Summer 8-2022

Listening to Remotely Monitored Home-based Preferred Music for Pain in Older Adults with Low Back Pain: A Pilot Study of Feasibility and Acceptability

Setor Kofi Sorkpor

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LISTENING TO REMOTELY MONITORED HOME-BASED PREFERRED MUSIC FOR PAIN IN OLDER ADULTS WITH LOW BACK PAIN: A PILOT STUDY OF FEASIBILITY AND ACCEPTABILITY

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
CIZIK SCHOOL OF NURSING

BY

SETOR KOFI SORKPOR, PhD(c), MPH, MSN, RN-BC

AUGUST, 2022
To the Dean for the School of Nursing:

I am submitting a dissertation written by Setor Kofi Sorkpor and entitled “Listening To Remotely Monitored Home-based Preferred Music for Pain in Older Adults with Low Back Pain: A Pilot Study of Feasibility and Acceptability.” I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.

Constance Johnson, PhD, RN, FAAN, Committee Chair

We have read this dissertation and recommend its acceptance:

Hyochoel Ahn, PhD, FAAN 6/2/2022
Hongyang Miao, MS, PhD 6/3/2022
Luca Pellonini, PhD 6/2/2022
Carolyn Moore, PhD, MT- BC 6/2/2022

Dean for the School of Nursing
Acknowledgments

I would like to express my gratitude to the entire faculty and staff of the Cizik School of Nursing for providing me with the chance to pursue my doctoral studies in our distinguished School of Nursing and to be a part of this excellent institution. My heartfelt gratitude to my advisor, Dr. Ahn Hyochol, who has been instrumental in providing me with guidance, support, and encouragement throughout this journey. I am also grateful to the members of my dissertation committee, chaired by Dr. Constance Johnson, for their thoughtful feedback, support, and encouragement, as well as their assistance in finalizing this manuscript.

Further, I would like to express my sincere gratitude to the Center of Nursing Research for funding my dissertation study through the Speros Martel Endowment for the Aging Award. I am grateful.

Finally, I want to express my gratitude to my family, friends, and colleagues for their unwavering support. Thank you to Irene, Kaden, and baby Jisselle for putting up with me staying up late at night and on weekends. We finished the task.

I dedicate this accomplishment to my dear mother Martinette Adzo Attipoe as a way of saying, "I am finally done, and you no longer need to worry about your lovely son not getting enough sleep." Thank you very much to everyone.
Liste

Listening to Remotely Monitored Home-based Preferred Music for Pain in Older Adults with Low Back Pain: A Pilot Study of Feasibility and Acceptability

Setor Kofi Sorkpor, PhD(c), MPH, MSN, RN-BC

August, 2022

Abstract

Background: Low back pain (LBP) is a complex, multifaceted, and widespread condition that impairs the quality of life of older adults aged 65 years or older. Although nonpharmacologic interventions informed by the biopsychosocial model are recommended as first-line therapy for LBP, pharmacologic therapies, including opioids, are commonly used as first-line interventions in practice. This could be attributed to a lack of understanding of the analgesic properties of most nonpharmacologic interventions. Nonetheless, some nonpharmacologic therapies, such as passive music listening, have been shown to modulate pain via pathways that target the neurophysiological mechanisms associated with pain.

Specific Aims: The specific aims were to determine: (1) the feasibility and acceptability of listening to one’s preferred music to relieve pain in older adults with LBP, aged 65 years or older, and (2) if music reduces pain and affects pain-related physiological markers such as cerebral hemodynamic response to experimental pain, as measured by function near-infrared spectroscopy (fNIRS), heart rate variability (HRV), and conditioned pain modulation (CPM).

Methods: This was a single-center, single-arm, open-label study. Twenty community-dwelling older adults (≥ 65 years) with LBP were recruited to use noise-isolating
headphones to listen to their preferred style of music for 20 minutes twice daily for four
days using the MUSIC CARE® app. Feasibility was measured by tracking enrollment,
adherence, attrition rates, and acceptability (measured by the treatment acceptability and
preference scale). Average daily clinical LBP scores as well as other pain-specific
physiological markers; fNIRS, HRV, and CPM were collected at baseline and post-
intervention. Repeated-measures ANOVA, a general linear model based on
autoregressive iteratively reweighted least squares (AR-IWLS), and custom Python codes
were used to evaluate clinical pain, fNIRS, and HRV data respectively. The Wilcoxon
signed-rank test was run on the CPM data as it violated the test of normality.

**Results:** Feasibility measures of enrollment, adherence, and attrition rates were 95.25%
100.00%, and 0.00%, respectively. When compared to baseline measurements,
acceptance rates were higher after the intervention. Pain scores on the numeric rating
scale (NRS) for pain decreased marginally but non-significantly from baseline to post-
intervention. The physiological measures (fNIRS, HRV, and CPM) revealed that
treatment has the potential to reduce pain.

**Conclusion:** These findings suggest that listening to preferred music for 20 minutes
twice a day for four days is a feasible and acceptable intervention for reducing pain in
older adults with LBP, aged 65 years or older. Also, listening to preferred music at home
resulted in marginal but nonsignificant reductions in clinical pain sensitivity (NRS).
Furthermore, the effects of listening to preferred music on pain were evident in the
selected pain-related physiological markers, implying that these markers may be
investigated as pain assessors in future studies. Future large randomized and ethnically
diverse studies should investigate the underlying mechanism of music-induced analgesia.
Keywords: music listening, conditioned pain modulation, functional near-infrared spectroscopy
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Summary of Study

The purpose of this study was to determine the feasibility, acceptability, and preliminary efficacy of listening to one's preferred kind of music to relieve pain in older adults aged 65 years or older with low back pain. This study used physiological pain biomarkers as well as well-established pain metrics to assess the severity of pain. Although the study protocol was approved in the fall of 2020, it was not launched until the spring of 2021, due in part to unexpected circumstances caused by the COVID-19 pandemic. Because this was primary research that required participants to come into the lab twice, the COVID-19-related suspension of participant recruitment contributed to the delay in initiation.

Prior to submitting the protocol to the IRB for approval, the following significant changes were made.

1. The design was changed from an observational study to a longitudinal study.
2. The objectives of the study were revised.
3. The intervention was carried out using the MUSIC CARE app.

These modifications were required to improve the study's robustness because longitudinal studies are better suited to provide the influence of time on the outcome variable of pain. The objectives of the study were revised to make them clearer, and the use of the MUSIC CARE app was necessary to ensure that the intervention was consistent throughout. The study was carried out according to the approved protocol. Except for one additional change that required a protocol deviation to be filed with the IRB. This modification was required to gain the trust of study participants. The original
protocol called for real-time monitoring of participants while they listened to the music intervention; however, early trial participants expressed dissatisfaction with being watched on camera while trying to relax and perform the intervention in the comfort and privacy of their homes. To preserve the dignity and privacy of the participants, all of whom were elderly, the protocol was modified to exclude real-time remote monitoring. To ensure that the study protocol was followed, the number of sessions individuals participated in each day was remotely monitored. Reminders were sent if the first section of the day was not completed by 11:00 a.m., and the second section was not completed by 9:00 p.m.
FEASIBILITY AND EFFICACY OF REMOTELY MONITORED HOME-BASED LISTENING TO PREFERRED MUSIC FOR PAIN IN OLDER ADULTS WITH LOW BACK PAIN: A PILOT STUDY OF FEASIBILITY AND ACCEPTABILITY

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THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON CIZIK SCHOOL OF NURSING

BY SETOR KOFI SORKPOR, PHD(C), MPH, MSN, RN-BC

SEPTEMBER 25, 2020
The Effects of Preferred Music on Selected Pain Physiological Parameters in Older Adults with Low Back Pain: An Open-Label Pilot Study of Feasibility and Acceptability

Study Proposal

Abstract

Introduction: Low back pain (LBP) is a complicated, multidimensional and universal phenomenon that impacts the quality of life of older adults 65 years and above. LBP is one of the leading causes of functional limitation and disability in older adults age 65 years and above. LBP is estimated to be among the most common reasons for physician visits in the United States, with an annual cost estimated to be in the excess of 90 billion United States Dollars. It is, therefore, imperative to explore more efficient means of treating LBP. The current treatment guidelines for non-specific LBP recommends the use of nonpharmacologic interventions informed by the biopsychosocial framework as initial treatment. Notwithstanding the evidence, the routine use of pharmacologic treatment including opioids as initial treatment for LBP is more common in practice. However, this anecdotal use of prescription opioids has recently been a subject of national discussion prompting the need for a shift toward the recommended nonpharmacologic treatment for LBP. Music listening is one such promising pain-reducing nonpharmacologic intervention that is hypothesized to modulates pain by stimulating the release of endogenous opioids to trigger activation of the descending pain modulation system to inhibit the nociceptive stimulus centrally in the brain stem and spinal cord. This study seeks to examine the feasibility, acceptability and preliminary efficacy of listening to preferred music on experimental pain in older adults age 65 years and above with LBP.
**Method:** This is a single-center, open-label, single-arm, cross-sectional study aiming to examine the effect of passive music listening intervention on pain through objective assessment of pain-related physiological parameters in older adults 65 years of age and older with LBP. Thirty community-dwelling older adults ≥ 65 years of age with LPB will be randomized into the music group and sham music group. Each participant will take part in one visit during which all measures will be obtained. Participants will undergo baseline testing: a measure of cortical activation using nears infrared spectroscopy, heart rate variability, and conditioned pain modulation. Participants in each group will then be exposed to listen to 30-minutes of intervention based on group allocation. Twenty minutes into the intervention a repeated measure of all baseline parameters will be assessed again. The primary outcome will be the difference between physiological changes taken at baseline and during the intervention as measured by function near-infrared spectroscopy.

**Discussion:** This study will delineate the neuromodulatory effects of music listening on selected physiological components of pain. It builds on prior research aimed at identifying effective nonpharmacologic interventions to reduce pain in older adults with LBP. The outcome from this study will inform future studies aimed at understanding the effective dose, frequency, and the underlying mechanisms behind the analgesic properties of passive music listening.

**Keywords:** Conditioned pain modulation; functional near-infrared spectroscopy; heart rate variability, music listening
Specific Aim

With the recent shift in demographics, there has been a significant increase in the aging population across the world including the United States (Roberts, Ogunwole, Blakeslee, & Rabe, 2018). Subsequently, this has led to an increase in the number of various health challenges confronted by older adults of which, low back pain (LBP) is one. LBP is typically defined as pain that manifests between the lower rib margins and the buttock creases (Hartvigsen et al., 2018). LBP is one of the leading causes of functional limitations, disability, and a decrease in quality of life in older adults aged 65 years and older (Hoy et al., 2014; Vos et al., 2017). LBP is estimated to be among the most common reasons for physician visits in the United States (Qaseem, Wilt, McLean, & Forciea, 2017) and a leading cause of years lived with disability (GBD, 2018). The annual cost associated with LBP in the United States is estimated to be in the excess of 90 billion United States dollars, with a third of this amount spent on older adults (≥ 65 years) older (Dieleman et al., 2016).

Non-specific LBP, which is defined as LBP with no recognizable pathology is the most prevalent type of LBP (Saragiotto et al., 2016). For this type of LBP, the existing clinical guidelines recommend interventions that are informed by the biopsychosocial framework, such as the use of nonpharmacologic interventions as first-line therapy, with an emphasis on tailoring such interventions to the specific needs of each patient. For those with recurrent symptoms, these interventions are to include education, exercise, and psychological interventions (Foster et al., 2018; Qaseem et al., 2017). In addition, these guidelines also support the sparingly use of pharmacologic interventions but only under specific conditions when nonpharmacologic interventions have been tried and proven not
to be effective (Qaseem et al., 2017). Notwithstanding the evidence, the routine use of pharmacologic treatment including opioids as first-line treatment for LBP is on the increase (Foster et al., 2018; Mesner, Foster, & French, 2016) possibly due to inadequate knowledge about the mechanism of action behind most nonpharmacologic therapies.

Although prescription opioids can provide LBP patients with some pain relief, their use as an initial treatment for LPB contradicts established guidelines for treating LBP (Dowell, Haegerich, & Chou, 2016; Foster et al., 2018; Qaseem et al., 2017). Moreover, the use of prescription opioids has been associated with numerous negative effects, including addiction and death (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2018). Furthermore, with over 17,000 prescription opioid-related deaths reported in 2017 alone, prescription opioid overdose-related mortality in the United States remains substantially high. (NIDA, 2020; Scholl et al., 2018). This anecdotal use of prescription opioids as first-line treatment for pain, in general, has recently been the subject of national debate, leading to a leaning against prescription opioids (Foster et al., 2018; Qaseem et al., 2017).

Some nonpharmacologic therapies have reported mechanisms of action that are ideally suited to target the neurophysiological mechanisms associated with LBP (Nijs et al., 2015; Nijs et al., 2011). One such promising pain-reducing nonpharmacologic intervention is passive music listening. Music is a safe, non-invasive, easy-to-administer, compact, and relatively cheap intervention that has been used in many conditions to alleviate pain. (Garza-Villarreal, Pando, Vuust, & Parsons, 2017; Hsu, Chen, Lee, & Lin, 2019; Hsu, Chen, & Hsiep, 2016; Kavakli et al., 2019; Ko, Leung, & Wong, 2019). Music is hypothesized to modulates by inducing the release of endogenous opioids such as β-endorphins (Almerud & Petersson, 2003) that stimulate the downward pain
regulation mechanism to suppress the nociceptive stimulus centrally in the brain stem and
spinal cord (Fields, 2000; Tracey & Mantyh, 2007). In addition, new research suggests
that passive listening to music can substantially reduce pain in older adults. (Garza-
Villarreal et al., 2017). In one recent study with a sample of 49 older adults with an
average age of 73.9 ± 7.5 years, the authors found that older adult total knee replacement
patients who listened to one session of music (Chinese and Taiwanese pop music,
classical music, and nature sounds) lasting for 25-minutes for two days experienced less
pain compared to those who did not listen to music (Hsu et al., 2019).

Previous literature suggests that the effective type of music for reducing pain is
one that is calming with a tempo between 60-80 beats per minute (Kuhlmann et al., 2018;
Poulsen & Coto, 2018). The evidence further suggests that a person’s cultural
background, social interactions, and personal experiences influence one's preference of
music in terms of genre, pitch, rhythm, style, and dynamics (Petot et al., 2019).
Therefore, listening to one’s preferred music may be better suited to elicit positive
sensory experiences to influence pain modulation (Costa, Ockelford, & Hargreaves,
2018; Mitchell & MacDonald, 2006; Tan, Yowler, Super, & Fratianne, 2012). However,
only a limited number of studies have investigated the pain modulation effects of
participants' preferred music. More so, a number of these studies used different
instruments to assess the primary outcome variables, thereby adding to heterogeneity
between the studies. Further, despite the plethora of evidence in favor of the therapeutic
use of music to alleviate pain, it is yet to be fully integrated into clinical practice, possibly
because the pain modulation mechanisms behind passive music listening is not well
understood. The current study is, therefore, designed to address this knowledge gap.
The goal of this study is to examine the feasibility and acceptability of listening to 20 minutes of preferred style of music twice-daily for 4 consecutive days on pain among 20 community-dwelling older adults (65+ years) with LBP. The central hypothesis is that listening to preferred music may reduce clinical pain and change pain-related physiological responses in older adults with LBP. The rationale for the proposed research is that an objective assessment of the magnitude of change in selected pain physiological parameters may provide relevant information on the analgesic effect of listening to one’s preferred style of music. The result of this study will provide valuable knowledge of the underlying mechanism behind music-induced pain modulation in older adults with LBP.

**Aim 1.** Determine the feasibility of music listening intervention on pain among community-dwelling older adults (65+ years) with LBP. We will track the following feasibility outcomes: (1) enrollment rate as the number enrolled/number who met inclusion criteria, (2) attrition rate as the number not completing the study/number enrolled at baseline, and (3) adherence rate as the number completing all measures/number enrolled. We will consider the protocol to be feasible if we can recruit 20 participants within 6 months of recruitment commencement and able to attain an average of > 80% on all three aforementioned feasibility outcomes.

**Aim 2.** Determine the acceptability of music listening intervention on pain among community-dwelling older adults (65+ years) with LBP. The perceived acceptability of the study protocol to participants will be evaluated using the treatment acceptability and preference (TAP) scale. (Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009) Additional attributes of pleasantness, intent to continue use, perceived negative effects, success or
failure of execution, and possible side effects of treatment will be assessed. We will consider our protocol to be acceptable with average TAP scores ≥ 3. (Sidani et al., 2009).

**Aim 3.** Further, we will also obtain data, as an exploratory aim, to investigate whether music intervention changes clinical pain (NRS), cortical hemodynamic activation in response to pain (fNIRS), heart rate variability (HRV), and conditioned pain modulation (CPM).

This study will provide valuable information on music listening intervention and guide future larger-scale randomized clinical trials of this promising intervention for older adults with LBP and other chronic pain conditions.

**Significance**

In response to the nationwide opioid crisis, limiting the use of prescription opioids to manage pain in older adults is vital, given the high likelihood of dependence with extended use (Institute of Medicine Committee on Advancing Pain Research & Education, 2011). LBP is considered a leading cause of functional limitation and disability in older adults age 65 years and above (Hoy et al., 2014; Vos et al., 2017) and also a major cause of years lived with disability (GBD, 2018). The estimated annual economic burden of LBP is in the excess of $87 billion (Dieleman et al., 2016). It is, therefore, critical to identify more judicious and effective therapies to manage LBP in older adults without compromising their health and quality of life. The recent public debate on prescription opioid abuse and the negative consequences associated with prescription opioids offers enough reasons to investigate the rationale behind the nonadherence to the recommended treatment guidelines for managing LBP in older adults.
This proposed study will be informed by the biopsychosocial model of pain, which posits that pain is the result of the complex interaction with multiple factors. (Fillingim, 2005; Miaskowski et al., 2019) Using passive music listening as an intervention, we seek to modulate pain through mechanisms that will disrupt the interactions within and between the constructs of the model.

