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A Proposal for the Development of an Exercise Program to Treat Post Thrombotic Syndrome

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This is to certify that the doctoral study by

Christy Hansen

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
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Walden University
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Abstract

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Project Submitted in Partial Fulfillment

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Abstract

Healthcare costs continue to escalate and hospitals need to use programs that encourage cost effectiveness, reduce resources and staffing, and increase patient accountability for their own healthcare risk factors, comorbidities, and participation in their healthcare decisions. Post Thrombotic Syndrome (PTS) is a debilitating disease with few treatment options. Allowing patients to have shared decision making in a care plan for this disease process that involves an exercise program may be a significant factor in the success or failure of their own healthcare goals and outcomes. The development of a proposal for an exercise program for PTS should provide patients with input regarding their healthcare plan and participation needs, reduce healthcare risk factors, reduce comorbidities, and increase participation in their healthcare decisions. Seven stakeholders were presented with the proposal for the exercise program for PTS via PowerPoint presentation and a paper handout. Data collection was completed via a 7-question assessment tool designed to provide formative feedback on the refinement of the project and to establish whether the proposed study was a feasible option for the intended vascular population. The analysis consisted of a review and description of all stakeholder responses. Eighty-two percent of the stakeholders indicated that there is a sufficient population, a perception of potential benefit for patients, and that adequate resources are available for the proposed study. Implications for social change include the potential that, through the future implementation of this project, providers could reduce healthcare expenses by decreasing the amount of follow-up and re-hospitalization, thus leading to improved healthcare outcomes.

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To my colleagues, who have endured the last few years of my continuous questions and research theories, this is for you.

Dedication

This project is dedicated to my husband Randy, to whom none of this would be possible. His never ending support and love has been the backbone of our family while I stay up late, miss school functions, or fall asleep at my desk completing my education. Finally, to my children, Kaitlyn, Kelsey, Kennedy, and Matthew, completing this project has been my life goal and I hope that you have seen how important higher education is. Share the knowledge you learn with others and always follow your heart.

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Section 1: Nature of the Project

Introduction

Deep vein thrombosis (DVT) affects between 300,000 to 600,000 people in the United States each year (Centers for Disease Control & Prevention [CDC], 2013). Of that population, roughly 20-50% of those who suffered a DVT will develop a chronic condition with pain, swelling, and discoloration to the affected extremity known as Post Thrombotic Syndrome (PTS; Holmes, Bambace, Lewis, Callas, & Cushman, 2014). The standards established by the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission (TJC) have allowed facilities to initiate guidelines that are instrumental in achieving the best patient outcomes. The ability of an organization to plan, implement, and evaluate evidence-based practice research can affect a variety of populations as well as serve a large population of chronically ill patients within the hospital setting.

Problem Statement

Up to 50% of DVT patients will develop the chronic, lifelong complication known as PTS (Baldwin, Moore, Rudarakanchana, Gohel, & Davies, 2013; Reich-Schupke, Altmeyer, & Stücker, 2010). Compression and anticoagulation therapy has remained the standard-of-care (SOC) treatment option for PTS, but the numbers remain high for symptoms of PTS (Reich-Schupke, Altmeyer, & Stücker, 2010). There is limited research on the effects that exercise programs have on PTS symptoms. In an effort to address the issue, I have created a proposal for an exercise training program to treat PTS as the focus of this project. This study will not be implemented, and only the

proposal was reviewed by stakeholders. Their reviews were used to make recommendations to enhance the proposal (see Appendix F).

Purpose Statement and Project Objectives

PTS is the development of chronic pain, cramping, paresthesia, sensation of heaviness in the extremity, hyperpigmentation, and vein ectasias that is associated after a patient experiences a DVT (Kahn et al., 2011, Reich-Schupke, Altmeyer, & Stücker, 2010). Ashrani and Heit (2009) noted that the average healthcare cost per year for the treatment of complications from PTS is around $7,000. This cost can become a burden for patients as well as hospitals. Kahn et al. (2011) completed an exercise study for PTS in which they demonstrated decreased symptoms for PTS. The authors measured Villalta scores, which assess symptoms of PTS, and documented an improvement of -3.6 (3.7) for the exercise group vs. -1.6 (4.3) vs. the control group who received no exercise therapy (Kahn et al., 2011). Their result documented the benefits of exercise therapy on symptom control in this chronically ill population.

Care facilitated by an exercise program may be a cost effective way to treat a person post-DVT while preventing unnecessary re-hospitalizations and decreased quality-of-life, as well as improving symptoms of PTS (Kahn et al., 2011). Exercise therapy can be completed at home with little or no additional cost to the consumer (Kahn et al., 2011). Exercise programs could provide benefits equivalent to alternative types of pharmacological, surgical, or other medical treatments (Kahn et al., 2011).

The purpose of this project was to develop a proposal for future implementation to investigate the effectiveness of using an exercise program to treat PTS. The project

question was focused on whether a study exercise program can help to improve the symptoms of PTS. The study population would include patients with unilateral symptomatic DVT diagnosed at least 6 months prior to enrollment and current ipsilateral manifestations in the leg consistent with PTS. The planned sample size is 20 patients. Successful outcome measurements will include a decrease in symptoms of PTS that include patient-rated venous symptoms: pain, cramps, heaviness, paresthesia, and puritis (Chitsike et al., 2012; de Wolf, Wittens, & Kahn, 2012). The clinician-rated venous signs assessment will include: pretibial edema, skin induration, hyperpigmentation, redness, venous ectasia, and pain on calf compression (Chitsike et al., 2012; Saedon & Stansby, 2010).

