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# Effect of a Single Live Group Music Therapy Intervention on Anxiety-State and Well-Being Levels During Chemotherapy: A Multicenter Randomized Clinical Trial Protocol

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## Abstract

**Introduction:** Many cancer patients experience high levels of anxiety during chemotherapy, which can negatively impact their mental health and their physiological, emotional, and spiritual well-being. Different complementary therapies aim to attenuate these effects, including music therapy. Although there is preliminary evidence on the positive effects of music therapy and music-based interventions in chemotherapy wards, few studies report live group interventions delivered by accredited music therapists.

**Objective:** To determine the effect of a single live group music therapy intervention on state anxiety and well-being levels of adult cancer patients during chemotherapy.

**Methodology:** This study protocol follows the SPIRT guidelines and reports a two-arm multicenter randomized clinical trial (RCT). The intervention group will receive standard care + a live group music therapy session and the control group will receive standard care only. The primary outcome is state anxiety, measured with the six-item State-Trait Anxiety Inventory (STAI-6). The secondary outcome is well-being, measured with the Well-being Numerical Rating Scales (WB-NRSs). The scales will be applied before and after each intervention. Sample size calculation resulted in a total of 102 participants.

**Conclusions:** This study seeks to contribute to the improvement of psycho-emotional health and well-being of cancer patients during chemotherapy. It is the first multi-center RCT on music therapy with cancer patients in [country, de-identified for peer review] and aims to gather knowledge about music's role to improve patients' mental health during acute treatment.

**Trial Registration:** clinicaltrials.gov (NCT06577324, submission date August 21st, 2024).

## Keywords

music therapy, anxiety, wellbeing, chemotherapy, oncology

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## Introduction

Cancer is currently the second most common cause of death in the world with approximately 10 million deaths per year.[1] For the year 2022, almost 20 million new cases were reported worldwide, and it is expected that by 2050, there will be nearly 35 million new cases of cancer across the globe.[2] Among the multiple treatment possibilities, chemotherapy continues to be 1 of the most frequently prescribed option.[3] During chemotherapy, cytotoxic drugs are administered – either orally, topically, subcutaneously, or intravenously – with the aim to destroy malignant cells in the body.[4]

However, chemotherapy represents also a major challenge for many patients and is associated with increased levels of pain, anxiety, and depression.[5] Chemotherapy can also disrupt social relationships, generate feelings of hopelessness, emotional vulnerability, and cause an imbalance in many dimensions of daily life.[6,7] Studies show that between 20%–50% of cancer patients need psychiatric support to cope with the symptoms of stress and anxiety associated with the disease.[8] Additionally, patients with mental health challenges perceive chemotherapy-induced side effects in a more exacerbated way.[9] Studies have shown that high levels of anxiety can influence patients' physical symptoms, such as nausea, pain, and vomiting, both before and after treatment.[10] Chemotherapy-induced side effects are frequent, with approximately 60%–70% of patients experiencing symptoms.[11–13] Besides physical and psychological challenges of chemotherapy, some patients can also suffer from neurological problems, including impaired attention, slowness in processing information, difficulty multitasking, neuropathy, and a decrease in fine motor skills and executive functions.[13,14] Mental health in chemotherapy patients can also be impacted by secondary factors, such as long waiting times before or during treatment.[15] Another factor that can cause psychological distress is the sound environment of the chemotherapy unit, which is composed of different types of noises, including the beeping of monitors or the sound of the infusion bombs.[16] Taking mental health seriously for chemotherapy patients is paramount, as patients' psychological health and well-being directly impact the trajectory of the disease and the ability to tolerate treatment.[17] Therefore, an increasing variety of alternative and complementary therapy approaches are being studied for this population, including music therapy and other music-based interventions.[18–20]

While music therapy and music-based interventions have a long tradition in general oncology and end-of-life care,[19] chemotherapy is still a relatively under investigated context. A recent meta-analysis including 7 studies reports a significant reduction of nausea and vomiting in gastrointestinal cancer patients during chemotherapy after listening to or participating in making music.[11] Another meta-analysis including 9 studies found that music therapy and other music-based interventions led to a statistically significant reduction of anxiety levels and an improvement in quality of life of chemotherapy patients.[20] Individual studies add to these results and demonstrate music's potential for improving quality of life, reducing physical side effects, and for decreasing anxiety.[21–24] The few studies conducted by certified music therapists report positive effects on mental health, resiliency, vital signs, pain, or negative mood and fatigue.[5,25–28] While this preliminary evidence is promising, studies included in the previously mentioned meta-analyses had a high risk of bias and the quality of the evidence was rated from low to very low.[20] Besides, most studies conducted during chemotherapy still use pre-recorded music and group approaches using live music therapy are particularly scarce.