In addition, this study will employ innovative yet inexpensive fNIRS technology to validate brain regions that are engaged in the modulation of pain as a result of passive music listening. fNIRS is an optical imaging method that relies on the differences in absorption maxima of oxygenated and deoxygenated hemoglobin to estimate variation in the ratio of oxyhemoglobin to deoxyhemoglobin in the brain at any given time (Hill & Bohil, 2016). This ratio provides a crucial indication of the presence and severity of pain with increased cortical activation patterns indicating pain severity (Boas, Elwell, Ferrari, & Taga, 2014; Peng et al., 2018; Yucel et al., 2015). Further, this study will employ the use of CPM and HRV paradigms to evaluate the state of the endogenous central pain pathway and disruptions in autonomic balance respectively, since these mechanisms play a role in pain processing and modulation. CPM provides an indirect measure of the functional integrity of the descending pain modulation pathway, which is an endogenous pain-reducing network. Higher CPM indicates better pain inhibitory functionality (Ahn et al., 2018). HRV, as a proxy measure of the functional integrity of the central autonomic network, provides relevant information that can be used to evaluate activities of endogenous pain modulation.

**Innovation**

The proposed study is innovative from several key perspectives in that it:
1) Proposes utilizing a remotely monitored smartphone-based music intervention with a daily reminder to participants who do not meet the needed minimum listening level to ensure adherence to the study protocol. Because older adults with LBP have limited mobility that could restrict their access to clinic-based interventions, home-based interventions provide feasible and practical solutions to their pain problems.

2) Will be among the first to use the innovative “U sequence” (Guetin et al., 2012) styles of music to reduce pain in community-dwelling older adults (65+ years) with LBP. Music is safe, non-invasive, easy-to-administer, portable, relatively inexpensive, and readily available. The “U sequence” approach steadily guides participants through three distinct phases of (i) steady reduction of the musical rhythm, frequencies, and volume, (ii) maximum relaxation, and (iii) revitalizing stage into a state of relaxation (Demirtas, Houssais, Tanniou, Misery, & Brenaut, 2020; Guetin et al., 2012).

3) Is the first to combine multiple observer-independent methods such as fNIRS, HRV, and CPM to explore physiological parameters to objectively measure pain in community-dwelling older adults (65+ years) with LBP. The Principal Investigator (PI) has produced a first-authored publication in the fNIRS methodology (Sorkpor, Ahn, Pollonini, & Do, 2019) and co-authored peer-reviewed publications involving CPM (Ahn, Zhong, Miao, et al., 2019) and quantitative sensory testing (Ahn, Zhong, Sorkpor, & Miao, 2019). The use of these innovative observer-independent physiological parameters to assess pain is beneficial to this population because the widely accepted self-reporting pain
assessment methods may not be applicable in older adults who are not able to process and communicate their pain due to cognitive impairment (Breivik et al., 2008).

**Design and Methods**

**Study Design**

This is a single-center, single-arm, remotely monitored, longitudinal study design where participants (older adults age 65 years and above with LBP) will listen to 20 minutes of their preferred style of music two times a daily for four consecutive days in the comfort of their homes as an intervention for pain.

**Participants and Study Setting**

The study will take place at the brain stimulation and imaging laboratory located in the Jane and Robert Cizik School of Nursing at the Cizik School of Nursing at UT Health Science Center at Houston. Participants will be recruited from the community, outpatient clinics of a large teaching hospital in the Houston metro area, and social media. After IRB approval, enrollment into the study will begin on November 1, 2020, and continue through May 31, 2021.

**Inclusion criteria**

Community-dwelling individuals (both male and female) 65 years and older will be considered eligible if they (1) have a self-report of LBP, (2) have LBP in the past 3 months with an average rating of at least 30 on a 0 - 100 NRS for pain, (3) have intact cognition, (4) have no plans to change their pain medication regimens during the study time, (5) can read and understand English, (6) can travel to the study center and, (7) agree to sign an informed consent.
Exclusion criteria

Participants will be excluded if they (1) are deaf or have severe hearing loss, (2) are pregnant or lactating, (3) have an implantable pain-reducing device, (4) have a history of hospitalization within the preceding year for psychiatric illness, (5) have a diagnosis of Raynaud’s disease, (6) have a functional limitation that requires the use of an ambulatory aid such as a cane, walker, or wheelchair; and (7) have a history of brain surgery, brain tumor, or stroke, (8) have severe depression (PROMIS Depression T-score ≥ 70) (Kroenke et al., 2020), (9) have severe anxiety (PROMIS Anxiety ≥ 70) (American Psychiatric Association, 2013), and (10) a Mini-Mental State Examination score less than 24 (Creavin, Wisniewski, Noel-Storr, et al., 2016).

Recruitment and retention strategies

Based on previous home-based studies in older adult populations in Dr. Ahn’s laboratory (Ahn, Zhong, Miao, et al., 2019; Ahn, Zhong, Sorkpor, et al., 2019), Several strategies will be employed to mitigate attrition and increase adherence to the study protocol. These strategies include establishing and maintaining a strong relationship with people in the community, remotely monitoring participants' smartphone-based music app usage on a daily basis with reminders to those not meeting daily listening requirement, reminding participants to fill out the outcome measures, reimbursing participants for the cost of parking, and offering compensation to incentivize participants to remain in the study.

Sample size

To the best of our knowledge, there is no evidence of prior studies using the physiological parameters as we proposed to examine the effect of listening to preferred
music on pain in adults (65+ years) with LBP. Due to this gap in the literature, an accurate calculation of statistical power is impossible. Nevertheless, consistent with other comparable feasibility studies (Ahn, Sorkpor, et al., 2019), a sample size of 20 participants is considered a feasible number to enroll within a reasonable time to meet the purpose of the study. Given a significance level 0.05 without Bonferroni correction and a sample size n=20, the calculated power based on an effect size 0.8 and a paired two-sample t-test is 0.92.

**Informed Consent**

The PI will seek ethical approval from the Committee for the Protection of Human Subjects at the University of Texas Health Science Center at Houston before the beginning of the study. The PI will also be responsible for obtaining written informed consent from all participants before enrolling them in the study.

**Participant Safety**

This study will be performed following the guidelines and principles of the Declaration of Helsinki. Although no serious adverse effect is anticipated, any report of an adverse effect will be documented and handled according to regulations of the Committee for the Protection of Human Subjects at the University of Texas Health Science Center at Houston. All study procedures will be carried out following strict infection control protocol to mitigate the risk of contracting or spreading possible communicable diseases such as COVID-19.

**Compensation**

Each participant will be compensated with a $100 Walmart gift card for their time and travel. The breakdown of this compensation will be $30 for each data collection o
which two visits will be required and $5 per each intervention session of which eight sessions will be required. Participants will also be reimbursed with a parking voucher at a rate of $8 per visit to cover the cost of parking at the Texas Medical Center parking garage. Participants who do not complete the study will receive partial compensation to be determined as a percentage of the study they complete.

**Instruments**

**The Mini-Mental Status Examination (MMSE).** The MMSE is a copyrighted assessment instrument that provides a quick and simple way to assess cognitive function and screen for cognitive loss. (Folstein, Folstein, & McHugh, 1975; Mitchell, 2009) The MMSE is an 11-item assessment that has demonstrated validity and reliability in geriatric populations. The MMSE is a paper and pencil test that takes about 15 minutes to complete with scores ranging from 1 to 30. The conventional cut-off score is 24 with a score lower than 24 indicating cognitive impairment (Creavin, Wisniewski, Noel-Storr, et al., 2016; Mitchell, 2009). (see Appendix A)

**Sociodemographic information.** Sociodemographic information will be collected using a paper-and-pencil form specifically created for this study. The questionnaire will capture information on age, gender, race, marital status, level of education, and employment status. (see Appendix B).

**The Numeric Rating Scale (NRS).** The NRS is designed to measure pain intensity in adults (Childs, Piva, & Fritz, 2005). The 101-point iteration of the NRS will be used similar to Anh et al. study(Ahn et al., 2020; Ahn et al., 2017; Ahn, Zhong, Miao, et al., 2019). The NRS has demonstrated evidence of reliability and validity in adult populations. The reliability of NRS in chronic pain patients is estimated at $r = .95$ with a
good correlation with the visual analog scale estimated at $r = 0.71$ to $r = 0.78$ (Ferraz et al., 1990). The NRS is scored by asking the respondent to select a number on the continuum from 0 = “no pain” to 101 = “worst imaginable pain ever.” (see Appendix C)

**PROMIS Short Form v1.0 - Emotional Distress - Anxiety Short Form 8a.** This is a paper and pencil-based scales that are scored on a 5-point scale (1 = never to 5 = always). It consists of 8-items that measure “fear, anxious misery, hyperarousal, and somatic symptoms related to arousal” (Cella et al., 2010). Participants respond by indicating the number of times they have experienced emotions such as fearfulness, overwhelmedness, nervousness, and anxiousness over the last seven days. This scale has demonstrated acceptable evidence of reliability and validity and has been used in multiple chronic pain studies (Ahn, Sorkpor, et al., 2019; Low, Lacson, Zhang, Kesslick, & Bradt, 2020). (see Appendix D)

**PROMIS Short Form v1.0 - Emotional Distress - Depression 8b.** This is a paper and pencil-based scales that are scored on a 5-point scale (1 = never to 5 = always). It consists of 8-items that measure “negative mood, decrease in positive affect, information processing deficits, negative views of the self, and negative social cognition”(Cella et al., 2010). Participants respond by indicating the number of times they have experienced negative affects such as worthlessness, unhappiness, and hopelessness over the past seven days. This scale has demonstrated acceptable evidence of reliability and validity and has been used in multiple chronic pain studies (Ahn, Sorkpor, et al., 2019; Low et al., 2020). (see Appendix E)

**Functional Near-Infrared Spectroscopy (fNIRS).** fNIRS is a noninvasive, portable, and inexpensive optical imaging method that directs low power light in the
near-infrared spectrum (700–1000 nm wavelength) through the scalp to examine blood oxygenation level-dependent response of brain tissue. PI has produced peer-reviewed a publication about fNIRS methodology (Sorkpor et al., 2019). Because oxyhemoglobin and deoxyhemoglobin have different absorption maxima, variation in the ratio of oxyhemoglobin to deoxyhemoglobin in the brain can be calculated (Hill & Bohil, 2016) therefore, offering suitable solutions to the study of pain (Boas et al., 2014; Peng et al., 2018; Yucel et al., 2015). A reduction in hemodynamic response will indicate a decrease in pain (Watanabe et al., 2011; Yucel et al., 2015). A continuous-wave, multichannel NIRS imaging system (LIGHTNIRS, Shimadzu, Kyoto, Japan) comprising of an array of eight sources and eight detectors will be used in this study with optodes arranged bilaterally over the motor and somatosensory cortical areas of the scalp. This optode arrangement is chosen to be consistent with a previous publication written by Sorkpor et al. (2019).

**Heart Rate Variability (HRV).** HRV represents the variations in a heartbeat on a time interval. These variations in heart rate result from complex, nonlinear interactions among several different physiological systems (McCraty & Shaffer, 2015). HRV, therefore, provides an indirect measure of heart-brain interactions and dynamic non-linear autonomic nervous system processes (Adler-Neal et al., 2019; McCraty & Shaffer, 2015; Shaffer, McCraty, & Zerr, 2014). An increased HRV indicates proper functioning of the central autonomic network which is critical for the activation of pain inhibition pathways in the central nervous system. (Thayer, Hansen, Saus-Rose, & Johnsen, 2009). HRV will be obtained per recommendations from the European Society of Cardiology and North American Society of Pacing and Electrophysiology Task Force using lead II

**Conditioned Pain Modulation (CPM).** CPM is an indirect method of measuring pain processing that is presumed to indicate the function of the descending pain modulation pathway. CPM is assessed as a change in pain perceived in one body region (test stimulation) as a result of pain-induced in another body region (conditioned stimulation). The CPM paradigm has reported evidence of good intrasession reliability with intra-class coefficients of 0.75 (Lewis, Heales, Rice, Rome, & McNair, 2012). This study will evaluate the pressure pain threshold before and after the conditioned stimulation. CPM will be determined as a change in pressure pain threshold on the lower back, 5 cm to the left of the median line on the intercristal line (the Jacoby line) using a handheld digital pressure algometer (Wagner, Greenwich, CT, USA) while the participant lays in the prone position on a massage bench.

**Treatment Acceptability and Preference (TAP) scale.** The TAP scale is a self-report Likert-style scale that measures perceived acceptability of an intervention in terms of four characteristics of (1) appropriateness, (2) effectiveness (3) suitability as a treatment, and (4) willingness to adhere, on a scale ranging from “0 (not at all) to 4 (very much)”. The total TAP scale score is obtained by taking the mean score of each of the items. The TAP scale has demonstrated internal consistency reliability (Cronbach alpha > .80) and factorial validity in prior research. (Sidani et al., 2009). An additional section will be added to the TAP to evaluate the following variables on a similar scale; pleasantness, intent to continue use, perceived negative effects, and success or failure of execution with one open-ended question to collect information on possible side effects.
Music Intervention

A recent systematic review to determine the pain-reducing effects of listening to music concluded that music was effective in reducing chronic pain. The authors reported the mean duration of the 14 included studies to be 30 minutes ± 10.05 (Garza-Villarreal et al., 2017). Further, Poulsen and Coto (2018) recommends that for therapeutic music to be effective in reducing pain, it should be played at least twice a day for 15-30 minutes at a time. Based on this and other prior research, the frequency and duration of the music intervention will be twice a day for 20 minutes per session for four consecutive days (Demirtas et al., 2020; Guetin et al., 2012). The study will employ an individual receptive relaxation music method with participants selecting music based on their preference from a selection of various styles from the MUSIC CARE© app. MUSIC CARE© offers individualized music intervention sessions using a standardized protocol that conforms with international scientific guidelines (Guetin et al., 2012). The music intervention will last 20 minutes per session and will be administered twice daily for 4 consecutive days. This duration was chosen based on prior research (Demirtas et al., 2020; Guetin et al., 2012). Participants will be given an electronic tablet with the MUSIC CARE© app loaded on it and trained on how to access the app to select their preferred style of music. Participants will be instructed to use the provided headphone during all interventions and to sit in a quiet area while wearing an ocular mask to avoid distractions. The sequence of the music will be broken down into several phases following the innovative “U sequence” method (Guetin et al., 2012). The music sequence construction will be explicitly constructed for this study by the Music Care (Paris, France) company. The PI will remotely monitor participants' smartphone-based music app usage on a daily basis to
ensure that they are following the study protocol. Participants who do not complete the
specified amount of music listening sessions (20 minutes twice daily) will receive a
phone call reminding them to do so.

**Data Procedure**

Participants will be recruited from approved pain clinics within the Memorial
Hermann hospital system and from within the community. The PI will contact approved
outpatient clinics, community organizations such as churches and mosques to present the
proposed study to potential participants. Also approved recruitment flyers with a
summary of the study, criteria for participation and contact information of the PI (Setor K
Sorkpor) will be posted in the community. Potential participants contacting the PI will be
screened in person or over the phone for eligibility. Those meeting the inclusion criteria
will be scheduled to meet with the PI at the study center at a date and time agreeable to
both the eligible participant and the PI.

During the visit to the study center, the PI will review the informed consent form
with each eligible participant. The eligible participants will be given time to read and
encouraged to ask questions. The PI will answer questions and provide clarification to the
participants as needed. After demonstrating an understanding of the purpose of the study,
eligible participants will be asked to sign the written consent form if they elect to
continue with the study.

**Experimental Design**

After consenting into the study, the PI will hand each participant the MMSE and
the basic health and sociodemographic form to complete. This will be followed by asking
participants to rate their mean clinical pain intensity on the NRS scale. Mean clinical pain
intensity is defined as the average pain intensity that was experienced in the past 7 days. Participants will then complete the PROMIS short-form questionnaires for both anxiety and depression. Next, the baseline physiological assessment (fNIRS, HRV, CPM) will be obtained. Table 1 shows all interventions and time points where each measure will be administered.

To obtain physiological data, participants will be assisted to sit comfortably in a recliner and assisted to place and secure the fNIRS cap on their head. The fNIRS optodes will be placed bilaterally over the motor and somatosensory cortical regions of the scalp after carefully parting the participant's hair to obtain direct contact with the scalp. Figure 1 shows the fNIRS optode placement arrangement. The ECG sensors will be placed on the chest using a lead II 3-electrode arrangement. Figure 2 shows the ECG lead placement arrangements. Next, the participant will be assisted to lie down on the massage table in the prone proposition. Participants will be draped to maintain modesty. The anatomical location where the pressure stimuli will be applied will be marked using a tape measure and a skin marker. Table 2 depicts previously published neuroimaging studies and the various types of stimuli used to elicit a brain-related pain response in chronic pain patients. Pressure pain will be used in this study. The pretest pressure pain threshold will be determined following a quantitative sensory testing paradigm using a handheld digital pressure algometer (Wagner, Greenwich, CT, USA). The baseline physiological measures will be collected with HRV collected simultaneously with the fNIRS recordings followed by CPM. Following the completion of the experiment, the participants will be assisted to sit in the recliner to complete the TAP Scale to assess their
acceptability of the procedure. The physiological data collection procedure will be repeated post-intervention.

**Data protection**

All paper-based data including written consent forms will be kept confidential in a secure locked file cabinet located in a locked laboratory on campus. Digital records including electronic files and digital recordings will be stored in a password-protected file on a secure server approved for storing research data per the research governance policy of the University of Texas Health Science Center at Houston. Access to all research data will be restricted only to the PI and immediate supervising dissertation committee members on a need to know basis.

**Data Analysis**

Descriptive statistics for demographic data will be computed using SAS v9.4 (SAS Institute Inc., Cary, NC). The normality assumption will be assessed by the Shapiro-Wilk test and visual inspection of the Q-Q plot. Outliers will be identified using the Median Absolute Distance and handled for conclusion robustness. The daily pain scores (NRS) will be assessed for linear trends using simple linear regression. (Barnes & Barnes, 2015) Feasibility and acceptability outcomes will be described using summary statistics, including mean with standard deviation, median with interquartile range, frequency, percentages, as well as the corresponding 95% confidence intervals when appropriate. Also, a one-sample proportion test will be performed to verify whether these rates are significantly different from zero. For exploratory data analysis, we expect that LBP (NRS) will show lower pain scores post-intervention compared to baseline. We will
derive summary statistics of the baseline and final measures of NRS and compare the means to understand the changes in NRS before and after music intervention. While we recognize that the small sample size may prevent us from achieving any statistical significance, we will conduct a repeated-measures ANOVA (Maurissen & Vidmar, 2017; Zhao, Wang, Totton, Cullen, & O'Connor, 2019) to examine the effect of listening to preferred music on pain over time. If the assumptions of repeated-measures ANOVA is violated, the Friedman test will be used. Absolute effect sizes between the baseline and finals measures will be evaluated to establish the level of difference between the baseline measures and the final measure.