Significance/Relevance to Practice

There is limited evidence that Rutosides, an herbal remedy, is effective in treating other venous conditions including chronic venous insufficiency. In one study it was Rutosides improved PTS symptoms in short term (Morling, Yeoh, & Kolbach, 2013). However, evidence is limited, and long term safety and benefits have not been evaluated. Surgical or revascularization treatments for PTS, such as venous valve repair, venous bypass, or endovenectomy, appear to provide some benefit, but have been evaluated primarily in small patient series at single, specialized centers (Kahn et al., 2011). Further research into surgical interventions is needed in order to effectively evaluate and determine appropriate surgical treatment recommendations when other conservative measures have failed.

Project Question

Does the use of an exercise program improve symptoms of patients with PTS?

Evidence-based Significance of the Project

The ability to apply the information learned in clinical trials allows evidence based practice (EBP) to be processed and the information to be used for the most current patient care. This allows valid care plans to be developed that have been thoroughly researched and proven to be effective. Krom, Batten, and Bautista (2010) indicated that the Iowa Model was one that allows practice change by a "step-by-step process" and integration of EBP (p. 55). In addition to enhancing patient care, nursing research allows the promotion of EBP to influence care and help nurses to make informed decisions through every stage of the nursing process.

Implementation for EBP could be inhibited if areas within the organization were unwilling to use the suggested methods that are supportive of better care and health outcomes. Many people do not like change and getting staff to embrace new therapeutic options and treatment modalities while becoming engaged in the idea that the previous way of doing things may not have been the best modality can sometimes be a challenge. The ability to motivate staff to function at a high performance level, as well as to empower others to become involved in the effort of EBP change, could be an issue that would need to be addressed. Another drawback can be the lack of data collected regarding a specific area of study (Grove, Burns, & Gray, 2013). Nurses have the responsibility to continue to support each other and to obtain all data necessary to achieve the best practices possible.

If the addition of a simple exercise program can be developed and diminish the cost even slightly, this could decrease the burden of costly treatments and procedures done to this population of patients. Kahn et al., (2011) noted that PTS treatments that have proven ineffective include the use compression whose cost and treatment often times become a financial burden to the patient and cumbersome to maintain, medications such as anticoagulants have not proven to prevent to occurrence of PTS for long term prevention of symptoms. White and Dudley-Brown (2012) noted the importance of taking evidence-based practice and the best available research evidence and translating that into workable practice guidelines that improve patient outcomes. The collaborative effort of these elements can lead to improved patient care and better patient outcomes.

The proposed development of a new standard of care for PTS will assist in better QOL and symptom control for patients who suffer from this lifelong condition. If symptoms are manageable and patients are able to assist in their own care expected outcomes would include decreased hospitalizations, use of medications, physician office visits, and clinic resources. All of the outcomes would effectively save money for the hospitals, insurance companies, Medicare and Medicaid, as well as the consumer. According to Kahn et al. (2011), the time that is spent on those who are consistently coming into the hospitals and clinics could be effectively spent treating those who are the most significantly ill if effective alternative to treatments are developed.

Clinical research is the testing process that evidence-based practice is based upon (Grove, Burns, & Gray, 2013). Kahn et al. (2011) explained that exercise programs for venous disease were promising in the development of symptom control of PTS including

vein recanalization, edema, and patient QOL scales. While the exercise study was completed on a small scale (n = 41), the evidence was favorable and offers a different and beneficial approach when treating venous disease. The proposed exercise option allows patients the freedom from compression as well as the independence to participate in care. By educating the policy makers and stakeholders regarding the population involved, informed decision making and plans of care can be addressed. Effective teaching and relevant research is where nurses will be most effective. Programs at home can be initiated with little or no cost.

Implications for Social Change in Practice

White and Dudley-Brown (2012) noted the importance of taking evidence-based practice and the best available research evidence and translating that into workable practice guidelines that improve patient outcomes. The proposed collaborative effort of these elements can lead to improved patient care and better patient outcomes. According to Simmons (2010), clinical reasoning is a "complex cognitive process that uses formal and informal thinking strategies to gather and analyze patient information, evaluate the significance of this information and weigh alternative actions" (p. 1155). The stakeholder evaluation of what information is relevant and essential in the coordination of patient care helps to guide treatment options within the vascular practice that I work within.

Definitions of Terms

Developing a clear understanding of any research project is essential to project design. The following terms have been defined for a better understanding and to provide clarity within the document and following project:

Anticoagulation therapy: Anticoagulation therapy is a prophylactic treatment approach to medically reduce the risk of blood clots with medications. This approach includes the use of various stages of coagulation (Carolyn, 2011).

Compression therapy: Prescription stockings are to provide supply gradient pressure on the leg muscle, which reduces the pooling of blood (NÃ¸rregaard, Bermark, & Gottrup, 2014).

Deep vein thrombosis (DVT): Deep vein thrombosis can occurs when a blood clot, also known as a thrombus, forms in one or more of the deep veins in your body. This can develop in a person's legs usually in your legs and can cause pain or swelling within that extremity. A person may also be asymptomatic with a DVT (CDC, 2013).

Informed consent: This is the process of learning facts about a clinical trial before deciding whether or not to participate. It is also an ongoing process throughout a study to provide key information for subjects who are participating in a trial. This process assists in the decision whether or not to participate. The physicians and nurses involved in the trial explain the details of the study to the participant (Nishimura et al., 2013).

Post thrombotic syndrome (PTS): PTS is a form of chronic venous stasis that follows an episode of DVT. This usually experienced by symptoms such as edema, lower limb discoloration, and pain. The most serious complication of this condition is a stasis

ulcer resulting from poor circulation to the area making chronic lesions difficult to treat and heal (Roumen-Klappe et al., 2009).

Revascularization: A surgical procedure for the provision of a new, additional, or augmented blood supply to a body part or organ (Chitsike et al., 2012).

Quality of life (QOL): A subjective assessment of a subject's well-being in regards to perceptions involving his/her enjoyment with what is important and what is considered important to that individual (Andela et al., 2014).

Standard of care (SOC): The generally accepted rule of care or model that guides current therapy.

