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# Improvement of Pain-Free Walking Distance with Implementation of Treadmill Protocol

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**Abstract**

Peripheral arterial disease (PAD) may cause lower extremity pain that can impair activities of daily living. At a vascular clinic in rural New Mexico, peripheral arterial disease patients are managed but their symptoms continue to worsen so an evidence- based solution was sought. The purpose of this quantitative, quasi-experimental project was to determine if or to what degree the translation of McDermott et al.'s published research on the Gardner-Skinner Protocol will impact the pain-free walking distance when compared to current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico over four weeks. Dorothea Orem's self-care theory and Kurt Lewin's change theory provided the project's theoretical foundations. Data on walking distance was measured using the Six-Minute Walk Test in PAD patients ($n$ = 12) and were compared at baseline and four weeks post-implementation of the intervention. A paired t-test showed no statistically significant difference in pain-free walking distance from baseline ($M$ = 267.85, $SD$ = 244.05) to post-intervention ($M$= 339.58, $SD$= 191.42), $t$ (11) = -1.27, $p$= .23. Despite the lack of statistical significance, there was clinical significance in that the mean increase in pain-free walking distance increased by 70.83 feet. Therefore, the implementation of the Gardner-Skinner Protocol may improve walking distance in this population of patients. Recommendations are to continue the implementation and continue to analyze data for six months prior to dissemination.

**Keywords**: Intermittent claudication, Pain-free walking, Supervised exercise therapy, Chronic venous disease, Exercise, Vascular disease, Gardner-skinner treadmill walking protocol, Orem's self-care theory, Lewin's change theory, Six-minute walk test

## Chapter 1: Introduction to the Project

Peripheral arterial disease (PAD) is a chronic atherosclerotic disease of the lower extremities affecting millions of Americans.[1] A primary symptom of peripheral arterial disease is intermittent claudication (IC), or pain in the lower extremities induced with activity and relieved with rest.[2] Living with claudication has seriously affected the walking capacity and quality of life of the peripheral arterial disease population.[3] In addition, the burden of peripheral arterial disease has significantly increased the risk of cardiovascular morbidity and mortality, causing three times the risk of mortality in older adults with claudication.[4] Evidence from multiple randomized clinical trials has shown the efficacy of treadmill-based walking programs and an improvement in walking distance, claudication pain, quality of life, and reduced risks of cardiovascular disease.[5-8] Furthermore, the American Heart Association and the American College of Cardiology Society consider treadmill walking the gold standard in treating claudication, rating this form of exercise a Class IA level of evidence.[4]

Current practice in the treatment of peripheral arterial disease patients with intermittent claudication at a rural vascular clinic includes ankle-brachial index measurements to evaluate atherosclerosis in the lower extremities, pharmacotherapy management such as anti-platelet and anti-coagulation medications, and lifestyle modifications such as smoking cessation, a heart-healthy diet, and adequate exercise to reduce cholesterol levels. However, these treatment recommendations have not been followed by patients. This quality improvement project aimed to improve the pain-free walking distance and quality of life for the peripheral arterial disease population by deploying a treadmill-walking-based program based on the translation of McDermott et al.'s research on the Gardner-Skinner Protocol.[6] Before the project implemented this protocol, a baseline measurement of each participant's pain-free walking distance was measured utilizing the Six-Minute Walk Test (6MWT). At the end of the five weeks, the pain-free walking distance for each participant was measured utilizing the 6MWT, and pre-and post-implementation data were compared to demonstrate the impact of the project.

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In the preceding sections of this chapter, an overview of peripheral arterial disease and its impact on walking distance and quality of life is discussed. In addition, the current problem among peripheral arterial disease patients with intermittent claudication in a rural vascular clinic was investigated. Moreover, a clinical question will address the problem statement of this project, and a definition of terms will provide a collective understanding of the concepts within this project. Finally, a summary of key points from this chapter will be discussed.

**Background of the project**

Peripheral arterial disease impedes activities of daily living. The severe consequences of this condition warrant further investigation. Pain associated with claudication significantly affects the mobility of peripheral arterial disease patients, forcing them to become less active and have a poorer quality of life.[5] In addition to becoming sedentary, peripheral arterial disease patients with intermittent claudication have an increased risk of obesity, cardiovascular disease, 3 cardiovascular events such as stroke, comorbidities, and all-cause mortality.[4,9]

A global health concern among peripheral arterial disease patients is the risk of amputations associated with foot ulceration and critical limb ischemia.[10] Moreover, peripheral arterial disease patients incur a financial burden. One million Americans with peripheral arterial disease receive medical care costing more than 4 billion dollars.[11] Currently, peripheral arterial disease patients with intermittent claudication in a rural vascular clinic have become sedentary, therefore increasing their risk of limb ischemia and amputation. Furthermore, a supervised exercise program can improve blood flow to the lower extremities and increase walking distances, thereby reducing the risk of critical limb ischemia and amputation.[12]

This quality improvement project aimed to enhance outcomes for individuals with peripheral arterial disease. Current practice includes educational teaching of peripheral arterial disease, claudication, and the impact of lifestyle modifications on disease progression to assure cognitive understanding and compliance with exercise. Thus, the translation of McDermott's research on the Gardner-Skinner Protocol was worth implementing to improve the overall health and quality of life for peripheral arterial disease patients with intermittent claudication.

**Problem statement**

Peripheral arterial disease with intermittent claudication disrupts activities of daily living and limits individuals' quality of life.[2,9] Although peripheral arterial disease is shared, associated severe comorbidities such as hypertension, diabetes, and smoking can profoundly impact the overall health of4 this population.[13] Peripheral arterial disease is a growing health concern in the United States as it affects eight million Americans (Duscha 2018). Peripheral arterial disease patients with intermittent claudication suffer from lower extremity pain that impairs their walking ability, thereby causing a decrease in activity levels and negative health outcomes.[5]

Current practice at a rural vascular clinic treating peripheral arterial disease patients with intermittent claudication includes medication management to improve blood flow to the lower extremities, reduce cholesterol levels, and claudication pain management. In addition, vascular medicine specialists counsel patients on lifestyle modifications such as smoking cessation, a heart-healthy diet, and walking two to four times a week for 10 to 45 minutes. However, peripheral arterial disease patients with intermittent claudication are not adhering to lifestyle changes or recommended routine walking activity. These individuals have become more sedentary, have increased body mass indexes (BMIs) and continue to smoke. It was not known if or to what degree the translation of McDermott's published research on the Gardner-Skinner Protocol would impact walking distance when compared to current practice among peripheral arterial disease patients with intermittent claudication.

This quality improvement project aimed to translate evidence-based research and apply it into practice. The translation of Mc Dermott's research on the Gardner- Skinner Protocol consists of having the participant walk on a treadmill at a constant speed of two miles per hour (mph), beginning with the treadmill grade at zero percent and increasing it by two percent every two minutes and walking the participant until mild to moderate levels of claudication is experienced.[6,14] The project aimed to improve the pain-free walking distance, decrease claudication pain, and increase the quality of life for the peripheral arterial disease population. Implementing an evidence-based intervention such as the translation of McDermott's research on the Gardner-Skinner Protocol was ideal for this population because it offered an exercise program that improved pain-free walking distance while providing a network of support.

**Purpose of the project**

The purpose of this quantitative, quasi-experimental quality improvement project was to determine if or to what degree the translation of McDermott's published research on the Gardner-Skinner Protocol would impact the pain-free walking distance compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico over four weeks. The Gardner-Skinner Protocol is considered a standardized graded treadmill exercise protocol for supervised exercise therapy.[15] Furthermore, the independent variable for this quality improvement project was the translation of McDermott's research on the Gardner-Skinner Protocol. As previously stated, the protocol requires that the treadmill speed be held constant at two miles per hour (mph). Initially, the treadmill grade begins at 0% and increases by 2% every two minutes.[14]

Each participant was asked to walk on the treadmill until moderate claudication was experienced. The total time walked and treadmill grade was documented for each participant. The education plan for providers included how treadmill walking can enhance claudication and walking distances, the translation of McDermott's research on the Gardner-Skinner Protocol and how it was implemented, and lifestyle modifications such as smoking cessation, a heart-healthy diet, and daily exercise.

The dependent variable was the pain-free walking distance. Quantitative data on walking distance was collected at baseline and five weeks post-intervention of the translation of McDermott's research on the Gardner-Skinner Protocol utilizing the Six-Minute Walk Test. The Six-Minute Walk Test measures how far a patient can walk in a 100-foot flat, solid surface hallway over six minutes.[16] The patient sample for this quality improvement project was comprised of peripheral arterial disease patients with mild to moderate levels of claudication. Moreover, the intended purpose of this project was to improve the pain-free walking distance for intermittent claudication patients and enhance the overall quality of life.

This quality improvement project aimed to educate nurses and providers with scientific evidence-based research that demonstrated the importance of incorporating exercise such as walking into a care plan. In addition, this quality improvement project aimed to provide an educational platform for nurses and their peripheral arterial disease patients that can be utilized upon discharge from a hospital or in an outpatient setting.

Finally, this project serves to advance the nursing profession by laying the groundwork and foundation to build a peripheral arterial disease rehabilitation program and salvage limb program for this population.

### Clinical question

Evidence shows that supervised exercise therapy improves walking distance and quality of life in patients with peripheral arterial disease and intermittent claudication.[17,18] In addition, supervised exercise therapy improves cardiovascular risk factors and claudication onset time.[5,17] Current practice within a vascular specialty clinic includes counseling peripheral arterial disease patients with intermittent claudication to walk 10 to 45 minutes two to four times a week. However, the population is not adhering to this recommendation from vascular specialists. Return follow-up visits with the vascular clinician showed that claudication pain had worsened frequently, and their activity levels had declined. There are no supervised exercise therapy services offered to this population at the project site.