Also, we expect that cortical hemodynamic response to pain will be reduced post-intervention. The NIRS Brain AnalyzIR Toolbox (Santosa, Zhai, Fishburn, & Huppert, 2018) will be used to analyze the acquired data. The raw NIRS data will be imported into the NIRS Brain AnalyzIR Toolbox (Santosa et al., 2018) software, which is an open-source Matlab-based analysis package for fNIRS data management, pre-processing, and first- and second-level analysis (Santosa et al., 2018). The data will be pre-processed (resampling, conversion to optical density, and the application of the modified Beer-Lambert law). The preprocessed data will then be analyzed by comparing the summary statistics of the baseline fNIRS measures with those of the final fNIRS measure. Next image reconstructions of the brain will be generated for both measures. In addition, we expect that HRV will be increased post-intervention. AcqKnowledge version 5.0 signal analysis software (Biopac Systems, Inc, Goleta, USA) will be used to evaluate the ECG data. The ECG data will be cleaned to remove artifacts, such as irregular heartbeat activity to eliminate interference with the software’s ability to identify distances and
times between consecutive R-waves from the ECG data. Tachograms will be created for visual inspection and where applicable a data correction factor will be applied. The time-domain HRV parameter such as the standard deviation in R-R length (SDNN) and root mean squared of successive differences (RMSSD) will be computed. Similarly, frequency-domain HRV parameter including low frequency, high frequency, and their ratios will be computed. We will compare the baseline HRV measures with the post-intervention measure.

Moreover, we expect that conditioned pain modulation will be increased after participants listen to preferred music. We will compare the summary statistics of the baseline CPM measures and the final CPM measures, and absolute effect sizes between the two measures will be evaluated to establish the level of difference.

Discussion

This study is a protocol for a single-center, single-arm, cross-sectional study to examine the feasibility, acceptability, and preliminary efficacy of listening to preferred music on experimental pain in older adults age 65 years and above with LBP. This study is important in the sense that it explores the effects of readily available therapy for managing pain. It builds on prior research aimed at identifying effective nonpharmacologic interventions to reduce pain in LBP. Also, the analgesic properties of music have been demonstrated to be effective in reducing pain in different conditions (Garza-Villarreal et al., 2017; Kavakli et al., 2019) therefore this study will establish its feasibility and acceptability for LBP. Furthermore, passive listening to music has been recommended in a recent systematic review as viable adjuvant therapy in reducing pain
in chronic pain patients. However, prior studies have been criticized for having methodological challenges ranging from a small sample size, inconsistency with outcome evaluation, lack of clarity on the type of music evaluated, and substandard control conditions (Garza-Villarreal et al., 2017). The current study, therefore, takes some of these shortcomings into consideration by employing an objective and innovative means of measuring pain using fNIRS, HRV, and CPM. Further, since central mechanisms rather than peripheral factors are involved in the amplification of neural signals within the central nervous system to elicits pain hypersensitivity (Nijs et al., 2015; Nijs et al., 2011), we hypothesized that music selected by participants may be more pleasing and therefore, better positioned to target the neurophysiological mechanisms associated with LBP.

**Potential Pitfalls and Alternate Strategies**

NIRS has its shortfalls, in that, this technique is sometimes exposed to noise when contact with the scalp is not well established. Because of this, participants with coarse hair types may not be ideal candidates since the probes must have direct contact with the scalp to capture accurate data. There are tested ways to part the hair to make way for the probes to contact the scalp, however, this can be time-consuming leading to participant fatigue with a possible effect on study outcome. Nonetheless, because this is a dissertation study, this potential problem may be controlled by excluding participants with hair types that may impede the capturing of noise-free data. This may need to be considered as a screening condition when talking to potential participants over the phone. Secondly, due to the limited number of parking spots available at the Texas Medical Center, participants will have to park in toll parking garages and walk to the study center. The cost of parking and
walking distance from the available parking garage to the study center could discourage some potential participants from enrolling in the study. However, we hope to assuage this reluctance by incentivizing would-be participants with an offer to pay for their parking. Further, older adults are more likely to have limited means of transportation (Choi, Adams, & Kahana, 2012) therefore, excluding qualified candidates with limited means of transportation. We anticipate this will create a recruitment challenge and therefore propose to recruit over 3 months period. Further, due to the COVID-19 pandemic, this data collection in this study has been delayed with no known date to begin data collection.

**Summary**

Findings from this study will establish initial efficacy, feasibility, and acceptability of using preferred style of music to manage pain in older adults with LBP. This study will also provide valuable information to inform sample size calculations in future large studies. Findings from this study will also add to the growing body of literature evaluating the effectiveness of nonpharmacologic pain-reducing therapies for reducing pain in the older adult populations.
References


experimenter- and participant-blinded, randomized, sham-controlled pilot clinical study. *Brain Stimul, 10*(5), 902-909. doi:10.1016/j.brs.2017.05.007


*Prog Brain Res, 122, 245.*


Institute of Medicine Committee on Advancing Pain Research, C., & Education. (2011). The National Academies Collection: Reports funded by National Institutes of Health. In Relieving Pain in America: A Blueprint for Transforming Prevention,

doi:10.1097/BRS.00000000000001930

doi:10.1016/j.ctim.2019.04.005


in women: a pilot study. *BMJ open, 9*(6), e026152-e026152.

doi:10.1136/bmjopen-2018-026152


Table 1

*Table showing the time points where each measure will be administered.*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Music Intervention #</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>MMSE</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographic</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PROMIS Anxiety</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROMIS Depression</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>fNIRS</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HRV</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPM</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAP Scale</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2  
Table showing the different kinds of stimuli used to evoke brain-related pain response in neuroimaging studies in chronic pain patients.

| Author (year) | Purpose of the study | Sample size (n=?) | Functional stimuli and number of blocks | Brain region of interest (ROI) | Brain imaging method | Brain response 
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Author (year)</td>
<td>Purpose of the study</td>
<td>Functional stimuli</td>
<td>Sample size &amp; characteristics</td>
<td>Brain Region of Interest (ROI)</td>
<td>Brain imaging method</td>
<td>Sample size &amp; characteristics</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------</td>
<td>-------------------</td>
<td>-----------------------------</td>
<td>-------------------------------</td>
<td>---------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Roy et al. (2018)</td>
<td>To assess brain activity during a visually guided grip force task and a pain-eliciting thermal stimulus on the forearm in chronic low back pain patients</td>
<td>Thermal Stimuli to the right volar forearm [30 seconds, 5 blocks]</td>
<td>Chronic low back pain</td>
<td>Whole-brain fMRI</td>
<td>Roy et al. (2018)</td>
<td>Increased activity in chronic low back pain controls compared to healthy controls.</td>
</tr>
<tr>
<td>Sofat et al. (2013)</td>
<td>To assess if central sensitization mediates pain perception in osteoarthritis of the hand</td>
<td>Finger flexion-extension of the right hand [30 seconds, 3 blocks]</td>
<td>Right-handed hand osteoarthritis patients (n = 13) and right-handed controls (n = 13)</td>
<td>Whole-brain fMRI</td>
<td>Sofat et al. (2013)</td>
<td>Hand osteoarthritis patients exhibited increased activation in the thalamus, cingulate, frontal and somatosensory cortex. These regions implicated in central sensitization.</td>
</tr>
<tr>
<td>Diers et al. (2007)</td>
<td>To compare the perceptual sensitization and brain activation patterns in response to intramuscular and intracutaneous painful stimulation in chronic low back pain patients and healthy controls</td>
<td>An electrical stimulus to specific sites on the left lower arm, the third lumbar vertebra in the left lower back. Stimuli delivered both intramuscular and intracutaneous [Eight hundred painful electrical pulses in one block per site]</td>
<td>Chronic low back pain</td>
<td>Whole-brain EEG</td>
<td>Diers et al. (2007)</td>
<td>Increased perceptual sensitization and increased processing of the sensory-discriminative aspect (N80 component) of pain in chronic low back pain patients compared to controls.</td>
</tr>
</tbody>
</table>

**Abbreviations:** fMRI – Functional Magnetic Resonance Imaging; fNIRS – Functional Near-Infrared Spectroscopy

Table 2 cont.
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Purpose of the Study</th>
<th>Sample characteristics</th>
<th>Sample size &amp; characteristics</th>
<th>Brain imaging method</th>
<th>Brain region of interest (ROI)</th>
<th>Functional stimuli</th>
<th>Brain imaging results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seretny et al. (2019)</td>
<td>To inform the feasibility and design of a future RCT using brain fMRI to determine the mechanism of action of gabapentin in managing chronic pelvic pain in women. fMRI data is to inform future sample size calculation</td>
<td>Chronic pelvic pain patients (N = 12)</td>
<td>Intervention (n= 6)</td>
<td>Whole-brain fMRI</td>
<td>A thermal stimulus at the individual threshold to arm and abdomen [15 seconds, 24 blocks]</td>
<td>To evaluate the activity of the nucleus accumbens in response to the individual threshold to the arm and abdomen.</td>
<td>A minimum of 7 women per group are required to achieve 80% power and ( p = 0.05 ) ( \alpha ) in future fMRI studies with 1:1 sampling ratio with two independent samples and two-sided testing.</td>
</tr>
<tr>
<td>Matsuo et al. (2017)</td>
<td>To examine the details of such inhibitory mechanisms possibly modified in chronic low back pain patients.</td>
<td>Chronic low back pain patients (n=11) and healthy controls (n = 13)</td>
<td>Pressure stimulus at 500 kPa to lumber region [30 seconds, 3 blocks]</td>
<td>Whole-brain fMRI</td>
<td>Chronic low back pain</td>
<td>To examine the details of the changes in the size of the low back pain patients.</td>
<td>The chronic back pain group showed reduced reactivity to pain in known cortical areas mediating affective component, and top-down modulation.</td>
</tr>
<tr>
<td>Kanieko et al. (2017)</td>
<td>To evaluate the activity of the nucleus accumbens in response to lumbar mechanical stimulation in patients with chronic low back pain</td>
<td>Chronic low back pain patients (N = 21). Divided into two groups based on baseline BS-POP scores</td>
<td>Pressure stimulus at the individual threshold to lumbar region [30 seconds, 24 blocks]</td>
<td>Whole-brain fMRI</td>
<td>Chronic low back pain</td>
<td>To inform the sample size calculation</td>
<td>Participants in the high baseline score group had more intense daily pain and lower quality of life than those in the other group.</td>
</tr>
</tbody>
</table>

Abbreviations: fMRI – Functional Magnetic Resonance Imaging; BS-POP – Brief Scale for Psychiatric problems in Orthopedic Patients.
### Table 2 cont.

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Purpose of the Study</th>
<th>Functional stimuli used to evoke brain-related pain response in neuroimaging studies in chronic pain</th>
<th>Sample size and number</th>
<th>Brain Imaging method</th>
<th>Brain Imaging ROI</th>
<th>Brain region of interest (ROI)</th>
<th>Sample size &amp; characteristics</th>
<th>Brain imaging results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kobayashi et al. (2009)</td>
<td>To clarify cerebral activation specific to chronic low back pain</td>
<td>Pressure stimulus at the individual threshold to lumber region [30 seconds, 3 blocks]</td>
<td>Chronic low back pain patients (n = 8) and healthy controls (n = 6)</td>
<td>fMRI</td>
<td>Whole-brain fMRI</td>
<td>Pressure stimuli to the right insula, supplementary motor, and cerebellum.</td>
<td>Chronic low back pain</td>
<td>LBP patients showed augmented activation compared with healthy volunteers specifically at the right insula, supplementary motor, and posterior cingulate cortex.</td>
</tr>
<tr>
<td>Kodama et al. (2019)</td>
<td>To assess the effects of myofascial trigger points compression on brain hemodynamics and EEG oscillation in subjects with chronic low back pain</td>
<td>Pressure stimulus to the lumbar quadratus muscle at the myofascial trigger points [30 seconds, 5 blocks]</td>
<td>Chronic low back pain patients (N = 32). Divided into two equal groups. Compression at myofascial trigger points (n=16) and no compression (n=16)</td>
<td>fNIRS</td>
<td>Cerebral fNIRS</td>
<td>Pressure stimuli to the lumbar quadratus muscle</td>
<td>Chronic low back pain</td>
<td>Compression in the quadratus lumborum muscle improved hyperalgesia, LBP, and decreased hemodynamic activity in the prefrontal cortex in the myofascial trigger points group.</td>
</tr>
</tbody>
</table>

**Abbreviations:** fMRI – Functional Magnetic Resonance Imaging; fNIRS - Functional Near-Infrared Spectroscopy
Figure 1

fNIRS probe placement arrangement
Figure 2

Electrocardiography lead placement. lower left rib (positive electrode), right clavicle (negative electrode), and right lower rib (ground electrode)
Appendix A

MMSE Sample Items
MMSE Sample Items

Orientation to Time
“What is the date?”

Naming
“What is this?” [Point to a pencil or pen.]

Reading
“Please read this and do what it says.” [Show examinee the words on the stimulus form.]
CLOSE YOUR EYES
Appendix B

Basic Health and Sociodemographic Form
Basic Health and Sociodemographic Form

ID #: ___________________________  DATE: ________________

1. Age: ___________
2. Height (inches): _____________
3. Weight (lbs): _________________
4. Medications: _________________________________________________
5. Gender?
   a. Male   b. Female
6. What is your race or origin? (Choose one or more number(s) from the list below):
   a. Asian
   b. Black African American
   c. White
   d. Hispanic or Latino
7. What is your occupation? ______________________________
8. What is your highest level of educational achievement? (choose one): ____
   a. Some school but did not complete high school
   b. High school degree.
   c. Two-year college degree.
   d. Four-year college degree.
   e. master’s degree.
   f. Doctoral degree.
9. What is your current annual household income? (circle one)
   a $0 - 9,999 f $50,000 - 59,999
   b $10,000 - 19,999 g $60,000 - 79,999
   c $20,000 - 29,999 h $80,000 - 99,999
   d $30,000 - 39,999 i $100,000 - 149,999
   e $40,000 - 49,999 j $150,000 or higher
10. What is your marital status? (select one item from the list below)
    a. Married
    b. Widowed
    c. Divorced
    d. Separated
    e. Never Married
    f. Living with Partner
    g. Refused
    h. Don’t Know
11. List any health condition you been diagnosed now or in the past
    ___________________________________________________________
    ___________________________________________________________
    ___________________________________________________________
12. List of current medications
    ___________________________________________________________
Appendix C

Numeric Rating Scale
Numeric Rating Scale

0 - 100 Numeric Pain Rating Scale

No pain

Moderate pain

Worst possible pain
Appendix D

PROMIS Emotional Distress – Anxiety – Short Form 8a
### PROMIS Emotional Distress – Anxiety – Short Form 8a

Please respond to each question or statement by marking one box per row.

<table>
<thead>
<tr>
<th>In the past 7 days…</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>I felt fearful</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I found it hard to focus on anything other than my anxiety</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>My worries overwhelmed me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt uneasy</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt nervous</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt like I needed help for my anxiety</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt anxious</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt tense</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Appendix E

Emotional Distress – Depression – Short Form 8a
Emotional Distress – Depression – Short Form 8a

Please respond to each question or statement by marking one box per row.

<table>
<thead>
<tr>
<th>Item</th>
<th>Question</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I felt worthless</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>I felt helpless</td>
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<tr>
<td>3</td>
<td>I felt depressed</td>
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<tr>
<td>4</td>
<td>I felt hopeless</td>
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<tr>
<td>5</td>
<td>I felt like a failure</td>
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<tr>
<td>6</td>
<td>I felt unhappy</td>
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<tr>
<td>7</td>
<td>I felt that I had nothing to look forward to</td>
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<tr>
<td>8</td>
<td>I felt that nothing could cheer me up</td>
<td></td>
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</tbody>
</table>
LISTENING TO REMOTELY MONITORED HOME-BASED PREFERRED MUSIC
FOR PAIN IN OLDER ADULTS WITH LOW BACK PAIN: A PILOT STUDY OF
FEASIBILITY AND ACCEPTABILITY

A DISSERTATION MANUSCRIPT

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
CIZIK SCHOOL OF NURSING

BY

SETOR KOFI SORKPOR, PhD(c), MPH, MSN, RN-BC

JUNE, 2022
Abstract

Background

Low back pain (LBP) is a complex, multifaceted, and widespread condition that impairs the quality of life of older adults aged 65 years or older. Although nonpharmacologic interventions informed by the biopsychosocial model are recommended as first-line therapy for LBP, pharmacologic therapies, including opioids, are commonly used as first-line interventions in practice. This could be attributed to a lack of understanding of the analgesic properties of most nonpharmacologic interventions. Nonetheless, some nonpharmacologic therapies, such as passive music listening, have been shown to modulate pain via pathways that target the neurophysiological mechanisms associated with pain.

Specific Aims

The specific aims were to determine: (1) the feasibility and acceptability of listening to one’s preferred music to relieve pain in older adults with LBP, aged 65 years or older, and (2) if music reduces pain and affects pain-related physiological markers such as cerebral hemodynamic response to experimental pain, as measured by function near-infrared spectroscopy (fNIRS), heart rate variability (HRV), and conditioned pain modulation (CPM).

Methods

This was a single-center, single-arm, open-label study. Twenty community-dwelling older adults (≥ 65 years) with LBP were recruited to use noise-isolating headphones to listen to their preferred style of music for 20 minutes twice daily for four
days using the MUSIC CARE® app. Feasibility was measured by tracking enrollment, adherence, attrition rates, and acceptability (measured by the treatment acceptability and preference scale). Average daily clinical LBP scores as well as other pain-specific physiological markers; fNIRS, HRV, and CPM were collected at baseline and post-intervention. Repeated-measures ANOVA, a general linear model based on autoregressive iteratively reweighted least squares (AR-IWLS), and custom Python codes were used to evaluate clinical pain, fNIRS, and HRV data respectively. The Wilcoxon signed-rank test was run on the CPM data as it violated the test of normality.

Results

Feasibility measures of enrollment, adherence, and attrition rates were 95.25%, 100.00%, and 0.00%, respectively. When compared to baseline measurements, acceptance rates were higher after the intervention. Pain scores on the numeric rating scale (NRS) for pain decreased marginally but non-significantly from baseline to post-intervention. The physiological measures (fNIRS, HRV, and CPM) revealed that treatment has the potential to reduce pain.

Conclusion

These findings suggest that listening to preferred music for 20 minutes twice a day for four days is a feasible and acceptable intervention for reducing pain in older adults with LBP, aged 65 years or older. Also, listening to preferred music at home resulted in marginal but nonsignificant reductions in clinical pain sensitivity (NRS). Furthermore, the effects of listening to preferred music on pain were evident in the selected pain-related physiological markers, implying that these markers may be
investigated as pain assessors in future studies. Future large randomized and ethnically
diverse studies should investigate the underlying mechanism of music-induced analgesia.

