

COVER PAGE FOR PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official Study Title: The Effects of a Music Intervention on Stress, Anxiety and Academic Performance on Nursing Students

NCT number: NCT05590910

IRB Approval Date: 05.23.2022

Unique Protocol ID: HSC20210672H

Protocol Template Form

Item 1 UTHSCSA Tracking Number	HSC20210672H: The Effects of a Music Intervention on Stress, Anxiety and Academic Performance on Nursing Students
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Item 2 Abstract / Project Summary	Provide a succinct and accurate description of the proposed research. State the purpose/aims. Describe concisely the research design and methods for achieving the stated goals. This section should be understandable to all members of the IRB, scientific and non-scientific. DO NOT EXCEED THE SPACE PROVIDED.
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Purpose/Objectives: The purpose of this study is to assess whether a music intervention, compared with no music intervention, influences stress and anxiety levels and academic performance of undergraduate nursing students.

Research Design/Plan: A randomized controlled approach will explore the effects music has on stress and anxiety levels and academic performance among undergraduate nursing students.

Methods: Students will be divided and randomized into two recording groups: 1.) Music Intervention Group, 2.) Non-Music Control Group. The music intervention group will receive a 15-minute music intervention and variables such as heart rate, blood pressure, anxiety, and academic performance will be measured. The non-music control group will not receive the intervention; however, the same variables will be measured.

Clinical Relevance: Music has been shown to beneficially affect stress-related physiological, as well as cognitive, and emotional processes. The proposed study has the potential to highlight the acceptance of music used as a strategy for impacting stress and anxiety experienced by nursing students during their undergraduate studies. Evidence of any effect music has on stress and anxiety levels among undergraduate studies can determine existence by the measurement of vital signs, STAI responses, and skills performance. This type of study can be beneficial to further research and can be implemented by nurse educators, healthcare institutions, and wellness clinics.

Item 3 Background	
<i>Describe past experimental and/or clinical findings leading to the formulation of your study.</i> <i>For research involving unapproved drugs, describe animal and human studies.</i> <i>For research that involves approved drugs or devices, describe the FDA approved</i>	Nursing students experience higher levels of stress than students in any other health science academic programs (Kinchen & Loerzel, 2019). Since most nursing students are not able to avoid these stressors, students must be able to cope with them. If students are not able to manage their stress, it can affect their performance, health, attitude, and role satisfaction as a nurse (Rafati et al., 2017). The levels of stress may vary during students' educational training, depending on their ability to adopt various strategies or coping with stress, and other factors. Even though numerous studies have been published regarding stress and anxiety among nursing students, few studies are found addressing the benefits of music utilized as an intervention to decrease emotional stress.

<p><i>uses of this drug/device in relation to your protocol.</i></p>	
<p>Item 4 Purpose and rationale <i>Insert purpose, objectives and research questions/hypotheses here.</i> <i>If you cut and paste from another document, make sure the excerpted material answers the question</i></p>	<p>Music is an immensely powerful emotional tool that can be used as a coping mechanism for stress, but there is truly little existing research about its use by students. This study aims to explore the effects of music intervention on the stress and anxiety levels among nursing students in their first semester of undergraduate studies. Increased awareness of their own strategies used, as well as the willingness to use holistic methods such as music, can offer a non-pharmacological and inexpensive intervention to many institutions.</p> <p>Research Questions:</p> <ol style="list-style-type: none"> 1. Is there a relationship between listening to music and stress, anxiety, and academic performance among new undergraduate nursing students? 2. Does listening to music help in decreasing anxiety among new undergraduate nursing students who are anticipating a skills assessment? 3. Does listening to music help in decreasing stress among new undergraduate nursing students who are anticipating a skills assessment? 4. Does listening to music help to improve academic performance among new undergraduate nursing students?

<p>Item 5 Study Population(s) Being Recruited</p>	<p>In your recruitment plan, how many different populations of prospective subjects do you plan to target? Provide number: 1</p>	
<p><i>e.g., a population can be individuals with type 2 diabetes controlled with diet and/or a population of healthy controls. Or a population can be individuals attending an education program, etc.</i></p> <p><u>List each different population</u> on a separate row and provide a short descriptive label: <i>(e.g., normal-healthy, diabetics, parents, children, etc.)</i></p>	<p>Identify the criteria for inclusion:</p>	<p>Identify the criteria for exclusion:</p>
<p><i>To add rows use copy & paste</i></p> <p>Nursing Students</p>	<p>18 years and older Enrolled at UTHSCSA- School of Nursing Enrolled in a Foundations of Nursing Clinical course First semester undergraduate nursing student</p>	<p>Younger than 18 years old 2nd , 3rd ,4th semester undergraduate nursing student</p>

Insert response here	Insert response here	Insert response here
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Item 6

Research Plan / Description of the Research Methods *a. Provide a comprehensive narrative describing the research methods. Provide the plan for data analysis (include as applicable the sample size calculation).*

Step-by-Step Methods:

A randomized controlled approach will explore the effects music has on stress and anxiety levels and academic performance among undergraduate nursing students. The study will be conducted with nursing students in the first semester of the undergraduate BSN program at UT Health Science Center at San Antonio. The study will consist of Phase 1 (pilot) and Phase 2 (larger dissertation study). Phase 1 will be the pilot study conducted in Spring 2022. The total population of the cohort typically consists of \approx 108 students. Approximately half-way through the semester, the students are required to sign-up for a skills competency recording. The students select the best date and time for their schedule. Students sign-up electronically into a group consisting of up to 10 students. Typically, there are 30 min time slots available for sign-up. For Phase 1, the pilot study will use a cluster randomization procedure to randomly assign two of the sign-up groups. The two groups will be 1) the music intervention group (n=up to 10 participants), and 2.) the non-music control group (n= up to 10 participants). An online randomizer will be used to create the groups. Students assigned to these groups will be allowed to remove themselves. The academic performance of these students will be recorded for the study.