This aim of this study is determine the effect of a live group music therapy intervention conducted by certified music therapists on state anxiety and well-being levels of adult cancer patients during chemotherapy in the hospitals [hospital names, de-identified for peer review].

## Materials and Methods

### Study Design

This study follows the SPIRIT guidelines for reporting randomized clinical trial (RCT) protocols[29] and is a multicenter, pragmatic randomized clinical trial with 2 parallel arms[30]:

- Intervention group (IG): standard care during chemotherapy + a music therapy group session
- Control group (CG): Standard care alone during chemotherapy

### Participants and Setting

Participants are cancer patients who assist at their scheduled outpatient chemotherapy session at the hospitals [hospital names de-identified for peer review]. The chemotherapy wards of both hospitals are comparable in terms of size (7 patients in each hospital), and available standard care. Therefore, the intervention and control groups will be conformed of a maximum of 7 participants.

### Inclusion and Exclusion Criteria

Inclusion criteria are: patients over 18 years of age; having an oncological diagnosis; attending intravenous chemotherapy session at the hospital sites; having not received music therapy before; and having necessary cognitive and literacy skills to fill out the informed consent and questionnaires. Exclusion criteria are: patients who report hearing problems, and who do not give consent to participate in the study.

### Sample Size

The sample size calculation was performed to detect a 5-points difference on the STAI (pre- vs post-intervention

difference between groups). We do not expect the day of the week to influence the outcome of interest. Sample size was calculated using the statistical software Stata (v13.0). Obtaining a power of 80% and taking a *P*-value of 5%, the number of participants expected in this study is n = 84. The formula used to calculate the sample size was:

$$z = \frac{(\bar{x}_2 - \bar{x}_1) - (\mu_2 - \mu_1)}{\sqrt{\sigma_1^2/n_1 + \sigma_2^2/n_2}}$$

Estimating a 20% attrition rate, a total of 102 patients will be randomized.

## Randomization and Sampling

Participants will be selected by convenience sampling. Interventions will take place 4 times a week at the same weekdays (Monday, Tuesday, Thursday, and Fridays) and hours (9 a.m.-10 a.m.) at both sites. However, the order of the condition (control or intervention) will be randomized by intervention days. Block randomization using a computer software (Microsoft Excel) will be applied to ensure the balance of the groups, being A the intervention condition and B the control condition.

## Concealment and Masking

Concealment of the random assignment will be guaranteed using opaque, sealed, and sequentially numbered envelopes, which will be 15 minutes before the start of the intervention on each intervention day. Due to the nature of the intervention, masking of the participants, data collectors, and music therapists is not possible. All data will be stored in a REDCap database and analysis will be conducted by a blinded member of the research team.

## Study Procedure

Recruitment will be performed by a member of the healthcare team who is not the music therapist. Prior to each intervention, the study procedure and aims will be explained. If patients are willing to participate, the informed consent form will be handed out and recollected by the member of the healthcare team. After signing the informed consent, the first set of questionnaires will be filled out by the participants, and subsequently, the result of the randomization will be announced. Then, either the intervention or control condition will take place for the same duration of time. Finally, the second set of questionnaires will be filled out again by the participants. The socio-demographic and medical data will be retrieved from each patient's electronic medical history. In case a patient does not give consent to participate or does not meet the inclusion criteria, he/she can optionally join the music therapy group session without filling out the questionnaires, or just decide not to participate.

## Primary Outcome Measure

The primary outcome measure in this study is the state anxiety scale of the State-trait Anxiety Inventory (STAI). The full version of the STAI consists of 2 forms with 40 items rated on a 4-point Likert scale (1-4), of which 20 measure trait anxiety and 20 items measure state anxiety.[31] For this study, only the state anxiety form will be used. The total scores range from 20 to 80, with higher scores indicating higher state anxiety levels. Cut-off scores for the STAI are usually >40,[32] and the Minimal Clinically Important Difference (MCID) for the STAI has been suggested to be between 8 and 10 points.[33,34] The STAI has previously been successfully used in music-based intervention studies in chemotherapy wards [eg, 35–37]. The STAI will be applied before and after each intervention.