Villalta: A clinical measurement test that incorporates rating scale of five patient-rated venous symptoms including pain, cramps, heaviness, paresthesia and pruritus as well as six clinician-rated venous signs pretibial edema, skin induration, hyperpigmentation, redness, venous ectasia and pain on calf compression in the leg ipsilateral to a DVT (Galanaud et al., 2012)

Assumptions and Limitations

The proposed project limitations are expected to be sample size related. When implemented, the enrollment of 20 patients will enable trial feasibility to be established.

Summary

The proposal and development of an exercise program that evaluates the effectiveness of a PTS exercise program not only will assist in the establishment of EBP among this chronically ill population, but in the financial assistance to those who provide care. Upon implementation, patients can participate in their care plan and be a part of the

collaborative effort within the healthcare team. The development of a framework of care that provides management of symptoms with a supervised exercise program could establish better health outcomes and increased QOL.

Section 2: Review of Literature and Theoretical and Conceptual Framework

Introduction

This section will include an overview of the literature related to the current treatment for PTS. Disseminating various research studies and completing literature reviews enables researchers to analyze and compile all of the data currently available regarding a specific topic. Surgical, medicinal, and the current compression treatments will be reviewed.

Library Database Search

For this review, I conducted a search of the available literature using CINAHL and MEDLINE with Full Text. These search engines were researched using the terms: *post thrombotic syndrome, exercise programs for post thrombotic syndrome, treatment for post thrombotic syndrome, post thrombotic syndrome and compression,* and *PTS and exercise*. The literature searches included information that supported the conceptual models and theoretical frameworks for the potential research proposal.

The scope of literature relevant to the proposed project included the years 2002 and 2013. The lack of exercise programs in relationship to treating PTS remained a large gap within current literature. The only available study regarding exercise and PTS was the randomized controlled two-centre trial conducted by Kahn et al. (2011) which demonstrated effectiveness and the need for further research. Other literature and evidence is limited regarding the long term safety and benefits of treatment regarding Rutosides, an herbal remedy, in effectively treating PTS symptoms short term (Morling, Yeoh, & Kolbach, 2013).

Specific Literature

The available conventional treatment options for PTS include anticoagulation, compression therapy, and surgical intervention. Three PTS assessment scales are available and have been used in clinical trials. Researchers have noted that the validity and comprehensive evaluation of their reliability has not been evaluated (Kahn &Ginsberg, 2002). The Villalta remains the standard evaluation for patients who suffer from PTS (Kahn et al., 2011, Morling, Yeoh, & Kolbach, 2013). Current anticoagulation therapy includes Warfarin, Dabigatran, Rivaroxaban, Factor XA inhibitors, Apixaban, and clinical trials that are evaluating limitation of new oral anticoagulants (Prandoni, 2012; Saedon & Stansby, 2010). Benefits for the new oral anticoagulants include the price associated with maintaining the regimented dosing (Prandoni, 2012). The new medications are more cost effective than pharmacologics of the past.

Maintenance of an additional drug when patients have multiple comorbidities can prove difficult to maintain even when the price is reduced (Prandoni, 2011). The slow onset of action and continued maintenance of patients is also an added component of patient management and clinician follow-up that must be sustained (Saedon & Stansby, 2010). Compression therapy with stockings at level of 30-40 millimeters of mercury (mmHg) prescribed to alleviate symptomatic edema and assist with blood flow in the affected extremity (Roumen-Klappe et al., 2009).

According to NÃ¸ Bermark, and Gottrup (2014), one of the most difficult aspects of treating patients with PTS is the fact that outcomes are almost always dependent on patient compliance. For the treatment to be effective, the patient has to use the prescribe

regiment continuously. Compression therapy often becomes uncomfortable, painful, with the dressing becoming dislodged resulting in temporary or complete discontinuation of treatment (NÃ et al., 2014).

Saedon and Stansby (2010) noted that angioplasty with possible stenting and venous bypass are effective treatment alternatives for PTS, but the variability and need for correction of superficial venous reflux makes surgical corrective surgery limited and time limited (Kahn et al., 2011). Surgical intervention is warranted when there is a severe clinical manifestation that cannot be controlled by compression management and pharmaceutical support (Prandoni & Kahn, 2009).

General Literature

Exercise programs can demonstrate benefits equivalent to alternative types of pharmacological, surgical, or other medical treatments. Kahn et al. (2011) completed a 6-month exercise program for PTS patients that demonstrated an improvement in pain free physical activity as well as prolonged time to additional medical or surgical intervention. Upon review of the available PTS literature, there is room for further investigation regarding this treatment approach to treat and monitor symptoms of PTS.

Gaps within the current literature include overall quality of data within the studies. Rutosides, a compound made up from horse chestnut showed that statistically this did not affect symptom management in PTS patients (Morling, Yeoh, & Kolbach, 2013). Compression and anti-coagulation therapy has remained the standard-of-care treatment option for PTS but the numbers remain high for symptoms of PTS (Reich-Schupke, Altmeyer, & Stücker, 2010). There is limited research available for the effects

that exercise programs have on PTS symptoms. The small sample size ($n = 41$) was a common theme among the literature for PTS treatment regarding exercise therapy. Larger sample size studies are needed to validate the efficacy of development of a proposal for an exercise therapy program in the treatment of PTS.

Strengths	Weaknesses
Patient outcomes regarding exercise and PTS was positive documenting the need for further studies	The size of the sample populations is small and is evident of the need for further research.
The relationship between PTS and an exercise program showed the promise of improvement in a similar study conducted.	The studies demonstrated numerous unreported biases among the literature.
An exercise program is a useful tool for the promotion of self-care behaviors in the PTS population.	Poorly designed study was a common theme.