The translation of McDermott's research on the Gardner-Skinner Protocol (independent variable) is a standardized graded treadmill exercise protocol for supervised exercise therapy that has been approved by the American College of Cardiology Society.[6,14] Pain-free walking distance (dependent variable) was the measurable outcome for this practice improvement project to determine whether the pain-free walking distance prior to implementing the translation of McDermott's research on the Gardner-Skinner Protocol improved afterward. This project aimed to implement the translation of McDermott's research on the Gardner-Skinner Protocol to improve pain-free walking distance and the overall quality of life for peripheral arterial disease patients with intermittent claudication. The project answered the clinical question:

> To what degree does the translation of McDermott's published research on the Gardner-Skinner Protocol impact the pain-free walking distance when compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico?

### Advancing scientific knowledge

Understanding the benefits of implementing a supervised exercise program for peripheral arterial disease patients with intermittent claudication is essential for improving quality and patient outcomes.[19,20]

Although supervised exercise therapy is considered a first-line treatment for peripheral arterial disease patients with intermittent claudication, it remains underutilized.[15] There is potential to advance patient education and enhance the walking capacity for peripheral arterial disease patients with intermittent claudication.

This quality improvement project advanced scientific knowledge by contributing to the literature on supervised exercise therapy for patients with intermittent claudication.

In addition, this project contributed to the current literature that supports high-intensity exercise such as walking until moderate claudication pain is experienced for this population. Furthermore, this project advanced scientific knowledge by contributing to the evidence supporting exercise therapy to enhance pain-free walking distance and quality of life among peripheral arterial disease patients.

Dorothea Orem's self-care theory and Kurt Lewin's change theory provided the theoretical foundations for this practice improvement project. Orem's self-care theory emphasizes the importance of self-care in promoting well-being.[21] This theory includes practices that individuals perform on their behalf to maintain their health and life.[21] A person's knowledge of lifestyle modifications in the treatment of peripheral arterial disease is necessary for promoting self-care behaviors, thereby improving claudication pain. Orem's self-care theory was utilized to advance scientific knowledge by incorporating an educational platform of self-care practices such as smoking cessation, a heart-healthy diet, and routine exercise prior to measuring the baseline walking distance of peripheral arterial disease patients.

Lewin's change theory consists of three phases: unfreezing, change, and refreezing.[22] The unfreezing stage was comprised of analyzing the patient's old way of thinking, behavior, and processes during patient education, therefore, providing the driving force of this practice improvement project. The second stage, change, included the translation of McDermott's research on the Gardner-Skinner Protocol for peripheral arterial disease patients with intermittent claudication. The refreezing stage established a supervised exercise program integrated into an outpatient cardiac rehabilitation center with a referral process for inpatient and outpatient services.

Furthermore, Lewin's change theory was helpful in successfully implementing this project to guide practice and sustain change within the organization.

**Significance of the project**

At a vascular specialty clinic in a rural area of New Mexico, intermittent claudication patients are not adhering to a recommended walk routine at home. Intermittent claudication patients are medically managed with antiplatelet therapy, antihypertensive medications, statins, controlled blood sugar levels, and lifestyle modification counseling. Lifestyle modifications included smoking cessation, eating a heart-healthy diet, and recommended walking, which aligns with the American Heart Association clinical practice guidelines.[23] Moreover, supervised exercise therapy has been shown to improve walking distance, claudication pain levels, and reduce cardiovascular risk factors.[5,18] There was no supervised exercise program in place at the project site, which this project addressed.

The problem with peripheral arterial disease patients with intermittent claudication and lack of exercise is significant because of the increased risk of all-cause and cardiovascular mortality.[23] In addition, the rural area of New Mexico has minimal resources for offering support and education for the peripheral arterial disease population. Implementing supervised exercise therapy for intermittent claudication patients could serve as an available resource and provide a supportive and educational environment while improving their pain-free walking distance and quality of life. Furthermore, research shows that supervised exercise programs can promote the growth of collateral arteries, thus improving pain-free walking distances and improving the quality of life.[5,24]

Peripheral arterial disease affects over eight million adults in the United States, and 7% of those affected are adults 40 years of age and older.[23] The rural clinic primarily serves a retired community. In a recent census of New Mexico, diabetes was found to affect the minority populations and the elderly.[25] Furthermore, diabetes can significantly impact the functional and overall health of peripheral arterial disease patients with intermittent claudication.

The incidence of peripheral arterial disease not only increased with age but with other factors such as diabetes, smoking, and cardiovascular disease.[10] Therefore, the application of this project for intermittent claudication patients was to improve pain-free walking distances and extend the quality of life for these individuals. A second potential application of the project was weight loss and better control of glycemic indexes, thus reducing cardiovascular risk factors and improving the overall health of this population.

**Rationale for methodology**

This project utilized a quantitative methodology to produce measurable data with numbers, thus generating new knowledge.[26] Moreover, a quantitative methodology efficiently provided accurate results utilizing numerical data.[27] Hence, the data collected was used to perform a statistical analysis to illustrate the relationship between the variables. Furthermore, the quantitative method was the best fit for this project to collect measurable data on patients' walking distance to determine if there was a statistically or clinically significant improvement.

A qualitative methodology was not appropriate for this project. Qualitative research collects and analyzes non-numerical data. Moreover, a qualitative study further understands a phenomenon utilizing an interpretive approach.[26] Therefore, a qualitative methodology would not be helpful for this project since it analyzes non-numerical data.

This quality improvement project aimed to answer whether the pain-free walking distance (dependent variable) was impacted by the translation of McDermott's research on the Gardner-Skinner Protocol (independent variable), thus indicating the need to use the quantitative method. Before implementing the translation of McDermott's research on the Gardner-Skinner Protocol, each participant completed a Six-Minute Walk Test. Each participant's pain-free walking distance was documented in an Excel spreadsheet. After implementing the translation of McDermott's research on the Gardner-Skinner Protocol, each participant was asked again to walk for six minutes, and the pain-free walking distance was recorded. Finally, the data was analyzed to determine the association between the independent and dependent variables.

**Nature of the project design**

This practice improvement project utilized a quasi-experimental design to answer whether the translation of McDermott's research on the Gardner-Skinner Protocol would impact the pain-free walking distance among peripheral arterial disease patients with intermittent claudication. A quasi-experimental design was appropriate for this practice improvement project because it allowed for the implementation of the intervention, the translation of McDermott's research on the Gardner-Skinner Protocol, to determine its effect on pain-free walking distance. In addition, a quasi-experimental design does not require much control as an experimental design. An experimental design requires control, and participants are randomly assigned to a treatment group and a control group (Research Connections, n.d.). Therefore, a quasi-

experimental design was a better fit than an experimental design because it provided an opportunity to implement an intervention to determine its effect.

Evidence-based literature and current practice guidelines from the American Heart Association and the American College of Cardiology Society have demonstrated distinct associations between the Gardner-Skinner Protocol and walking distance among peripheral arterial disease patients with intermittent claudication.[17] The population sample investigated were adults aged forty and older with a diagnosis of peripheral arterial disease with mild to moderate intermittent claudication. Before implementing the translation of McDermott's research on the Gardner-Skinner Protocol, each participant performed the Six-Minute Walk Test, documenting the pain-free walking distance. After implementing the translation of McDermott.'s research on the Gardner-Skinner Protocol, each participant performed the Six-Minute Walk Test again, and the pain-free walking distance was documented. A paired *t*-test analysis was performed to illustrate the correlation between the independent and dependent variables, which aligns with the quasi-experimental design.

## Definition of terms

This project evaluated and applied evidence-based literature and clinical guidelines into practice and measured patient outcomes.[28] This quality improvement project focused on patients with peripheral arterial disease and intermittent claudication. Defining terms related to this project is essential to understanding the content. The following terms were utilized operationally within this project.

### *Clinical significance*

Clinical significance determines if project outcomes are meaningful to clinicians.[29]

### *Comparison and intervention group*

The sample for this project consisted of peripheral arterial disease patients with mild to moderate intermittent claudication. The comparison group was the sample of peripheral arterial disease patients with intermittent claudication in which within-group differences were analyzed.[30] The intervention group was the sample of peripheral arterial disease patients with intermittent claudication.

