DOES PHYSICAL EXERCISE HAVE AN IMPACT ON GENERALIZED ANXIETY DISORDER IN ADULTS MEASURED BY GAD7 SCORES?

Presented in Partial Fulfillment of the
Requirements for the Degree of
Doctor of Nursing Practice

Nova Southeastern University
Health Professions Division
Assaf College of Nursing

Antoinette Watson
March 25, 2024

Ron and Kathy Assaf College of Nursing
NOVA SOUTHEASTERN UNIVERSITY | NSU Florida

DNP Project Chair Form

We, the undersigned, agree to serve as the DNP Project Chair of: Antoinette Watson, MSN, AG-ANCP-BC, PMHNP-BC, who is developing a DNP Project proposal tentatively titled: Does Physical Exercise Have An Impact On Generalized Anxiety Disorder In Adults Measured By GAD7 Scores?

Teresa Gore 2/10/2024

Teresa Gore ___/___/___

Signed, DNP Project Chair | Dr. Teresa Gore | Date

Kimberly Sand 2/9/2024

Kimberly Sand ___/___/___

Signed, Program Director | Dr. Kimberly Sand | Date

Kniaka Bethel 2/10/2024

Kniaka Bethel ___/___/___

Signed, Chair, Graduate Programs | Dr. Kniaka Bethel | Date

Agreement too be the DNP Project Chair, does not imply acceptance of the proposal

Ron and Kathy Assaf College of Nursing
NOVA SOUTHEASTERN UNIVERSITY | NSU Florida

Nova Southeastern University
Health Professions Division
Assaf College of Nursing
Doctor of Nursing Practice

Certification of Authorship

Antoinette Watson, MSN, AG-ANCP-BC, PMHNP-BC, a DNP Student submitted

Does Physical Exercise Have An Impact On Generalized Anxiety Disorder In Adults Measured By GAD7 Scores? as my DNP project.

I hereby certify that I am the author of this document and that any assistance I received in its preparation is fully acknowledged and disclosed in the document. I have also cited all sources from which I obtained data, ideas, or words that are copied directly or paraphrased in the document. Sources are properly credited according to accepted standards for professional publications. I also certify that this paper was prepared by me for this purpose.

Student's Signature: _____ Date: 2/14/2024

DNP Project Chair: Teresa Gove Date: 2/10/2024

After the completion of the project the student must complete this form and the *Certification of Authorship,* then return these to the DNP Project Chair. This should be completed before the defense of the project.

Abstract

Background: During COVID, the world was exposed to a different set of living circumstances and in response to this, generalized anxiety disorder diagnosis and treatment increased at an alarming rate. An additional 26% of the population has been diagnosed with anxiety of some form as of 2019. The increased amount of anxiety treatment needed has researchers exploring the effects of exercise as a method of treatment.
Purpose: The goal of this literature is to examine an adjunctive treatment strategy of physical exercise and contribute to gaps in research for adults diagnosed with Generalized Anxiety Disorder. The basis of the literature will focus on, "Does physical exercise have an impact on Generalized Anxiety Disorder in adults measured by GAD-7 scores?"
Theoretical Framework: The Transtheoretical Model of Behavior (TTM) will serve as the framework for the study as exercise as a treatment regimen will involve the need for consistency and discipline of a participant. The TTM allows the researcher to follow the behavioral patterns of individuals while also examining how their level of anxiety responds to exercise.
Methods: By allowing the participants to continue their current exercise routine and complete GAD-7 assessments daily and pre/post exercise, data can be obtained to determine if exercise is an effective treatment for anxiety. The participants will also stage themselves on the TTM to allow researchers to track their behavioral progression, regression, or maintenance.
Results: Based on the data obtained, exercise was proven as an effective treatment for generalized anxiety disorder. Due to the small sample size of the study, the data obtained is not statistically significant and thus larger studies are recommended in the future.
Conclusion: Natural methods of treatment of generalized anxiety disorder are available and have proven effective but only in small groups that cannot be generalized to larger, more varying subjects. Further studies are recommended with additional thought for limitations including but not limited to exercise variance, level of commitment, duration of the study, sample size, etc.

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Chapter One: Introduction

Background

In 2019, there were 301 million individuals in the US diagnosed with anxiety, with another 26% increase after COVID-19 ("Mental disorders," 2022). The purpose of this paper is to attempt to determine the impact of exercise on anxiety using Generalized Anxiety Disorder (GAD-7) questionnaire screenings.

Exercise is associated with mental health conditions as a form of coping. Research discusses the use of exercise as an adjunct treatment to individual psychotherapy as well as psychotropic medication (Kandola et al., 2018). When examining this fact more closely, exercise has been demonstrated to assist with anxiety and depression, but there are some suspicions about mood disorders and whether exercise can be activating for these individuals (Saeed et al., 2019). Different forms of exercise, such as yoga and tai chi, and more physical types, such as running, are assessed. The results remain that exercise positively impacts mental health (Saeed et al., 2019). The gap in the literature is present when determining if exercise impacts anxiety without being in combination with depression.