**Keywords:** music listening, conditioned pain modulation, functional near-infrared
spectroscopy.
Introduction

The world’s aging population has grown significantly due to the recent demographic shift (Roberts et al., 2018). Consequently, the number of chronic illnesses experienced by older adults has increased correspondingly. Among these chronic illnesses is low back pain (LBP), which is defined as pain that manifests between the lower rib margins and the buttck creases (Hartvigsen et al., 2018). LBP is regarded as one of the most common causes of functional limitation, disability, and a decline in quality of life in elderly individuals (Hoy et al., 2014; Vos et al., 2017) and is thus a significant contributor to the number of years lived with disability (Abate et al., 2018). Moreover, LBP is one of the most prevalent reasons for doctor visits in the United States (Qaseem et al., 2017), costing over 90 billion dollars per year, with adults 65 years or older accounting for one-third of this total expenditure (Dieleman et al., 2016).

LBP can be caused by various factors, but the most common type is non-specific LBP, which has no discernible pathology (Saragiotto et al., 2016). Because of its unknown etiology, non-specific LBP presents a major problem for diagnosis and treatment (Allegri et al., 2016; Amirdelfan, McRoberts, & Deer, 2014; Wong, Karppinen, & Samartzis, 2017). However, the current clinical guidelines for the treatment of LBP recommend individually tailored nonpharmacological interventions such as exercise, education, and psychological interventions informed by the biopsychosocial paradigm as first-line therapy (Foster et al., 2018; Qaseem et al., 2017). Although these guidelines also support the use of pharmacotherapeutics, they should be used sparingly and as a last resort in situations where nonpharmacologic options have been tried and proven to be ineffective (Qaseem et al., 2017). Notwithstanding the evidence, the use of pharmacologic therapies
such as opioids as a first-line intervention for LBP is widespread in practice (Foster et al., 2018; Mesner et al., 2016), most likely due to a lack of understanding of the mechanisms by which these nonpharmacologic interventions modulate pain.

Some nonpharmacologic therapies have been shown to have mechanisms of action that are well adapted to targeting the neurophysiological mechanisms associated with LBP (Nijs et al., 2011, 2015). One such promising nonpharmacological pain-relieving therapy is passive music listening. Music is a safe, non-invasive, easy-to-administer, and relatively inexpensive intervention that has been used to relieve pain in a variety of pain disorders (Garza-Villarreal et al., 2017; Hsu et al., 2016; Hsu et al., 2019; Kavakli et al., 2019; Ko et al., 2019). Music is hypothesized to modulate pain by causing the release of endogenous opioids such as β-endorphins (Almerud & Petersson, 2003), which stimulate the descending pain regulation pathways in the brain stem and spinal cord, suppressing nociceptive stimuli (Fields, 2000; Tracey & Mantyh, 2007).

Furthermore, current research indicates that passive music listening can significantly reduce pain in older adults (Garza-Villarreal et al., 2017). For example, in a recent study of 49 older adults, the researchers noted that listening to one 25-minute session of music (Chinese and Taiwanese pop music, classical music, and nature sounds) for two days reduced pain in total knee replacement patients with an average age of 73.9 ± 7.5 years (Hsu, Chen, Chen, Tseng, & Lin, 2016).

Previous research has shown that the most beneficial music genre for relieving pain is one that is calming with a tempo between 60-80 beats per minute (Kuhlmann et al., 2018; Poulsen & Coto, 2018). Earlier studies also indicate that a person’s musical preferences in terms of genre, pitch, rhythm, style, and dynamics are influenced by their
cultural background, social interactions, and personal experiences (Petot et al., 2019). As a result, it is hypothesized that listening to one’s preferred music may be better suited to eliciting pleasurable sensory experiences and thus influencing pain modulation (Costa et al., 2018; Mitchell & MacDonald, 2006; Tan et al., 2012). Notwithstanding this hypothesis, only a few studies have been conducted to investigate the pain-relieving effects of listening to one’s preferred music. However, there is a high level of methodological heterogeneity among these few studies, making it difficult to compare their findings. The authors of a recent systematic review and meta-analysis on the effects of music on pain in adults undergoing colonoscopy identified multiple forms of variation as possible contributory factors to methodological heterogeneity, including lack of consistency in the instruments used to examine the primary outcome variables, type of music intervention, and duration of music intervention, among others (Sorkpor et al., 2021). These methodological inconsistencies make it difficult to conduct a meaningful meta-analysis of the existing literature, which is required to strengthen the case for music listening interventions for pain management. More research utilizing rigorous methodologies is needed to better understand the mechanism of action of music-induced analgesia. As such, the current study was designed to fill these gaps by utilizing standardized instruments to evaluate the primary outcome variable of pain.

The goal of this study was to examine the feasibility and acceptability of 20 minutes of listening to a preferred style of music twice-daily for four consecutive days to treat pain in 20 community-dwelling older adults with LBP. The study further investigated secondary aims to determine whether listening to home-based self-selected preferred music causes changes in pain-related physiological markers, including cortical
hemodynamic changes to experimental pain measured by fNIRS, heart rate variability (HRV), and conditioned pain modulation (CPM) in older adults with LBP. The central hypothesis was that in older adults with LBP, listening to their preferred music could reduce clinical pain and alter pain-related physiological responses through mechanisms believed to reverse the dysregulation in the natural pain modulation pathway.

Methods

This study was conducted in line with the Declaration of Helsinki guidelines. The study protocol was approved by the Institutional Review Board of The University of Texas Health Science Center at Houston and was registered at www.clinicaltrials.gov (NCT04644757) before initiation. All participants signed a written informed consent form before participating in the study, which was conducted from May 2021 to July 2021. All on-site study procedures were performed in Dr. Ahn’s lab at The University of Texas Health Science Center at Houston’s Cizik School of Nursing in Houston, Texas.

Participants

Participants were recruited from the Greater Houston metropolitan area via advertisement flyers distributed within the community. Community-dwelling older adults (both male and female), 65 years or older, were considered eligible if they (a) had self-reported LBP, (b) have had LBP in the past three months with an average rating of at least 30 on a 0 - 100 Numeric Rating Scale (NRS) for pain, where 0 equals no pain, and 100 equals worst pain imaginable, (c) have had intact cognition, (d) have no plans to change their pain medication regimens during the study time, (e) can read and understand English, (f) can travel to the study center, and (g) agree to sign an informed consent. Potential participants were excluded for the following: (a) deaf or have severe hearing
loss, (b) pregnant or lactating, (c) have an implantable pain-reducing device, (d) have a history of hospitalization within the preceding year for psychiatric illness, (e) have a diagnosis of Raynaud’s disease, (f) have a functional limitation that requires the use of an ambulatory aid such as a cane, walker, or wheelchair, (g) have a history of brain surgery, brain tumor, or stroke, (h) have severe depression (PROMIS Depression score $\geq 70$; Kroenke et al., 2020), (i) have severe anxiety (PROMIS Anxiety $\geq 70$; American Psychiatric Association, 2013), and (j) have a Mini-Mental State Examination score less than 24 (Creavin et al., 2016).

**Study Design**

The study was designed as a single-center, single-arm, open-label, longitudinal study that involved four consecutive days of twice-daily self-directed music listening at home with daily remote monitoring of the number of sessions. Each session lasted for 20 minutes, with a total of eight sessions.

**Home-Based Music Intervention**

The intervention consisted of a receptive music technique where participants actively listened to the music 20 minutes twice a day for four consecutive days (a total of 8 sessions). During the baseline visit, the MUSIC CARE® app (MUSIC CARE® Paris, France) was downloaded onto the participant’s smartphone or tablet, followed by a 20-minute training by the principal investigator (PI) on how to access and use the MUSIC CARE® app and the provided pain log (NRS). Following training, the participants demonstrated their understanding by performing their first music listening practice session and recording their pain level on the given pain log in the presence of the PI. The
PI then provided additional coaching to the participants, as needed, to successfully and independently perform the intervention at home. Participants were given brand new over-ear noise-isolating headphones (OneOdio® Studio HIFI Wired Headphones; OneOdio, Wan Chi, Hong Kong) and an ocular mask to cover their eyes during the intervention to avoid distraction. The participants were also instructed to sit in a quiet environment and not use their phones or engage in other distracting activities while listening to the music.

To use the MUSIC CARE® app, participants launched it from their phone or tablet, selected the option to treat pain, and then chose a session based on their preferred music genre. They were then presented with a window that asked them to rate their pain on a scale of 0 to 10 (0 = no pain; 100 = worst pain imaginable). The app then queued up 20 minutes of pain-relieving music that was divided into multiple phases known as the “U” sequence, based on the selections made above. Previous studies have shown that “U” sequenced music is effective in reducing pain through a series of mechanisms. The “U” sequence is assumed to achieve its impact through the reduction of “musical tempo, orchestral size, frequencies, and volume,” which corresponds to the downward arm of the “U” to reach a maximal relaxation phase at the bottom of the “U” and revitalization, which occurs in the ascending arm of the “U”. Additional explanation of the “U” sequence can be found in the article by Guétin et al. (2012). Participants were allowed to adjust the music volume to their liking and were required to complete two sessions per day. Immediately following the second intervention of the day, participants recorded their average LBP rating for the previous 24 hours using the 101-point NRS, i.e., one LBP measurement per day that sums up their average LBP score for that day (24 hours prior).
The intervention lasted four consecutive days and consisted of two sessions per day (morning and evening) for a total of eight sessions.

**Remote Monitoring**

Participants were assigned an unique study identification number for the MUSIC CARE® app. The PI tracked the MUSIC CARE® app access daily. A text message was sent, or a phone call was made to participants if the participant did not use the app by 11:00 a.m. for the first session or 9:00 p.m. for the second session. Each participant’s preferred mode of communication was determined during the baseline session. The primary rationale for tracking daily app usage was to assure adherence to the study protocol without invading the participant’s privacy, as might be the case with video monitoring.

**Data Collection**

Baseline data, which included sociodemographic characteristics such as age, sex, race, height, weight, occupation, household income, and marital status, were collected using a sociodemographic form specially designed for this study. Additional baseline data on anxiety, depression, and mental status were collected using the Patient-Reported Outcomes Measurement Information System (PROMIS) anxiety-short form (Cella et al., 2010), PROMIS depression-short form (Cella et al., 2010), and the Mini-Mental States Exam (MMSE) (Folstein et al., 1975; Mitchell, 2009), respectively. Feasibility was measured by tracking enrollment, adherence, and attrition rates, and acceptability was measured by the Treatment Acceptability and Preference (TAP) scale (Sidani et al., 2009). Clinical pain was assessed using the Numeric Rating Scale (NRS) for pain (Childs et al., 2005) at baseline and once a day after the second music session of the day until the
study was completed. Physiological assessments involving function near-infrared spectroscopy (fNIRS), heart rate variability (HRV), and conditioned pain modulation (CPM) were evaluated at baseline and after the eight consecutive sessions of music listening.

**Baseline Data**

To score the PROMIS anxiety-short form, participants responded by indicating the number of times they had experienced emotions such as fearfulness, overwhelmedness, nervousness, and anxiousness in the seven days preceding the assessment. The scale was scored on a range of 8 – 40, with higher scores indicating greater severity of anxiety (Driban et al., 2015). Similarly, the 8-item PROMIS depression - short form was scored on a range of 8 - 40, with higher scores indicating greater severity of anxiety (Cella et al., 2010). Both scales have demonstrated acceptable internal consistency in older adult chronic musculoskeletal pain populations with Cronbach’s alpha of .85 and .92 respectively (Deyo et al., 2016). Validity of these PROMIS anxiety-short form and PROMIS depression – short form has been well documented in older adult chronic back pain patients (Nayfe et al., 2020). The MMSE, which provides a quick and simple way to assess cognitive function and screen for cognitive loss (Folstein et al., 1975; Mitchell, 2009) consisted of an 11-item assessment was graded on a scale of 1 to 30, with cut-off scores below 24 indicating cognitive impairment. (Creavin et al., 2016; Mitchell, 2009).
Feasibility

The following feasibility outcomes were tracked: (a) enrollment rate was estimated as the number of participants enrolled divided by the number of potential participants who met inclusion criteria after being assessed for eligibility, (b) attrition rate as the number of participants who enrolled but did not complete the study divided by the number of participants enrolled into the study at baseline, and (c) adherence rate as the number of participants who completed all measures of the study divided by the number of participants enrolled into the study at baseline. A priori, the protocol was considered feasible if the following conditions were met: enrollment and adherence rates of 80% or greater and an attrition rate of less than 20%, and the ability to recruit 20 participants within six months of study commencement. This cutoff was determined based on previous music intervention study that considered 80 percent adherence rate as feasible (Khan et al., 2020). Furthermore, in clinical trials, an adherence rate of 80 percent is typically considered adequate (Kim, Combs, Downs, & Tillman, 2018).

Acceptability

The perceived acceptability of the study protocol to participants was evaluated using the Treatment Acceptability and Preference (TAP) scale (Sidani et al., 2009). Prior research demonstrates that the TAP scale has internal consistency reliability with Cronbach alpha >.80 and factorial validity (Sidani et al., 2009). The scale measured participant’s perceived acceptability of the music intervention on a 5-point self-report Likert-style scale ranging from 0 (not at all) to 4 (very much) in four domains: appropriateness, effectiveness, suitability as a treatment, and willingness to adhere. The total scale score was derived as the average of the four item scores to indicate the degree
of treatment acceptance. The total scale scores ranged from 0 (*low acceptability*) to 4 (*high acceptability*), with high scores indicating high acceptability (Sidani et al., 2009). An additional open-ended question was added to the TAP scale to evaluate the presence and severity of possible side effects. *A priori*, the protocol was considered acceptable with a total TAP scale score greater than or equal to 3.

**Clinical Pain**

Clinical pain was measured via the Numeric Rating Scale (NRS) for pain, designed to measure pain intensity in adults (Childs et al., 2005). The 101-point version of the NRS with terminal descriptions of 0 (*no pain*) to 100 (*worst pain imaginable*) was used. The NRS has demonstrated evidence of reliability and validity in adult populations. The test-retest reliability of NRS in chronic pain patients is estimated at $r = .95$ with a good correlation with the visual analog scale estimated at $r = 0.71$ to $r = 0.78$ (Ferraz et al., 1990). The NRS was scored by asking the respondent to select a number on the continuum from 0 (*no pain*) to 100 (*worst pain imaginable*) to represent their pain. The NRS has been used in assessing clinical pain in recent studies with satisfactory outcomes (Ahn et al., 2017, 2019, 2020).

**Physiological Data**

During fNIRS and HRV data collection, participants were placed in a prone position on a massage table. Mechanical pressure was applied to their right lower back via a handheld digital pressure algometer (Wagner, Greenwich, CT, USA) in a block design paradigm, consisting of a series of six stimuli with each lasting for 20 seconds followed by an interstimulus interval of 30 seconds where no stimulus was applied. A 60
second period during which no pressure stimulus was applied preceded the first stimulus and also after the last stimulation. In all, the stimulation lasted for 690 seconds.

**Functional Near-Infrared Spectroscopy (fNIRS).** fNIRS is a non-invasive, portable, and inexpensive optical imaging method for assessing cerebral hemodynamic changes, making it a good fit for pain research (Boas et al., 2014; Peng et al., 2018; Yucel et al., 2015). The fNIRS neuroimaging technology examines brain functions by indirectly assessing regional blood flow and tissue oxygenation through changes in light absorption using near-infrared light. The changes in light absorption are influenced by changes in the concentration of oxygenated hemoglobin (HbO) and deoxygenated hemoglobin (HbR; Hill & Bohil, 2016; Scholkmann et al., 2014). Pain-related cortical response data were measured with a continuous-wave, multichannel function Near-Infrared Spectroscopy (fNIRS) imaging system (LIGHTNIRS, Shimadzu, Kyoto, Japan). The instrument has eight light sources and eight detectors coupled to a head-fitting headgear by optical fibers. Each source employs three semiconductor lasers operating at 780nm, 805nm, and 830nm wavelength. The probe, which included 16 optodes (8 sources and 8 detectors), yielding 10 channels, was attached to the participant’s scalp in a geometrical pattern that covered the primary motor and somatosensory cortices on each hemisphere with eight optical emitters/detectors on each side. This probe placement arrangement is comparable to optode placement arrangements used in prior studies (Pollonini et al., 2020; Sorkpor et al., 2019; Yucel et al., 2015).

**Heart Rate Variability (HRV).** HRV represents the variability in the interval between successive heartbeats. It provides an indirect measure for evaluating the activities of the autonomic nervous system (Adler-Neal et al., 2019; Appelhans &
Luecken, 2006; McCraty & Shaffer, 2015; Shaffer et al., 2014). Reduced HRV and other dysregulations of the autonomic nervous system have been implicated in the etiology of various chronic pain conditions, including LBP (Meeus et al., 2013; Tracy et al., 2016). Therefore, therapies directed at increasing HRV in LPB conditions could promote proper functioning of the central autonomic network, which is critical for the activation of pain inhibitory pathways in the central nervous system. (Thayer et al., 2009). The HRV data were acquired using the BIOPAC MP160 system and AcqKnowledge software version 5.0 signal analysis software (Biopac Systems, Inc., Goleta, USA) following the recommendations by the European Society of Cardiology and the North American Society of Pacing and Electrophysiology Task Force (Task Force of the European Society of Cardiology, 1996). The electrocardiogram (ECG) data were acquired using a lead II arrangement consisting of three electrodes. The negative electrode was placed under the right collar bone, the positive electrode beneath the left rib cage, and the ground electrode beneath the right ribs, as recommended by BIOPAC (see https://www.biopac.com/wp-content/uploads/ECG-Guide.pdf). The HRV data were continuously recorded for each participant at baseline and final visit during the six-minute experimental pain procedure.

To evaluate Pressure Pain Threshold (PPT), a handheld digital pressure algometer with a 1 cm diameter flat rubber probe (Wagner, Greenwich, CT) was used to apply the test stimulus. The probe of the algometer was placed orthogonally on the intercristal line (the Jacoby line), 5 cm to the left of the median line on the lower back, consistent with stimulation targets used in previous studies (Kaneko et al., 2017; Kobayashi et al., 2009; Matsuo et al., 2017). Manual pressure was applied to the algometer at a rate of approximately 0.3 kgf/cm² per second until participants alerted the experimenter of their
first perceived sensation of the stimulus as painful. The corresponding pressure of the painful sensation was recorded as the PPT. Pressure algometry has demonstrated reliability and validity in previous studies (Balaguier et al., 2016; Srimurugan Pratheep et al., 2018).