### *Gardner-skinner protocol*

This standardized, well-accepted treadmill walking protocol is utilized frequently in randomized controlled trials.[17] This protocol begins with having the peripheral arterial disease patient with intermittent claudication walk on a treadmill at grade zero and two miles per hour. The speed of two miles per hour stays the same throughout testing, while the treadmill grade increases by 2% every two minutes.[17] Participants are asked to walk until they experience mild to moderate pain, fatigue, or other symptoms that may prevent them from walking any further.[17]

### *Intermittent claudication*

Intermittent claudication is a pain in the lower extremities induced with exercise and relieved with rest.[31]

### *Peripheral arterial disease*

Peripheral arterial disease is caused by plaque blockage in the vessels of the lower extremities.[32]

### *Six-minute walk test*

The six-minute walk test is a well-validated measurement of an individual's ability to walk in a 100-foot hallway clear of obstructions in a six-minute period. The distance walked until six minutes have elapsed is documented. Participants are allowed to rest; however, the time does not stop while the participant is resting. The duration of rest is documented.[17]

### *Statistical significance*

Statistical significance tests a hypothesis and is determined by a *p*-value.[29] Furthermore, statistical significance is determined if the *p*-value is less than the predetermined alpha value.[33]

### *Supervised exercise therapy*

For this project, supervised exercise therapy was defined as walking on a treadmill until mild to moderate claudication was experienced three times a week.[4]

## Assumptions, Limitations, Delimitations

This quality improvement project was based on several assumptions. It was assumed that each participant was selected without bias from the vascular specialists to ensure an accurate representation of the population of interest. Moreover, reducing selection bias within the project will maintain the internal and external validity of the quality improvement project.[34] Second, it was assumed that the staff documenting the data would document all necessary data accurately without bias to minimize misinterpretation. Accurate documentation of the data adds validity to the project.[35] In addition, data that is accurately reported ensures that the data can be understood. Third, it was assumed that each participant experienced lower extremity pain with an exercise related to decreased blood flow. This assumption was based on the premise that neurological disorders can imitate symptoms of vascular claudication.[36] Thus, supervised exercise therapy promotes blood flow to the lower extremities in patients with mild to moderate claudication pain in peripheral arterial disease patients.[37]

The brief period of four weeks to implement this quality improvement project was a limitation. Benefits of a supervised exercise program are evident after four weeks of treadmill walking

sessions. However, maximum benefits are profoundly significant at 12 weeks.[7]

Although the brief period of four weeks was a limitation for this project, the benefits of implementing supervised exercise therapy for peripheral arterial disease patients with intermittent claudication were worth investigating. A second limitation of this project was the small sample size of 12 participants. Due to the COVID-19 pandemic, obtaining an adequate sample size was challenging. A third limitation was the use of one project site in the rural area of New Mexico located outside the city limits. One project site in a rural area restricts the convenience and availability a multi-center would offer. A fourth limitation was the strict adherence to three weekly walking sessions over five weeks to implement this quality improvement project. Multiple weekly walking sessions would disrupt routine work schedules or care for a family member.

Supervised exercise therapy has received a Level I Class A level of evidence for peripheral arterial disease patients with intermittent claudication.[4] In the future, limitations could be overcome with the implementation of mobile health technology and the utilization of a step tracker versus supervised exercise therapy. In addition, a delimiting demographic sample can be overcome in the future by recruiting peripheral arterial disease patients with intermittent claudication from other areas of New Mexico that are culturally diverse such as big cities and Indian reservations.

### Summary and organization of the remainder of the project

Peripheral arterial disease is a growing health concern in the United States as it 17 affects millions of Americans, causing impaired walking function and a decreased quality of life.[9,38] Evidence shows that supervised exercise therapy can improve walking distance and claudication.[5,18] This project determined the impact of the translation of McDermott's research on the Gardner-Skinner Protocol on pain-free walking distance of patients with intermittent claudication over four weeks.

Chapter 2 reviews the current literature and evidence central to peripheral arterial disease and supervised exercise therapy. Chapter 3 explores the project methodology, design, and procedures. Moreover, Chapter 4 will outline how the data was analyzed and the results discussed and illustrated with graphs. Finally, Chapter 5 presents a comprehensive overview of this quality improvement project and includes the project's conclusions, implications, and recommendations.

## Chapter 3: Methodology

Peripheral arterial disease with intermittent claudication is a progressive condition that impairs individuals' functional capacity and quality of life, thus increasing the risk for cardiovascular disease.[9] Evidence demonstrated the efficacy of a supervised exercise program in improving peripheral arterial disease patients' walking distances and quality of life, thereby reducing cardiovascular risk factors.[5,18] Gardner-Skinner's Protocol has been implemented in studies as a supervised exercise for peripheral arterial disease patients to measure maximal treadmill walking distance.[15] The purpose of this quantitative, quasi-experimental quality improvement project was to determine if or to what degree the translation of McDermott's published research on the Gardner-Skinner Protocol would impact the pain-free walking distance compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico over four weeks.

This quality improvement project discovered the impact of the translation of McDermott's research on the Gardner-Skinner Protocol on pain-free walking distance of peripheral arterial disease patients with intermittent claudication. Pain-free walking distances were measured for a particular group of patients utilizing the Six- Minute Walk Test. This chapter explains that the project employed a quantitative method with a quasi-experimental design. Discussions also include the data collection and analysis processes and ethical considerations.

### Statement of the problem

In a rural area of New Mexico, intermittent claudication patients in a vascular specialty clinic are medically managed to reduce symptoms and risk factors for cardiovascular disease. In addition, patients are counseled on the importance of lifestyle modifications such as smoking cessation, a heart-healthy diet, and exercise. However, these patients were not compliant with lifestyle changes; therefore, claudication pain was worsened. It was not known if or to what degree the translation of McDermott's published research on the Gardner-Skinner Protocol would impact pain-free walking distance when compared to current practice among peripheral arterial disease patients with intermittent claudication.

The standard treatment for patients with intermittent claudication is medical management with antihypertensives, antiplatelet therapy, and statins to improve symptoms associated with this disease.[39] General problems associated with peripheral arterial disease patients and intermittent claudication are the lack of adherence to lifestyle modifications such as smoking cessation, proper nutrition, and exercise. Moreover, the lack of adherence to lifestyle changes invokes an unnecessary financial burden on this population. This quality improvement project sought to elicit adherence in three distinct phases—first, educational teaching of peripheral arterial disease, including proper nutrition and exercise. The second phase was the translation of McDermott's research on the Gardner-Skinner Protocol. The third was a follow-up assessment of the pain-free walking distance measured by the Six-Minute Walk Test.

### Clinical question

Evidence shows that supervised exercise therapy improves walking distance and quality of life in patients with peripheral arterial disease and intermittent claudication.[8,18] In addition,46

supervised exercise therapy improves cardiovascular risk factors such as blood pressure and claudication onset time.[5,17] The following clinical question guided this quality improvement project:

> To what degree does the translation of McDermott's published research on the Gardner-Skinner Protocol impact the pain-free walking distance when compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico?

The Gardner-Skinner Protocol is a standardized graded treadmill exercise protocol for supervised exercise therapy approved by The American College of Cardiology Society.[14] The independent variable, the translation of McDermott's research on the Gardner-Skinner Protocol, was measured at a nominal level. The pain-free walking distance (dependent variable) was the measurable outcome for this quality improvement project and was measured at a ratio level. The pain-free walking distance was measured by the Six-Minute Walk Test, which the research has validated. This project examined if implementing the translation of McDermott's research on the Gardner-Skinner Protocol improved pain-free walking distance and the overall quality of life for peripheral arterial disease patients with intermittent claudication.

A baseline measurement of each participant's pain-free walking distance was collected before implementing the translation of McDermott's research on the Gardner-Skinner Protocol, utilizing the Six-Minute Walk Test. The Six-Minute Walk Test measures the functional capacity by measuring how far a patient can walk in a 100- foot flat, firm surface hallway for over six minutes.[16] The total pain-free distance walked by each participant was recorded. After implementing the intervention, the participant's pain-free walking distance was again measured by the Six- Minute Walk Test. These two results were compared as this method was the best approach to answer the clinical question.

**Project methodology**

A quantitative methodology was utilized to collect numerical data on pain-free walking distances among individuals with peripheral arterial disease and intermittent claudication. Quantitative research produces measurable data with numbers. In addition, an objective measurement of the data is attained utilizing a statistical analysis approach.[40] Furthermore, a quantitative methodology was appropriate for the implementation of this project to ensure an accurate collection and data analysis with the collection of measurable numerical data.[41]

A qualitative methodology is based on subjective data utilizing non-numerical data.[40] Moreover, a qualitative study can further understand a natural phenomenon utilizing an interpretive approach.[26] Furthermore, a qualitative methodology was not the best fit for this project because it collects and analyzes subjective data to understand natural phenomena further.

However, the quantitative method was appropriate for this project due to the numeric nature of the data collected on the dependent variable. Quantitative data collected from this project was the pain-free walking distance pre- and post- implementation of the translation of McDermott's research on the Gardner-Skinner Protocol. In addition, the duration of each walking session was documented for each participant.

**Project design**

This practice improvement project utilized a quasi-experimental design to answer whether the translation of McDermott's research on the Gardner-Skinner Protocol would impact pain-free walking distance among peripheral arterial disease patients with intermittent claudication. A quasi-experimental design was appropriate for this quality improvement project because it would allow the independent variable, the translation of McDermott's research on the Gardner-Skinner's Protocol, to be implemented to determine its effect on the pain-free walking distance among patients with intermittent claudication. Furthermore, a quasi-experimental design allows an intervention to be implemented to determine its effect on a population without control, such as randomization of participants.[42] An experimental design utilizes control, and participants are randomized into groups. Therefore, a quasi-experimental design was appropriate for this quality improvement project.

Before implementing the translation of McDermott's research on the Gardner-Skinner Protocol, each participant performed a Six-Minute Walk Test, and their pain-free walking distance was documented (baseline data). After implementing the translation of McDermott's research on the Gardner-Skinner's Protocol, each participant performed another Six-Minute Walk Test, and the pain-free walking distance was documented (post-implementation data). Finally, an analysis was performed to determine the correlation between the independent and dependent variables and answer the clinical question.

**Population and sample selection**

The project site for this quality improvement project was a university activity center in rural New Mexico. The activity center was set in a retirement community, and much of the demographic population was comprised of Hispanics and Whites (U.S. Census Bureau, n.d.). The population of this rural area consists of retirees and veterans. There are two small hospitals, each with an outpatient cardiac rehabilitation center. Although there are outpatient cardiac rehabilitation services offered to cardiac patients, no rehabilitation services are offered for peripheral arterial disease patients with intermittent claudication.