Needs Assessment at Project Site

As a current psychiatric nurse practitioner, this researcher has been involved in conversations with patients regarding coping skills for mental health conditions. While efficacious treatments exist with psychotropic medications, natural supplements, and individual psychotherapy, some patients seek natural methods to handle their symptoms of anxiety. Natural methods can include herbal treatments, cannabinoids, vitamins, teas, and even physical exercise. The scientific data available to explain the impact of exercise on minimizing anxiety symptoms

is variable at best and leaves a gap in evidence-based practice. This literature will try] to close that gap by contributing to the subject.

The psychiatric mental health outpatient practice in question currently has 1669 patients registered in the system, with 566 claims billed in the last year. The DNP mentor at this site has 437 patients, of which 237 patients have a diagnosis of Generalized Anxiety Disorder based on a search of these patients with ICD-10 code F41.1 placed on the visit under billing. Of these 237 patients, there are approximately 11-15 patients seen by this provider daily, with up to 33% of patients inquiring about natural treatments for generalized anxiety during their visits.

Problem Statement and Guiding Question

As anxiety becomes more prevalent in the US and more patients choose medications as a latter option, natural options like exercise are being highlighted as adjunctive options for treatment. The basis of the literature will focus on "Does physical exercise impact Generalized Anxiety Disorder in adults measured by GAD-7 scores?"

Goals and Objectives

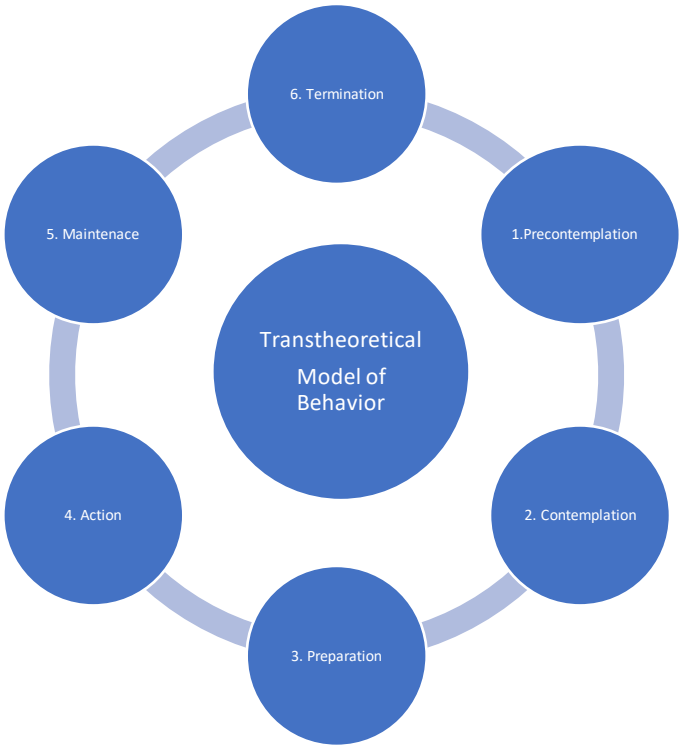
The goal of this project is to examine an adjunctive treatment strategy of physical exercise and contribute to gaps in research for adults diagnosed with Generalized Anxiety Disorder. The objective is to determine if physical exercise has an impact on decreasing symptoms of anxiety and facilitate an understanding of the mental health effects of physical exercise. The literature will also observe the progression of behavioral changes using the Transtheoretical Model of Behavior (TTM).

Theoretical Framework/Evidence-Based Practice Model

The theoretical framework used for this research is the Transtheoretical Model for Behavior. The TTM was originally developed in 1983 by Prochaska and DiClemente to focus on

addictive behaviors of smoke cessation and how to facilitate change (Marshall & Biddle, 2001). The model comprises six different behavioral stages, as demonstrated in Figure 1. Over the years, the TTM has been adapted to research involving exercise as this model highlights the basis of individuals' decision-making when trying to create a new routine or make behavioral changes (Marshall & Biddle, 2001). Each stage of the TTM explains the cycle of individual behavior and the intention of change (Marshall & Biddle, 2001). As it applies to physical activity, the TTM separates each stage to determine the progression of behavior and the change process.

Figure 1: Transtheoretical Model of Behavior



This model serves as the framework due to its acknowledgment of behavior progression and regression in decision-making, emphasizing self-efficacy and routine (Marshall & Biddle, 2001). In this research, the TTM will allow individuals to track their behavioral stage as they continue their exercise journey and monitor for change. Some individuals may gradually regress

and lose consistency, while others may progress and challenge themselves. In either direction, individuals can assess their behavioral stage throughout the allotted time.

Chapter Two: Literature Review

A DNP project should be based on evidence published in the literature. The role of the DNP nurse is to take the evidence from the literature and incorporate the interventions into clinical practice. The goal of the literature review was to obtain and review research on the topic of generalized anxiety disorder and physical exercise and determine any connections between the two concepts, studies that could be replicated, and limitations that could be corrected. The DNP project will be based on evidence found in the literature that can be conformed to clinical practice with a focus on the specific area in question.

Problem Statement and Guiding Question

As anxiety becomes more prevalent in the US and more patients choose medications as a latter option, natural options like exercise are being highlighted as adjunctive options for treatment. The basis of the literature will focus on "Does physical exercise have an impact on Generalized Anxiety Disorder in adults measured by GAD-7 scores?"