Phase 2 of the study will be informed from the findings of Phase 1, the pilot study. It is anticipated there will be no intended changes in the methodology or randomization procedures from Phase 1 to Phase 2. The only difference would be in Phase 2 the total population in the Summer 2022 cohort (\approx 108) will be randomized into approximately 6 slots per half hour. Any changes to be made for Phase 2 will be immediately communicated to the IRB for approval prior to implementation.

The following procedures will be used for Phase 1 and Phase 2:

The study will be conducted at the UT Health Science Center - San Antonio's Center for Simulation Innovation (CSI). Two classrooms will be reserved in the CSI area at the School of Nursing. Students will be divided into the recording time slots consisting of no more than 10 students at a time. The students receiving the music intervention will be assigned an iPad (only used to sync smartwatch), a hard copy of State Trait Anxiety Inventory (STAI) survey forms Y-1 and Y-2, a demographic data form, pencil, and smart watch. Students will be advised to sit quietly, with desks spread out, in the reserved room. The participants will be asked to complete the STAI survey forms prior to music listening. Students will be advised to wear the watch, and watches will be previously logged in and synced by researcher to measure heart rate and blood pressure. Vital sign sheet will be completed by researcher using the data from the iPad. Fifteen minutes of classical music will be played overhead in the classroom. The students will be instructed not to use other electronic devices such as ear buds or phones during this time. The STAI survey Y-1 will be completed again post-intervention, and heart rate and blood pressure re-assessed. Students will then proceed to perform the skills competency assessment. Vitals and STAI survey Y-1 will then be reassessed post-skills competency and academic performance (pass/fail) will be measured.

The students who will not be receiving the music intervention (control group) will be seated in a second reserved classroom and will be repeating the same process as the music intervention group except without music, instead they will be sitting quietly for 15 minutes waiting to record their skills competency. The students will also be instructed not to use other electronic devices such as ear buds or phones during this time. For any students who have been randomly assigned to either group, and refuse to be in the study, they

will be allowed to leave. Only the academic performance will be measured on these students that refuse to be assigned to a group.

Data Analysis Plan:

A priori power analysis was conducted using G*Power 3.1.9 to determine the minimum sample size required to find statistical significance using a 3 (group) x 4 (time) repeated measures analysis of variance (i.e., a mixed-model ANOVA). With a desired level of power set at .80, an alpha (α) level at .05, and a moderate effect size of .25 (f), it was determined that a minimum of 30 total participants would be required to ensure adequate power (Cohen, 1988).

Mean heart rate, mean blood pressure, mean scores on STAI, and academic performance score (Pass/Fail) will be calculated for all groups. Demographic data will be analyzed in terms of frequencies and comparisons between groups. For RQ1: Pearson's correlation will examine the relationship between the music intervention on stress, anxiety, and academic performance. For RQ2: To measure anxiety, STAI mean scores will be analyzed. For RQ3: To measure stress levels, the mean heart rate and mean blood pressure will be analyzed. For RQ4: To assess academic performance, Pass/fail scores will be looked at. MANOVA will be considered for data analysis since there is one independent variable (music intervention) and multiple dependent variables. If any variables are not correlated, running a repeated-measures ANOVA to detect any overall differences between any related means would be considered. A paired samples t-tests could also be used for pre-and post-comparisons of vital signs. Using a Chi-Square test can also be beneficial in determining any differences in demographics and anxiety and/or stress. Alpha will be set at 0.05 for the study.

Item 7 Risks Section:

Complete the following table to describe the risks of all **research procedures** listed in Step 2, Institutional Form (items 28-34). *Do not list risks of Routine care procedures here.*

N/A, Risks are described in the informed consent document – do not complete this table.

Research procedures	Risks
<p>example:</p> <ul style="list-style-type: none"> • History and physical • Questionnaire • Laboratory tests 	<p>List the reasonably expected risks under the following categories as appropriate:</p>
<i>Add or delete rows as needed</i>	
Vitals Signs obtained via SmartWatch	<p>Serious and likely;</p> <ul style="list-style-type: none"> ○ None <p>Serious and less likely;</p> <ul style="list-style-type: none"> ○ None
Heart Rate Blood Pressure	
Demographic data form, paper and pencil	<p>Serious and likely;</p> <ul style="list-style-type: none"> ○ None
STAI Survey: paper and pencil survey	<p>Serious and likely;</p> <ul style="list-style-type: none"> ○ None
Academic Performance	<p>Serious and likely;</p> <ul style="list-style-type: none"> ○ Pass/Fail