have guided music therapy for postoperative orthopedic rehabilitation in half a year; (4) have a drug and alcohol abuse history; (5) have a history of heart disease or other severe diseases; (6) have additional disabling conditions that might confound treatment effects; (7) have neurocognitive disorders or normal aging; (8) have a neurological condition, i.e., Parkinson's disease and stroke; (9) have clinically proved psychiatric disorders, such as depression; (10) have a fatal illness, such as cancer; and (11) have considerable visual impairment, hearing impairment, and/or color blindness. Table 1 represents the characteristics of participants on both groups at baseline.
Table 1
Characteristics of participants on both groups at baseline

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Music therapy group (n = 60)</th>
<th>control group (n = 60)</th>
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<tbody>
<tr>
<td>Age, mean (SD), y</td>
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<td>Smoking per day, mean (SD)</td>
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<td><strong>Current knee osteoarthritis pain intensity</strong></td>
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<td>Most serious pain in previous week, mean NRS score (SD)</td>
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<td>Average pain in previous week, mean NRS score (SD)</td>
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<td>Characteristic</td>
<td>Music therapy group (n = 60)</td>
<td>control group (n = 60)</td>
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<td>Current pain intensity, mean NRS score (SD)</td>
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<td>Work absence or reduced hours, mean (SD), h</td>
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<td><strong>Medical expenditure on knee osteoarthritis pain last year, mean (SD), RMB (Chinese Yuan)</strong></td>
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<td><strong>Medication use in previous three months</strong></td>
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<td><strong>Expectation that invention works</strong></td>
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<td>Others, mean (SD), h</td>
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<td><strong>Influence of knee osteoarthritis pain on work</strong></td>
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<td>Moderate, No. (%)</td>
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<td>Severe, No. (%)</td>
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<td><strong>Pain mode in 24-hour</strong></td>
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<td>Characteristic</td>
<td>Music therapy group (n = 60)</td>
<td>control group (n = 60)</td>
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<td>No change, No. (%)</td>
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<td>Others, No. (%)</td>
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Study setting

The data collection will be performed by researchers assistants blinded to the group assignment at Shanghai Shangti Orthopedic Hospital, Shanghai, China. Each participant will complete written informed consent.

Randomization and blinding

The study will take a randomized approach in which participants will be grouped in a 1:1 allocation by numbers given by the analyst. The G-Power Software will be applied to calculate the overall sample size with the method of t test-means (difference between two independent means measured in two groups [7]). All analysts do not know the allocation of groups.

Intervention condition

The randomization procedure will consist of three steps. First, participants will not know the hypothesis of the study. Second, regarding hidden assignments, one researcher will use a program to generate the random numbers for these participants. This will help randomize the participants into either the music therapy group or the control group. This researcher is not involved in either recruitment or intervention session. Third, index cards will be enclosed in the same type of envelope. Researchers, who will be blinded to the whole baseline test, will open the envelope and assign each participant to their respective groups.

2.6.1 Music therapy group

With the aid of professional therapists and researchers, the music therapy activity will be designed and established. Studies have shown that music therapy is commonly applied for patients’ postoperative recovery [17, 18]. Also, music therapy has positive effects on pain management, cognitive function, and emotion; it has potential benefits in various areas of people's life [19]. In addition, music listening can improve the patients’ contentment during pain management [20]. Hence, this study will use music as the main treatment.
In the music therapy group, patients will have the standard care followed by a 20 min music therapy session. During the music therapy training process, the researcher will initially explain the detailed descriptions of the music therapy protocol to patients. Participants will then be asked to choose the following types of music: soft, relaxing, and regular rhythmic patterns. Based on recommendations from the literature, the chosen music should not include extreme changes in its dynamics. The participants are expected to choose one of the following: classical, relaxing, and artistic music. The selected music tempo will be 60–80 beats/min to mimic the human heart rate.

2.6.2 Control group

In the control group, participants will not receive music therapy sessions; however, they will receive the standard training including for post-operation orthopedic surgery. Regular treatment will last for 20 min per session. Sessions will be conducted twice a day for 8 weeks. A research assistant or an investigator will visit these patients three times per week and ask them to complete the same measurements as the music therapy group participants.

