

**Introduction of a music-based intervention for patients receiving infusions at the Lifespan  
Cancer Institute Infusion Center in the Miriam Hospital**

**NCT # Unassigned**

**5/20/2024**

## **Background**

An estimated 17 million Americans are living with cancer, and the majority of this population will receive chemotherapy as part of their treatment plan each year. In addition to common side effects like pain, fatigue, nausea/vomiting, and hair loss, chemotherapy infusions can also take a significant psychological and emotional toll on patients. Many studies have shown increased prevalence of depression and anxiety among cancer patients due to both disease and therapeutic burden, with prolonged chemotherapy treatment in particular serving as a significant risk factor. Thus, there begs the question of nonpharmacological and non-invasive treatment methods to reduce the negative emotional states, psychological burden, and stress that often accompany chemotherapy.

Music has increasingly been utilized in many clinical settings as a complementary intervention. One population that has benefited greatly from music intervention is individuals with dementia-related disorders. Active music therapy with these individuals can help in treating cognitive and/or behavioral symptoms of the disease by engaging participants through social interaction amongst other acute benefits. Even more, studies have shown that passive music therapy techniques (e.g., listening to recorded or live music) can ease psychosocial symptoms associated with dementia, even when a trained music therapist is not present. Overall, music therapy interventions have been proven to promote wellness, manage stress, alleviate pain, express feelings, enhance memory, improve communication, and promote physical rehabilitation. In addition to these cognitive benefits, music therapy has also been shown to improve physical systems. For example, just four weeks of passive music therapy exercises in a population of hypertensive young adults significantly lowered systolic blood pressure and heart rate. This suggests a soothing and possibly rehabilitative effect of music on patients as they are battling their illnesses. In addition, singing along to music was found to boost the body's cytokine levels, a sign of strengthening immunity. One can think about music's ability to boost immunity as a beneficial chain reaction: music improves people's moods and lowers stress, which affects activity of the autonomic nervous system, which then ramps up immune function. Altogether, while music therapy does not actually affect diseases themselves, it has a great impact on mood, and sometimes can make a difference in the way the patient copes with and feels about their disease.

The idea that patients with cancer may benefit from musical expression and musical experiences has been supported by music therapy research. For instance, a randomized trial by Harper et. al found that at an adult outpatient chemotherapy infusion center, listening to self-selected music during infusion was associated with improved positive mood and reduced negative mood and distress in patients. Another study by Mondaro et al. found that music therapy served as an outlet for patients to express their emotions and led to increased feelings of resilience, both of which were associated with promoting patients' endurance through their chemotherapy regimens.<sup>10</sup> And another study by Massimiliani et al. found that music intervention resulted in decreased anxiety level and heart rate in oncological patients receiving chemotherapy. Overall, many studies have shown the usefulness of music therapy in oncology

settings, and its low-touch, low-risk, and low-cost administration makes it an attractive method for managing patients' psychological well-being during challenging chemotherapy sessions.

However, despite the demonstrated benefit of music intervention in the clinical setting, there has not been widespread implementation. In particular, music therapy services from licensed musicians are severely under-resourced and underrepresented in Rhode Island as a whole, let alone in an oncological context. In the American Music Therapy Association 2021 Workforce Analysis, only one music therapist in Rhode Island responded to the association's survey; they reported seeing around 2000 clients for the entire year of 2020 and delivering services to eight facilities across the state. While this number likely underreports the amount of music therapy services provided—especially when factoring in unlicensed music therapists working with various patient populations—jobs in this workforce have only decreased since the onset of the COVID-19 pandemic. Importantly, Miriam Hospital is a major outpatient clinic in Rhode Island providing infusion services for patients undergoing cancer treatment and would be an impactful initial location to launch this music therapy intervention. Thus, given the lack of structured music therapy programs for oncology patients in Rhode Island, this project serves to examine the success of receptive music therapy to improve the health and well-being of patients undergoing chemotherapy and to create a formal music therapy offering at the Miriam Hospital. Successful implementation at the Miriam Hospital could set the grounds for expansion to other Lifespan Infusion Centers, including Rhode Island Hospital and Newport Hospital which are two of the largest hospitals in Rhode Island.

## **Objectives**

The aims of the project are to (1) provide patients receiving infusions at the Miriam Hospital a relaxing therapeutic music experience, (2) qualitatively and quantitatively evaluate the effectiveness of this intervention to reduce physical and psychological symptom burden, and (3) investigate if there are beneficial effects of receptive music based interventions upon physiological parameters such as heart rate, respiratory rate, and blood pressure.

## **Design and Methods**

We will screen patients undergoing infusion services at the Miriam Hospital outpatient infusion clinic to meet eligibility criteria for this study, including: (1) age >18 years, (2) sufficient hearing capacity to hear music, (3) scheduled for a chemotherapy infusion lasting at least 30 minutes, (4) having had at least one prior infusion session without music therapy intervention, and (5) ability to complete pre- and post-assessments in English. On each day of the study where researchers are on site at Miriam Hospital, researchers will approach patients at the infusion clinic and screen them for eligibility based on Q3 before their infusion session. Eligibility screening will be completed upon approaching patients where researchers will ask patients verbally if they qualify. Student researchers will follow an IRB-approved recruitment script as the recruitment process will all be done verbally with each patient on the day of their

infusion session. For prospective subjects who are eligible, we will ask if they would like to participate in the study and obtain informed consent via our consent form which requires a signature.

This study will be a self-controlled case series with 150 participants (an amount that will probably decrease due to natural attrition); each participant will serve as a control for themselves to evaluate any changes due to the music therapy intervention. Prior to intervention administration, we will directly obtain demographic data from each participant—including age, gender, diagnosis, and current infusion type.

Before the infusion, participants will be given a pre-assessment survey, the Edmonton Symptom Assessment Scale (ESAS) regarding their current mood and symptoms, a tool that has been previously reported and clinically validated in the literature for assessing patient symptom burden among patients with cancer. During the infusion, participants will be asked if they have their own device, i.e. a phone or tablet, with music on it. If not, participants will use an iPad provided by the infusion clinic. Researchers will guide participants through the music selection process, which will include choosing emotionally salient songs unique to each patient's preferences. Headphones will then be connected to the device for participants to listen to a self-selected playlist (e.g. on YouTube or Spotify) for at least 30 minutes. Vitals such as blood pressure, respiratory rate, and heart rate will also be monitored before and after the music intervention. After the session, participants will be given the ESAS again as a post-assessment survey to evaluate outcomes of the music-based intervention. Outcomes will be self-reported changes in positive and negative mood, anxiety, distress, and pain using the ESAS. Participants will also be asked a set of qualitative questions about their overall experience with the music therapy session, including how their infusion session with music compared to previous sessions without music, as well as if they would want music included with infusions in the future.

There are no statistical analyses to run on this data, including adjustments made for testing multiple variables. Differences in symptom data from the ESAS between the pre-assessment and post-assessment surveys will be compiled across participants and reported in a chart. Similarly, differences in vital signs between baseline and after the 30-minute music listening intervention will be plotted on a chart. Data from the participant satisfaction feedback questions are qualitative in nature and will be listed out in a table.

We will be raffling four \$25 gift cards to local Rhode Island businesses to participants in December 2024. Participants will have about a 4 out of 100, or 4% chance of winning. To distribute gift cards to the winners, email addresses will be collected separately from the data gathered in the study; however, the emails will only be used for this purpose and be deleted after the study is completed.