Figure 1. Strengths and weaknesses of literature review

Conceptual Models, Theoretical Frameworks

The Stetler evidenced-based practice (EBP) model can assist clinicians in the assessment of research findings and the practical application of those recommendations into everyday practice (Romp & Kiehl, 2009). The model shows practitioners how to use evidence-based practice and formally prepare change within a facility. This framework provides a working relationship between research practice and evidence-informed practice. The five phases in development of a model include (Romp & Kiehl, 2009):

- Phase I: Preparation
- Phase II: Validation
- Phase III: Comparative Evaluation/Decision Making

- Phase IV: Translation/Application
- Phase V: Evaluation

Hyrkäs and Harvey (2010) noted the importance of "leaders who understand innovation and how it spreads, who respect the diversity of change itself, and who can nurture innovation" (p. 1). Saedon and Stansby (2011) noted that the pathophysiology of PTS is often times not understood or misinterpreted by the clinicians. Throughout the literature that I reviewed, I noted that, despite widespread use of anticoagulants, compression therapy, and after, the incidence of DVT, there has not been a decrease of symptom management in the patients who suffer from this disease (Kahn & Ginsberg, 2002). I used the Stetler EVP model as a guide to developing the pilot study implementing structure and evaluating successful completion of the trial.

Summary

The current SOC treatment for PTS patients has shown that an exercise program could be an effective alternative in treating patients. Anticoagulants, while having benefits, also have drawbacks such as expense and side effects associated with their administration. The lack of education regarding this disease often times proves difficult for the practitioner to translate the most effective treatment plan for the individual. Development of an appropriate evidenced-based model for practice could establish a framework for clinicians in guiding treatment practice for the treatment of PTS.

Section 3: Methodology

Proposal Evaluation

The purpose of this project was to develop a proposal for a study for later implementation using a quasi-experimental control group pretest-posttest design. This research project will not be implemented. The proposal for the project was presented to group of preselected stakeholders for evaluation of the feasibility of study criteria and to allow for feedback of clinical trial protocol development.

Sample Population

Stakeholder input for the project included vascular surgeons, vascular clinic manager, vascular rehabilitation and vascular clinic nursing staff, chief financial officer for regional hospital services, and a clinical research staff. The stakeholder group was selected for their experience with the vascular population, ability to assess financial feasibility for the proposed study, and experience with clinical research proposals and protocols.

Data Collection

Stakeholders were presented with the proposal for the project via Power Point presentation and the feasibility of the final project was assessed for implementation at a later date (See Appendix G). A paper handout of the proposal was distributed with the Power Point presentation. Data was collected using an assessment tool, Evaluation of Proposal for Exercise Program for Post Thrombotic Syndrome (see Appendix F). The assessment tool was designed to provide formative feedback on the refinement of the project and to establish whether the proposed study is a feasible option for the intended

vascular population. The participants were given the opportunity to ask questions during the presentation and immediately post presentation. The stakeholders who evaluated the proposal had 1 week to return the questionnaires and provide feedback. Specific evaluation questions for proposal to include:

- Description of reviewer occupation
- What are the two greatest strengths of the proposed feasibility study
- What are the two biggest challenges of the proposed feasibility study?
- Does the site have adequate resources to fulfill study needs?
- Are there an adequate number of patients to fulfill enrollment?
- Please provide one example of how this prospective study could benefit this patient population.

Data Analysis

Data analysis was completed upon receipt of all paper questionnaires. If a majority of respondents (greater than 80%) answer that there is a sufficient population, benefit to the patient, and adequate resources available to proceed with the proposal, the proposed study will then be sent to the ProMedica Clinical Research Board of Directors for final assessment and implementation.

Section 4: Findings, Discussion, and Implications

Introduction

In this section, I will address the proposed project design, methods, population, sampling, data collection, analysis, and project evaluation plan for the implementation of the feasibility study proposal for an exercise program to treat PTS. The development of a clearly defined project approach and evaluation can provide validity to a study (White & Dudley-Brown, 2012). The tools that I describe will demonstrate how the proposed study would be used to gain a better understanding of this debilitating disease. The purpose of this proposal is to develop a feasible study within the vascular rehabilitation area in the ProMedica Toledo, Ohio vascular clinic area.

Summary and Evaluation of Findings

The initial stage of this formative evaluative was the evaluation of key stakeholders feedback consisting of three vascular surgeons, one vascular clinic manager, one vascular rehabilitation nurse, one vascular nursing assistant, one chief financial officer for regional hospital services, and four members of the clinical research staff. Upon completion of the power point presentation of the study proposal, the assessment tool was given to each of the individuals for feedback regarding the proposed study.

Assessment Tool Testing

All stakeholders completed the assessment tool directly after the presentation. There were seven questions to be answered (see Appendix F), with one area left for narrative comments. Table 1 includes a summary of all the results in the stakeholder

assessment tool feasibility survey. There was 81.8% feedback from the stakeholders that there was a sufficient population, benefit to the patient, and adequate resources available for the proposed study (See Table 1).

Table 1

Evaluation of Proposal for Exercise Program for Post Thrombotic Syndrome (N = 11)

Question	Domain	Stakeholders	
		Yes %	*No* %
Does the site have adequate resources to fulfill study needs?	Overall	81.8	18.1
Is there adequate number of patients to fulfill enrollment?	Design	81.8	18.1

Included in the narrative feedback were comments that included strengths for the proposal:

- "Quick enrollment will be possible due to the patient population" (Respondent 1).
- "Small sample size will allow for easy enrollment" (Respondent 2).
- "This will benefit the patients as well as decrease the burden on the vascular clinic" (Respondent 6).

Biggest challenges noted in the narrative comments included:

- "Maintaining patient compliance with exercise program" (Respondent 2).

- "Sample size too small" (Respondent 10).

The project proposal is in the formative stages and all feedback has been reviewed. The stakeholders noted that, if the feasibility project is approved, a larger sample size would be used in the multicenter approach. The study proposal will now be sent to the ProMedica Clinical Research Board of Directors for final assessment and implantation at a later date.

