

COVER PAGE

Study Title: Enhancing Health in Rural Populations: Music as Therapy

Clinical Trials Registration Number: NCT not yet assigned

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Study Protocol

Background

Since the COVID-19 pandemic, approximately one in five adults in Arizona report symptoms of mental health disorders each year.¹ These outcomes are particularly concerning in rural and medically underserved areas, where long-term care residents face elevated risks of chronic stress, cognitive decline, physical pain, and social isolation.¹ Older adults with memory-related impairments are especially vulnerable to the loss of meaningful interpersonal and sensory engagement.¹

Music-based interventions (MBIs) have demonstrated strong potential to support both cognitive and emotional well-being.² Existing studies report significant analgesic effects of music and reductions in symptoms of anxiety, stress, and depression, supporting the use of MBIs as non-pharmacological health interventions.^{3,4} However, there is limited research examining how familiarity, personalization, and continuity of musical exposure influence intervention outcomes among older adults with cognitive or emotional health challenges, particularly those living in long-term care settings.

Older adults with cognitive impairment often experience reduced autonomy, fragmented social networks, and limited access to therapies that support holistic well-being.² Despite the frequent use of music in caregiving environments, few interventions have been systematically adapted or rigorously evaluated. This study addresses that gap by evaluating a structured music-based intervention designed to support mental and physical health among adults residing in two long-term care communities in northern Arizona.

Study Design

This study uses a single-group quasi-experimental design with pre- and post-intervention assessments. All participants will receive the same music-based intervention and will complete surveys prior to the first session and again after the completion of the six-week program. In addition, a subset of participants, facilitators, and musicians may be invited to participate in qualitative interviews to provide more detailed information about their experiences with the intervention.

Setting

The study is being conducted at two residential long-term care communities in northern Arizona: Haven Health and The Peaks. These settings serve adults who may be experiencing physical health challenges, emotional distress, cognitive impairment, and limited access to behavioral health resources.

Intervention Description

Participants will engage in a six-week music-based intervention delivered in a group format. Sessions will occur once per week and will last approximately 60 minutes. The intervention emphasizes active music participation rather than passive listening and includes activities such as drumming, rhythm exercises, flute music, and other culturally grounded music practices led by experienced musicians.

The curriculum has been refined through collaboration with a Community Advisory Board, care staff, and local musicians to ensure that it is contextually appropriate and therapeutically relevant for older adults in long-term care settings. Particular attention has been given to creating an intervention that is engaging and accessible for participants with varying levels of cognitive functioning.

Recruitment

Participants will be recruited directly through Haven Health and The Peaks in collaboration with facility staff and activity coordinators. Research staff will attend each site prior to the beginning of classes to explain the study, answer questions, obtain informed consent, and administer baseline assessments. Recruitment will continue as needed prior to the start of intervention sessions.

Outcomes

The primary outcomes of interest include changes in depression symptoms, anxiety symptoms, perceived stress, and chronic physical pain from pre- to post-intervention.