3 Outcomes

The demographic questionnaire consisting of participants (sex, age, body mass index, education) and history of postoperative orthopedic rehabilitation will be performed before the treatment.

Table 1 indicates the measurements used to evaluate the outcomes. The primary outcomes will be measured applying a numerical rating scale (NRS) and Knee injury and Osteoarthritis Outcome Score (KOOS). Secondary outcomes focused on four areas, namely cognitive, physical, and mood assessment, among others (Table 2).

Table 2 Outcome measures
3.1 Primary outcome measures

### 3.1.1 NRS-the Maximum and the average pain

NRS requires patients to rate their pain level on the defined scale form. For a scale range of 0–10, 0 means the absence of pain, whereas 10 shows the worst pain imaginable [21, 22]. Given the positive correlation of NRS with other measures of pain, it is considered as a valid and reliable measure. Additionally, NRS shows sensitivity to pain treatments that are anticipated to affect pain scale [23]. Considering that NRS scale is an interval-level scale, it can offer data for sensitivity analysis of the solution to the problem at hand. Also, NRS has been used to deliver graphical or verbal analysis of data [24].

### 3.1.2 KOOS

KOOS has a 42-item self-administered self-explanatory questionnaire that includes five divisions, namely, pain, additional symptoms, function in daily living, function in sport and recreation, and knee-related quality of life [25]. The scale scores range from 0 to 100. Zero refers to the worst and most extreme knee problems, whereas 100 refers to the best knee health with no problem [26]. Typically, a KOOS aggregate
score is not calculated because of the desire to analyze and interpret the five dimensions individually [27]. In addition, an MICD of 8–10 is considered appropriate for KOOS [28].

Secondary outcome measures

3.1.3 Cognitive assessments

1). Cognitive performance test (CPT): each participant will be asked to complete the following cognitive tests; executive function (trial making test A/B), working memory (n-back task), attention (digital span test), neural processing speed (digital symbol substitution test), and cognition inhibition (flanker task) [29]. Using concurrent validity, the CPT has been validated by comparison with other measures of daily and cognition activities [30].

2). Rey Auditory Verbal Learning Test (RAVLT) has a 15 noun-word list, which is used to evaluate learning and memory. The RAVLT test is widely used in neuropsychology literature [29]. In the RAVL test, 15 words will be presented for the participants to read at a rate of “one word per second.” After viewing the 15 words, the participants will be required to remember many words, in no specific order. This testing procedure will be repeated five times with each participant [31].

3). Digit Span Task (DST) is a task that consists of two spans: a Digit Span Forward and Digit Span Backward. The DST is used to evaluate a person’s attention and verbal working memory [32]. During the DST, the participants will first be required to listen to a sequence of numbers. Then, they will be guide to repeat the same sequence in the forward or backward order. The forward span will be used to evaluate the participants’ attention efficiency and capacity, whereas the backward span will be used to evaluate their working memory [33].

3.1.4 Physical assessments

In this protocol, the physical assessment portion will be completed by the following four validated questionnaires:

1). The 6 min walk test (6MWT): 6MWT is a short walk test that measures the recovery of function after TKA [34]. This test requires the patients to walk around in a set of walking circuits for 6 min. In this text, 14.0 m to 30.5 m may be clinically important across different groups [35]. Notably, the 6MWT is a valid test to measure the patients’ functional outcomes after TKA [36].

2). Time up and go (TUG): TUG is a short walk test that measures the recovery of function after TKA [37]. This test evaluates the duration of the following process: without assistance, the patient rises from an armchair (seat height, 46 cm), walks for 3 m, turns, and returns and sits in the same chair [38].

3). Manual muscle testing (MMT): MMT assesses the knee joint muscle strength [39]. The MMT does not employ any equipment to evaluate the strength of the participants. Rather, it employs the following ratings: 0 as zero (O), 1 as trace (T), 2 as poor (P), 3 as fair (F), 4 as good (G), and 5 as normal (N). The MMT procedure assesses the function and strength of the participant’s muscles based on their
effectiveness when performing a movement. Their ability to perform a movement is assessed by comparing with gravity and resistance.