Discussion of Findings in the Context of Literature and Frameworks

Often, the lack of appropriate prophylaxis regarding DVT and education at the clinician, nurse, and patient level can lead to poor management and recurrence of symptoms in this chronically ill population. Education regarding PTS and how the translation of EBP can provide better outcomes to this set of patients might be the most effective way to get the message across. Documentation regarding current literature will help in preparation as well as decision making regarding change efforts.

Implications

If implemented, the study will be an open, comparative, single center study. The overall project question was related to whether use of an exercise program will improve symptoms in patients with PTS in a future feasibility study. Patient assessments would consist of: First visit, a Villalta baseline assessment of muscle strength, flexibility and walking endurance will be completed, baseline assessment of edema, venous ectasia, hyperpigmentation, eczema, pain scales, and varicose collateral veins will be collected. In addition, upon implementation, the patients will be taught how to take their own heart rate during the proposed study and record for data collection. Following this assessment,

for the interventional group, an individualized exercise program will be prescribed and explained to the patient.

The subject will perform this exercise prescription for a total period of 3 months. Each subject will be provided an exercise regimen that is specific to their capacity and provided guidance on advancing their activity as warranted. The subject will meet with the rehabilitation nurse monthly. The subject will be called weekly to follow-up and ensure that they are following exercise guidelines. The subject will be instructed to perform the prescribed exercise on his or her own, when not scheduled to meet with the rehabilitation nurse. To ensure that the patient is working at the prescribed intensity, the subject will be asked to take and record his or her heart rate during exercise and also record the frequency and duration of flexibility, strength, and walking performed each week/day.

Patients will be asked to submit their records at the end of the 3-month program. After the three months of exercise has been completed the subjects will complete a second Villalta score, and repeated assessments of strength, flexibility and walking endurance. Assessment of symptoms of PTS compared to baseline will be made during the proposed study. The control group will undergo and complete all assessments but will maintain their own normal exercise routine. The eventual data obtained will be compared to determine whether there is a significant difference between the control and interventional group.

Population and Sampling

The proposed population sample will include patients with unilateral symptomatic DVT diagnosed at least 6 months prior to enrollment and current ipsilateral manifestations in the leg consistent with PTS. The population will be referred from the vascular clinic database. The possible study candidates for inclusion would include:

- Patients with unilateral symptomatic DVT diagnosed at least 6 months prior to enrollment with current ipsilateral manifestations in the leg consistent with PTS.
- Potential subjects who sign consent will be required to undergo a supervised treadmill exercise stress test. If the participant reports any symptoms during the exercise test that that may put the patient at risk, the patient will be excluded from the study.
- Score of 5 or above on Villalta scale.
- Successfully complete preprogram Supervised Exercise test to gauge baseline level of exercise capacity.

Possible patients that would be excluded include:

- Contraindications to exercise
- Pregnant or plans on becoming pregnant
- Open venous ulcers
- Documented pulmonary embolism (PE)
- Patients who stop preprogram exercise stress test due to any reason other than fatigue.

Data Collection (instrument and protection of human subjects)

Patients will potentially be referred to the Jobst Vascular Institute by their vascular surgeon or primary care physician for the proposed exercise study. The proposed study randomization assignment will be completed via a paper envelope method. Upon implementation, 10 patients will be assigned to the exercise group, and 10 to the standard of care group. The potential patients will have to have had a history of ipsilateral manifestations of PTS symptoms consistent with the inclusion criteria.

When implemented, the Informed Consent Form (ICF) will be given to the patient by the clinical research coordinator (CRC) or principle investigator (PI) to read. All questions, concerns, risks, benefits, timelines, and rationale will be explained in detail to the patient. All questions and concerns are to be answered by the study coordinator. If the participant wishes to proceed at that time with signing the Informed Consent then the ICF document will be signed at that time. Documentation of the date and time will then be noted accordingly. A copy of the signed consent would be distributed to the patient for his/her records. No tests or study related procedures are completed prior to the consent being signed.

In the proposal, participants will be notified by the CRC or the PI that health information will usually does not directly identify them (e.g., name, address, or social security number). Instead, the study doctor will use his or her initials and a predetermined code number set prior to study start-up. If any HIPAA-identifier is contained within the case report form for the patient, it should be described here:

> The study data sent to the study sponsor may include your date of birth, hospital admission and discharge dates and date of death. The study sponsor, people who work with the sponsor on the study, and government agencies and other groups that watch over research studies like this one may look at all your health information. Regulatory authorities may also require that the study doctor turn over to them copies of all your health information. The reason these people may look at your health information is to make sure the study has been done the right way. They also want to make sure that any possible health information has been collected the right way, or for other reasons that are allowed under the law (Jobst Vascular Institute, 2014, p. 4).

Upon later implementation of proposed feasibility study, the ProMedica IRB will require that all sponsored and Investigator initiated studies submit documentation to facilitate the ethical conduct of all research conducted at ProMedica facilities. The IRB meets monthly at the Toledo Hospital. Future submission documents to include:

- Cover letter signed by the PI
- Request for review of research proposal/protocol
- Final version of the research proposal/protocol
- The proposed Informed Consent Form
- A copy of each questionnaire or survey to be used
- All investigators or other key personnel must complete the required Collaborative Training Initiative (CITI; ProMedica IRB, 2014).

Future documentation for the proposed study to measure objectives include the Quality of Life Questionnaires (VEINES and SF-12), Villalta scoring by physical exam, as well as instruction, and baseline assessment of muscle strength, flexibility, and walking endurance will be measured outcomes. The VEINES was developed by Kahn et al. (2002) and used in the original exercise therapy study. The VEINES has been validated using standard methods confirmed the acceptability, reliability, validity of using the questionnaire in patients who have experienced DVT. The SF-12 is the current standard for measuring QOL in research patients (Kahn et al., 2011). It is proposed within this study that the patient will need a score of five or above on the Villalta scale and have no contraindications to the exercise training. The Villalta has been used in numerous studies for PTS from diagnoses to severity (Kahn et al., 2011). The VEINES, SF-12, and Villalta are available for use publically online for non-commercial use.