## Secondary Outcome Measure: Well-Being (WB-NRSs)

The secondary outcome measure is the Well-Being Numerical Rating Scales (WB-NRSs),[38] which evaluate well-being in 5 different dimensions; physical, psychological, social, spiritual and general well-being. Each of the dimensions is measured with a numerical rating scale from 1-10, in which 1 means complete distress and 10 means complete well-being. The WB-NRSs will be applied before and after each intervention.

## Socio-Demographic and Medical Data

The following data will be collected from the patient's medical history: age, sex, oncological diagnosis, quality of the support network, the presence of a companion or caregiver during their current chemotherapy treatment, level of education, mental health diagnosis, number of chemotherapies received, and cycle of chemotherapy treatments.

## Intervention

The following intervention description follows the EQUATOR Network guidelines for reporting music-based interventions.[39] While the group music therapy session is not based on a single theoretical framework, the aims of this group are similar to those reported in previous music therapy group interventions, eg, fostering creativity, encouraging communication and expression of emotions and thoughts, and creating a sense of belonging and connectedness among the participants[40,41] The music therapy group will be led by a certified music therapist, will last for 45 minutes, and is organized in different steps:

1. Cleaning and disinfection of the musical instruments according to a previously published protocol.[42] The instruments that will be used are: an acoustic guitar

(Yamaha C-40), a Samafon (an instrument, in which tuned aluminum tubes of different sizes are held by strings and played using a soft mallet producing mellow and long-lasting tones), an ocean drum (a double-skinned drum over which small metal balls or seeds roll producing sounds similar to those of waves), and egg shakers (small plastic shakers that are played using rhythmical movements with the arms). Participants will stay in their chairs and chemotherapy will continue as programmed for each patient.

2. Participants will be verbally greeted and asked about their current mood, if anything in particular is going on, and about their musical preferences and any ideas, thoughts, feelings, or emotions they want to share with the group. If caregivers are present, the music therapy group will be explained to them, and they will be asked not to intervene or interrupt as far as possible.
3. Next, a body awareness and movement experience with up-beat and rhythmic pre-recorded music will be carried out. The music will be played back by a wireless Bluetooth speaker (JBL Go 3). For this, the music therapist proposes a simple movement synchronized to the rhythm of the music (eg, moving arms up and down, stamping with the feet), and participants will be invited to imitate the movements along with the music therapist. Then, each participant will be encouraged to choose a new movement representing them, and the rest of the group will imitate it. When all the participants have presented their own personal movement, a memory game will be played, in which some participants are randomly elected, and rest of the group must remember and repeat their respective movements. At the end, soft and slow music will be played back, accompanied by stretching different body parts (considering the mobility abilities of each patient). Participants will be invited to pay attention to their body sensations and breathing. A few seconds of silence will be left to start the next musical experience.
4. As the central part of the session, different songs will be sung together accompanied by live music and the use of the musical instruments available. Participants can either choose to sing and/or participate using the musical instruments, or just listen. The songs will be based on the musical preferences of the group members discussed at the beginning of the session, or songs can also be proposed spontaneously. Between each song, participants can verbally reflect on the meaning of the song and the music, or share memories and emotions the song brought up.
5. For bringing closure to the session, participants will be invited to reconnect with their breathing and body sensation, accompanied by entrained live music with a stable and slow pulse played by the music therapist on the acoustic guitar. While listening to the music, participants will be asked to think of a word that resonates with their experiences during the group session and if appreciated, they are invited to share this word with the group.

The control group will receive the standard care provided by the healthcare team personnel during chemotherapy, but without being exposed to music therapy. Standard care in both hospital sites include availability of medical and nursing staff, who are responsible for providing information, canalizing veins, cleaning catheters, administering hydrating fluids, antihistamines, and chemotherapy, among others, ensuring the physical well-being of each patient. Patients are seated in a chair during chemotherapy, and they are free to bring their personal objects, books, or music to distract themselves or work during the treatment.

## Data Handling

All data will be collected by a research assistant and subsequently entered in a REDCap database. Regular audits of the paper questionnaires and electronic database will be performed to guarantee data consistency and coherence.