Conditioned Pain Modulation (CPM) was obtained at baseline and after the final music intervention. CPM was assessed as a measure of descending pain inhibition by determining the change in PPT (test stimulus) on the lower back after the immersion of the left hand up to the wrist in a cold-water bath (conditioning stimulus; Neslab, Portsmouth, NH) maintained at 12°C for one minute. At thirty seconds following hand immersion, participants rated their cold pain severity from the immersed hand on a 101-point NRS. CPM was then estimated as an increase in PPT after hand immersion in the cold water. This CPM paradigm is consistent with previous pain studies in similar patient populations (Ahn et al., 2018, 2019). CPM has demonstrated exceptional intrasession reliability with intra-class coefficients of 0.75. (Lewis et al., 2012).

**Data Analysis**

Participants’ demographic characteristics and intervention feasibility were analyzed using descriptive statistics such as the frequency, percentage, mean, and standard deviation. The Shapiro-Wilk test and visual inspection of respective histograms revealed that with the exception of NRS scores, which were normally distributed, the TAP scale scores, CPM, PPT, and cold pain measurements deviated from a normal distribution. Therefore, the Wilcoxon signed-rank nonparametric test was used to compare the pain scores (NRS) before and after listening to the music intervention. The effect sizes were
determined using Rosenthal’s formula \((R = Z/\sqrt{2N})\), similar to the analysis performed by Ahn et al. (2019), where \(Z\) is the \(z\)-score obtained by dividing the Wilcoxon signed-rank test statistic by its standard deviation and \(N\) is the number of participants. Repeated-measures analysis of variance (ANOVA) was used to evaluate the effect of the music intervention on pain ratings measured by the NRS over time (baseline, days 1, 2, 3, 4, and post-intervention). Post hoc pairwise comparison was performed with Bonferroni correction for the ANOVA.

The fNIRS data were analyzed in two stages. First, data quality validation was performed, followed by statistical analysis, which included six different analyses: a mixed-effects model with a univariate approach for HbO2 and HHR variables separately, a mixed-effects model with multivariate (joint HbO2-HHR) approach, and a t-test contrast (post – pre) over HbO2 and HHR variables. The three approaches were conducted over the data set with and without channel pruning. In the data quality validation phase, the raw optical data were visually inspected, and channels containing artifacts (e.g., noisy scans from movement artifacts) were manually removed. Then, using quantitative techniques (Quality Testing of Near-Infrared Scans) previously demonstrated to be effective in detecting movement artifact and noisy optical signals resulting from poor optode to scalp contact, additional low-quality recordings and motion artifacts were identified and excluded from the analysis (Hernandez & Pollonini, 2020; Pollonini et al., 2014, 2016). As a result, 13 scans representing the pre-and post-intervention scans of subjects 1, 3, 10, 11, 12, 17, and only the pre-intervention scan of subject 16 were identified as overly noisy and excluded from the statistical analysis. Four additional scans representing the pre-and post-intervention scans of subjects 4 and 5 were excluded.
because they did not complete baseline fNIRS scans due to their hairstyles that impeded fNIRS data capture (one had a hair extension, and the other had braids). The parameters used in Quality Testing of Near-Infrared Scans were Scalp Coupling Index = 0.6, Peak Spectral Power = 0.1, Quality threshold = 0.7, and cardiac pulsation frequencies: [0.5, 2.5].

In the statistical analysis phase, the AnalyzIR software was utilized (Santosa et al., 2018), with all code execution accomplished in MATLAB (Natick, MA, USA). The remaining raw optical data were transformed to optical density and subsequently to changes in oxygenated (HbO) and deoxygenated hemoglobin (HbR) concentrations over time using the modified Beer-Lambert law (Cope & Delpy, 1988; Delpy et al., 1988). The changes in cortical hemodynamic activity in response to mechanical stimulation of the lower back, as measured by changes in HbO and HbR over time, were assessed using a general linear model based on an autoregressive iteratively reweighted least squares (AR-IWLS) approach. This approach was first proposed by Barker et al. (2013) and has recently been used in related chronic pain studies (Pollonini et al., 2020). With this approach, only optical channels with regression coefficient $\beta$, which differs statistically from zero, were deemed to be significantly active. Group-level analyses were performed using a mixed effect model to examine the relationship between the estimated beta coefficients of each optical channel and the interaction of time and treatment with the subject-specific intercept value treated as a random variable. In the multivariate analysis, a Hotelling’s T square test was performed on both HbO2 and HHb. Finally, a t-test was used to determine whether the strength of activation (beta values) in the post-treatment scans was greater than that observed in the pre-treatment scans (post > pre).
The HRV data were preprocessed using proprietary functionalities in AcqKnowledge software version 5.0 (Biopac Systems, Inc, Goleta, USA). First, the data were subjected to a bandpass filter ranging from 0.5 to 35 Hz, which facilitated the detection of QRS peaks. After that, the data was visually inspected for artifacts, and those that were found were removed. The remaining data were further preprocessed using a template matching algorithm to identify and retrieve the best ECG R-R interval data. The extracted R-R interval data were exported into SPSS 28.0 software package for Windows (SPSS, Chicago, IL, USA) and then z-score transformed. Values with absolute z-scores greater than 2 were considered as outliers and discarded. Finally, some commonly reported time-domain HRV indices which are often used to evaluate HRV data were computed. These include the mean interbeat intervals between all successive heartbeats (mean RR interval), mean heart rate (mean HR), standard deviation of the average Normal-to-Normal (NN) inter-beat intervals (SDNN), and the root mean square of successive RR interval differences (RMSSD). All these were calculated with an in-house python script. See appendix for python script.

CPM was measured as an increase in PPT on the right lower back following a one-minute immersion of the left hand up to the wrist in a cold-water bath (Neslab, Portsmouth, NH), maintained at 12 degrees Celsius. The CPM was calculated for each participant as the difference between the pre-and post-cold-water immersion PPT, with a positive value indicating a decrease in pain. The pre-and post-music intervention CPM were compared using the Wilcoxon signed-rank test.
Results

Participants

The baseline and demographic characteristics of the participants are shown in Table 1. Although participant recruitment was not limited to only one race, all participants were African American/Black with a mean age (standard deviation [SD]) of 70 (5.04) years. This could be attributed to recommendations from early study participants who were African Americans and shared study flyers with their friends on social media platforms and church bulletin boards. Of the 20 participants who completed the study requirements, 13 (65%) were female, 5 (25%) were divorced, and 12 (60%) had a minimum of four years of college education.

Feasibility

During the two-month recruitment period, a total of 21 eligible individuals were approached (see Figure 1). Of these, one declined to participate in the study. The refusal to participate was due to the lack of transportation to commute to and from the study center. As such, 20 participants were enrolled, and all 20 completed the study requirements. Consequently, the enrollment, adherence, and attrition rates were estimated as (95.25%, 100.00%, and 0.00% respectively.

Acceptability

There were no negative side effects reported by any of the participants. Of all the participants who completed the intervention (n = 20), the majority recorded a total TAP score of 3 or greater. Participants scoring 3 or greater on the total TAP scale score during the pre-intervention assessment compared to post-intervention assessment were (80.00%;
CI = 56.34, 94.27) and (90.00%; CI = 68.30, 98.76), respectively. After completing the study requirements, more participants rated the protocol as being acceptable \((M = 3.39, SD = .58)\) compared to their perception of the intervention before undergoing the intervention \((M = 3.29, SD = .64)\) \([t (19) = 7.72, p = 0.10]\). Table 2 summarizes the participants’ treatment acceptability and preference ratings.

**Clinical Pain Severity**

Due to violations of the assumption of sphericity, a univariate repeated measure ANOVA with the Greenhouse-Geiser correction revealed that participants who listened to 20 minutes of their preferred music twice daily experienced a significant change in NRS score \([F (2.36, 44.88) = 5.61, p = .004, \text{Partial Eta Squared }= .23]\). Notwithstanding the significant \(p\)-value \((p =.004)\) reported above, the associated error bars shown in Figure 2 show that the decline in mean NRS scores was not significantly different from each other, as evidenced by the overlap between the error bars. A post hoc pairwise comparison with adjustment for multiple comparisons using the Bonferroni correction showed a significant decrease in pain scores between day 2 (day one of music listening) and days 4, 5, 6, \(p = .023, p = .002, \text{and } p = .006, \text{respectively}\). Similarly, the decrease in pain severity as rated on the NRS was significant between day 3 and day 5 (last day of music intervention), \(p = .002\).

**fNIRS**

The results show a significant difference in cortical activation patterns in response to pressure stimuli to the lower back. These brain activation patterns were particularly pronounced in the somatosensory regions of the brain, with post-intervention scans
revealing a significant decrease in hemodynamic activities in these regions. Figure 3 depicts differences in cortical hemodynamic activity for HbO and HbR in response to pressure pain to the right lower back in participants before and after music intervention. The observed reductions were more pronounced when the data set was considered after channel pruning and for the multivariate test.

**HRV**

HRV measures of all participants are summarized in Table 3. The pre-and post-intervention means inter-beat intervals between all successive heartbeats (R-R interval) were 988.13 and 641.01, respectively. The pre-intervention and post-intervention standard deviations of normal-to-normal R-R intervals (SDNN) and the root mean square of successive differences between normal heartbeats (RMSSD) were 108.36: 159.89 and 116.74: 231.47, respectively. The increase in RMDSS, a major HRV metric from baseline to post-intervention, suggests that the intervention had an impact on the autonomic function, which is thought to play a role in the pathogenesis of several chronic pain conditions, including LBP (Fournié et al., 2021; Makovac et al., 2021). In a healthy heart, variations in heart rate are expected due to the balance between the sympathetic nervous system and parasympathetic parts of the autonomous nervous system. Deviations from this norm are manifested as changes in heart rate variability with decreased RMDSS associated with stress and illness conditions such as LBP (Makovac et al., 2021).

**CPM**

The Wilcoxon signed-rank test results showed that listening to preferred music for 20 minutes twice a day for four consecutive days resulted in a nonsignificant but
marginal decrease in CPM pain scores in older adults with LBP (Z = -0.09, p = 0.93).
Similarly, the reduction in pain sensitivity following the intervention, as measured by
NRS, was marginal but not statistically significant. (Z = -1.04; p = 0.30, Rosenthal’s R
= 0.16). The mean CPM before and after the music intervention were 0.90 and 0.85,
respectively. PPT, on the other hand, was significantly reduced following the music
intervention (Z = -2.24, p = 0.03, Rosenthal’s R = 0.36). Table 4 shows the comparison of
baseline and post-intervention CPM measures.

Discussion
To the author’s knowledge, the current study is the first to simultaneously
investigate the feasibility and acceptability of home-based, remotely-monitored, preferred
music listening intervention in older adults with LBP, as well as changes in pain-related
physiological markers such as cerebral hemodynamic activity, HRV, and CPM. The
primary aim of the study was to determine if listening to one’s preferred music at home to
relieve pain in older adults with LBP was feasible and acceptable. Another goal was to
see if music could alleviate pain and influence pain-related physiological markers such as
cerebral hemodynamic activity, HRV, and CPM.

The results from this study indicate that older adults 65 years or older with LBP
who listened to 20 minutes of their preferred music at home twice daily for four
consecutive days found it feasible and acceptable as a form of therapy for pain relief.
Post-music intervention clinical pain sensitivity measures were marginally reduced
compared to baseline pain measures (a decrease in NRS). In addition, when compared to
baseline fNIRS measurements, substantial reductions in cortical hemodynamic activation
patterns were detected in the somatosensory regions after the music intervention (changes
in HbO and HbR concentration). Furthermore, CPM measurements revealed a marginal reduction in NRS scores (pain sensitivity). Additionally, an increase in RMSSD, a crucial HRV assessment indicator following the music intervention, indicated improvement in the balance between the sympathetic nervous system and the parasympathetic autonomous nervous system, which is an essential prerequisite for effective exogenous pain modulation.

Enrollment, adherence, and attrition rates were considerably greater than the a priori defined feasibility thresholds of 80% or greater for enrollment and adherence and 20% or less for attrition. All 20 participants were recruited within two months, which far exceeded the six-month anticipated recruitment time for the study. Also, a sizable proportion of participants (90%) indicated that the intervention was appropriate, effective, and suitable for treating their pain, as well as their willingness to adhere to this regimen to manage their pain.

These findings are consistent with previous research, suggesting a relationship between home-based music interventions and the modulation of pain in older adult chronic pain patients. For example, a recent randomized controlled trial among residents of older adult care homes discovered that listening to 30-minutes of preferred music daily for three weeks significantly reduced pain (Costa et al., 2018). In another related randomized controlled study among older nursing home residents, the authors reported a significant reduction in pain among those who listened to music compared to those who did not (Castillejos & Godoy-Izquierdo, 2021). Moreover, several recent meta-analytic studies have also shown that music listening has analgesic properties (Martin-Saavedra et al., 2018; Sorkpor et al., 2021). Similarly, the changes in physiological pain markers such
as fNIRS, CPM, and HRV are consistent with previous research that used these markers to explore pain perception in response to pain treatments (Forte et al., 2022; Karunakaran et al., 2021; Pollonini et al., 2020a; Pollonini et al., 2020b). These findings support the current study's central hypothesis, which asserted that in older adults with LBP, listening to their preferred music could reduce clinical pain and alter pain-related physiological responses via mechanisms thought to reverse dysregulation in the natural pain modulation pathway. These findings further add to the growing body of literature investigating the possibility of using these physiological markers (fNIRS, CPM, and HRV) as objective pain measures.

Although the current study demonstrated the feasibility and acceptability of music listening to relieve pain and improve well-being and quality of life in older adults, the active mechanisms underlying music-induced analgesia is not fully understood (Garza-Villarreal et al., 2014; Linnemann et al., 2015). Hitherto, music listening interventions are thought to relieve pain by targeting pain-related brain networks via mechanisms that facilitate the reversal of neural plasticity and other impairments to the central nervous system's natural pain regulation pathways, as seen in chronic pain conditions such as LPB (Doan et al., 2015; Karunakaran et al., 2021; Kregel et al., 2015). As a result, the current study contributes to the body of knowledge, paving the way for future research into the underlying mechanism of music-induced analgesia.

**Limitations**

Despite the extensive effort to assure the integrity of the current study, it is equally vital to recognize that the current study has limitations. First, there was no control group, which limits the ability to ascertain if improvement noted in pain relief was due to
listening to the music intervention as opposed to other factors such as standard care. As a result, these preliminary findings must be interpreted with considerable caution. Second, the sample size was small, therefore, reducing the statistical ability to detect significant changes when they occurred. However, the current study was designed as a pilot study assessing feasibility and acceptability, and as such, it is not uncommon for small sample sizes to be used in these types of studies. This protocol, having been deemed feasible and acceptable, may need to be repeated with a larger sample. Third, despite the desire to standardize the intervention time among participants, this was not achieved since each participant had a distinct daily schedule that had to be taken into consideration. As a result, the time intervals between music listening sessions varied slightly from day to day and among participants. However, this circumstance closely resembles real-life scenarios in the lives of older adults; therefore, it cannot be completely controlled for. Finally, because our sample was largely African American females, with no representation of other racial and ethnic groups, the results may not be generalizable to the general population of older adults.

**Implications for Research**

The results of this study lay a solid platform for future research. First, future large randomized controlled trials in multiethnic populations are needed to validate and extend these preliminary findings of the analgesic effects of home-based self-directed preferred music listening to relieve pain in older adults with LBP. This need for more research on the topic is backed by the current state of knowledge, as evidenced by the feasibility and acceptability outcomes in the current study. Second, the need to examine the potential underlying mechanisms that contribute to the efficacy of home-based self-directed
preferred music listening on clinical pain in older adults with LBP is warranted, given its feasibility and acceptability among this population. The author intends to investigate gender differences in pain modulation using passive music intervention among older adults with LBP in the future, using quantitative methods such as fNIRS, CPM, and HRV to assess pain in a large and diverse population.

**Implications for Clinical Practice**

As music listening therapies have demonstrated a promising effect on pain and are readily available with minimal to no documented adverse effects, integrating music listening interventions into the management of pain in older adults with LBP can dramatically improve their pain and quality of life. Clinicians are encouraged to familiarize themselves with the literature on music-induced analgesia to better educate their patients on its benefits and how to properly use music to relieve their pain. In jurisdictions where nurses can recommend music listening as an adjuvant therapy to their homebound patients without violating their scope of practice, they are strongly urged to make such recommendations to help improve the quality of life of their patients.

**Conclusions**

The current study suggested that home-based self-directed preferred music listening is a feasible and acceptable intervention for reducing pain in older adults with LBP, aged 65 years or older. Also, listening to preferred music at home resulted in considerable reductions in clinical pain sensitivity. Furthermore, the effects of music on pain were evident on selected pain-related physiological markers, indicating that these markers may be useful in assessing pain in future studies. This study adds to the growing
body of evidence in support of home-based nonpharmacologic therapies such as preferred music listening. Future studies with larger ethnically diverse samples utilizing robust study designs such as randomized, double-blind placebo control methods are needed to replicate and extend these findings and to investigate the underlying mechanism behind music-induced analgesia.

**Funding**

This study was supported by the Speros Martel Endowment for the Aging Award from The University of Texas Health Science Center at Houston, Houston, Texas.

**Declaration of Competing Interest**

The author declares that there is no conflict of interest.