Following the proposed assessments, an individualized exercise program will be potentially prescribed by the PI and explained to the participants by the rehabilitation nurse in the future study. In the proposed study, subjects will comply with the exercise program for a period of 3 months. Each participant's exercise program will be individualized specific to that subject's capacity and advanced as necessary throughout the study. Individual sessions with the rehabilitation nurse will be arranged throughout the proposed trial.

The potential subjects will be instructed to perform the prescribed exercise on their own when not scheduled to meet with the rehabilitation nurse. To ensure that the patient is working at the prescribed intensity, the subjects will be asked to record their

heart rate during exercise as well as the frequency and duration of flexibility, strength, and walking performed daily or weekly. Potential participants will be asked to submit their diary records at the end of each of the 3-month program. After the 3 months of exercise has been completed, the subjects will complete and second set of the QOL surveys, Villalta score, and repeated assessments of strength, flexibility and walking endurance via a second exercise stress test assessment.

Data capture and analysis plan would be completed at that time via SPSS software. Outcomes evaluated will include patient-rated venous symptoms: Pain, cramps, heaviness, paresthesia, and puritis. Clinician-rated venous signs of PTS will include: Pretibial edema, skin indurations, hyperpigmentation, redness, venous ectasia, and pain on calf compression.

Project Strengths and Limitations (Strengths, Limitations, Recommendations)

The intended purpose of this project was to introduce the discussion of a potential treatment option for PTS. Strengths for the proposed study include the possibility in offering an effective treatment option to reduce the symptoms of PTS. Stakeholder feedback allowed an open forum to evaluate the proposed study and offer insight into the PTS population that is currently underserved within the Northwest Ohio. According to Terry (2012) the DNP prepared nurse shall have preparation within a distinct specialty that envelops both expertise and specialty practice roles. The engagement and maintenance of stakeholders as well as institutional support for clinical research at all levels requires that the healthcare team demonstrate the effective participation in research projects that provide better patient outcomes. The project outcomes provided by this

proposed study is not limited solely to research participants. The potential for institutional, system wide, and disease burdened population that may effectively benefit from participation in the proposed feasibility study was a considered strength in the proposed study among stakeholder feedback participants. Limitations included the small sample size for the proposed feasibility study. Stakeholder recommendations include widening the sample size to accommodate any patients who discontinue during the study.

Analysis of Self as Project Developer

The development of a feasibility study that could potentially assist the PTS patients within vascular practice has been a professional goal since I began working with vascular patient population. Furthermore, as I continued to research the current treatment options available for PTS I have found that much research is needed in order to develop EBP options that remain cost effective, assist in the decreasing the signs and symptoms of PTS, as well as allow the patient to participate in their own healthcare. I have accomplished the goals that I have set forward and I believe that developing projects such as this will enhance my ability to coordinate clinical trials as well as develop sound projects for dissemination. Development of clinical research and the resources necessary to evaluate, implement, and follow-through can be costly and resource draining. This project proposal has allowed fulfillment of project planning from the initial stage of development, identifying project milestones, financial feasibility, through presentation processes, as well as stakeholder feedback.

Data Analysis

Statistical analyses of the proposed study include analysis following the second exercise stress test at month three. Enrollment of 20 patients is expected in the proposed study. Successful data capture and analysis will be considered with 60% compliance with patient exercise program and diaries. To minimize the incidence of a type I error the level of significance will be set at 0.05. Analysis will be completed using SPSS statistical software. A statistician will assist in the data analysis.

Project Evaluation Plan

The implementation of a proposal for an exercise program for PTS will assist in the development and validation of a possible new treatment option for PTS. Through the cooperation of vascular services, rehabilitation, and patients who suffer from PTS, this potentially new way to treat PTS patients could be a viable treatment option for many PTS sufferers. Short term goals for the program included assessment of protocol feasibility, discussion of correct study subject population, and how to maintain those subjects who are eventually enrolled in a future feasibility study. Stakeholder feedback prior to study implementation and review of recommendations will assist in determination if there is sufficient cause, support, and patient population for proposed study. Long term goals would include evaluation of the data after implementation of the study to determine efficacy of the exercise program and the overall effect that it had on symptoms of PTS and QOL.

Summary

The ability to critically think and problem solve by using the fundamentals of research, theory, knowledge, and evidence-based practices can assist in the use of ethical principles, scientific knowledge, and patient centered care. Development of EBP standards of care based upon the most current data ensures that patients are getting the most appropriate care for their health condition. Researching current data and applying the knowledge into workable questions, assessing barriers to practice, developing interventions, evaluation outcomes, and sustaining that knowledge will help nurses to promote quality care (White & Dudley-Brown, 2012). This role will become paramount as society ages and healthcare management becomes more overwhelmed with patients who require chronic care and supervision. The development of a new standard of care for PTS will assist in better QOL and symptom control for patients who suffer from this lifelong condition. The development of this proposal within the vascular area could assist in defining measurable outcomes and data that could assist in managing this chronically debilitating disease. If symptoms of PTS are manageable and patients are able to assist in their own care expected outcomes would include decreased hospitalizations, use of medications, physician office visits, and clinic resources. The proposed feasibility study including target population, sampling, inclusion and exclusion criteria, data collection, primary outcomes and financial sustainability was presented to the stakeholders within the Vascular rehabilitation and Wound Care Clinic at ProMedica Toledo Hospital for final approval and overall impact within the study population. Approved for implementation, the outcomes could effectively save the hospital, insurance companies,

Medicare and Medicaid, as well as the consumer's money that is spent on expensive treatments. The time that is spent on those who are coming into the hospitals and clinics can be effectively spent treating those who are the most significantly ill.