## Statistical Analysis

Categorical variables will be presented using absolute and relative frequencies. Quantitative variables will be reported through measures of central tendency and dispersion, according to their statistical behavior. The normality of these variables will be evaluated with the Shapiro Wilks test. Initially, a bivariate analysis will be carried out considering all the variables collected to detect potential differences between the intervention group and the control group. Categorical variables will be compared using chi-square statistic or Fisher's exact test, and quantitative variables using the *t* test or Wilcoxon test according to statistical behavior. For the primary outcome, mean differences of the post-intervention STAI between the control group and the intervention group will be calculated, using the *t* test or Wilcoxon test will be used as appropriate. A Generalized Linear Mixed Model (GLMM) will be used to evaluate the effect of music therapy on changes in STAI and WB-NRSs scores from pre- to post-intervention. This model will include fixed effects for treatment group and time and an interaction term to assess differential effects over time by treatment group. Random effects for each center will be included to account for variability between centers. Statistical significance will be determined with a two-tailed hypothesis test, with $P$-values $<0.05$ considered significant.

## Ethics Approval and Informed Consent

This study was approved by the Research Ethics Committee of the Fundación Universitaria Sanitas (CEIFUS 2439-24, date of approval August 12$^{th}$, 2024). All participants will sign a written informed consent to participate in the study. This

study was registered in clinicaltrials.gov (NCT06577324, submission date August 21st, 2024).

The flow diagram of the study is displayed in Figure 1 below.

## Discussion

This study aims to determine the effect of a single live group music therapy intervention on state anxiety and well-being levels of adult cancer patients during chemotherapy. During chemotherapy treatment, patients face various challenges. On the 1 hand, patients must cope with the physical symptoms of the disease itself, but also with chemotherapy-induced side effects, such as fatigue, hair loss, nausea, vomiting, or loss of appetite and weight, among others.[13,14,43] On the other hand, many patients experience psychological distress, uncertainty in the face of the disease, economic burden, fear of limb mutilation, pain or death, which can negatively affect their mental health.[44] Several studies have shown that both living with cancer and facing chemotherapy treatment can lead to high levels of stress and anxiety.[10,45]

A variety of alternative and complementary therapies are currently investigated to help patients attenuate these challenges, including aromatherapy, acupuncture, reiki, yoga, or homeopathy, among others.[46] Likewise, resources such as the use of virtual reality, games, films, and clown accompaniment have been used.[47-49] Music therapy and other music-based interventions have a long history in oncology settings, but studies focusing on the chemotherapy process are scarce. While there is preliminary evidence of music's potential to improve both physiological and psychological outcomes of patients during chemotherapy,[11,20] live music therapy approaches – and in particular live group music therapy – are yet in the need of being more rigorously studied.

Music therapy in a group setting has the potential to foster communication, expression, and creativity despite patients' challenges regarding their illness and chemotherapy treatment. Previous studies show that group music therapy can help enhance a sense of togetherness, belonging, and intimacy among participants.[41,50,51] Additionally, music might help improve the atmosphere of the chemotherapy ward. Studies on medical architecture demonstrate how different elements within the hospital environment can affect the subjective experience of patients during chemotherapy cycles.[52,53] Music, having an evocative and metaphorical character, has the potential to elicit positive personal and autobiographical experiences and can encourage the expression reminiscences, thus promoting a pleasant experience, without the need to physically modify the environment or to have to withdraw from it.[54]

## Potential Limitations

There are several potential limitations of this study. First, the intervention group will participate in a single group music therapy session. This is because as different patients have