The targeted population group for this project was individuals with a diagnosis of peripheral arterial disease with mild to moderate intermittent claudication who attended the vascular specialty clinic. Sampled participants belonged to this targeted population group and were non-compliant with lifestyle modifications. Utilizing G*Power, a sample size of 30 participants was calculated as the minimum sample necessary to determine statistical significance.[43]

Recruitment of 12 peripheral arterial disease patients with intermittent claudication occurred within the vascular specialty clinic in rural New Mexico. Inclusion criteria for participation in this project were adults ages 40 and older, diagnosis of peripheral arterial disease with mild to moderate intermittent claudication, ankle-brachial index <0.90, cognitively ability to make informed decisions, and physically able to walk on a treadmill without an assistive device. Exclusion criteria included unstable angina, uncontrolled cardiac arrhythmias, decompensated heart failure, severe or symptomatic heart disease, critical limb ischemia, and wounds to plantar surfaces.[44] The first 30 eligible participants selected by vascular specialists utilizing a chart review of the electronic medical record of peripheral arterial disease patients with intermittent claudication were screened to participate in this quality improvement project. Nine patients declined participation due to a long-distance commute to and from the project site thrice a week. Four patients became ill and were hospitalized. Five patients dropped out of the project. Therefore, only 12 eligible patients participated in this quality improvement project.

The vascular specialists (vascular surgeons and one nurse practitioner) prescreened patients eligible for a supervised exercise program. Once eligible participants were identified, any of the above vascular specialists approached the participants. Before implementation, a flyer was given to each eligible participant that explained the quality improvement project, including the benefits, dates, times, location, and duration of the project. Patients were identified through a chart review and recruited by the vascular specialists within the clinic. Confidentiality measures were defined according to the Health Insurance Portability and Accountability Act (HIPAA). Confidential patient information was secured within the electronic health record at the vascular clinic.

**Instrumentation**

The instruments used in this project were the translation of McDermott's research on the Gardner-Skinner Protocol and the European Respiratory Society/American Thoracic Society Six-Minute Walk Test. Before the intervention, each participant performed the European Respiratory Society and American Thoracic Society Six-Minute Walk Test to collect data on baseline pain-free walking distances. The Six-Minute Walk Test measures endurance and aerobic capacity (American Journal of Respiratory and Critical Care Medicine, 2022). Each participant was required to walk a 100-foot hallway for six minutes at their own pace.

The registered nurse recorded the total pain-free distance walked in six minutes.

The Gardner-Skinner Protocol is a standardized treadmill walking protocol commonly utilized in supervised exercise programs for peripheral arterial disease patients with intermittent claudication. Moreover, the Gardner-Skinner Protocol has been utilized in many studies to assess walking distance and functional capacity in peripheral arterial disease patients with intermittent claudication.[6,45] The translation of McDermott's research on the Gardner-Skinner Protocol required a nurse to monitor each participant on the treadmill, walking the patient to mild and moderate levels of claudication each walking session. The nurse documented the total time walked by each participant and treadmill grade on an Excel spreadsheet.

**Validity**

The Gardner-Skinner Protocol was initially developed to determine the reliability of claudication pain during treadmill testing.[46] The protocol compares the effects of a treadmill test and its impact on walking distance and claudication pain among peripheral arterial disease patients. In the original study by Gardner[46] the investigators analyzed and compared two types of treadmill testing: progressive versus single-stage treadmill test.

Gardner[46] theorized that a progressive, multiple-stage treadmill test would reduce claudication pain, maximal walking distance, and maximal walking time among peripheral arterial disease patients. The authors of this study concluded that the claudication pain distance and maximal walking distance were more dependable after a 52 progressive treadmill test (claudication pain, $R = 0.89$, maximal walking distance, $R = 0.93$) than the single-stage treadmill test (claudication pain, $R = 0.53$, maximal walking distance, $R = 0.55$). Therefore, the severity of peripheral arterial disease is better assessed using a progressive treadmill test because measurements are more dependable during exercise and recovery.[46]

Guidelines published by the European Respiratory Society and American Thoracic Society provide a guide to the use and application of the Six-Minute Walk Test to assess the functional capacity and treatment response for peripheral arterial disease patients and chronic respiratory diseases.[47] Therefore, with permission from the authors, the guidelines published by the European Respiratory Society and American Thoracic Society for the Six-Minute Walk Test were utilized to measure the pain-free walking distance among peripheral arterial disease patients with intermittent claudication. In a cross-sectional study by Montgomery and Gardner[48] the authors investigated the relationship between the total distance covered during a six- minute walk test and clinical measures of peripheral arterial disease. The authors concluded that the six-minute walk test produced exceptionally reliable results (distance walked, $R = .94$, steps taken, $R = .90$) concerning the functional capacity of peripheral arterial disease patients with intermittent claudication.[48]

**Reliability**

The Gardner-Skinner Treadmill Walking Protocol is one of two distinct types of treadmill protocols utilized. The Gardner-Skinner protocol is considered a graded treadmill protocol, whereas the continuous treadmill is the other. In a meta-analysis of eight studies and 658 patients, Nicolai determined the reliability of a constant versus graded treadmill protocol for initial claudication distance and absolute claudication distance. The estimated reliabilities of continuous and graded treadmill protocols were 0.85 and 0.83 without the dependency of the reliability on velocity or grade of the treadmill. Furthermore, the reliability for absolute claudication distance was significantly better for the graded treadmill protocol (0.95. 95% *CI:* 0.94-0.96) than for the continuous treadmill protocol (95% *CI*: 0.54-0.88).[49]

The Six-Minute Walk Test is commonly utilized to measure the functional capacity of individuals with peripheral arterial disease.[47] Hamilton and Haennel[50] examined the validity and reliability of the Six-Minute Walk Test in a cardiac rehabilitation program. In a sample size of 94 patients, each participant completed three six-minute walk tests on nonconsecutive days.[50] In addition, the participants completed the Duke Activity Status Index and Short Form 36 Health Survey. Maximum metabolic equivalents from a graded exercise test were obtained from patient files.[50]

The study concluded that the six-minute walk was related to maximum metabolic equivalents ($r = 0.687$, $p < 0.001$), supporting the validity of the test. Furthermore, participants walked significantly further in each Six- Minute Walk Test ($F = 19.83$, $p < 0.001$); hence, a strong test-retest reliability was demonstrated.[50]

**Data collection procedures**

The data collection process began following approval from Grand Canyon University's Institutional Review Board. Once approval was received, the vascular specialists received a presentation of the project in a PowerPoint presentation. A presentation of the independent variable, the translation of McDermott.'s research on the Gardner-Skinner Protocol, and the dependent variable, pain-free walking distance, were discussed. In addition, the use of the validated tool, the Six-Minute Walk Test, was presented and discussed.

Vascular specialists such as nurse practitioners and vascular surgeons identified eligible participants at the vascular clinic. Each eligible participant was approached by a vascular specialist, educated on this quality improvement project, including the benefits of walking, and given a handout of dates, times, location, and instructions to begin participation. The registered nurse's point of contact information was provided to each participant for any questions.

Current practice within the vascular clinic includes educational teaching of peripheral arterial disease, pathophysiology, and management of symptoms at each office visit. The importance of lifestyle modifications was emphasized, and the opportunity was provided to ask questions. Moreover, the benefits of a treadmill walking program were discussed with each eligible participant to improve pain-free walking distances and overall quality of life. Next, each participant was asked to walk self-paced a 100-foot hallway for six minutes, taking as much rest as needed. However, the stopwatch was not paused during rest breaks. Each participant's total pain-free distance walked (dependent variable) was documented on an Excel spreadsheet. The translation of McDermott's research on the Gardner-Skinner Protocol (independent variable) occurred three times a week. Each participant walked until the initial onset of moderate claudication. On the final day, each participant performed a Six-Minute Walk Test again, and the total pain- free distance walked was documented on an Excel spreadsheet.

Documentation containing patient information and data collected from this quality improvement project was stored in a desk drawer with a lock at the vascular specialty clinic. The vascular nurse practitioner and a registered nurse had access to patient information coded to protect patient information. Data collected was retained for the project duration (five weeks total). After five weeks, the data was destroyed by placing the Excel spreadsheet in a paper shredder at the vascular clinic.

Each participant was identified by gender, age, and race and assigned a number 1-30 on the spreadsheet to track pain-free walking distances, treadmill grade, and treadmill walking time. No patients' identifying information was documented on the Excel spreadsheet. The rights and well-being of each participant were protected by designating the chief quality officer as the quality improvement leader for this project to ensure safe and equitable healthcare was delivered. A statistician analyzed the data to interpret results accurately and without bias.

**Data analysis procedures**

A G*Power analysis determined that a sample size of 30 participants would determine statistical significance.[51] Therefore, the first 30 eligible participants were selected for this project. The project investigated the degree to which implementing the translation of McDermott's research on the Gardner-Skinner Protocol would impact the pain-free walking distance of patients with peripheral arterial disease and intermittent claudication. The data analysis for this quality improvement project occurred in the following steps. First, the data collection process began with the56 Six-Minute Walk Test to obtain baseline pain-free walking distance measurements. The Six-Minute Walk Test measured the participant's total pain-free walking distance for six minutes. The pain-free walking distance was documented on an Excel spreadsheet for each participant. Second, each participant attended three treadmill walking sessions per week over five weeks. The treadmill walking sessions followed the translation of McDermott's

research on the Gardner-Skinner Protocol, and each participant walked until mild to moderate claudication was experienced. Third, each participant performed the Six-Minute Walk Test after the implementation phase. Each participant's pain-free walking distance post-implementation of the intervention was documented on the Excel spreadsheet and paired with the baseline results.