**Acknowledgments**

The author wishes to express gratitude to the individuals listed below for their contributions to the completion of this manuscript. Dr. Samuel Henandez for processing the fNIRS data. Dr. Gideon Gogovi for writing the Python codes for executing the HRV data, and Ms. Lindsey Park for assisting with lab setup and data collection. The author would also like to thank MUSIC CARE© for allowing the MUSIC CARE© app to be used in this research at no cost.
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Table 1

Participant Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, year, mean (SD)</td>
<td>71.6 (5.04)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>7 (35)</td>
</tr>
<tr>
<td>Female</td>
<td>13 (65)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>20 (100)</td>
</tr>
<tr>
<td>Education, n (%)</td>
<td></td>
</tr>
<tr>
<td>High School diploma</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Two- year college degree</td>
<td>7 (25)</td>
</tr>
<tr>
<td>Four-year college degree</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Living with partner</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Married</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Never married</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Widowed</td>
<td>4 (20)</td>
</tr>
</tbody>
</table>
Table 2

Comparison of Baseline and Post-Intervention Treatment Acceptability and Preference (TAP) Scale Measures

<table>
<thead>
<tr>
<th>TAP Scale Questionnaires</th>
<th>Baseline (n = 20)</th>
<th>Post-Intervention (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1. How effective do you think this treatment will be in improving your back pain?</td>
<td>3.05 ± .95</td>
<td>3.15 ± .93</td>
</tr>
<tr>
<td>Q2. How acceptable/logical does this treatment seem to you?</td>
<td>3.25 ± .91</td>
<td>3.45 ± .76</td>
</tr>
<tr>
<td>Q3. How suitable/appropriate does this treatment/assessment seem to be to your back pain?</td>
<td>3.15 ± .81</td>
<td>3.30 ± .92</td>
</tr>
<tr>
<td>Q4. How willing are you to comply with this treatment?</td>
<td>3.85 ± .37</td>
<td>3.85 ± .37</td>
</tr>
<tr>
<td>Q5. List any side affects you experienced with this intervention</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Total TAP Score:</td>
<td>3.29 ± .65</td>
<td>3.39 ± .58</td>
</tr>
</tbody>
</table>

Note. Mean ± standard deviation are presented in the baseline and pre-intervention columns. The scale was scored as 0, not at all; 1, somewhat not; 2, neutral; 3, somewhat probable; and 4, very much.
### Table 3

*Comparison of Pre-Intervention and Post-Intervention Autonomic Function*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Units</th>
<th>Pre-Intervention Value</th>
<th>Post-Intervention Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean RR</td>
<td>(ms)</td>
<td>988.13</td>
<td>642.01</td>
</tr>
<tr>
<td>SDNN</td>
<td>(ms)</td>
<td>108.36</td>
<td>159.87</td>
</tr>
<tr>
<td>Mean HR</td>
<td>(1/min)</td>
<td>60.72</td>
<td>93.46</td>
</tr>
<tr>
<td>STD HR</td>
<td>(1/min)</td>
<td>108.36</td>
<td></td>
</tr>
<tr>
<td>RMSSD</td>
<td>(ms)</td>
<td>116</td>
<td>231.47</td>
</tr>
<tr>
<td>NN50</td>
<td>(count)</td>
<td>34.00</td>
<td>27.00</td>
</tr>
<tr>
<td>pNN50</td>
<td>(%)</td>
<td>26.77</td>
<td>33.75</td>
</tr>
</tbody>
</table>

*Note.* RR intervals, interbeat intervals between all successive heartbeats; SDNN, standard deviation of normal to normal R-R intervals; HR, heart rate; RMSSD, root mean square of successive differences between normal heartbeats; NN50, the number of adjacent NN intervals that differ by more than 50 ms; pNN50, percentage of successive RR intervals that differ by more than 50 ms.

### Table 4

*Comparison of Baseline and Post-Intervention Measures*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-Intervention</th>
<th>Post-Intervention</th>
<th>Z-score</th>
<th>Effect size R</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPM, M ± SD</td>
<td>.90 ± .98</td>
<td>.84 ± 063</td>
<td>-.09</td>
<td>.01</td>
<td>.93</td>
</tr>
<tr>
<td>PPT, M ± SD</td>
<td>2.50 ± .93</td>
<td>2.07 ± .82</td>
<td>-2.24</td>
<td>.36</td>
<td>.03</td>
</tr>
<tr>
<td>Cold pain, M ± SD</td>
<td>66.50 ± 21.77</td>
<td>62.05 ± 23.91</td>
<td>-1.04</td>
<td>.16</td>
<td>.30</td>
</tr>
</tbody>
</table>

*Note.* M, mean; SD, standard deviation PPT, pressure pain threshold; CPM, conditioned pain modulation. R, Rosenthal’s R, Cold pain intensity was measured from 0 to 100.
Figure 1

Participant Flow Diagram

- Assessed for eligibility (n = 21)
- Enrolled (n = 20)
- Completed all study visits (n = 20)

Declined to participate
  - Not interested (n = 1)
Figure 2

Profile Plots: Displaying the Mean NRS Score at Each of the Assessment Points with Associated Standard Deviation Error Bars

Error Bars: 95% CI
Error Bars: +/- 2 SD
Figure 3

*Cortical Hemodynamic Activity in Optical Channels*

Note. Functionally active optical channel (colored links) for (a) HbO and (b) HbR in response to pressure stimulation to the right lower back measured in participants before and after music intervention. Only channels with statistically significant values (p-value <0.05) are shown as solid, thicker lines.
Appendix

Custom Python Code for HRV analysis
Custom Python Code for HRV analysis

```python
#!/usr/bin/env python3
#
- *-* coding: utf-8 -*-

""
Created on Tue Mar  8 15:03:32 2022

# data science libraries
import pandas as pd
import numpy as np
import matplotlib.pyplot as plt
import seaborn as sns
# signal processing
from scipy.ndimage import label
from scipy.stats import zscore
# style settings
sns.set(style='whitegrid', rc={'axes.facecolor': '#EFF2F7'})
# sample frequency for ECG sensor
settings = {}
settings['fs'] = 500
df = pd.read_csv("PostData.csv")
plt.figure(figsize=(20, 7))
start = 0
stop = 200000
duration = (stop-start) / settings['fs']
plt.title("ECG signal, slice of %.1f seconds" % duration)
plt.plot(df[start:stop].index, df[start:stop].heartrate, color="#51A6D8", linewidth=1)
plt.xlabel("Time (ms)", fontsize=16)
plt.ylabel("Amplitude (arbitrary unit)")
plt.show()
def detect_peaks(ecg_signal, threshold=0.3, qrs_filter=None):
    ""
    Peak detection algorithm using cross correlation and threshold
    ""
    if qrs_filter is None:
        # create default qrs filter, which is just a part of the sine function
        t = np.linspace(1.5 * np.pi, 3.5 * np.pi, 15)
        qrs_filter = np.sin(t)

    # normalize data
    ecg_signal = (ecg_signal - ecg_signal.mean()) / ecg_signal.std()

    # calculate cross correlation
    similarity = np.correlate(ecg_signal, qrs_filter, mode="same")
    similarity = similarity / np.max(similarity)
```

# return peaks (values in ms) using threshold
return ecg_signal[similarity > threshold].index, similarity

def get_plot_ranges(start=10, end=20, n=5):
    
    Make an iterator that divides into n or n+1 ranges.
    - if end-start is divisible by steps, return n ranges
    - if end-start is not divisible by steps, return n+1 ranges, where the last range is
      smaller and ends at n
    
    distance = end - start
    for i in np.arange(start, end, np.floor(distance/n)):
        yield (int(i), int(np.minimum(end, np.floor(distance/n) + i)))

sampfrom = 60000
sampto = 70000
nr_plots = 1
for start, stop in get_plot_ranges(sampfrom, sampto, nr_plots):
    
    # get slice data of ECG data
    cond_slice = (df.index >= start) & (df.index < stop)
    ecg_slice = df.heartrate[cond_slice]
    
    # detect peaks
    peaks, similarity = detect_peaks(ecg_slice, threshold=0.3)
    
    # plot similarity
    plt.figure(figsize=(20, 15))
    plt.subplot(211)
    plt.title("ECG signal with found peaks")
    plt.plot(ecg_slice.index, ecg_slice, label="ECG", color="#51A6D8", linewidth=1)
    plt.plot(peaks, np.repeat(600, peaks.shape[0]), label="peaks", color="orange",
             marker="o", linestyle="None")
    plt.legend(loc="upper right")
    plt.xlabel("Time (milliseconds)"")
    plt.ylabel("Amplitude (arbitrary unit)"")
    plt.subplot(212)
    plt.title('Similarity with QRS template')
    plt.plot(ecg_slice.index, similarity, label="Similarity with QRS filter", color="olive",
             linewidth=1)
    plt.legend(loc="upper right")
    plt.xlabel("Time (milliseconds)"")
    plt.ylabel("Similarity (normalized)"")

def group_peaks(p, threshold=5):
    
    The peak detection algorithm finds multiple peaks for each QRS complex.
    Here we group collections of peaks that are very near (within threshold) and we take
    the median index

    # initialize output
    output = np.empty(0)
# label groups of sample that belong to the same peak
peak_groups, num_groups = label(np.diff(p) < threshold)
# iterate through groups and take the mean as peak index
for i in np.unique(peak_groups)[1:]:
    peak_group = p[np.where(peak_groups == i)]
    output = np.append(output, np.median(peak_group))
return output

# detect peaks
peaks, similarity = detect_peaks(df.heartrate, threshold=0.3)
# group peaks
grouped_peaks = group_peaks(peaks)
# plot peaks
plt.figure(figsize=(20, 7))
plt.title("Group similar peaks together")
plt.plot(df.index, df.heartrate, label="ECG", color="#51A6D8", linewidth=2)
plt.plot(peaks, np.repeat(600, peaks.shape[0]), label="samples above threshold (found peaks)", color="orange", marker="o", linestyle="None")
plt.plot(grouped_peaks, np.repeat(620, grouped_peaks.shape[0]), label="median of found peaks", color="k", marker="v", linestyle="None")
plt.legend(loc="upper right")
plt.xlabel("Time (ms)")
plt.ylabel("Amplitude (arbitrary unit)")
plt.gca().set_xlim(0, 200)
plt.show()

# detect peaks
peaks, similarity = detect_peaks(df.heartrate, threshold=0.3)
# group peaks so we get a single peak per beat (hopefully)
grouped_peaks = group_peaks(peaks)
# RR-intervals are the differences between successive peaks
rr = np.diff(grouped_peaks)
# plot RR-intervals
plt.figure(figsize=(20, 7))
plt.title("RR-intervals")
plt.plot(np.cumsum(rr), rr, label="RR-interval", color="#A651D8")
plt.show()

plt.figure(figsize=(20, 7))
rr_corrected = rr.copy()
rr_corrected[np.abs(zscore(rr)) > 2] = np.median(rr)
plt.title("RR-intervals")
plt.plot(rr, color="red", label="RR-intervals")
plt.plot(rr_corrected, color="green", label="RR-intervals after correction")
plt.legend()
plt.show()

sampfrom = 2000000
sampto = 11000000
nr_plots = 1

# detect peaks
peaks, similarity = detect_peaks(df.heartrate, threshold=0.3)
# group peaks so we get a single peak per beat (hopefully)
grouped_peaks = group_peaks(peaks)
# RR-intervals are the differences between successive peaks
rr = np.diff(grouped_peaks)

for start, stop in get_plot_ranges(sampfrom, sampto, nr_plots):
    # plot similarity
    plt.figure(figsize=(20, 10))
    plt.title("ECG signal & RR-intervals")
    plt.plot(df.index, df.heartrate, label="ECG", color="#51A6D8", linewidth=1)
    plt.plot(grouped_peaks, np.repeat(600, grouped_peaks.shape[0]), markersize=10,
             label="Found peaks", color="orange", marker="o", linestyle="None")
    plt.legend(loc="upper left")
    plt.xlabel("Time (milliseconds)", fontsize=16)
    plt.ylabel("Amplitude (arbitrary unit)", fontsize=16)
    plt.gca().set_ylim(400, 800)
    ax2 = plt.gca().twinx()
    #ax2.plot(np.cumsum(rr_manual)+peaks[0], rr_manual, label="Corrected RR-intervals", fillstyle="none", color="#A651D8", markeredgewidth=1, marker="o", markersize=12)
    ax2.plot(np.cumsum(rr)+peaks[0], rr, label="RR-intervals", color="k", linewidth=2,
             marker=".", markersize=8)
    ax2.set_xlim(start, stop)
    ax2.set_ylim(-2000, 2000)
    ax2.legend(loc="upper right")
    plt.xlabel("Time (ms)")
    plt.ylabel("RR-interval (ms)")

def timedomain(rr):
    results = {}
    hr = 60000/rr
    results['Mean RR (ms)'] = np.mean(rr)
    results['STD RR/SDNN (ms)'] = np.std(rr)
    results['Mean HR (Kubios\ style) (beats/min)'] = 60000/np.mean(rr)
    results['Mean HR (beats/min)'] = np.mean(hr)
    results['STD HR (beats/min)'] = np.std(hr)
    results['Min HR (beats/min)'] = np.min(hr)
    results['Max HR (beats/min)'] = np.max(hr)
    results['RMSSD (ms)'] = np.sqrt(np.mean(np.square(np.diff(rr))))
    results['NNxx'] = np.sum(np.abs(np.diff(rr)) > 50)*1
    results['pNNxx (%)'] = 100 * np.sum((np.abs(np.diff(rr)) > 50)*1) / len(rr)
return results
print("Time domain metrics - automatically corrected RR-intervals:\n")
for k, v in timedomain(rr).items():
    print("- %s: %.2f" % (k, v))
print()
Appendix A

A  Grant Award
MEMORANDUM

TO: Setor Sorkpor, PhD(c), MSN, MPH, RN-BC

FROM: Constance M. Johnson, PhD, RN, FAAN
        Associate Dean for Research

SUBJECT: Speros Martel Endowment for the Aging Award

DATE: September 2, 2020

Congratulations! Your proposal "The Effects of Preferred Music on Selected Pain Physiological Parameters in Older Adults with Low Back Pain: An Open-Label Pilot Study of Feasibility and Acceptability" has been selected for funding in the amount of $10,000. Your research may begin and the funding will be released once IRB approval is completed. Please meet with Charmaime D. Wilson, Administrative Director, Center for Nursing Research, for post award support. She will help you plan expenditures, order supplies, and manage your budget.

Please plan to expend grant funds within two years. Please submit a progress report every year, at which time an extension to complete the project can be requested in the last six month interval. An extension of your research will require approval of the Associate Dean of Research. Please acknowledge the source of funding in all oral and written dissemination of this project.

I want to thank you for your excellent proposal. We truly appreciate your effort in informing us about your proposed research project. Supporting nursing research is a foundational component of our commitment to UTHealth McGovern School of Nursing.

I congratulate you and wish you great success with your endeavor!

Cc: Diane M. Santa Maria, DrPH, MSN, RN, PHNA-BC, FAAN
     Charmaine D. Wilson, M.S.
Appendix B

Grant Application
Grant Application

COVER SHEET

<table>
<thead>
<tr>
<th>Applicant Name</th>
<th>Setor Kofi Sorkpor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email Address</td>
<td><a href="mailto:Setor.K.Sorkpor@uth.tmc.edu">Setor.K.Sorkpor@uth.tmc.edu</a></td>
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<tr>
<td>Telephone</td>
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</tr>
<tr>
<td>Mailing Address</td>
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</tr>
</tbody>
</table>

If Student: Current Enrollment Status at SON
Part-time Ph.D. Student

If Student: Advisor's Name
Dr. Hyochol Ahn

If Student: GPA
3.924

How has your previous scholastic and/or professional work demonstrated your interest in improving the health and quality of life for disadvantaged elderly individuals?

During my Ph.D. program, I have published one first-authored peer-reviewed publication focused on functional neuroimaging using functional near-infrared spectroscopy and 4 co-authored peer-reviewed publications focused on nonpharmacological pain intervention with my mentor (Dr. Ahn). Additionally, I currently have a systematic review paper on music listening under review. My previous scholastic work has been dedicated to improving the health and wellbeing of older adults. I have assisted in Dr. Ahn’s lab as a graduate research assistant over the past 2.5 years mainly on research projects devoted to improving the health and wellbeing of older adults. Conceding that older adults are more vulnerable to the untoward side effects of most pain-reducing pharmacologic agents, the primary focus of the work I have been involved in is to investigate nonpharmacologic pain-reducing therapies (e.g., music intervention, transcranial direct current stimulation) to improve the health and quality of life of older adults.

How does this proposal meet the criteria to improve quality care with a disadvantaged/indigent elderly population?

The prevalence of low back pain (LBP) in older adults is significantly high and is expected to proportionally increase as the aging population increases. LBP significantly impacts the quality of life of older adults by causing functional limitations and sometimes disability. To limit or manage their pain, older adults with LBP often abandon active lifestyles for sedentary ones which predispose them to co-morbidities such as diabetes and cardiovascular diseases. Although recent treatment guidelines recommend the use of nonpharmacologic therapies as first-line therapy to manage LBP in older adults, providers continue to increasingly prescribe pharmacologic therapies as first-line treatment for LBP in older adults, possibly due to inadequate knowledge about the mechanism of action behind most nonpharmacologic therapies. Regrettably, older adults with LBP, who seek to avoid pharmacologic therapies, are often undertreated because of the aforementioned knowledge gap.

This study will evaluate the feasibility and acceptability of one nonpharmacologic therapy, listening to one’s preferred style of music on pain in older adults age 65 years and above with LBP. The outcome of this study will provide valuable information on the acceptability of passive music listening as a pain modulation intervention, and serve as a foundation to inform larger studies in the future. This study will employ innovative methods, including an inexpensive neuroimaging technique (functional near-infrared spectroscopy) to evaluate pain-related neuroimaging biomarkers and provide an objective assessment of the analgesic effect of listening to music. Because music is a readily available, portable, non-invasive, easy-to-administer, and relatively inexpensive intervention, older adults are likely to benefit from it since this can be conveniently administered at home.

Reviewer comments. All reviewer comments have been addressed in this version. Thank you.
Specific Aims

Low back pain (LBP) is a complicated, multidimensional, and widespread problem that has gained attention as a leading cause for an increase in healthcare utilization among older adults, aged 65 years and older. LBP is one of the leading causes of functional limitation and disability in older adults and a contributor to years lived with disability among older adults aged 65 years and older. Although current treatment guidelines recommend nonpharmacologic interventions as the first-line therapy for LBP, the routine use of pharmacologic therapies, including opioids, as first-line therapy for LBP is rampant in practice. However, prescription opioid use has been linked to several negative outcomes including addiction and death; therefore, a paradigm shift toward nonpharmacologic therapies for managing LBP is imperative. Some nonpharmacologic interventions including music listening have documented mechanisms of action that are better suited to target the neurophysiological mechanisms associated with LBP. Music listening is hypothesized to modulate pain by stimulating the release of endogenous opioids to trigger the activation of the descending pain modulation system to inhibit the nociceptive stimulus centrally in the brain stem and spinal cord. Music is a safe, non-invasive, easy-to-administer, portable, and relatively inexpensive intervention that has been used to relieve pain in many conditions. Music with a tempo between 60-80 beats per minute is considered to be calming and effective in reducing pain. Also, recent evidence suggests that listening to one's preferred style of music, which is influenced by a person's cultural background, social interactions, and personal experiences, may be more effective in reducing pain.