Section 5: Scholarly Product

Introduction

This project proposal was developed with the intended purpose of enhancing nurse practice that is both innovative and evidence-based, as well as a reflection of the application of credible research findings (AACN, 2006). Upon evaluation of stakeholder feedback and the future submission to the ProMedica Clinical Research Board of Directors for final assessment the implantation will continue after my DNP clinical rotation has completed. A power-point presentation has been developed for the Clinical Research Board of Directors and will be utilized in the presentation of the proposed study (See Appendix G). The intended publication of all study results will be submitted to a peer-reviewed journal once full feasibility study has been completed.

Summary

In summary, the dissemination of this DNP project has been created in the hopes of developing an evidenced- based intervention that could assist in the treatment of PTS and those who suffer from this chronic condition. Stakeholder involvement in the projected research project proposal and evaluation process that is likely to enhance dissemination of the scholarly project. This potential treatment option would allow patients the freedom to have input regarding their healthcare plan and participation needs, own healthcare risk factors, co-morbidities, and how they participate in their healthcare decisions.

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Appendix A: Rehabilitation Summary List

Patient Name: _____ Phone: _____ Date of Birth: _____

Emergency Contact: _____ Phone: _____ Preferred Language_____

PCP: _____ PCP Phone: _____

Referral Source: _____ Referral Phone: _____

Date/Yr.	Past/Current Conditions	Date/Yr.	Invasive Procedures

ALLERGIES/REACTION: _____

Start	Stop	Medication/Dose/ Frequency	Start	Stop	Medication/Dose/ Frequency

Reviewed and Updated:

_____ _____ _____ _____ _____ _____

Initials Signature Initials Signature Initials Signature

Appendix B: Rehabilitation Program-Initial Assessment Form

Name: _____ D.O.B._____ Evaluation Date: _____

PCP: _____ Referral Source: _____

Male Female Race: _____ Ethnicity: _____

HEALTH REVIEW

Is there a history of problems regarding:

1. Heart	Yes No	
2. Lungs	Yes No	
3. Bones/Joints	Yes No	
4. Feet	Yes No	
5. Blood Pressure	Yes No	
6. Diabetes	Yes No	
7. Blood Clots	Yes No	
8. Claudication	Yes No	
9. Rest Pain	Yes No	
10. Ulcerations	Yes No	
11. Venous Disease	Yes No	
12. Cancer	Yes No	

HOSPITALIZATIONS AND INVASIVE PROCEDURES

Date/Yr.	Description

Nurse's Notes: _____

Name: _____ D.O.B._____ Date: _____

MEDICATIONS

Medication	Dose	Purpose

ALLERGIES/REACTIONS: _____

_____

NUTRITION

1. What kind of diet do you follow? _____
2. Do you have any difficulty preparing meals? _____

PERSONAL HISTORY

1. Smoker: Yes No Packs per day? ____ How many years? _____
2. Marital Status: Single Married Divorced Widow(er)
3. Work Status: Working Retired Occupation: _____

Nurse's Notes: _____

Name: _____ D.O.B._____ Date: _____

ACTIVITY/EXERCISE

1. What limits your walking? _____
2. How far can you walk? around the house ½ block 1 block 2 blocks

   ½ mile or more
3. Do you exercise on a regular basis? Yes No

   If yes, what type of exercise do you do? _____

   How often? _____ For how long? _____
4. Do you experience any problems with exercise? Yes No

   If yes, what are the problems? _____
5. Do you need to climb steps at home? Yes No

   If yes, how many? _____
6. Do you own any exercise equipment? Yes No

   If yes, what type? _____

Nurse's notes: _____

_____

EDUCATIONAL NEEDS

1. What do you hope to accomplish with this program? _____

2. How do you learn best (mark all that apply)? Reading Visual Verbal

3. Special Considerations? None Cultural Religious Emotional

Motivation Cognitive Physical Language Other

4. Preferred Language: _____Preferred Language for health care: _____

Name:_____ D.O.B._____ Date:_____

VASCULAR/FUNCTIONAL ASSESSMENT

Resting heart rate: _____ Regular Irregular

Blood pressure: R: _____ L: _____

Radial pulses: R: _____ L: _____

Lung sounds: _____

Upper Extremities:

ROM R: _____ L: _____

Lower Extremities:

ROM R: _____ L: _____

Gait: _____

Height: _____ Weight: _____

Skin: _____

GOALS

Long-term goals	Short-term goals
To increase distance to claudication	To become independent with static stretching
To increase functional capacity	To tolerate ____ minutes of exercise
To understand lifestyle modification education	Other:
Other:	

Reviewed

_____	_____	_____	_____
Signature	Date	Signature	Date

Appendix C: Vascular Rehabilitation – Exercise Therapy Log

Name: _____ Date: _____ Arrival Time: _____
Session #:_____

	PRE	POST
BP		
HR		
Laps		
Stretching		

Date of birth: _____ Weight: _____

W=Walk AD=Airdyne TM=Treadmill
NS=NuStep SM=StairMaster

AD seat: _____ NS (seat-arms-intensity):_____

Special Needs/Goals:

_____

Exercise Prescription

ACTIVITY						
INTENSITY						
TIME						

Actual Therapy Total Time_____

ACTIVITY						
INTENSITY						
TIME						
RPE						
PAIN						
LOCATION						
BP						
HR						

PROGRESS NOTES:

_____

HOME EXERCISE-Goal:

_____

HOME EXERCISE-Progress:

_____

____ _____ _____ _____

Initials VRP Signature Date Time

Appendix D: Rehabilitation – Maintenance Exercise Log

Name: _____ D.O.B._____
Month/Year: _____
Activity Key: **AD**=Airdyne **TM**=Treadmill **NS**=NuStep
W/U=Warm-up **W/D**= Warm-down **SM**=StairMaster
Laps/Stretching: _____ AD seat height: _____
NS (seat-arms-intensity): _____

Activity					
Intensity					
Time					

Date	Time	Wt.	BP	HR	W/ U	Activity	W/D	BP	HR	Init.