The statistical analysis appropriate for this project was a paired *t*-test to compare the difference between the independent variable, the translation of McDermott's research on the Gardner-Skinner Protocol, and the dependent variable, the pain-free walking distance pre-and post-intervention. Therefore, the paired measurement of the pain-free walking distance pre-and post-intervention was the best fit for this quality improvement project. A statistician analyzed the pain-free walking distance pre-and post-intervention utilizing the Statistical Package for the Social Sciences (SPSS) software and the Excel spreadsheet. The independent variable (the translation of McDermott's research on the Gardner-Skinner Protocol) within this quasi-experimental design was designated a nominal level of measurement. The pain-free walking distance was designated a ratio level of measurement; therefore, a non-parametric statistical analysis was performed to answer this project's clinical question.[52] The level of statistical significance was set to a *p*-value of less than 0.05.

### Potential bias and mitigation

A potential bias for this project was the recruitment of participants by vascular specialists within a vascular clinic. This bias comes from using a convenience sample for this project. Random samples determine whether inferences from projects and studies are trustworthy. However, obtaining a random sample is not feasible because the project utilizes a quasi-quantitative methodology. To ensure that bias did not occur within this project, all data was reported entirely, and a statistician completed the data interpretation with no interest in the project results.

### Ethical considerations

Ethical issues surrounding this quality improvement project included protecting patient information and treating human subjects. First, it was of the utmost importance that each participant was well-informed of the project, cognitively aware and able to make decisions, and was treated with respect. Therefore, the project adhered to the three principles of the Belmont Report: respect for persons, beneficence, and justice.[53]

In compliance with the Health Insurance Portability and Accountability Act (HIPAA), patient information was protected and safeguarded against threats to the security of the information by ensuring confidentiality. In addition, patient information was utilized for the purpose related to this project and was not misused.[54] The chain of command reported no breach of patient information or mistreatment of human subjects. Finally, patient information and data collected were stored in a locked drawer at the vascular specialty clinic and destroyed after the project was completed.

### Limitations

A limitation to this project was the brief period of four weeks to implement this quality improvement project. Although benefits are evident after four weeks, maximum benefits are achieved after 12 weeks. Moreover, improved pain-free walking distance and peak walking distance are achieved at 24 weeks.[38]

A second limitation was the small sample size of 12 participants with peripheral arterial disease and intermittent claudication who met inclusion criteria. During the COVID-19 pandemic, patients were reluctant to leave their homes and go out into public areas. The third limitation was the reduced number of staff to supervise the participants. The facility experienced a high turnover rate of registered nurses and staff; therefore, the organization collaborated with minimal staff. In addition, one project site posed a limitation to this project. Participants were restricted to the use of one facility, whereas multiple facilities would offer more accessibility and convenience. A fourth limitation to this project was the adherence to thrice-weekly treadmill walking sessions. The commitment to three weekly sessions interrupted daily work schedules or caring for a family member. Therefore, the existing limitations were unavoidable and negatively affected this project's results.

### Summary

Peripheral arterial disease with intermittent claudication is a progressive condition that impairs individuals' functional capacity and quality of life, thus increasing the risk for cardiovascular disease.[9] The literature shows the efficacy of supervised exercise programs, such as one following the Gardner-Skinner Protocol, in improving patients' walking distances and quality of life.[5,18] This project analyzed the translation of McDermott's research on the Gardner-Skinner Protocol effect on pain-free walking distance compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in New Mexico over four weeks.

The project was implemented utilizing a quantitative methodology with a quasi- experimental design. A sample size of 30 peripheral arterial disease patients with mild to moderate intermittent claudication was selected. The pain-free walking distance for each participant was measured utilizing the Six-Minute Walk Test at baseline and four weeks post-implementation of the translation of McDermott's research on the Gardner- Skinner Protocol. Statistical analysis was completed utilizing a paired *t*-test. In Chapter 4, this quality improvement project's data analysis and results are summarized, analyzed, and discussed.

## Chapter 4: Data Analysis and Results

This chapter will summarize the data collected for this quality improvement project, how the data was analyzed, and the presentation of the results. This quality improvement project addressed pain-free walking distances after implementing the translation of McDermott's research on the Gardner-Skinner Protocol in an activity center. The purpose of this quantitative, quasi-experimental quality improvement project was to determine if or to what degree the translation of McDermott's published research on the Gardner-Skinner Protocol (independent variable) would impact the pain- free walking distance (dependent variable) when compared to current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico.

Before implementing the translation of McDermott's research on the Gardner-Skinner Protocol, participants were less active, sedentary, and experiencing worsening claudication. This project aimed to improve pain-free walking distance in patients with peripheral arterial disease and intermittent claudication. Data included descriptive statistics for independent and dependent variables. Second, the group's pre-intervention and post-intervention pain-free walking distance was examined. The primary investigator determined the sample size by performing a G Power* analysis. For this project, a sample size of ($n$=30) was needed to illustrate the project's validity and reliability.

This project's quantitative methodology focused on data from a vascular clinic in rural New Mexico after implementing the translation of McDermott's research on the Gardner-Skinner Protocol. The selected statistician exported data from the spreadsheet in Microsoft Excel into the Statistical Package for the Social Sciences (SPSS), utilizing SPSS version 28 to analyze and code the data to determine statistical significance. Data collection occurred over a five-week period by the trained medical staff of a vascular clinic. Chapter 5 will explore a summary of the data collected for this quality improvement project, how the data was analyzed, and the presentation of the results.

### Descriptive data

The peripheral arterial disease affects millions of Americans without prejudice to race or gender. In addition, peripheral arterial disease is strongly associated with the aging population. Risk factors associated with peripheral arterial disease include smoking, diabetes, and cardiovascular disease. This project aimed to determine the impact of a treadmill walking protocol in patients over 40 years of age.

Descriptive statistics for this project reveal a sample size of $N$= 12. Descriptive data for age, gender, and ethnicity are displayed in Table 1. The mean age was 68.58 ($SD$= 7.57), ranging from 53 to 79. There were eight females (66.7%) and four males (33.3%). Ethnicity was 83.3% Hispanic ($n$ = 10) and 16.7% Caucasian ($n$ = 2).

**Table 1:** Descriptive data for participants

| Variables | *n* | % |
|---|---|---|
| **Gender** | | |
| Male | 4 | 33 |
| Female | 8 | 67 |
| **Race/Ethnicity** | | |
| Caucasian | 2 | 17 |
| Hispanic | 10 | 83 |
| | *M* | SD |
| **Age** | 68.6 | 7.6 |

*Note: M* = mean; *SD* = standard deviation; due to rounding, percentages may not equal 100

### Data analysis procedures

The following clinical question guided this project: To what degree does the translation of McDermott's published research on the Gardner-Skinner Protocol impact the pain-free walking distance compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico. A series of steps were utilized to analyze the data from this quality improvement project. Following approval from the project site and Grand Canyon Institutional Review Board (see Appendix A), a retrospective chart review was performed to establish a comparison group and obtain raw data on pain-free walking distances. Data was input into a Microsoft Excel (2016) spreadsheet for the patients. In addition, raw data was collected on total treadmill walking time for each session.

Data was collected over five weeks (March 2022- May 2022) to obtain the number of participants. Gender, age, and ethnicity of patients were collected in addition to the clinical measures. The pain-free walking distance was measured pre-intervention of the translation of McDermott's research on the Gardner-Skinner Protocol utilizing the Six-Minute Walk Test. The independent variable was the translation of McDermott's research on the Gardner-Skinner Protocol, and the dependent variable was the pain-free walking distance, a ratio-level continuous variable. No patient identifiers were included in the Microsoft Excel Spreadsheet file. After data was exported into International Business Machine (IBM) SPSS-28, a statistical analysis was performed utilizing a paired $t$-test as data were collected for the pre-and post-intervention. The data was evaluated to ensure assumptions of the paired $t$-test were met using a Shapiro-Wilk test. A paired $t$-test was performed to address the clinical question because the paired $t$- test examines the differences between pre-and post-intervention on a continuous interval or ratio level dependent variable. The level of significance was set to .05.[52]

### Results

A paired $t$-test was conducted to compare the pain-free walking distance pre-and post-intervention of the translation of

McDermott's research on the Gardner- Skinner Protocol. A sample size of *N* = 12 patients was used as the project sample. The results are displayed in Table 2 and showed an increase in pain-free walking distance from pre (*M* = 267.85, *SD* = 244.05) and post-intervention (*M* = 339.58, *SD* = 191.42), *t* (11) = -1.27, *p* = .23. The *p*-value is greater than .05, indicating that the difference was not statistically significant. The mean increase in pain-free walking distance was 70.83 feet (*95% CI* = 52.17 to 193.84).64

**Table 2:** Paired t-Test of pain-free walking distance

| Variable | Pre | | Post | | t(11) | *p* |
|---|---|---|---|---|---|---|
| | *M* | *SD* | *M* | *SD* | | |
| Pain-Free Walking Distance | 268.75 | 244.1 | 339.58 | 191.4 | -1.27 | 0.2 |

*Note: M* = mean; *SD* = standard deviation

Summary of statistics (*n, %*) were computed for demographics of age, gender, and ethnicity for pain-free walking distance for a comparison group (*n* = 11) of patients before the intervention. Figure 1 displays the information for pain-free walking distance and means age. As shown, the mean age for 50 feet was 69.75. The mean age for 75 feet was 70.50. The mean age for 100 feet was 61.50, and the mean age for 150 feet was 57.67.