Literature Review Synthesis with Matrix

The literature review for this study was conducted using *PubMed* within the *National Library of Medicine* and the findings of such review have been summarized. Using the keywords "physical exercise," "adults," and "anxiety" initially yielded 5,882 articles. This was simplified to 2,200 articles when a timeframe of five years was applied. This reduced even further to 2,174 articles once the full-text filter was applied to the results. Only a few of the 2,174 articles yielded were selected to contribute to this literature.

Ströhle et al. (2018) discuss statistics of anxiety disorder and how to make a diagnosis of the condition. Based on data from 2010, 61.5 million individuals were diagnosed with a form of anxiety disorder; women were diagnosed two to three times more than men. Saeed et al. (2019)

discusses the different types of exercise and the impact they have on anxiety and depression. The article does not differentiate the types of exercise that will specifically help with symptoms of generalized anxiety; rather, it infers the impact on anxiety. Yoga was found to have uncertain effects on improving anxiety symptoms with adjunct treatment in place with cognitive behavioral therapy or psychotropic medications. Tai chi was found to have a reduction of anxiety symptoms in older adults in conjunction with other medical treatments.

Schuch and Vancampfort (2021) discuss the comorbid medical conditions associated with mental health disorders and highlight the shorter life expectancy of 15-20 years of these individuals. The study goes on to discuss a meta-analysis of 11 studies that demonstrate a 95% CI for positive effects on anxiety symptoms with high levels of physical activity. Kandola et al. (2018) obtained evidence demonstrating the impact of physical exercise on anxiety symptoms. However, the study had multiple areas of variance (exercise activity, comorbid conditions that may impact exercise potential, cost, etc.) and recommended further studies. Ramos-Sanchez et al. (2021) also demonstrated that physical exercise has a positive impact on anxiety symptoms. However, the study was too small (effect size 0.58) to have statistical significance to research, and larger studies are recommended.

The literature review supports the use of the GAD-7 questionnaire as well as the Transtheoretical Model of Behavior. Using the keywords “transtheoretical model” yielded 1,967 articles in *PubMed*, and a Google search using the keywords “original transtheoretical model” yielded 307,000 articles, with one of the top articles written by Prochaska in 1997. Modifying the keywords in *PubMed* to “Prochaska transtheoretical model physical activity” yielded 24 article results, the first being written by Marshall and Biddle (2001). This article provides information to serve as the framework for the study, as behavioral change is also being monitored along with

changes in the mental health of individuals. Further solidifying the use of the TTM is Hashemzadeh et al. (2019) which demonstrates the use of the TTM in healthcare when evaluating the behaviors of individuals with chronic diseases. Their results indicate a low usage of the TTM in healthcare despite the positive results of the TTM when it is used. The Transtheoretical Model was discussed more in-depth in the previous chapter under the Theoretical Framework.

The article obtained by Spitzer et al. (2006) was obtained from *PubMed* as well using the words "GAD7." The search yielded 3,314 articles, with the top choice being the article by Spitzer et al. (2006), which details the origin of the GAD7 questionnaire. The GAD7 is discussed further in chapter three under Methodology. The article by Dhira et al. (2021) details the validity of the GAD7 questionnaire as it is used in a different construct and still proves valid with a Cronbach's alpha of 0.895. Noting the amount of variance in this study, research was obtained to discuss the analysis of variance. Kotronoulas et al. (2023) provides a detailed overview of quantitative statistics including descriptive statistics and analysis of variance.

Utilization of Findings for Intervention

The findings in the literature review supported the need for this research study. Strohle et al. (2018) discuss the high prevalence of anxiety and the diagnosis of the disorder. Each article obtained supports the need to continue to validate any correlation between physical exercise and anxiety symptoms. The wide range of information available to review the relationship between physical exercise and anxiety symptoms does not provide a statistically significant, research-based answer on whether physical exercise is a beneficial intervention for anxiety disorder. As a collective, the information found in the literature review supports the research study in attempting to answer the guiding question and close the literature gap on this topic. Research

supports the framework of behavioral change, the Transtheoretical Model, and proves the GAD7 is a valid tool for consistently assessing individuals' anxiety levels. The framework and assessment tool add statistical significance to the structure of the study and serve as a basis for potentially gathering information to support recent studies that did not have enough evidence.

Chapter Three: Project Design and Methodology

Methodology

This will be quantitative research, conducted over four weeks, using a pre-post design with a convenience sample. A flyer will be posted in the selected office for patients to read and self-determine their interest in participation. For those willing, education will be provided regarding the GAD-7 screening tool and TTM for behavioral staging. Individuals with interest will be provided with a consent form that details each step of the study and defines the exercise. Exercise is defined as low, moderate, or high intensity. Respectively, activities for each level would include walking with little no to incline, yoga, or Pilates; walking with a mild incline, light weightlifting, running; or moderate to heavy weightlifting, running long distances, walking with a steep incline, or cross-fit. Everyone will be encouraged to maintain their current level of exercise for four weeks.

Intervention

The intervention used in this research is the Generalized Anxiety Disorder Questionnaire or GAD-7 screening tool. Individuals will be asked to complete a GAD-7 screening tool each morning before starting their day and encountering any stress; this will serve as the baseline for the day. They will also complete a GAD-7 screen before and after their exercise routine and report their results using their unique individual identifier for tracking or record results via self-tracking. This will take place for four weeks. Individuals will also stage themselves on the Transtheoretical Model for Behavior at the beginning and the end of the research to track any progression or regression. This information will also be tracked using their unique identifier for reporting.