Nonetheless, only a limited number of studies have investigated the pain modulation effects of listening to preferred style of music. The goal of this study is to examine the feasibility and acceptability of listening to 20 minutes of preferred style of music twice-daily for 4 consecutive days on pain among 10 community-dwelling older adults (65+ years) with LBP. The central hypothesis is that listening to preferred music may reduce clinical pain and change pain-related physiological responses in older adults with LBP. The rationale for the proposed research is that an objective assessment of the magnitude of change in selected pain physiological parameters may provide relevant information on the analgesic effect of listening to one's preferred style of music. The result of this study will provide valuable knowledge of the underlying mechanism behind music-induced pain modulation in older adults with LBP.

**Aim 1.** Determine the feasibility of music listening intervention on pain among community-dwelling older adults (65+ years) with LBP. We will track enrollment and attrition rates and determine the acceptability of music intervention. Feasibility will be assessed by tracking the rates of enrollment, attrition, and adherence: (1) enrollment rate = number enrolled/number who met inclusion criteria, (2) attrition rate = number not completing the study/number enrolled at baseline, and (3) adherence rate = number completing all measures/number enrolled.

**Aim 2.** Determine the acceptability of music listening intervention on pain among community-dwelling older adults (65+ years) with LBP. The perceived acceptability of the study protocol to participants will be evaluated using the treatment acceptability and preference (TAP) scale which has demonstrated evidence of reliability and validity in prior research. Additional attributes of pleasantness, intent to continue use, perceived negative effects, success or failure of execution, and possible side effects of treatment will be assessed. Further, we will also obtain data, as an exploratory aim, to investigate whether music intervention changes clinical pain (NRS), cortical hemodynamic activation in response to pain (fNIRS), heart rate variability (HRV), and conditioned pain modulation (CPM).

This study will provide valuable information on music listening intervention and guide future larger-scale randomized clinical trials of this promising intervention for older adults with LBP and other chronic pain conditions.
Setor Kofi Sorkpor

Significance
In response to the nationwide opioid crisis, limiting the use of prescription opioids to manage pain in older adults is vital, given the high likelihood of dependence with extended use. LBP is considered a leading cause of functional limitation and disability in older adults age 65 years and above and also a major cause of years lived with disability. The estimated annual economic burden of LBP is in the excess of $87 billion. It is, therefore, critical to identify more judicious and effective therapies to manage LBP in older adults without compromising their health and quality of life. The recent public debate on prescription opioid abuse and the negative consequences associated with prescription opioids offers enough reasons to investigate the rationale behind the nonadherence to the recommended treatment guidelines for managing LBP in older adults.

This proposed study will be informed by the biopsychosocial model of pain, which posits that pain is the result of the complex interaction with multiple factors. Using passive music listening as an intervention, we seek to modulate pain through mechanisms that will disrupt the interactions within and between the constructs of the model.

Innovation
The proposed study is innovative from several key perspectives in that it: (1) Proposes using a home-based, remotely delivered intervention with real-time monitoring via a secured video conferencing interface to ensure adherence to study protocol. Because older adults with LBP have limited mobility that could restrict their access to clinic-based interventions, home-based interventions provide feasible and practical solutions to their pain problems. (2) Will be among the first to use the innovative "U sequence" styles of music to reduce pain in community-dwelling older adults (65+ years) with LBP. Music is safe, non-invasive, easy-to-administer, portable, relatively inexpensive, and readily available. The "U sequence" approach steadily guides participants through three distinct phases of (i) steady reduction of the musical rhythm, frequency, and volume, (ii) maximum relaxation, and (iii) revitalizing stage into a state of relaxation. (3) Is the first to combine multiple observer-independent methods such as fNIRS, HRV, and CPM to explore physiological parameters to objectively measure pain in community-dwelling older adults (65+ years) with LBP. The Principal Investigator (PI) has produced a first-author published in the "NIRS methodology" and co-authored peer-reviewed publications involving CPM and quantitative sensory testing. The use of these innovative observer-independent physiological parameters to assess pain is beneficial to this population because the widely accepted self-reporting pain assessment methods may not be applicable in older adults who are not able to process and communicate their pain due to cognitive impairment.

Study Design and Methods
Study Design. This is a single-center, open-label, single-arm, longitudinal study design with 4 days of twice-daily 20 minutes sessions of remotely supervised home-based listening to preferred style of music as an intervention for pain in older adults (65+ years) with LBP.

Music Intervention. Individual receptive relaxation music method will be used with participants selecting music based on their preference from a selection of various styles from the MUSIC CARE® app. MUSIC CARE® offers individualized music intervention sessions using a standardized protocol that conforms with international scientific guidelines. The music intervention will last 20 minutes per session and will be administered twice daily for 4 consecutive days. This duration was chosen based on prior research. Participants will be given an electronic tablet with the MUSIC CARE® app loaded on it and trained on how to access the app to select their preferred style of music. Participants will be instructed to use the provided headphone during all interventions and to sit in a quiet area while wearing an ocular mask to avoid distractions. The sequence of the music will be broken down into several phases
following the innovative "U sequence" method. The music sequence construction will be explicitly constructed for this study by the Music Care (Paris, France) company. Dr. Stéphane Guetin, President and CEO of Music Care has agreed to provide this service at no cost.

Setting and Sources of Subjects. The study will take place at Dr. Ahn's laboratory located in the Czik School of Nursing at UT Health Science Center at Houston. Participants will be recruited from the community, outpatient clinics of a large teaching hospital in the Houston metro area, and social media. Potential participants contacting the PI will be screened in person or over the phone for eligibility. Those meeting the inclusion criteria will be scheduled to meet with the PI at the study center at an agreed date and time. Community-dwelling individuals (both male and female) 65 years and older will be considered eligible if they (1) have a self-report of LBP, (2) have LBP in the past 3 months with an average rating of at least 30 on a 0 - 100 NRS for pain, (3) have intact cognition, (4) have no plans to change their pain medication regimens during the study time, (5) can read and understand English, (6) can travel to the study center, and, (7) agree to sign an informed consent. Participants will be excluded if they (1) are deaf or have severe hearing loss, (2) are pregnant or lactating, (3) have an implantable pain-reducing device, (4) have a history of hospitalization within the preceding year for psychiatric illness, (5) have a diagnosis of Raynaud's disease, (6) have a functional limitation that requires the use of an ambulatory aid such as a cane, walker, or wheelchair; and (7) have a history of brain surgery, brain tumor, or stroke, and (8) a Mini-Mental State Examination score less than 24. 85

Recruitment and retention strategies. Based on previous home-based studies in older adult populations in Dr. Ahn's laboratory, 82,86 several strategies will be employed to mitigate attrition and increase adherence to the study protocol. These strategies include establishing and maintaining a strong relationship with people in the community, real-time monitoring of each intervention session via secure videoconferencing software (e.g., WebEx), reminding participants to fill out the outcome measures, reimbursing participants for the cost of parking, and offering compensation to incentivize participants to remain in the study.

Sampling Method & Sample size. Participants meeting the inclusion criteria will be recruited into the study between September 1, 2020, through December 31, 2020. To the best of our knowledge, there is no evidence of prior studies using the physiological parameters as we proposed to examine the effect of listening to preferred music on pain in adults (55+ years) with LBP. Due to this gap in the literature, an accurate calculation of statistical power is impossible. Nevertheless, since the purpose of this study is to establish feasibility, a sample size of 10 participants is considered a feasible number to enroll within a reasonable time to meet the purpose of the study. Given a significance level 0.05 without Bonferroni correction and a sample size n=10, the calculated power based on an effect size 0.8 is 0.62.

Method of Data Collection. At the entry point to the study, participants will be assessed for their understanding of the informed consent process, after which the MiniMADRS will be administered to assess their cognitive function. Other baseline measures will be collected as indicated in table 1. Participants will then be provided with study equipment and supplies (a tablet preloaded with the MUSIC CARE® app, headphones, NRS, PROMIS anxiety, PROMIS depression, an ocular mask, and instructions). Participants will also be trained on how to use the MUSIC CARE® app, video conferencing software, and how to complete the three validated outcome measures (NRS, PROMIS anxiety, PROMIS depression). The home music interventions will be done twice daily for four consecutive days with all sessions being remotely monitored by the PI via a secured video conferencing interface to ensure adherence to the protocol. Post-intervention data collection will be collected in-person in Dr. Ahn's laboratory as reflected in table 1. Table 1 summarizes the timetable for the collection of data.

Ethical considerations. Ethical approval for this study will be sought from the UT Health Institutional Review Board before commencement. Written consent will be required before enrolling in the study. All study procedures will be carried out following strict infection contri
protocol to mitigate the risk of contracting or spreading possible communicable diseases such as COVID-19.

Table 1. Timetable for Collection of Data

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Table 1. Timetable for Collection of Data

<table>
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<th>Measurements/Instruments</th>
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| The Mini-Mental Status Examination (MMSE) is a copyrighted assessment instrument that provides a quick and simple way to assess cognitive function and screen for cognitive loss. The MMSE is an 11-item assessment that has demonstrated validity and reliability in geriatric populations. The MMSE is a paper and pencil test that takes about 15 minutes to complete with scores ranging from 1 to 30. The conventional cut-off score is 24 with a score lower than 24 indicating cognitive impairment.

Sociodemographic information will be collected using a paper-and-pencil form specifically created for this study. The questionnaire will capture information on age, gender, race, marital status, level of education, and employment status.

The Numeric Rating Scale (NRS) is designed to measure pain intensity in adults. The 11-point iteration of the NRS will be used. The NRS has demonstrated evidence of reliability and validity in adult populations. The reliability of NRS in chronic pain patients is estimated at $r = 0.95$ with a good correlation with the visual analog scale estimated at $r = 0.71$ to $r = 0.78$. The NRS is scored by asking the respondent to select a number on the continuum from 0 indicating “no pain” to 100 indicating “worst imaginable pain ever.”

PROMIS Short Form v1.0 - Emotional Distress: Anxiety Short Form. 8a is a paper and pencil-based scales that are scored on a 5-point scale (1 = never to 5 = always). It consists of 8-items that measure “fear, anxious misery, hyperarousal, and somatic symptoms related to arousal.” Participants respond by indicating the number of times they have experienced emotions such as fearfulness, overwhelmedness, nervousness, and anxiousness over the last seven days. Both scales have demonstrated acceptable evidence of reliability and validity and have been used in multiple chronic pain studies. This scale has demonstrated acceptable evidence of reliability and validity and has been used in multiple chronic pain studies.

PROMIS Short Form v1.0 - Emotional Distress: Depression 8b is a paper and pencil-based scales that are scored on a 5-point scale (1 = never to 5 = always). It consists of 8-items that measure “negative mood, decrease in positive affect, information processing deficits, negative views of the self, and negative social cognition.” Participants respond by indicating the number of times they have experienced negative affects such as worthlessness, unhappiness, and hopelessness over the past seven days. This scale has demonstrated acceptable evidence of reliability and validity and has been used in multiple chronic pain studies.

Functional Near-Infrared Spectroscopy is a noninvasive, portable, and inexpensive optical imaging method that directs low power light in the near-infrared spectrum (700–1000 nm wavelength) through the scalp to examine blood oxygenation level-dependent response of brain tissue. PI has produced peer-reviewed a publication about fNIRS methodology. Because oxy/hemoglobin and deoxyhemoglobin have different absorption maxima, variation in the ratio of
Setor Kofi Sorkpor

Oxyhemoglobin to deoxyhemoglobin in the brain can be calculated. A decrease in hemodynamic response will indicate a decrease in pain. A continuous-wave, multichannel NIRS imaging system (LIGHTNIRS, Shimadzu, Kyoto, Japan) comprising of an array of eight sources and eight detectors will be used in this study with optodes arranged bilaterally over the motor and somatosensory cortical areas of the scalp. This optode arrangement is chosen to be consistent with a previous publication written by Sorkpor, Ahn, Pollonni, Do.

Heart Rate Variability (HRV) represents the variations in a heartbeat on a time interval. These variations in heart rate result from complex, nonlinear interactions among several different physiological systems. HRV, therefore, provides an indirect measure of heart-brain interactions and dynamic non-linear autonomic nervous system processes. An increased HRV indicates proper functioning of the central autonomic network which is critical for the activation of pain inhibition pathways in the central nervous system. HRV will be obtained per recommendations from the European Society of Cardiology and North American Society of Pacing and Electrophysiology Task Force using lead II arrangement with the MP160 equipment (Biopac Systems, Inc., Goleta, CA, USA).

Conditioned Pain Modulation (CPM) is an indirect method of measuring pain processing that is presumed to indicate the function of the descending pain modulation pathway. CPM is assessed as a change in pain perceived in one body region (test stimulation) as a result of pain-induced in another body region (conditioned stimulation). The CPM paradigm has reported evidence of good intersession reliability with intra-class coefficients of 0.75. This study will evaluate the pressure pain threshold before and after the conditioned stimulation. CPM will be determined as a change in pressure pain threshold on the lower back, 5 cm to the left of the median line on the intercrystal line (the Jacoby line) using a hand-held digital pressure algometer (Wagner, Greenwich, CT, USA) while the participant lays in the prone position on a massage bench.

Treatment Acceptability and Preference (TAP) scale is a self-report Likert-style scale that measures perceived acceptability of an intervention in terms of four characteristics of (1) appropriateness, (2) effectiveness, (3) suitability as a treatment, and (4) willingness to adhere, on a scale ranging from 0 (not at all) to 4 (very much). The total TAP scale score is obtained by taking the mean score of each of the items. The TAP scale has demonstrated internal consistency reliability (Cronbach alpha > 0.8) and factorial validity in prior research. An additional section will be added to the TAP to evaluate the following variables on a similar scale: pleasantness, intent to continue use, perceived negative effects, and success or failure of execution with one open-ended question to collect information on possible side effects.

Methods of Data Analysis: Descriptive statistics for demographic data will be computed using SAS v9.4 (SAS Institute Inc., Cary, NC). The normality assumption will be assessed by the Shapiro-Wilk test and visual inspection of the Q-Q plot. Outliers will be identified using the Median Absolute Distance and handled for conclusion robustness. Feasibility and acceptability outcomes will be described using summary statistics, including mean with standard deviation, median with interquartile range, frequency, percentages, as well as the corresponding 95% confidence intervals when appropriate. Also, a one-sample proportion test will be performed to verify whether these rates are significantly different from zero. For exploratory data analysis, we expect that LDP (NRS) will show lower pain scores post-intervention compared to baseline. We will derive summary statistics of the baseline and final measures of NRS and compare the means to understand the changes in NRS before and after music intervention. While we recognize that the small sample size may prevent us from achieving any statistical significance, we will conduct a repeated-measures ANOVA to examine the effect of listening to preferred music on pain over time. If the assumptions of repeated-measures ANOVA is violated, the Friedman test will be used. Absolute effect sizes between the baseline and final measures will be evaluated to establish the level of difference between the baseline measures and the final measure. Also, we expect that cortical hemodynamic response to pain will be
reduced post-intervention. The NIRS Brain AnalyzIR Toolbox will be used to analyze the acquired data. The raw NIRS data will be imported into the NIRS Brain AnalyzIR Toolbox software, which is an open-source Matlab-based analysis package for NIRS data management, pre-processing, and first- and second-level analysis. The data will be pre-processed (resampling, conversion to optical density, and the application of the modified Beer-Lambert law). The preprocessed data will then be analyzed by comparing the summary statistics of the baseline fnNIRS measures with those of the final fnNIRS measure. Next image reconstructions of the brain will be generated for both measures. In addition, we expect that HRV will be increased post-intervention. AcqKnowledge version 5.0 signal analysis software (Biopac Systems, Inc, Goleta, USA) will be used to evaluate the ECG data. The ECG data will be cleaned to remove artifacts, such as irregular heartbeat activity to eliminate interference with the software's ability to identify distances and times between consecutive R-waves from the ECG data. Tachograms will be created for visual inspection and where applicable a data correction factor will be applied. Time-domain HRV parameter such as the standard deviation in R-R length (SDNN) and root mean squared of successive differences (RMSSD) will be computed. Similarly, frequency-domain HRV parameter including low frequency, high frequency, and their ratios will be computed. We will compare the baseline HRV measures with the post-intervention measure. Moreover, we expect that conditioned pain modulation will be increased while participants listen to preferred music. We will compare the summary statistics of the baseline CPM measures and the final CPM measures, and absolute effect sizes between the two measures will be evaluated to establish the level of difference.

Collaborative Team. Setor K Sorkpor, MSH, MPH, is a Ph.D. candidate at Cizik School of Nursing at UT Health Science Center at Houston with one first-authored peer-reviewed publication and 4 co-authored peer-reviewed publications focused on nonpharmacological pain intervention with my mentor (Dr. Ahn). Additionally, I currently have a systematic review paper on music listening under review. Hyochol Ahn, Ph.D., is an associate professor and Tumble professor in aging at the Cizik School of Nursing at UT Health Science Center at Houston. Dr. Ahn has sufficient expertise in pain focused research in the older adult population using quantitative research methods such as conditioned pain modulation to evaluate pain. Constance Johnson, Ph.D., is an associate dean for research at Cizik School of Nursing at UT Health Science Center at Houston. Dr. Johnson has over 25 years of experience in research and informatics in the area of health promotion and disease prevention. Hongyu Miao, Ph.D., is an associate professor in the department of biostatistics and data science at the School of Public Health at UT Health Science Center at Houston. Dr. Miao’s expertise in the use of cutting-edge biostatistics, computational, and quantitative data science approaches in biomedical and health science research and practice. Luca Pollonini, Ph.D., is an assistant professor at the College of Technology at the University of Houston in Houston. Dr. Pollonini has expertise in the quantitative assessment of the mechanisms of transport and utilization of oxygen at cardiovascular and muscular levels using optical technologies (fnNIRS). Carolyn Moore, Ph.D., is an assistant professor of music therapy at Sam Houston State University. Dr. Moore is a board-certified music therapist with extensive experience serving individuals with a variety of needs including pain in healthcare and other settings.