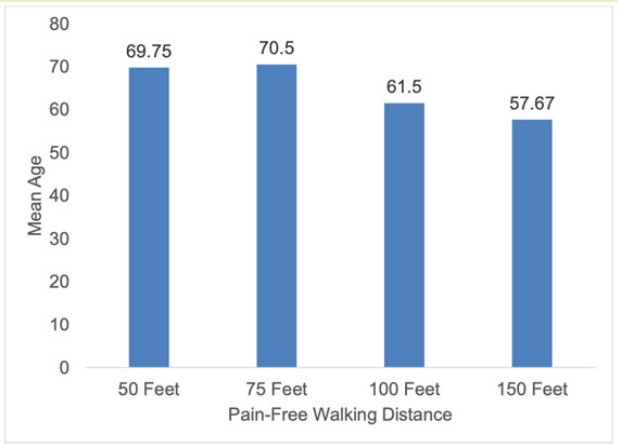


**Figure 1:** Mean age according to pain-free walking distance for comparison group

Figure 2 shows the mean pain-free walking distance according to gender. Males had a mean of 57.50 feet (*SD* = 9.19), and females had a mean distance of 66.78 (*SD* =6.97).

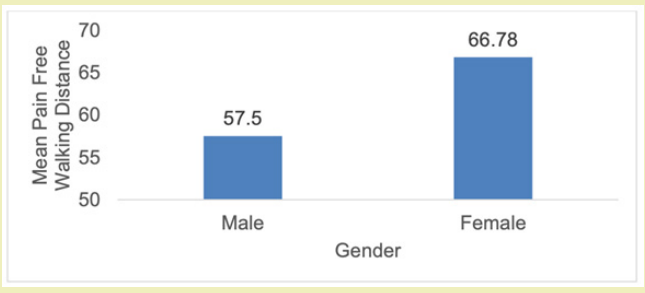


**Figure 2:** Pain-free walking distance by gender in comparison group

Figure 3 displays the mean walking distance according to ethnicity. The mean walking distance for Caucasian patients was 64 feet (*SD* = n/a), and the mean walking distance for Hispanic patients was 65.2 (*SD* = 8.26). Only one patient was Caucasian in the comparison group, and thus, the standard deviation could not be computed.

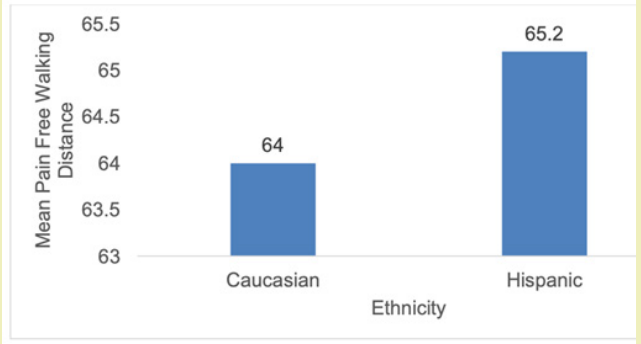


**Figure 3:** Pain-free walking distance by ethnicity in comparison group

Data analysis was conducted on pain-free walking distance for a comparison and intervention group of patients. The paired *t*-test results showed a *p*-value of .23, indicating that the distance difference was not statistically significant. The results support the clinical significance of the project as reflected in a mean increase in pain-free walking distance of 70.83 feet after the translation of McDermott's research on the Gardner-Skinner Protocol intervention.

## Summary

This quality improvement project implemented the translation of McDermott's research on the Gardner-Skinner Protocol to gather data to support the clinical question: To what degree does the translation of McDermott's published research on the Gardner-Skinner Protocol impact the pain-free walking distance compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico. The project findings did not demonstrate statistical significance in pain-free walking distance. This could be due to the sample size and the four-week period to conduct the project.

Patients with peripheral arterial disease and intermittent claudication were counseled on lifestyle modifications such as smoking and walking 10- 45 minutes daily to improve pain and walking distances. However, these patients were not adhering to these recommendations. The translation of McDermott's research on the Gardner- Skinner Protocol was implemented to improve pain-free walking distances and quality of life and provide a network of support to this target population.

The project included 12 patients. The mean age was 68.58 (*SD* = 7.57), ranging from 53 to 79. There were eight females (66.7%) and four males (33.3%). Ethnicity was68 83.3% Hispanic (*n* = 10) and 16.7% Caucasian (*n* = 2). A paired *t*-test was conducted and showed an increase in pain-free walking distance from pre (*M* = 267.85,

*SD* = 244.05) and post-intervention (*M* = 339.58, *SD* = 191.42*), t* (11) = -1.27, *p* = .23. The *p*-value is greater than .05, indicating that the difference was not statistically significant. Clinical significance was supported by the mean increase in pain-free walking distance was 70.83 feet (95% *CI* = 52.17 to 193.84). Based on the data from this quality improvement project and the proper implementation of the translation of McDermott's research on the Gardner-Skinner Protocol for future goals, it is recommended that a newly developed program for this population be developed incorporating the protocol and utilized in cardiac rehabilitation centers for outpatient therapy.

Chapter 5 will present a comprehensive summary of this quality improvement project. In addition, Chapter 5 will discuss how the primary investigator contributed to the body of knowledge. Finally, Chapter 5 will explore recommendations for future practice and implications acquired from the project.

## Chapter 5: Summary, Conclusions, and Recommendations

Peripheral arterial disease is an atherosclerotic condition of the lower limbs that impairs these individuals' functional capacity, resulting in an inferior quality of life.[1] Moreover, intermittent claudication is caused by a reduced supply of oxygen to the muscles in the lower limbs, causing pain with activity and relief with rest.[2] Furthermore, the enfeebling effects of this disease succumb these individuals to a sedentary lifestyle.

Millions of Americans are affected each day by the debilitating effects of peripheral arterial disease. In addition to hindering the walking ability of these individuals, peripheral arterial disease significantly increases the risk of cardiovascular morbidity and mortality. It is the primary cause of severe limb ischemia amputations. Moreover, amputations related to severe limb ischemia carry a five-year mortality rate post-amputation.[5,13]

The growing epidemic of peripheral arterial disease incurs a financial burden on the individual, with annual costs of over $11,000 (Scully 2018). By comparison, an individual without PAD carries an annual cost of $4,000 (Scully 2018). Furthermore, supervised exercise therapy can reduce these burdensome costs by improving pain-free walking distances and quality of life for individuals with peripheral arterial disease.

The translation of McDermott's research on the Gardner-Skinner Protocol was implemented to improve pain-free walking distances for this quality improvement project. Staff members were educated on the protocol and trained in the steps to ensure70 proper implementation of the evidence-based practice. This chapter summarizes the project findings, conclusions of the project, and implications derived from the project.

### Summary of the project

The targeted population selected for this project was peripheral arterial disease patients with intermittent claudication over 40 years. The rationale for choosing this population was that these patients at a vascular clinic were not complacent with a daily walking regime at home, causing worsening pain in their lower limbs. Moreover, there was an opportunity to improve the distance these patients would walk without pain.

### This quality improvement project was intended to answer the following question

To what degree does the translation of McDermott's published research on the Gardner-Skinner Protocol impact the pain-free walking distance compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico? The independent variable was the translation of McDermott's research on the Gardner-Skinner Protocol, and the dependent variable was the pain-free walking distance. This chapter identifies a summary of the project's findings and implications.

The independent variable for this quality improvement project was the translation of McDermott's research on the Gardner-Skinner Protocol. The translation of McDermott's research on the Gardner-Skinner Protocol was beneficial to individuals with peripheral arterial disease and intermittent claudication because it improved pain-free walking distances. Improved pain-free walking distances for individuals with intermittent claudication further enhance the quality of life. The intention was to fill the gap in evidence that supervised exercise therapy be utilized in conjunction with medical management in treating peripheral arterial disease patients with intermittent claudication.

The dependent variable was the pain-free walking distance among peripheral arterial disease patients with intermittent claudication. Improved pain-free walking distances enhance the quality of life and reduce healthcare costs. This project intends to utilize evidence to increase pain-free walking distances among patients with claudication in the community by developing a walking program in an outpatient cardiac rehabilitation center.

The performance of the intervention is discussed in the following section. In addition, the impact on patient outcomes is discussed. Finally, this chapter reviewed the empirical findings, implications, and recommendations for clinical practice and future projects.

### Summary of findings and conclusion

As discussed in Chapter 4, pain-free walking distances improved after implementing the translation of McDermott's research on the Gardner-Skinner Protocol, as evident by increased pain-free walking distances. Before implementing the protocol, vascular

specialists counseled patients on the importance of a daily walking routine. Patients would ignore the recommendations governed by evidence-based practice rather than adhere to a recommended walking schedule to promote blood flow. These patients became more sedentary, thereby accruing high health care costs to restore blood flow to the lower extremities.

The clinical question guiding this project was: To what degree does the translation of McDermott's published research on the Gardner-Skinner Protocol impact the pain-free walking distance compared to the current practice among peripheral arterial disease patients with intermittent claudication in a university activity center in rural New Mexico. The project included 12 patients who met inclusion criteria. The mean age was 68.58 (*SD* = 7.57), ranging from 53 to 79. There were eight females (66.7%) and four males (33.3%). Ethnicity was 83.3% Hispanic (*n* = 10) and 16.7% Caucasian (*n* = 2).