Sample, Sampling, and Sample Size

Convenience sampling will occur within this researcher's private outpatient mental health practice. The goal number of patients is as many as possible to gain as much data as possible for analysis but realistically a goal of 10-20 patients will suffice for this study.

Inclusion Criteria

Inclusion criteria are as follows: current patients of another provider at the selected clinical site and will be willing, 18 years of age or older, patients with an ICD-10 diagnosis code of F41.1 Generalized Anxiety Disorder, patients taking antidepressant medication or participating in individual psychotherapy for treatment, and adults with a current exercise routine.

Exclusion Criteria

Exclusion criteria are as follows: current patients of the primary researcher, individuals under the age of 18 years, patients taking medications for breakthrough anxiety such as benzodiazepines, pregnancy or planned pregnancy, patients with neurocognitive diagnosis, patients with a mood disorder or schizophrenia diagnosis, patients that are not currently participating in an exercise routine, patients with a chronic medical diagnosis that restricts exercise.

Recruitment Procedure

A flyer advertising the study will be displayed in the office for patients to review as they present for in-person follow-up visits or new patient evaluations. Patients selected will belong to the other provider in the practice and will not be personal to this provider. The care of these patients will not be changed or compromised should they decline to take part or start to participate and later choose to stop participating.

Setting Facilitators and Barriers

For this study, facilitators are the clinical site that is currently treating patients with generalized anxiety disorders who seek a natural, nonpharmacological option for the treatment of anxiety. Barriers to the study could be the split between virtual and in-office patients. If the number of virtual patients outnumbers office patients, this may limit the number of patients that will see the flyer advertising the study posted in the office. This could also result in a small study size, limiting the amount of data that can be obtained and analyzed and potentially weakening the study. Other barriers identified could be the time needed to complete the GAD-7, patients not committing to completing the project, the short time frame of the project, variance in response due to different levels of physical fitness in each patient.

Cost/Budget

While the cost of this study is expected to remain relatively low, there are costs associated. The tools used in the study to measure anxiety symptoms and stage behavior are free. These tools are available to the public, free of charge and without permission, using a simple Google search. As the patients selected for this study will continue their current exercise routine, they do not have to purchase any extra memberships or materials for the study. The cost incurred to the participants of the study will vary as gym memberships or exercise programs will vary in cost. The researcher will not incur these costs.

At present, this researcher is performing work for this study unpaid. Should another researcher want to duplicate this study, the researcher's hourly rate should be considered. As an advanced practice provider is performing this study, the hourly rate for a researcher of similar training is being considered for this calculation. The average hourly rate for a psychiatric nurse practitioner in the Tampa Bay area is $57.69 per hour. The total number of hours from start to

finish for the study has not been determined at this time, but the minimum considered should be 150 hours, which calculates to $8,653.50.

Measurement of Outcomes

This study will measure anxiety symptoms and any change from the baseline following physical exercise. The GAD-7 tool is used to measure anxiety symptoms. The study will also evaluate stages of behavior and any change noted using the Transtheoretical Model of Behavior.

Instrument(s)

This is a seven-question tool that assesses symptoms of anxiety in individuals for two weeks. The GAD-7 was initially created in 2005 and started as a nine-item tool based on criteria in the Diagnostic and Statistical Manual of Mental Disorders Four (DSM-4) combined with four more questions from existing anxiety scales (Spitzer et al., 2006). The GAD-7 was condensed down to seven questions following the feedback and data analysis of 965 participants using the 13-item tool (Spitzer et al., 2006). The GAD 7 questionnaire and the transtheoretical behavior model are free tools easily accessible to the public via Google search. As they are readily accessible to the public, they do not require permission from the author for use.

Instrument Validity and Reliability

The GAD7 questionnaire was developed following research in 2005 and the construction of a 7-item questionnaire that measures anxiety symptoms. The original questionnaire started as 13 items derived from criteria from the DSM 4 and four additional items taken from existing anxiety scales (Spitzer et al., 2006). After significant testing via 965 patients, the 13-item questionnaire was scaled down to seven items based on the performance of these seven questions in the initial research. Based on the data analysis, the GAD7 produced an internal consistency of

0.92 Cronbach alpha, and the test-retest reliability and good procedural validity were demonstrated.

The Transtheoretical Model, initially created to measure behavioral changes in patients with addictive behaviors, has been proven beneficial across multiple empirical applications when applied to physical activity using a meta-analysis of multiple studies. The TTM considers the varying levels of physical activity among individuals and measures self-efficacy and change processes within these individuals (Spitzer et al., 2006). Despite the significant amount of variance, incorporating the transtheoretical model into different contexts helps improve the reliability and provides evidence of construct validity in the model. Credibility and confidence intervals of 95% were computed, and multiple empirical studies applied the transtheoretical model to physical activity.

Data Collection Process/Procedure

Data collected from participants in the study will be stored via RedCap. Each participant will create a unique ID for themselves so they can remain anonymous in the study. This unique ID will also allow the researcher to track data individually without developing bias towards any participant. For those participants who are not able to report their data in RedCap due to technological challenges, they may store their data on paper and send their data in its entirety at the end of the study. Allowing both ways to track data will create a multifaceted environment for participants with or without experience with technology. Ideally, data will be collected daily, up to three times per day.