Limitation. Since this is an open-label design, placebo response rates can be high; therefore, to compensate for this, objective measures of pain using fnNIRS, HRV, and CPM will be pursued. Summary. This study will be among the first to investigate remotely supervised preferred style of music intervention for pain management in community-dwelling older adults 65 years and above with LBP. Findings from this study will provide important feasibility and acceptability data necessary to design a larger, adequately powered randomized, double-blind, placebo-controlled trial. We intend to seek NIH funding for future studies originating from this feasibility study.
Setor Kofi Sorkpor

References


Setor Kofi Sorkpor


# Requested Budget

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<td>$100</td>
</tr>
<tr>
<td>Lab supplies (gloves, disinfectant wipes, stationery, paper towel, hand sanitizer)</td>
<td>1</td>
<td>$350</td>
<td>$350</td>
</tr>
<tr>
<td>2 pack of disposable massage table cover sheet (pack of 20)</td>
<td>2</td>
<td>$50</td>
<td>$100</td>
</tr>
<tr>
<td>2 pack of disposable gown for the privacy of participants (packet of 10)</td>
<td>2</td>
<td>$90</td>
<td>$180</td>
</tr>
<tr>
<td><strong>Compensation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parking voucher to participants (2 visits for study participation X $10/visit)</td>
<td>20</td>
<td>$8</td>
<td>$160</td>
</tr>
<tr>
<td>An incentive to participants for participating ($10 per intervention session X 8 sessions, $40 for each data collection visit X 2 times)</td>
<td>10</td>
<td>$160</td>
<td>$1600</td>
</tr>
<tr>
<td><strong>TOTAL COST</strong></td>
<td></td>
<td></td>
<td>$10,000</td>
</tr>
</tbody>
</table>
Appendix C

Study Recruitment Flyer
Do you suffer from **Low Back Pain**?

*You may qualify to take part in a research study!*

**Do you have low back pain?** If so, you may qualify to take part in a research study testing a nonpharmacologic intervention for reducing pain if you:

* Are an adult age 65 years and older
* Have good hearing and able to listen to music with or without hearing aid
* Able to understand English
* Please contact us

**Benefits may include:** Relief from pain.
**Risks may include:** Temporal discomfort.

Participation in this study will require two visits to our study center, located in the Texas Medical Center. Participants may be compensated for their time and travel.

This study is being conducted by

**UTHealth**

Cizik School of Nursing
6901 Bertner Ave. SON 564
Houston, TX 77030

Phone: 713-500-5000
Fax: 713-500-0266

For more information, contact

Email: Setor.K.Sorkpor@uth.tmc.edu

[UTHealth Logo]
Are You 65 years or older?

You may be eligible to participate in a research study being conducted at the University of Texas Health Science Center at Houston. The study is examining pain responses to music in adults with low back pain. Participation in this study will require two visits to our study center located in The Texas Medical Center. Monetary compensation provided.

To be eligible you must be:
- 65 years or older
- Free from serious medical conditions
- Able to come for two testing sessions

For further information call: Music and low back pain study at 281-4860. Please leave a message if no response.
Appendix D

Study Informed Consent
Study Informed Consent

CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: Listening to Preferred Music to Alleviate Low Back Pain in Older Adults

Full Study Title: Feasibility and Efficacy of Remotely Supervised Home-based Listening to Preferred Music for Pain in Older Adults with Low Back Pain: A Pilot Study of Feasibility and Acceptability.

Principal Investigator: Setor K. Sorkpor, MPH, MSN, RN-BC, Ph.D. Candidate at Cizik School of Nursing

Study Contact: Setor K Sorkpor, 281-922-4800

PURPOSE

The purpose of this study is to see how well listening to one’s preferred style of music works on pain in older adults aged 65 years and above with low back pain. The music will be specially recorded in a format that will promote relaxation and make listening pleasant.

This study will also determine the feasibility and preliminary efficacy of listening to one’s preferred music two times a day for four consecutive days on pain. You have been invited to join this research study because you are 65 years or older and you have low back pain. Participation in this research study is voluntary. If you choose to participate in this study, the principal investigator will train you on how to navigate the MUSIC CARE® app to select your play list.

Listening to one’s preferred style of music has been shown to reduce pain in some older adults. The rationale behind this study is that listening to one’s preferred music can produce a calming effect on the body which could help increase a person’s pain tolerance and possibly reduce the sensation of pain. This study will be conducted by Setor K Sorkpor (referred to as the Principal Investigator or PI) as part of dissertation research at Cizik School of Nursing at the University of Texas Health Science Center at Houston (UTHSC).

PROCEDURES

If you choose to participate in this study, you will be asked to sign a consent indicating your understanding of the study before undergoing these study procedures: During the one week study period, you will be asked to make a total of two visits to our research center at the Cizik School of Nursing at UTHSC. Each visit will last for approximately 1 hour. There will be a baseline visit, followed by four days of self-administered remotely supervised home sessions, and a second visit to our research center exactly five days from the baseline visit. At each study visit, you will participate in the following activities:

Contact Names Setor Kofi Sorkpor
Telephone: 281-922-4800

IRB NUMBER: HSC-SN 20-1992
IRB APPROVAL DATE: 11/03/2020
Informed Consent Listening to Preferred Music to Alleviate Low Back Pain in Older Adults

- Questionnaires: We will ask you to fill out a few questionnaires to help us understand your experience with low back pain, your thoughts and feelings about it, and any stress that you may have experienced.
- Assessment of Sensitivity to Pressure: We will use a handheld device with a small (less than 1/2 inch wide) rubber tip to apply pressure to your lower back. The pressure will be slowly increased, and you will be asked to tell the examiner when you begin to feel discomfort or mild pain. As soon as you tell us you feel pain, the pressure will be stopped.
- Assessment of Sensitivity to Combined Pressure and Cold: For the pressure sensitivity test, we will use a handheld device with a small (less than 1/2 inch wide) rubber tip to apply pressure to your lower back. The pressure will be slowly increased, and you will be asked to tell the examiner when you first feel pain, and the pressure will be removed. Immediately following that, we will ask you to do a cold test, by putting your hand up to the wrist in cold water and telling us how painful it feels. We will repeat the pressure sensitivity test while your hand is in the cold water and after you take your hand out of the cold water. We will perform this test at baseline and after listening to your preferred music.
- Listening to your preferred style of music: You will listen to your preferred style of music recordings via earphones from the MUSIC CARE® app on a tablet. You will select music that you feel will promote your relaxation and enhance your mood, feelings, and emotion from the MUSIC CARE® app.
- Non-invasive Brain Imaging: Functional near-infrared spectroscopy is an optical method that measures blood flow in the brain by illuminating your scalp with harmless light. You will be wearing an elastic cap that carries 8 light sources and 8 light detectors that will be in contact with your skin. You will feel a light pressure when these elements are placed on top of your scalp, but you will not feel anything when light is turned on and shone into your head. Some people may experience some discomfort due to the prolonged wearing of the cap. It is highly unlikely that you will feel any discomfort due to the objects touching your scalp. You can ask the experimenter to stop the experiment at any time if you feel uncomfortable. We will perform this assessment at baseline and during the time you listen to your preferred music.
- Heart Rate Variability: We will attach small pads (electrodes) to your chest wall (similar to those used for EKG) to record the intervals between your heartbeats. We will perform this assessment at baseline and during the time you listen to your preferred music.
- Laying in the Prone: Because we want to assess how music may affect low back pain, we will be simulating the low back pain by applying minimal pressure to your lower back. We will have you lie in the prone position (face down) on a massage table during this process. You will have pillow support under your knees, and elbows for comfort. The entire duration of laying prone should not be more than 10 minutes.

In addition to the study visits, you will be provided with a tablet, a headphone, and an ocular mask for the at-home music listening sessions. The tablet will be preloaded with the MUSIC CARE® app. You will be trained on how to use all the supplied items including how to select your preferred style of music. You will also be trained on how to connect with the principal investigator via video conferencing. Then, for four days, we will ask you to listen to your

Contact Name: Setor K Sorkpor  
Telephone: 281-922-4800  
UTHouston

IRB NUMBER: HSC-527-20-1092  
IRB APPROVAL DATE: 11/03/2010
preferred style of music at home two times a day for 20 minutes each while we monitor you through a secure video conferencing platform to answer questions and can help if there are any problems. After each music listening session, you will be asked to rate your average pain on a pain score sheet we will provide to you. Your participation in this research project will last for

TIME COMMITMENT

Your participation in this research project will last for about one week and will include two visits to our study center at the Cizik School of Nursing at UTHealth. Each visit will last for approximately 1 hour.

BENEFITS

You may or may not benefit from participating in this study; however, your participation in this study may help inform future studies aimed at finding better ways to treat pain in older adults in the future. This study will help us to understand whether listening to preferred music is beneficial to reducing pain in older adults with low back pain. Subsequently, findings from this study might lead to better therapies for low back pain patients.

RISKS AND/OR DISCOMFORTS

While on this study, you are at risk for side effects. The study team member will discuss these risks with you. This study may include risks that are unknown at this time.

This study might involve the following risks and discomforts to you:

- Questionnaires. You may be fatigued by answering some or all the questions on the questionnaires. You do not have to answer any questions you do not want to answer.
- Assessment of Sensitivity Pressure and Cold. The pain testing procedures may be uncomfortable or unpleasant. You will experience some temporary discomfort from the pressure and cold pain testing. The pressure applied will be based on your tolerance level. However, if you feel the pain is greater than you wish to tolerate, you can stop any of the procedures at any time.
- Noninvasive brain imaging. Near-infrared light is a non-visible, non-harmful type of light that is deemed safe for lighting human tissues. You may experience temporary discomfort while wearing the cap for a certain amount of time, particularly due to the tips of the optical fibers being in contact with your scalp. However, this is a lightweight cap and you can request for the test to be discontinued at any time.
- Possible risks associated with breach of confidentiality.

STUDY WITHDRAWAL

Your decision to take part in this study is voluntary. You may decide to stop taking part in the study at any time. Should you decide not to take part or to withdraw from the study, this will not change the services available to you. The person in charge of this study, also referred to as the

Contact Name: Setor K Sorkpor
Telephone: 281-922-4860

IRB NUMBER: M-20-1092
IRB APPROVAL DATE: 11/03/2020
principal investigator (Setor K Sorlagor) may also withdraw you from the research study for reasons such as failure to comply with the instructions, failure to complete all testing sessions, development of adverse condition that could interfere with your continued participation, or if the investigator determines that it is not in your best interest to withdraw you from the study. Should you withdraw from the study, your research information will no longer be collected from that point onwards, however, information that has already been collected will continue to be used to retain integrity of the research data.

IN CASE OF INJURY

If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You should report any such injury to Setor K Sorlagor at 281-922-4860. You will not give up any of your legal rights by signing this consent form.

COSTS, REIMBURSEMENT, AND COMPENSATION

If you decide to take part in this research study, you will not incur any additional costs. You will be paid for your participation in this study. You will be reimbursed for parking in the Texas Medical center garage with a parking voucher valued at $8 per visit. You will be paid $5 for each 20-minute music listening session completed and an additional $30 for each visit to our testing center. So, the total amount you will be paid for completing all study procedures is $100 in gift cards upon completion of this study, and you will receive a partial payment if you do not complete the entire study. The partial compensation amount will be determined as a percentage of the study completed.

If you receive payment for taking part in this study, please be informed that you will be asked to complete a copy of W-9 form that will be forwarded to the accounting department as a requirement by the Internal Revenue Service. You will also be issued a 1099-Misc form from this study for tax reporting purposes.

CONFIDENTIALITY

Your privacy is important and your participation in this study will be kept confidential to the extent possible. Please understand that research data without your personal identifiers such as name and address, may be shared with researchers outside UTHouston without your additional informed consent.

Clinical Trials, Gov. Language: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contact Names: Setor K Sorlagor
Telephone: 281-922-4860

IRB Number: MSc-20-1092

IRB Approval Date: 11/03/2020
NEW INFORMATION

Throughout the study, the PI will notify you of new information that may become available and might affect your decision to remain in the study. While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study. They will notify you of this information via phone.

QUESTION

If you have questions at any time about this research study, please feel free to contact the Setor K Sorkpor at 281-922-4860, as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject | Signature of Subject | Date | Time
---|---|---|---

Printed Name of Person Obtaining Informed Consent | Signature of Person Obtaining Informed Consent | Date | Time
---|---|---|---

Contact Name: Setor K Sorkpor
Telephone: 281-922-4860

IRB NUMBER: HSC-SN-20-1092
IRB APPROVAL DATE: 11/03/2020
CURRICULUM VITAE
Setor K. Sorkpor, Ph.D. (c) MPH, MSN, RN-BC
6901 Bertner Ave. Houston, TX 77030
sksetor@yahoo.com

EDUCATION

<table>
<thead>
<tr>
<th>Degree</th>
<th>Institution</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>PhD. Nursing (anticipated)</td>
<td>The University of Texas Health Science Center at Houston – Cizik School of Nursing</td>
<td>June 2022</td>
</tr>
<tr>
<td>Post Masters certification in Nursing Education</td>
<td>The University of Texas Health Science Center at Houston – Cizik School of Nursing</td>
<td>August 2018</td>
</tr>
<tr>
<td>Master of Science in Nursing, Nursing Informatics Track</td>
<td>Texas Tech University Health Science Center, Lubbock, Texas</td>
<td>December 2015</td>
</tr>
<tr>
<td>Master of Public Health (MPH) Environmental and Occupational Health focus</td>
<td>The University of Texas Health Science Center at Houston – School of Public Health</td>
<td>December 2012</td>
</tr>
<tr>
<td>Graduate Certificate in Public Health</td>
<td>The University of Texas Health Science Center at Houston – School of Public Health</td>
<td>December 2010</td>
</tr>
<tr>
<td>Bachelor of Science in Nursing</td>
<td>The University of Texas Medical Branch. Galveston, TX.</td>
<td>April 2006</td>
</tr>
<tr>
<td>Diploma in Marine Engineering</td>
<td>Regional Maritime University, Accra Ghana</td>
<td>June 2001</td>
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LICENSURE & CERTIFICATION

<table>
<thead>
<tr>
<th>License</th>
<th>Certifying Body/ State</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Nurse, 727305</td>
<td>Texas</td>
<td>October 2022</td>
</tr>
<tr>
<td>Certified Informatics Nurse 2014001765</td>
<td>American Nurses Credentialing Center</td>
<td>July 2025</td>
</tr>
<tr>
<td>BLS for Healthcare Provider</td>
<td>American Heart Association</td>
<td>July 2022</td>
</tr>
<tr>
<td>ACLS for Healthcare Provider</td>
<td>American Heart Association</td>
<td>July 2022</td>
</tr>
</tbody>
</table>
RESEARCH INTERESTS

Quantitative and experimental research methods in behavioral and biobehavioral studies. The use of home-based interventions such as music delivered via wearables, smartphone-based mobile applications, and other consumer-facing devices, the application of emerging technology such as non-invasive brain stimulation (ex. Transcranial Direct Current Stimulation [tDCS]); neuroimaging techniques (ex. functional near-infrared spectroscopy [fNIRS]); Quantitative Sensory Testing (QST); and the use of physiological and biological markers to understand the manifestation of chronic health conditions and promote the health and well-being of vulnerable and underserved populations such as older adults with chronic health conditions.

RESEARCH EXPERIENCE

Graduate Research Assistant, 01/2018 – 09/2021
University of Texas Health Science Center at Houston - Jane and Robert Cizik School of Nursing. Brain Stimulation and Imaging Laboratory (Dr. Ahn) – Houston TX

- Collaborate with the principal investigator and other faculty and students across different departments to conduct interdisciplinary research primarily in older adults.
- Collaborates and coordinates with faculty, staff scientists, and fellow graduate students across institutions and departments to author manuscripts for publication.

TEACHING EXPERIENCE

Adjunct faculty, 08/2018 – Present
The University of St. Thomas, Carol and Odis Peavy School of Nursing - Houston TX

- Instructor of an on-line undergraduate two-credit hour course that introduces students to basic concepts and tools associated with the structure, management, and communication of information to support the role of the nurse as a knowledge worker.
- The course emphasizes the use of clinical information systems, electronic health records, and telecommunication technologies in nursing.

Adjunct faculty, March 2014 – 06/2015
The University of Phoenix (Online)

- Instructor of a capstone course for final year students: HCIS/2715 Practical Applications of Electronic Health Records.
This course is designed to give students the opportunity to use case studies and an electronic health record (EHR) software application to develop foundational skills related to data charting, usage, and application.

### PROFESSIONAL POSITIONS

<table>
<thead>
<tr>
<th>Organization</th>
<th>Position Held</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjunct Faculty</td>
<td>Adjunct Faculty</td>
<td>2018 - Present</td>
</tr>
<tr>
<td>Houston Methodist Hospital</td>
<td>Application Analyst</td>
<td>2017 – 2021</td>
</tr>
<tr>
<td>Capstone Informatics Consulting</td>
<td>Senior Informatics</td>
<td>2013 - 2017</td>
</tr>
<tr>
<td>Consultant</td>
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<tr>
<td>University of Phoenix</td>
<td>Adjunct faculty</td>
<td>2014 - 2015</td>
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<tr>
<td>maxIT-VCS Healthcare (Client: Alberta Health Services, Calgary, Canada)</td>
<td>Senior Informatics</td>
<td>2013 - 2013</td>
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<tr>
<td>Consultant</td>
<td></td>
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<tr>
<td>ESD (multiple clients throughout the United States)</td>
<td>Independent EMR</td>
<td>2012 - 2013</td>
</tr>
<tr>
<td>Consultant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoag hospital Presbyterian, Newport Beach</td>
<td>Clinical Adoption</td>
<td>2011 - 2011</td>
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<tr>
<td>Consultant</td>
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<tr>
<td>Houston Methodist Hospital</td>
<td>Clinical Systems Analyst</td>
<td>2009 - 2011</td>
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<tr>
<td>Registered Nurse</td>
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</tr>
</tbody>
</table>

### HONORS AND AWARDS

- Sigma Theta Tau International 2018 – Present
- Member, Texas Tech University - Honor Society of Phi Kappa Phi 2016 - Present
- First Place Award. Best Data Analytics Project Presentation from the Texas Tech University Health Science Center, Lubbock, Texas. 2015

### GRANTS

**Role, Project Title, Funding Agency, Amount**

Principal Investigator. *Feasibility and Efficacy of Remotely Supervised Home-based Listening to Preferred Music for Pain in Older Adults with Low Back Pain.* Center for Nursing Research, Cizik School of Nursing. Total: $10,000. 2020


**PRESENTATIONS**

1. Brown, L., Christy, L., Gideon, C., Nichols, A., & **Sorkpor, S.** (2017, April). Suicide ideation and risk factors: examining the tenth leading cause of death in the United States, Poster session presented at The University of Texas Houston Health Science Center School of Nursing, Houston, TX.


**TECHNICAL SKILLS**

- Data visualization utilizing Tableau
- SPSS, EMR Data extraction
- fNIRS data analysis
- Microsoft Visio