Institutional Review Board

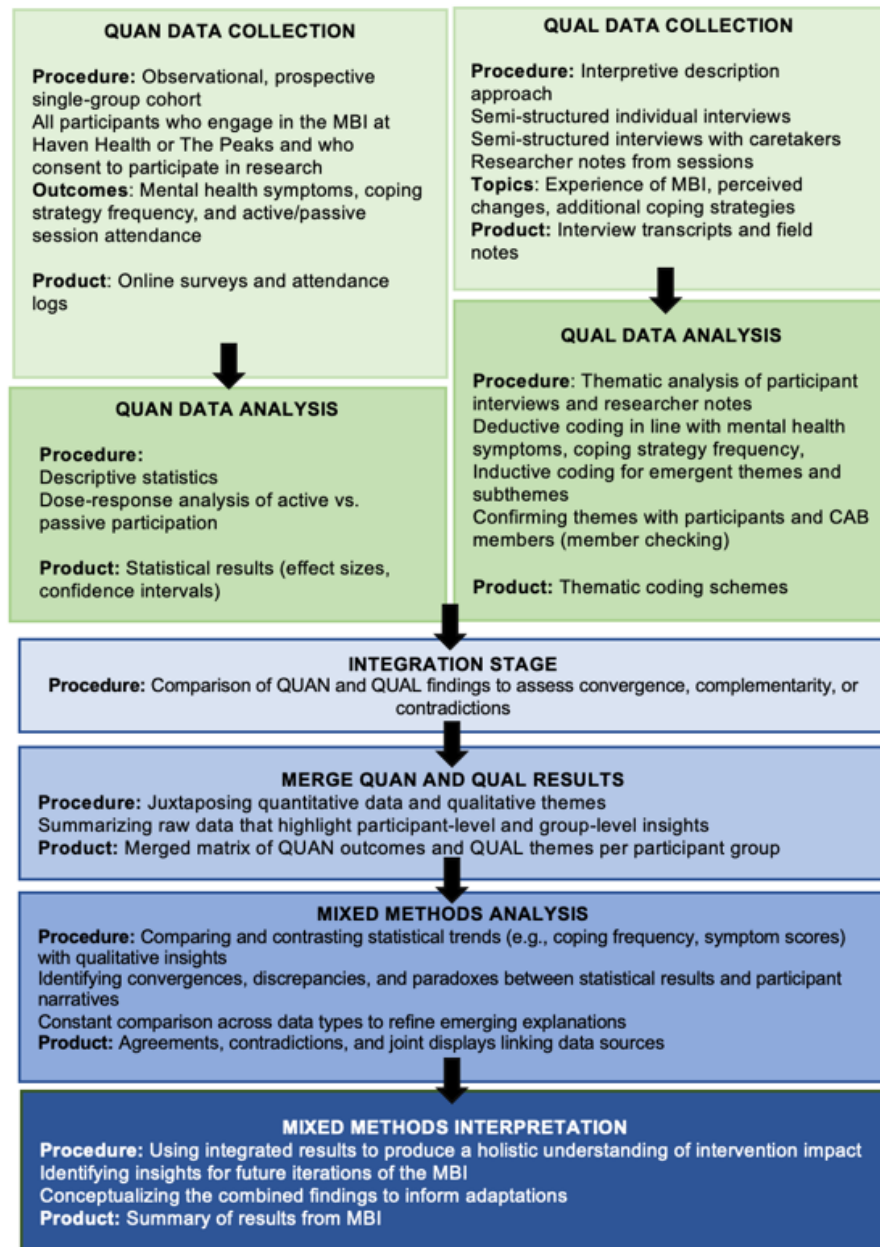
All study activities, including participant recruitment, consent procedures, survey administration, and interviews, have been approved by the Northern Arizona University Institutional Review Board under protocol # 2185298-9.

Analysis Plan

Mixed-Methods Framework

This study uses a convergent mixed methods design, in which quantitative and qualitative data are collected in parallel, analyzed separately, and then integrated at the interpretation phase to produce a more complete understanding of the intervention's impact. The convergent approach allows for direct comparison of findings across methods and supports triangulation to strengthen validity. Figure 1 demonstrates a visual representation of the mixed methods procedures.

Figure 1. Convergent Mixed Methods Framework



Quantitative Measures

We will collect data using an electronic survey to assess depression symptoms, chronic pain symptoms, stress, and isolation. The *Patient Health Questionnaire-2 (PHQ-2)*⁵ will be used to assess for depressed mood and lack of pleasure over the past two weeks. The *General Anxiety Disorder-5 (GAD-5)*⁶ will be used as an initial screening for anxiety symptoms. The *Von Korff Chronic Pain Scale*⁷ will be used to identify the degree and intensity of pain. The *Perceived Stress Scale (PSS)*⁸ will be used to assess the perception of stress and the degree to which certain life events are perceived as stressful. These will be quantitatively assessed using a dose-response framework. When considering the effects of the MBI, the number of MBI sessions will correspond to a higher “dose.” Dose-response curves will be compared between individuals with high attendance and active participation and low attendance and passive participation. Statistical tests, including paired t-tests and dose-response curves, will illuminate differences in index scores pre- and post-MBI. Further, the dose-response model will estimate the average number of sessions necessary to elicit a statistically significant change in the above measures. Analyses will be conducted using STATA18 statistical software.

Qualitative Measures

Thematic analysis will be used to identify emerging themes and patterns from 10 semi-structured interviews conducted by a research team member once the 6-week sessions are complete. We will conduct interviews with participants and/or participants’ caretakers (if the participant is not able to engage in an interview), group facilitators, and musicians. Analysis will occur over iterative stages involving systematic coding and comparative methods in an interactive, inductive process. ATLAS.ti Windows will be used to organize and store the data for analysis of themes. Qualitative instruments are included in Appendix C.

Anticipated Results

We expect increases in the use of music for managing physical and mental symptoms and decreases in anxiety, depression, stress, and pain. Improvements are anticipated to correlate with both overall attendance and active session participation. The integrated analysis will explore how these effects vary by level of engagement and experiences of mental and physical disability. This model enables estimation of both intervention efficacy and mechanisms of change.

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