For example, if Monday is a typical day planned for exercise, the participant will complete a GAD-7 screening in the morning shortly after awakening, complete another GAD-7 screening prior to their scheduled workout, and immediately following their workout and record

all three scores. If Monday were not a planned day for exercise, the participants would complete a GAD-7 screening in the morning and this would be their only scored recorded for the day. Participants will repeat this process for four weeks and record data daily, either in RedCap or via self-tracking. If the participants are not using RedCap for data entering daily, they will submit their self-tracking data after four weeks for the researcher to compile. Participants will also stage themselves at the beginning of the study and at the end of the study using the stages of the Transtheoretical Model.

Chapter Four: Implementation and Results

Implementation

Implementation of the project was slow to start. IRB compliance was maintained, and a flyer was displayed in the office and discussed with the other providers' patients during their follow-up appointments.

The implementation process originally started out very slow. Despite multiple patients expressing interest in participating in the study, communication was slow, delaying the start of patients becoming involved in the study. With further communication and reminders about participating in the study combined with the initiation of communication by the primary researcher, patients were more apt to respond, and the next step in the process to obtain consent was completed. In total, there were eight patients who expressed interest in the study: six females and two males. After verifying inclusion and exclusion criteria as discussed in IRB planning, two females and two males met the criteria and continued with the study. One female and one male successfully completed the four-week program, one female dropped out of the study, and one male stated he completed the study but never submitted any data to the primary researcher. Both participants who successively completed the study kept track of their data and did not use RedCap, as this was their preference.

Results

Three patients consented for this student. However, only two completed the study (n=2). Of the two participants who successfully completed the four-week program, both participants could deduce how their mental health and physical exercise patterns related to each other. One participant in the study was more consistent, and this reflected on the data turned in for this individual. The other participant in the study reflected on psychosocial difficulties in life along

with balancing work and how their mental health improved on the days of exercised. One participant never submitted any data to the primary researcher, so their progress or actual completion of the four-week program is inconclusive.

Due to the small sample size of the study, data obtained from each participant is not statistically significant to make any determinations for research. However, the participant the remained consistent with their exercise plan did demonstrate steady, low levels of anxiety based on the morning score from their GAD-7 completion. Along with low data yield, there were several limitations determined from this study. Some of them would include the time of year the study was completed, the location of advertising for the study, the lack of rapport between the participants and the primary researcher, difficulties with personal life, and psychosocial issues.

Participant Demographics

Participants in the study were of Caucasian race with ages ranging from mid-20s to early 40s located in the state of Florida. This project did not track other demographic data such as socioeconomic status, number of children, or geographical location in Florida.

Data Analysis

Summary statistics were calculated for each interval and ratio variable. Frequencies and percentages were calculated for each nominal variable. Because the number of participants in the study was very low, the anticipated ANOVA analyses for variance were not performed. Descriptive statistics are used to discuss the data obtained.

Outcome Measurement(s)

Both participants met inclusion and exclusion criteria, which removes further variance information. Frequencies and percentages are presented in Table 1.

Table 1

Summary Statistics Table for Interval and Ratio Variables

Variable	*M*	*SD*	*n*	SE_M	Min	Max
Average Baseline GAD7	8.50	0.71	2	0.50	8.00	9.00
Average Pre-Workout GAD7	10.00	1.41	2	1.00	9.00	11.00
Average Post-Workout GAD7	5.50	3.54	2	2.50	3.00	8.00

Interpretation / Discussion

The observations for Average Baseline GAD7 had an average of 8.50. The observations for Average Pre-Workout GAD7 had an average of 10.00. The observations for Average Post-Workout GAD7 had an average of 5.50. The summary statistics can be found in Table 1. Further statistical analysis on the data was not completed due to the small sample size.

The data revealed a positive trend towards a decrease in GAD-7 scores from pre-workout and post-workout. The average GAD-7 was increased in the baseline and the pre-workout. This would need to be further evaluated. There is a possible relation that participants implemented exercise when they felt anxious. This would reflect a positive correlation of the patient implementing interventions to improve their state of anxiety. The data cannot be generalized to a larger population because of the sample size.

Each participant staged themselves on the TTM as well. One participant entered the study at stage 5 (maintenance) and remained at stage 5. The other participant entered the study at stage 4 (action) and progressed to stage 5. The staging of behaviors allowed participants to self-reflect on their journey over four weeks and allowed this researcher to track their behaviors to facilitate change for their mental health.

Cost Benefit Analysis

Based on the current implementation process, as well as the data analysis process, the study proves to be cost-effective. The cost of mental health treatment in 2019 totaled $225 billion in the United States (Leonhardt, n.d.). This includes the cost of cognitive-behavioral treatment, psychotropic medications, and psychiatric facility treatment. The cost of this project was significantly lower than the average intervention for mental health care. Most of the financial expenses are spent on the primary researcher's time as there was time spent creating and displaying a flyer, communicating with patients before, during, and after the study, and spending time on data analytics. It is projected that a total of $8653.50 was spent on time for the primary researcher. The cost to print the flyers for the advertisement was $10.00, as calculated by the local print store. The tools for measurement are free of cost to researchers, so no cost was incurred to obtain the assessment tools.