A paired *t*-test was performed and showed an increase in pain-free walking distance from pre (*M* = 267.85, *SD* = 244.05) and post-intervention (*M* = 339.58, *SD* = 191.42*), t* (11) = -1.27, *p* = .23. The p-value is greater than .05, indicating that the difference was not statistically significant. The mean increase in pain-free walking distance was 70.83 feet (95% *CI* = 52.17 to 193.84), supporting clinical significance.

There is a direct correlation between implementing the translation of McDermott's research on the Gardner-Skinner Protocol and pain-free walking distances. According to the data results, implementing the translation of McDermott's research on the Gardner-Skinner Protocol improves pain-free walking distance. Data analysis showed an improvement in pain-free walking distances post-implementation of the protocol compared to the pain-free walking distance at baseline.

With the Institutional Review Board approval from Grand Canyon University (see Appendix A), baseline and post-intervention Six-Minute Walk Tests were performed on eligible participants who met inclusion criteria. Data were collected on Six-Minute Walk Tests, treadmill walking time, and treadmill grade. The analysis was performed using a paired *t*-test via SPSS version 28. Using the paired *t*-test, the primary investigator compared the pain-free walking distance pre-and post-intervention of the translation of McDermott's research on the Gardner-Skinner Protocol. There were expectations from the primary investigator that the translation of McDermott's research on the Gardner-Skinner Protocol would impact the pain-free walking distance.

**Implications**

It was revealed through the literature review that supervised exercise therapy can improve blood flow and walking distance among peripheral arterial disease patients with intermittent claudication.[18,24] In addition, exercise therapy can improve cardiovascular risk factors and quality of life.[5,9] This project improved pain-free walking distances among patients with intermittent claudication. Based on this project's findings and Lewin's change theory, a supervised exercise program for this population can be implemented into a cardiac rehabilitation program.

Strengths of this project include a positive association between the pain-free walking distance and the translation of McDermott's research on the Gardner- Skinner Protocol. Thus, it illustrates the impact of treadmill walking on increasing pain- free walking distance among patients with intermittent claudication. A weakness of this project includes a small sample size of 12. In addition to the small sample size, 8 participants were female. Therefore, the results could not be generalized to males.

The results of this project presented credibility in a variety of ways. First, given the quantitative methodology, the primary investigator illustrated a positive association between the translation of McDermott's research on the Gardner-Skinner Protocol and pain-free walking distance using numerical data collected from the Six-Minute Walk Test. Second, a quasi-experimental design provided substantial evidence and correlation between the intervention, the translation of McDermott's research on the Gardner-Skinner Protocol, and pain-free walking distance among patients with intermittent claudication.

***Theoretical implications***

This project's theoretical implications suggested that improving the process of identifying patients sooner would improve the timeliness of the intervention. Moreover, providing staff education and training improved the workflow. In addition, implementing the translation of McDermott's research on the Gardner-Skinner Protocol improves pain-free walking distance and quality of life. Fourth, physicians required continuous reminders of appropriate patient selection and inclusion criteria. Finally, patients lacked the motivation to participate in three days a week treadmill walking sessions.

Applying Dorothea Orem's self-care theory gives a theoretical foundation that promotes self-care behaviors that improve pain-free walking distances. The importance of self-care behaviors such as proper nutrition, smoking cessation, and daily exercise such as walking to improve claudication was discussed with each participant at their office visit. In addition, education was provided to discuss how self-care behaviors, as listed above, physiologically improve peripheral arterial disease and the progression of its symptoms.

Lewin's change theory gives a theoretical foundation that ensures changes in the patient's thinking on peripheral arterial disease and intermittent claudication. Utilizing the three-step process of Lewin's change theory, patients understood why their current behaviors did not improve claudication during the

unfreezing stage. During the changing stage, patients identified behaviors such as lack of exercise and the negative impact on claudication and pain-free walking distance. During the refreezing stage, patients understood that walking until moderate claudication was experienced can improve pain-free walking distance and thus should be incorporated into daily living activities.

In addition, Lewin's change theory gives a theoretical foundation to ensure change within clinical practice in a vascular clinic. During the unfreezing stage, providers were educated on the literature evidence that supports supervised exercise therapy for patients with peripheral arterial disease and intermittent claudication. During the changing stage, medical staff and providers were trained on implementing the translation of McDermott's research on the Gardner-Skinner Protocol and its impact on pain-free walking distance. During the refreezing stage, the integration of a referral system and a supervised exercise program was implemented.

### *Practical implications*

The practical implications of the translation of McDermott's research on the Gardner-Skinner Protocol were that treadmill walking should consist of three times a week session. Each session should last until the patient experiences mild to moderate claudication. The translation of McDermott's research on the Gardner-Skinner Protocol was simple, straightforward, and easy to implement. Second, educational teaching provided by the clinicians prior to a treadmill walking-based program enhanced the patients' knowledge and understanding of peripheral arterial disease and claudication. Third, an educational platform and a treadmill walking program bestowed a network of support and a sense of empowerment.

### *Future implications*

The purpose of this quality improvement project was to improve pain-free walking distance. The translation of McDermott's research on the Gardner-Skinner 76 Protocol was simple enough to explain its instructions to the participants. Since the project took place at a university activity center, future implications include implementing a supervised exercise program at an outpatient cardiac rehabilitation center. Cardiac rehabilitation facilities employ medical personnel trained to monitor patients on a treadmill. In addition, enlisting patients with peripheral arterial disease and post-revascularization procedures should be considered since this population dramatically benefits from a supervised exercise program. Finally, if a supervised exercise program is not feasible, a referral for mobile health that tracks steps taken by a pedometer would be ideal and convenient.

## Recommendations

Implementing the translation of McDermott's research on the Gardner- Skinner Protocol has assisted in treating peripheral arterial disease and improved pain- free walking distance. Identified fallouts from this project were not sufficiently pre- screening patients who met inclusion criteria. In addition, the chart did not properly annotate documentation of peripheral arterial disease diagnosis and intermittent claudication.

### *Recommendations for future projects*

Recommendations for a future project should begin by addressing the identified fallouts as discussed. Supervised exercise therapy is considered the gold standard for treating peripheral arterial disease and has been shown to improve the walking capacity of this population.[4,38] Identifying and pre-screening patients before the implementation of supervised exercise therapy ensures the patient's safety prior to the implementation of exercise therapy. Proper documentation of the diagnosis of peripheral arterial disease and intermittent claudication ensures reimbursement from the Centers for Medicare & Medicaid Services for supervised exercise therapy.

One recommendation for future direct practice improvement projects is implementing a supervised exercise program with a larger sample size to include a diverse group of males and females. The peripheral arterial disease affects African Americans, Hispanics, and Native Americans.[55] A larger, diverse sample group can generalize a specific race and gender.

A second recommendation is to compare the pain-free walking distance between groups that participated in supervised exercise therapy for four weeks versus 12 weeks (about 3 months). Benefits are evident after four weeks of supervised exercise therapy.

Functional benefits continue to improve over 12 weeks (about 3 months).

A third recommendation is implementing the translation of McDermott's research on the Gardner-Skinner Protocol in an outpatient facility like a cardiac rehabilitation center. Cardiovascular disease is associated with peripheral arterial disease.

Cardiac rehabilitation centers have staff that has specialized training to monitor cardiac patients. In addition, peripheral arterial disease patients can be included in phase three of an existing cardiac rehabilitation program, including maintenance/wellness classes.

A fourth recommendation is to link an electronic referral for supervised exercise therapy in the electronic medical record to alert physicians of eligible criteria met. A list of eligible criteria met would alert the provider that the patient qualifies for supervised exercise therapy. The provider would initiate a referral for the patient to attend supervised exercise therapy three days a week for 4, 6, or 12 weeks (about 3 months).

### *Recommendations for practice*

The vascular clinic is an entity of the largest healthcare facility in a rural area of New Mexico. Thus, it serves a sizeable population of peripheral arterial disease patients. The primary investigator shared the project findings with the vascular surgeons at the vascular clinic.

Implementing a supervised exercise program for intermittent claudication patients at the clinic would benefit this community. The program would provide routine exercise therapy utilizing a treadmill-grade protocol like the Gardner-Skinner Protocol. In addition, the supervised exercise program can be utilized for outpatient and inpatient services.

Integrating an educational forum on a heart-healthy diet, smoking cessation, and exercise prior to a supervised exercise program would reinforce evidence-based practice in treating peripheral arterial disease and intermittent claudication. An educational forum would offer a network of support to patients with peripheral arterial disease. Finally, an educational forum before beginning a supervised exercise program would empower these individuals by promoting self-care behaviors that promote well-being.[56-59]

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## Conflict of Interest

Regarding the publication of this article, the author declares that she has no conflict of interest.