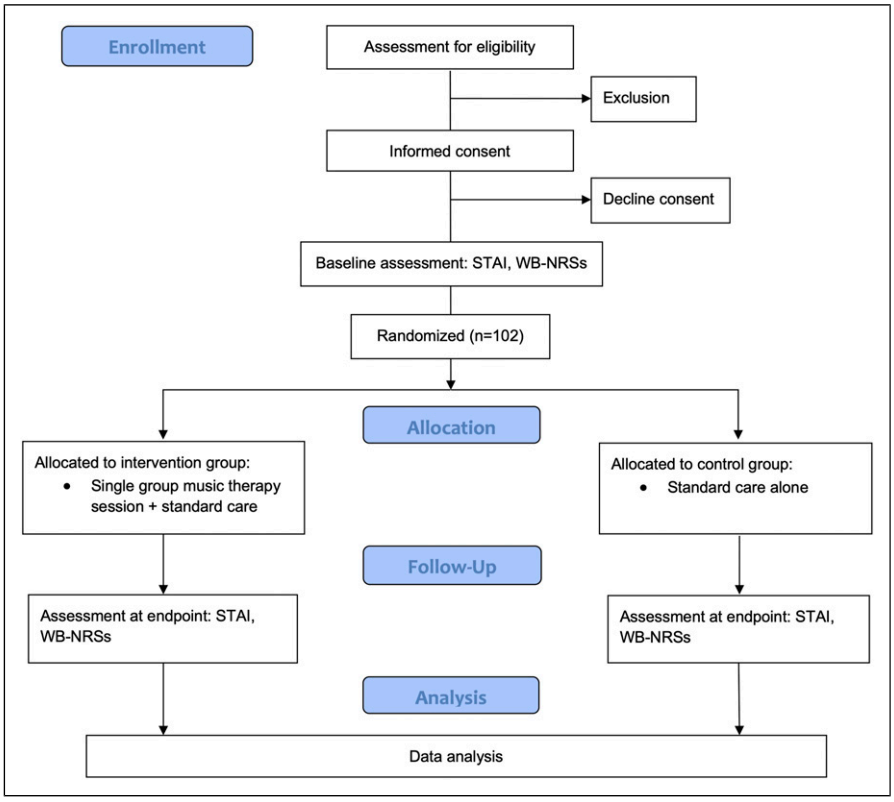


**Figure 1.** Flow diagram.

different chemotherapy cycles, in follow-up group sessions, patients would have different frequencies of previous exposure to music therapy. To avoid this, a single session with patients who have not previously been exposed to music therapy was chosen. Thus, we cannot estimate the effect of various sessions, potential habituation effects, or any statistical associations in relation to the number or frequency of the interventions. In a future study, a long-term music therapy process in chemotherapy wards might be indicated to address these factors. Second, while there are many other important health measures for chemotherapy patients, in this study, only state anxiety and wellbeing are being considered. As the intervention consists of a single group music therapy session, we believe more mid- to long-term outcomes such as coping, or sleep quality would require follow-up sessions targeting specifically such domains. Third, no alternative intervention for the control group is proposed in this study, only standard care. Thus, participants in the control group might or might not listen to music on their personal devices, which could be a confounding factor. We hope to provide an active control condition, such as listening to audiobooks or engaging in storytelling, in a future study. Fourth, in this study only patients are invited to participate, not their caregivers. It is known that cancer can also negatively affect patients' family members and caregivers and in future studies, caregivers might be invited to participate. Fifth, non-masking of the participants, data collectors, and the music therapists, and using self-reported outcome measures might increase the risk of bias. A previous meta-analysis on music interventions during chemotherapy[20] reported a high overall risk of bias in all included studies. While we have tried to mitigate some of these risks, eg, through describing the randomization and group allocation procedure, performing a calculation of the sample size, and providing detailed description of the intervention, due to the nature of the setting and the intervention not all risks can be adequately be avoided in this study. Sixth, while the intervention follows a clear structure, treatment fidelity will not be evaluated in this study. However, music therapists are asked to write down any deviations from the protocol and name the reasons.

And sixth, anxiety and wellbeing levels depend on a variety of factors. Furthermore, both hospital sites are located in different regions in the country. Thus, personal, cultural, and social factors cannot be controlled and might influence the outcomes. Although this is a pragmatic RCT acknowledging such complexity, the results of this trail cannot be generalized to the wider population of chemotherapy patients and should be interpreted with caution.

## Conclusions

This study aims to gain knowledge on the potential of music therapy to improve mental health and well-being in cancer patients during chemotherapy. To our knowledge, this is the first multi-site RCT on music therapy in this context and in the wider field of oncology in Colombia.

### Authors' Contributions

LRA, AMD, RS, MAA, CCCM, and ME designed the study. LR and ME drafted the manuscript, ME supervised the overall study process. All authors contributed to critical revision of the manuscript. All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

### Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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### Ethical Statement

#### *Ethical Approval*

This study was approved by the Research Ethics Committee of the Fundación Universitaria Sanitas (CEIFUS 2439-24, date of approval: August 22th, 2024). All participants will sign a written informed consent.

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