The participants in the study are not incurring any expenses as they are using an exercise routine that they already have in place, so no additional costs are added outside of their usual cost for a gym or exercise class. In comparison to the cost of psychotropic medications and individual psychotherapy, physical exercise is a very cost-effective intervention. This project was cost-effective in comparison to the total cost of healthcare for patients.

Sustainability of the DNP Project

At project completion, several factors are taken into consideration as to how this project can continue to improve the understanding of the connection between anxiety and physical exercise. As of current, research continues to find a void in the connection. Wanjau et al. (2023) discuss substantial evidence based on an intense literature review. Stonerock et al. (2023) reviewed randomized controlled trials that measured the response of anxiety symptoms to

physical exercise, and the data did not provide statistically significant evidence. However, Gordon et al. (2020) were able to determine statistically significant evidence of the effects of physical exercise on generalized anxiety symptoms in young adults.

Learning from Gordon et al. (2020), this project could improve by having a larger sample size and considering guidelines such as the *United States Physical Activity Guidelines*. Developing the project into a randomized controlled trial to remove excess variance is another factor to consider as well. Generalized considerations moving forward should also consider the place of advertisement, the timeframe for obtaining participants, the time of year to conduct the study, and the rapport between the researchers and the participants.

Conclusion

With the current available research knowledge, the void remains present when determining the connection between physical exercise and generalized anxiety disorder. As noted in this literature, other studies are being conducted, but none have yielded a statistically significant connection between physical exercise and anxiety disorder. There are multiple other variables to consider that could potentially turn this project into a research connection that explains physical exercise and its relationship with generalized anxiety disorder.

There were also multiple barriers identified in the study as well that could be addressed for future studies. The setting/location for the study to obtain participants could be more conducive to individuals who are exercising, such as a gym or recreational center. The relationship between participants and the researcher should also be considered, as this could be an incentive for participants to continue the study. Other considerations include the time of year and factoring in variances such as geographical location, age, sex, comorbid medical conditions, and motivation levels of each individual. The variance in participants' physical activity level

should be considered, as different levels of physical exercise may yield different results. Overall, the project did not successfully establish statistically significant data to bridge the literature gap between physical exercise and anxiety symptoms. The study provided information on individuals and their progression through the Transtheoretical Model of behaviors. One participant was able to reflect and determine how they progressed on the model from action to relapse. While this may seem unmotivating, the participant reported that this helped him see his potential with consistency and motivated him to work back on the model. Further research with less variance in the study is needed to continue to determine the relationship between physical exercise and anxiety disorder.

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APPENDIX

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INSTITUTIONAL REVIEW BOARD
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APPENDIX A IRB Permission Documents

MEMORANDUM

To: Antoinette Watson
Ron and Kathy Assaf College of Nursing

From: Mohammadali Shoja
Chair, Institutional Review Board

Date: October 9, 2023

Subject: IRB Initial Approval Memo

TITLE: Does physical exercise have an impact on Generalized Anxiety Disorder in adults measured by GAD-7 (Generalized Anxiety Disorder questionnaire) scores?– NSU IRB Protocol Number 2023-421

Dear Principal Investigator,

Your submission has been reviewed and approved by the Institutional Review Board under Expedited review procedures on October 9, 2023. You may proceed with your study.

NOTE: You are required to use the attached copies of all consent, assent, and recruiting materials stamped with approval date when recruiting and consenting or assenting participants.

Level of Review: Expedited

Type of Approval: Initial Approval

Expedited Review Category: Expedited Category 5
Expedited Category 7

Level of Risk: Minimal Risk

Continuing Review: Continuing Review is due for this protocol on October 8, 2024. A *Continuing Review xForm* (progress report) must be submitted one month prior to the continuing review date.

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INSTITUTIONAL REVIEW BOARD
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PHONE: (954) 262-5369

Changes: Any changes in the study (e.g., procedures, consent forms, investigators, etc.) must be approved by the IRB prior to implementation using the *Amendment xForm*.

Post-Approval Monitoring: The IRB Office conducts post-approval review and monitoring of all studies involving human participants under the purview of the NSU IRB. The Post-Approval Monitor may randomly select any active study for a Not-for-Cause Evaluation.

Final Report: You are required to notify the IRB Office within 30 days of the conclusion of the research that the study has ended using the *Closing Report xForm*.

Your study was approved under the following criteria:

- HIPAA Authorization to be used under 45 CFR 164.508
- HIPAA Authorization Waived under 45 CFR 164.512(i)(1)(i) • Consent Participants according to criteria 45 CFR 46.116 and 45CFR 46.117

Translated Documents: No

Retain this document in your IRB correspondence file.

CC: Holly Evans Madison

Teresa Gore, PhD, DNP, FNP

General Informed Consent Form
NSU Consent to be in a Research Study Entitled

Does physical exercise have an impact on Generalized Anxiety Disorder in adults measured by GAD-7 (Generalized Anxiety Disorder) scores?

Who is doing this research study?

College: Ron and Kathy Assaf College of Nursing

Principal Investigator: Antoinette Watson, APRN, AG-ACNP-BC, PMHNP-BC

Faculty Advisor/Dissertation Chair: Teresa Gore, PhD, DNP, FNP

Co-Investigator(s): None

Site Information: A Little HOPE LLC 100 S. Ashley Dr Suite 600 Tampa, FL 33602

Funding: Unfunded

What is this study about?