## References

1. Duscha BD, Piner LW, Patel MP, et al. Effects of a 12-Week mHealth Program on Functional Capacity and Physical Activity in Patients With PeripheralArtery Disease. *Am J Cardiol.* 2018;122(5):879-884.
2. Alqahtani KM, Bhangoo M, Vaida F, et al. Predictors of Change in the Ankle Brachial Index with Exercise. *Eur J Vasc Endovasc Surg.* 2018;55(3):399-404.
3. Pietraszewski B, Woźniewski M, Jasiński R, et al. Changes in Gait Variables in Patients with Intermittent Claudication. *Biomed Res Int.* 2019;2019:7276865.
4. Salisbury DL, Whipple MO, Burt M, et al. Experience Implementing Supervised Exercise Therapy for Peripheral Artery Disease. *J Clin Exerc Physiol.* 2019;8(1):1-12.
5. Cornelis N, Nassen J, Buys R, et al. The Impact of Supervised Exercise Training on Traditional Cardiovascular Risk Factors in Patients With Intermittent Claudication: A Systematic Review and Meta-Analysis. *Eur J Vasc Endovasc Surg*. 2019;58(1):75-87.
6. McDermott MM, Guralnik JM, Tian L, et al. Comparing 6-minute walk versus treadmill walking distance as outcomes in randomized trials of peripheral artery disease. *J Vasc Surg.* 2020;71(3):988-1001.
7. Oakley C, Spafford C, Beard JD. A Three Month Home Exercise Programme Augmented with Nordic Poles for Patients with Intermittent Claudication Enhances Quality of Life and Continues to Improve Walking Distance and Compliance After One Year. *Eur J Vasc Endovasc Surg*. 2017;53(5):704-709.
8. Treat Jacobson D, McDermott MM, Beckman JA, et al. Implementation of supervised exercise therapy for patients with symptomatic peripheral artery disease: A science advisory from the American Heart Association. *Circulation.* 2019;140:700-710.
9. Holmes MN, Weinman, JA, Bearne LM. A randomized controlled feasibility trial of a home-based walking behavior-change intervention for people with intermittent claudication. *Journal of Vascular Nursing.* 2019;37(2):135-143.
10. Farndon L, Stephenson J, Binns Hall O, et al. The pod PAD project: A podiatry-led integrated pathway for people with peripheral arterial disease in the UK – a pilot study. *Journal of Foot and Ankle Research.* 2018;11(1):1-9.
11. Embrey DG, Alon G, Brandsma BA, et al. Functional electrical stimulation improves quality of life by reducing intermittent claudication. *Int J Cardiol.* 2017;243:454-459.
12. Park SY, Kwak YS, Pekas EJ. Impacts of aquatic walking on arterial stiffness, exercise tolerance, and physical function in patients with peripheral artery disease: a randomized clinical trial. *J Appl Physiol.* 2019;127(4):940-949.
13. Sutton M, Kreider K, Thompson J, et al. Improving outcomes in patients with peripheral arterial disease. *J Vasc Nurs.* 2018;36(4):166-172.
14. American College of Cardiology Society. *Peripheral matters: Supervised exercise therapy for patients with peripheral artery disease.* 2020.
15. McDermott MM, Kibbe MR, Guralnik JM, et al. Durability of Benefits From Supervised Treadmill Exercise in People With Peripheral Artery Disease. *J Am Heart Assoc.* 2019;8(1):e009380.
16. Mänttäri A, Suni J, Sievänen H, et al. Six-minute walk test: a tool for predicting maximal aerobic power ($VO_2$ max) in healthy adults. *Clin Physiol Funct Imaging*. 2018.
17. Treat Jacobson D, McDermott MM, Bronas GU, et al. Optimal exercise programs for patients with peripheral artery disease: A scientific statement from the American Heart Association. *Circulation.* 2019;139(4):e10-e33.
18. Villemur B, Thoreau V, Guinot M, et al. Short interval or continuous training programs to improve walking distance for intermittent claudication: Pilot study. *Ann Phys Rehabil Med.* 2020;63(6):466-473.
19. Gardner AW, Montgomery PS, Wang M. Minimal clinically important differences in treadmill, 6-minute walk, and patient-based outcomes following supervised and home-based exercise in peripheral artery disease. *Vasc Med.* 2018;23(4):349-357.
20. Novaković M, Krevel B, Rajkovič U, et al. Moderate-pain versus pain-free exercise, walking capacity, and cardiovascular health in patients with peripheral artery disease. *J Vasc Surg.* 2019;70(1):148-156.
21. Orem DE. *Nursing: Concepts of practice*. McGraw-Hill Inc., U.S. 1985.
22. Lewin K. *Resolving social conflicts; Selected papers on group dynamics.* Harper. 1948.
23. Criqui MH, Matsushita K, Aboyans V, et al. Lower Extremity Peripheral Artery Disease: Contemporary Epidemiology, Management Gaps, and Future Directions: A Scientific Statement From the American Heart Association. *Circulation*. 2021;144(9):e171-e191.
24. Dopheide JF, Rubrech J, Trumpp A, et al. Supervised exercise training in peripheral arterial disease increases vascular shear stress and profunda femoral artery diameter. *Eur J Prev Cardiol.* 2017;24(2):178-191.
25. Healthy Paso Del Norte. *Adults with diabetes*. (2022).
26. McLeod S. *What's the difference between qualitative and quantitative research*? 2019.
27. Williams T. *Why is quantitative research important?* 2021.
28. Grand Canyon University. *What is a direct practice improvement webinar*? 2021.
29. Armijo Olivo S. The importance of determining the clinical significance of research results in physical therapy clinical research. *Braz J Phys Ther.* 2018;22(3):175-176.
30. Creswell JW, Creswell JD. *Research design: Qualitative, quantitative, and mixed methods approaches* (5th ed.). Thousand Oaks: CA. Sage Publications. 2018.

31. Gommans LNM, Smid AT, Scheltinga MRM, et al. Prolonged stance phase during walking in intermittent claudication. *J Vasc Surg.* 2017;66(2):515-522.
32. Russell KS, Yates DP, Kramer CM, et al. A randomized, placebo-controlled trial of canakinumab in patients with peripheral artery disease. *Vasc Med*. 2019;24(5):414-421.
33. Tenny S, Abdelgawad I. *Statistical significance*. StatPearls [Internet]. 2021.
34. Lesko CR, Ackerman B, Webster Clark M, et al. Target validity: Bringing treatment of external validity in line with internal validity. *Curr Epidemiol Rep.* 2020;7(3):117-124.
35. Aufmann E. The importance of documenting research. 2020.
36. Cleveland Clinic. *Claudication.* 2021.
37. Murrow JR, Brizendine JT, Djire B, et al. Near infrared spectroscopy-guided exercise training for claudication in peripheral arterial disease. *Eur J Prev Cardiol.* 2019;26(5):471-480.
38. Ehrman JK, Gardner AW, Salisbury D, et al. Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease: A REVIEW OF CURRENT EXPERIENCE AND PRACTICE-BASED RECOMMENDATIONS. *J Cardiopulm Rehabil Prev*. 2023;43(1):15-21.
39. Parvar SL, Fitridge R, Dawson J, et al. Medical and lifestyle management of peripheral arterial disease. *J Vasc Surg.* 2018;68(5):1595-1606.
40. University of Southern California. *Research guides*. 2022.
41. LeTourneau University. *Quantitative research and analysis: Quantitative methods overview*. 2022.
42. Maciejewski ML. Quasi-experimental design. *Biostatistics & Epidemiology.* 2018;4(1):38-47.
43. Faul F, Erdfelder E, Lang AG, et al. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods.* 2007;39(2):175-191.
44. American Heart Association. *PAD toolkit for health care professionals*. 2021.
45. Caldow E, Findlow A, Granat M, et al. Incorporating an exercise rehabilitation programme for people with intermittent claudication into an established cardiac rehabilitation service: A protocol for a pilot study. *Contemp Clin Trials Commun.* 2019;15:100389.
46. Gardner AW, Skinner JS, Cantwell BW, et al. Progressive vs single-stage treadmill tests for evaluation of claudication. *Med Sci Sports Exerc.* 1991;23(4):402-408.
47. Holland AE, Spruit MA, Troosters T, et al. An official European Respiratory Society/American Thoracic Society technical standard: field walking tests in chronic respiratory disease. *Eur Respir J.* 2014;44(6):1428-1446.
48. Montgomery PS, Gardner AW. The clinical utility of a six-minute walk test in peripheral arterial occlusive disease patients. *J Am Geriatr Soc.* 1998;46(6):706-711.
49. Nicolaï SP, Viechtbauer W, Kruidenier LM, et al. Reliability of treadmill testing in peripheral arterial disease: a meta-regression analysis. *J Vasc Surg.* 2009;50(2):322-329.
50. Hamilton DM, Haennel RG. Validity and reliability of the 6-minute walk test in a cardiac rehabilitation population. *J Cardiopulm Rehabil.* 2000;20(3):156-164.
51. Kang H. Sample size determination and power analysis using the G*Power software. *J Educ Eval Health Prof.* 2021;18:17.
52. Schober P, Vetter TR. Two-Sample Unpaired t Tests in Medical Research. *Anesth Analg.* 2019;129(4):911.
53. Parasidis E, Pike E, McGraw D. A Belmont Report for Health Data. *N Engl J Med.* 2019;380(16):1493-1495.
54. Centers for Disease Control and Prevention. *Public health professionals gateway: Health Insurance Portability and Accountability Act of 1996.* 2018.
55. Centers for Disease Control and Prevention. *Heart disease: Peripheral arterial disease*. 2021.
56. ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med.* 2002;166(1):111-117.
57. Lindgren H, Qvarfordt P, Åkesson M, et al. Primary Stenting of the Superficial Femoral Artery in Intermittent Claudication Improves Health Related Quality of Life, ABI and Walking Distance: 12 Month Results of a Controlled Randomised Multicentre Trial. *Eur J Vasc Endovasc Surg.* 2017;53(5):686-694.
58. Research Connections. (n.d.). *Experiments and quasi-experiments*.
59. U.S. Census Bureau. (n.d.). *Quick facts Las Cruces City New Mexico*.