4). Berg Balance Scale (BBS): BBS is a tool for balance assessment and it is a standard for measuring balance for patients with TKA in medical settings [40]. This test consists of the 14 movement tasks [41]. Each of the 14 tasks will be scored using a 5-point ordinal scale from 0 to 4. The 0 refers to the individual's inability to perform the task, whereas 4 refers to the individual's ability to independently complete the task [42]. In research done with older adults, the BBS scores are organized according to their performance in the functional status and their independence. Hence, the BBS scores are organized into the following three ranges: (a) in the first range, 0 to 20 means that mobility is available, albeit wheelchair-bound; (b) 21 to 40 means that people are walking with assistance; and (c) 41 to 56 means that people are walking independently [42].

5). Knee Range of Motion (ROM): postoperative knee range of motion is a key factor influencing the patient's satisfaction after TKA [43]. ROM includes the assessment of knee flexion and extension, tibial internal, and external rotation [44]. On average, most individuals have around 0 degrees when the knee is fully straightened and around 135 degrees when the knee is flexed [45]. There are three types of ROM at a joint, namely, active knee ROM, passive knee ROM, and active assisted ROM.

To identify any adverse or seriously adverse events that occur before the 40-week period, the following 3 methods will be used: a). copy of hospital records, b). patient self-report at follow-up visit, and c). report by the therapist. Adverse events are classified as those involving the index knee or sites other than the index knee. However, serious adverse events are recognized based on the U.S. Food and Drug Administration definition [28].

### 3.1.5 Mood assessments

The mood assessments will be measured by the following two instruments:

1). Self-Rating Depression Scale (SDS): the scale is allow the participants to reflect on their subjective depression experiences and depression severity, as well as any changes in depression [46]. According to the standard score, 53 points or less indicate that the participants do not suffer from depression, whereas scores above 53 points indicate that the participants suffer from depressive disorder. In other words, the higher the SDS score is, the higher the rate of depression is [45].

2). Self-rating anxiety scale (SAS): this scale is a norm-referenced measurement that is widely used as a screening scale for anxiety disorders [47]. The scale consisted of 20 questions, 15 of which dealt to increasing level of anxiety levels; the other five questions pertain to the decrease in anxiety [45]. The score of this test ranges from 20 to 80. Normal range is from 20 to 44 points; 45–59 points indicates a mild to moderate level of anxiety; a score of 60–74 indicates a significant anxiety level; and a score of 75–80 indicates extreme levels of anxiety [48].

### 3.1.6 Others
Some other assessments are as follows:

1). Short-form 12 (SF-12): the SF-12 is a measure that is widely used to assess the impact of health on an individual’s daily life [49]. Using this form, participants will fill out a 12-question survey, which will be scored by a clinician or researcher. These 12 questions measure eight domains that can be used to calculate the physical and psychological scores of participants. This measurement represents satisfactory internal consistency for the physical component (Cronbach’s alpha = 0.81) and mental component summary (Cronbach’s alpha = 0.83) [50].

2). Pittsburgh Sleep Quality Index (PSQI): the PSQI is used assess the overall quality of sleep in clinical populations. The questionnaire has seven subcategories with a total of 19 self-reported items. The questionnaire’s seven subcategories, such sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction [51]. The questions will be scored from 0 to 3; higher scores show the presence of acute sleep disturbances. Based on the results of a validation study, the scale has suggested a cutoff score of 5 [51]. The PSQI has an excellent test-retest reliability with a correlation coefficient of 0.77 [52].

3). Instrumental Activities of Daily Living Scale (IADL): this test is used to evaluate the independent living skills [53]. This scale includes eight domains that measure function. Considering that some of these domain items pertain to food preparation, housekeeping, and laundering, women will be scored on all of these items, whereas men will be scored on everything else. All participants will be scored according to their highest level of functioning in each of the eight categories. The score summary for women will range from 0 (low function, dependent) to 8 (high function, independent), whereas men will be scored from 0 to 5 [54].

We will also record the number of sessions that each participant attends and the reason for absence. Meanwhile, the occurrence of adverse events about interventions and sessions at home will be measured.