The study is to see if physical exercise can improve symptoms of anxiety and help with learning more about the mental health effects of physical exercise. The information in this study is going to be used to improve the treatment of anxiety by adding physical exercise.

Why are you asking me to be in this research study?

You are being asked to be in this study because you have Generalized Anxiety Disorder, also known as Anxiety, and you are being treated with anti-depressants and/or therapy to help with your anxiety. This study will include about 100 people.

What will you be doing if you agree to be in this research study?

While you are in this study, you will be checking your anxiety level to see if exercise helps to lower your anxiety level. You will create your own exercise routine that lasts about 30 minutes. The exercise routine can include but is not limited to walking, dancing, and running. This exercise routine you select should be something you can do each time. Due to the risks that can happen with all types of exercise, medical approval by your regular doctor is highly recommended before you start any exercise routine. If you do not exercise regularly, low-intensity exercises are better to start with. Examples are walking at a slow to moderate pace on a flat surface. High-intensity exercises such as CrossFit and heavy weight-lifting are not recommended for beginners.

You will not need to make extra visits to the clinic, A Little HOPE LLC if you decide to participate in this study.

Research Study Procedures - this is what you will be doing:

To be eligible for the study, your charts will be reviewed to check if you have a diagnosis of Anxiety and your current treatment plan. If you are female, you will be asked to self-report if you are pregnant, as this status has the potential to change between visits.

During your office visit, an Anxiety survey will be given to you to score your anxiety level. This survey is the GAD 7, which only has 7 questions. You will also be shown an image of the stages of change. You will pick out the stage you think you are related to changes to improve your anxiety level. Every morning before you start your day, you will score your anxiety level using the GAD 7 survey. You will take another GAD 7 survey before you exercise and right after you complete your exercise routine. The survey will be repeated every day for four weeks. You will select your stage of change at the end of the study to see if your level has changed during the study.

Your initial scores of anxiety with pre- and post-exercise scores is the standard procedure for this study. You will measure your anxiety level using the GAD7 survey three times a day for four back-to-back weeks on the days you exercise. You will measure your anxiety level using the GAD 7 survey once a day if you do not exercise that day.

Your exercise routine should be at least 30 minutes as part of your normal routine. For example, if you exercise three times per week, you will continue this routine. There is no minimum number of days of exercise required.

Could I be removed from the study early by the research team?

There are several reasons why the researchers may need to remove you from the study early. For example, pregnancy, starting a new medication for breakthrough anxiety, or your diagnosis being changed to mood disorder or other diagnosis.

Are there possible risks and discomforts to me?

This study involves very little risk to you. To the best of our knowledge, the things you will be doing have no more risk of harm than you would have in everyday life. When starting any exercise routine, there are risks associated, such as physical injury or worsening of chronic conditions. It is important to listen to your body when exercising.

What happens if I do not want to be in this research study?

You have the right to leave this study at any time. If you decide to leave or you do not want to be in the study, you will not lose any services you currently receive. If you choose not to participate, the care and services offered by Dr. Munz at A Little HOPE LLC will not be impacted. You will receive the same care you have been receiving. If you choose to stop being in the study before it is over, any information about you that was collected **before** the date you leave the study will be kept in the research records for 36 months from the end of the study and may be used as a part of the research. All records must be kept for a minimum of 36 months but may be kept longer if stated here.

What if there is new information learned during the study that may affect my decision to remain in the study?

If new information becomes available during the study, which may relate to whether you want to remain in this study, this information will be given to you by the researchers. You may be asked to sign a new Informed Consent Form if the information is given to you after you have joined the study.

Are there any benefits for taking part in this research study?

There are no direct benefits to being in this study, but we hope the information learned from this research study will help other people with anxiety conditions in the future.

Will I be paid or be given compensation for being in the study?

You will not be given any payments or compensation for being in this research study.

Will it cost me anything?

There are no costs to you for being in this research study.

Ask the researchers if you have any questions about what it will cost you to take part in this research study (for example bills, fees, or other costs related to the research).

How will you keep my information private?

The information we learn about you in this study will remain confidential, within the limits of the law, and will be limited to people who have a need to know this information. Information from chart reviews will be saved to a virtual cloud via a password-protected hard drive; Printed copies of the forms will be shredded immediately. This information will be available to the researcher, the Institutional Review Board and other representatives of this institution, and any regulatory and granting agencies (if applicable). If we publish the results of the study in a scientific journal or book, we will not identify you. All confidential information will be kept securely on a virtual cloud on a password-protected hard drive. All data will be kept for 36 months from the end of the study. All records must be kept for a minimum of 36 months but may be kept longer if stated here and destroyed after that time by deleting and erasing the data from the hard drive.

Whom can I contact if I have questions, concerns, comments, or complaints?

If you have questions now, feel free to ask us. If you have more questions about the research, your research rights, or have a research-related injury, please contact:

Primary contact:
Antoinette Watson, APRN, AG-ACNP-BC, PMHNP-BC can be reached at 813-714-7397

If primary is not available, contact:

Kristina Mamani, Office Assistant, 813-714-7397

Research Participants Rights

For questions/concerns regarding your research rights, please contact:

Institutional Review Board
Nova Southeastern University
(954) 262-5369 / Toll Free: 1-866-499-0790
IRB@nova.edu

You may also visit the NSU IRB website at www.nova.edu/irb/information-for-research-participants for further information regarding your rights as a research participant.

All space below was intentionally left blank.

Research Consent & Authorization Signature Section

Voluntary Participation - You are not required to be in this study. You may leave this study at any time. If you leave this study before it is completed, you will not lose any benefits you are already receiving.

If you agree to be in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction about the research

Adult Signature Section

I have voluntarily decided to take part in this research study.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent & Authorization	Date

Appendix B

Literature Review Matrix

Author(s)/ Year	Level of Evidence	Problem/Population and Purpose	Intervention	Comparison (if any)	Outcomes	Use of Evidence
Marshall, S. J., & Biddle, S. J. (2001)	2	Summarize findings and create a meta-analysis from empirical applications of the transtheoretical model applicable to physical activity	Database search for applicable studies combining use of the transtheoretical model (TTM), physical activity, and decision-making capacity	n/a	Supports the use of the TTM in physical activity domain	The evidence obtained will be the framework and basis of the study as it supports the physical activity domain

Kotronoulas, G., Miguel, S., Dowling, M., Fernández-Ortega, P., Colomer-Lahiguera, S., Bağçivan, G., Pape, E., Drury, A., Semple, C., Dieperink, K. B., & Papadopoulou, C. (2023)	8	Discussion of descriptive statistics used in analysis of data obtained in quantitative research studies.	Using a paired t test and ANOVA analysis	Compared descriptive and inferential statistics	Statistical analysis methods revied	Determining to use the appropriate strategies for the study to interpret the data
Spitzer, R. L.,	3	Discusses the	Testing the	PHQ8 depression	Determined 7	The GAD7

Kroenke, K., Williams, J. B., & Löwe, B. (2006)		creation of the GAD-7 questionnaire and the process of narrowing the questionnaire from 13 items to 7 items	questionnaire to determine reliability and validity	score	items performed at the same level as the original 13 items and the tool had significant reliability and validity	will be used as the assessment tool for the project
Saeed, S. A., Cunningham, K., & Bloch, R. M. (2019)	3	Detail evidence present on the effects of exercise on depression and anxiety	Providing an overview of various exercise modalities and the effects on anxiety and depression	Other treatments for anxiety and depression such as ECT or group therapy	Yoga determined to be a good alternative for depression, Tai Chi determined as a good	Evidence to demonstrate effects of different exercises on anxiety and depression

					alternative for anxiety, mindfulness behaviors were significant for anxiety, depression, or PTSD	
Schuch, F. B., & Vancampfort, D. (2021).	2	Discusses the preventative effects of exercise on mental health disorders as well as health promotion for individuals with mental health	Meta analysis of available data	N/a	Identifies barriers to individuals staying consistent with physical exercise	Increase understanding of potential barriers that may be encountered in the study

		disorders				
Ströhle, A., Gensichen, J., & Domschke, K. (2018).	8	Purpose of the study is to provide an update on anxiety statistics and note how to diagnose and treat the condition.	Educational review of available data on anxiety	N/a	Informative on types of anxiety disorders and clinical manifestations.	Provides background on anxiety diagnosis and treatment.
Kandola, A., Vancampfort, D., Herring, M., Rebar, A., Hallgren, M., Firth, J., & Stubbs, B. (2018).	3	Discuss the relationship between physical activity and anxiety and provide rationale for including it as a treatment option	Highlights the effects of anxiety on the body and the associated medical comorbidities that could develop	n/a	Has evidence that suggests physical activity helps anxiety but due to multiple variances in studies further research is	Helps researcher understand the associated medical comorbidities of anxiety

					needed	
Ramos-Sanchez, C. P., Schuch, F. B., Seedat, S., Louw, Q. A., Stubbs, B., Rosenbaum, S., Firth, J., van Winkel, R., & Vancampfort, D. (2021).	2	Provide an update on the evidence to demonstrate exercise as a treatment for anxiety	Meta-analysis of recent data with a focus on lifestyle changes in the promotion of anxiety treatment	Exercise and anxiety relief	Evidence supports previous notions of exercise in the treatment plan of anxiety, but study was small and had bias	Used to demonstrate a need for further investigation into the relationship between exercise and anxiety
Dhira, T. A., Rahman, M. A., Sarker, A.	3	To prove the validity and reliability of the GAD 7	Repeated cross-sectional survey design study	PHQ9	Cronbach's alpha – 0.895	Proves to be a valid tool for the study

R., & Mehareen, J. (2021).		questionnaire in a different construct				
Hashemzadeh, M., Rahimi, A., Zare-Farashbandi, F., Alavi-Naeini, A. M., & Daei, A. (2019).	3	Review the TTM in the setting of chronic conditions and follow individual behavior patterns.	Literature Review	n/a	TTM confirmed to be an adequate tool to measure behavioral changes in multiple constructs	Show how TTM can be used in other areas and remain significant

APPENDIX C

GAD -7 TOOL

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
Add the score for each column	+	+	+	
Total Score *(add your column scores)* =				

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all _____
Somewhat difficult _____
Very difficult _____
Extremely difficult _____

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Inern Med.* 2006;166:1092-1097.