4 Statistical Analysis

The Microsoft excel 2016 and IBM SPSS 22.0 software will be applied to the data analysis for this protocol. This statistician, who will perform the statistical analysis, will be blind to the grouping of participants. The independent samples \(t\) test will be used to analyze the statistical significance of continuous data, such as the participants’ age, height, weight, body mass index (BMI), and pain duration. Also, a chi-square test will be used to compare the statistical significance of categorical data between the two groups. As for the two-way repeated-measures analysis of variance (ANOVA) (group × time), this method will be used to evaluate the outcomes of the control group compared with the music therapy group. This comparison will be based on both unadjusted and adjusted analysis. We will also pre-specify and adapt the analysis by using multiple linear regression. These missing values at weeks 8, 24, and 48 will be imputed by utilizing the multiple imputation. For participants who fail to show up for follow-up, the treatment-by-intention analysis method will use.
About primary outcomes are the minimal clinically significant difference in NRS and KOOS scores for patients after 12 weeks of intervention. A paired-sample t-test will carry out to compare the differences.

About secondary outcomes, the differences in continuous variables between groups will be compared using an independent-samples t-test analysis. For the follow-ups phase, two-way repeated-measures analysis of variance (group × time) will be used to value the differences of the primary outcomes (NRS score and KOOS score) between patients of these two groups. In this study, a P-value of < 0.05 will be considered statistically significant.

5. Discussion

It is important to explore an effective and inexpensive non-pharmacological treatments for TKR surgical rehabilitation. Compared with other nonpharmacological treatments for elderly patients after TKA, music therapy is more convenient. It can be incorporated into day-to-day care in medical settings or during home care by individual patients. Compared with pharmacological treatments for elderly patients after orthopedic surgery, music therapy has no side effects and is relatively inexpensive. It is a promising alternative for elderly patients seeking pain relief [55]. We will perform an RCT to compare the effectiveness of music therapy with conventional treatment, that is, the music therapy group will be compared to the control group. Participants will listen to classical music and will be guided by researchers. Participants’ functional performance and pain symptoms will be determined by a professional therapist. The intervention duration will be 8 weeks. The long-term efficacy of music therapy will be observed at 24 and 48 weeks after the intervention.

The strengths of this protocol are listed in detail. This work will be the first RCT to prove the effect of music therapy on pain, physical function, cognitive function, and mood for senior citizens after TKR surgery. The short- and long-term effects of music therapy will be compared over the 8-week intervention and in the following 24 and 48 weeks. However, potential limitations are identified. All participants will not be blinded, and the recruited participants will be 50–80 years old. Thus, the findings of study will not be accurate for elderly adults over 80 years old.

6. Conclusions

This study will compare the effects of specific types of music therapy combined with regular care on the treatment of patients who underwent TKA. Findings from this research will guide the use of music therapy in TKA rehabilitation programs. Research on the use of additional music therapy will assist future clinical doctors and researchers in deciding the most appropriate music therapy for different patients depending on their clinical needs.

Abbreviations
TKA = total knee arthroplasty, KOA = knee osteoarthritis, RCT = randomized controlled trial, MCID = minimal clinical important change, NRS = numerical rating scale, KOOS = knee injury and osteoarthritis outcome score, CPT = cognitive performance test, RAVLT = rey auditory verbal learning test, DST = digit span task, 6MWT = 6 min walk test, TUG = time up and go, MMT = manual muscle testing, BBS = Berg balance scale, ROM = range of motion, SDS = self-rating depression scale, SAS = self-rating anxiety scale, PSQI = Pittsburgh sleep quality index, IADL = instrumental activities of daily living scale, SF-36 = short form 36

**Declarations**

**Acknowledgments**

We would like to thank the individuals who volunteered to participate in this study

**Author’s contributions**


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**Availability of data and materials**

The datasets of the current study are available from the corresponding author on reasonable request.

**Declarations**

**Ethics approval and consent to participate**

Ethics approval for the study was granted by Ethics Committee of Shanghai University of Sport, and all the participants provided signed informed consent at the time of participation. All procedures of the study were performed in accordance with approved guidelines and regulations.

**Consent for publication**

Not applicable.

**Competing interests**
The authors declare that they have no competing interests.

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References


Figures
Figure 1

Represents the study flow diagram