Nurse's notes:
_____
_____
_____
Initials: ____ Signature:_____

Appendix E: Home Exercise Log

Name: _____ **Date:**_____
Target Heart Rate**:** Time: Activity: _____
TM = Treadmill
O= Walking Outside RPE= Rating of Perceived Exertion (See Scale)
Strengthening (Write number of sets and reps performed for each exercise)
Back Leg Raise: _____ Heel Raise: _____
Leg Straightening:_____
Knee Curl: _____ Squats: _____

Week 1	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Date							
Activity							
Time							
Distance							
Speed (if on TM)							
HR							
RPE							
Gastroc Stretch							
Hamstring Stretch							
Quadriceps Stretch							
Back Leg Raise							
Heel Raise							
Leg Straightening							
Knee Curl							
Wall Squat							

Questions/Comments_____

_____

Week 2	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
Date							
Activity							
Time							
Distance							
Speed (if on TM)							
HR							
RPE							
Gastroc Stretch							
Hamstring Stretch							
Quadriceps Stretch							
Back Leg Raise							
Heel Raise							
Leg Straightening							
Knee Curl							
Wall Squat							

Week 3	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
Date							
Activity							
Time							
Distance							
Speed (if on TM)							
HR							
RPE							
Gastroc Stretch							
Hamstring Stretch							
Quadriceps Stretch							
Back Leg Raise							

Heel Raise							
Leg Straightening							
Knee Curl							
Wall Squat							

Questions/Comments_____

_____

Appendix F: Evaluation of Proposal for Exercise Program for Post Thrombotic Syndrome

1. Please check the answer that best describe your occupation

- ☐ Primary Care Provider
- ☐ Physician
- ☐ Physician's Assistant
- ☐ Nurse Practitioner
- ☐ Medical Assistant
- ☐ Nurse
- ☐ Manager
- ☐ Other (please specify):_____

2. What are the two greatest strengths of the proposed feasibility study?

A.

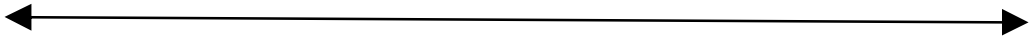
B

3. What are the two biggest challenges of the proposed feasibility study?

A.

B.

4. Please rate the presentation in terms of its impact and usefulness in the following areas, using the scale below. (**1 = Not useful at all, and 10 = Very Useful)**



1 2 3 4 5 6 7 8 9 10

5. **Please respond to the feasibility of this study by responding to the following questions. (1= Strongly Disagree, 3 = Neutral, and 5 = Strongly Agree)**

Area	**1**	**2**	**3**	**4**	**5**
Does the site have adequate resources to fulfill study needs?	1	2	3	4	5
Are there an adequate number of patients to fulfill enrollment?	1	2	3	4	5

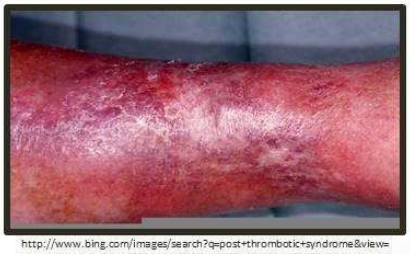
6. Please provide one example of how this prospective study could benefit this patient population.

7. Other comments:

Appendix G: PowerPoint: Proposal for the Development of and Exercise Program for Post Thrombotic Syndrome

Proposal for the Development of an Exercise Program to Treat Post Thrombotic Syndrome

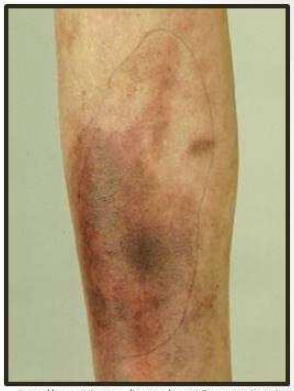
Christy Hansen
Walden University
July 2015



http://www.bing.com/images/search?q=post+thrombotic+syndrome&view=detailv2&&id=D7A26FF9CA18092E2A4B8E31461ECA447355728C&selectedIndex=0&ccid=aVb3V7F&simid=607994166502622664&thid=JN.IXek0IHO7ewxpu8YTj19KA&ajaxhist=0

Introduction

- Deep vein thrombosis (DVT) affects between 300,000 to 600,000 people every year in the United States alone (Centers for Disease Control & Prevention, 2013).
- Of that population, roughly 20-50% of those who suffered a Deep Vein Thrombosis (DVT) will develop a chronic condition with pain, swelling, and discoloration to the affected extremity known as Post Thrombotic Syndrome (PTS) (Holmes, Bambace, Lewis, Callas, & Cushman, 2014).



http://www.bing.com/images/search?q=post+thrombotic+syndrome+pictures&view=detailv2&id=B823B3EA041DDF89CBBA5D98B8185033D8C1C7DC&selectedindex=3&ccid=t7PI3VVr&simid=608006359907175496&thid=HN.608006359907175496&ajaxhist=0&first=1

Current Treatment Options

Current SOC

- Compression Therapy
- Anticoagulation
  - Warfarin
  - Dabigatran
  - Rivaroxaban
  - Factor XA inhibitors
  - Apixaban

Other Treatments Available

- Rutosides
- Surgical Intervention
  - Venous Valve Repair
  - Bypass
  - Endovenectomy
- Exercise Therapy

Purpose Statement

The purpose of this proposed study is to develop a proposal to investigate the effectiveness of using an exercise program to treat PTS.

Project Objectives

The project question asks whether exercise can improve symptoms of PTS. The proposal includes patients with unilateral symptomatic DVT diagnosed at least six months prior to enrollment and current ipsilateral manifestations in the leg consistent with PTS.

Specific Outcomes Measured

- Outcomes measured will include symptoms of PTS. Patient-rated venous symptoms assessed will be pain, cramps, heaviness, paresthesia, and puritis.
- Clinician-rated venous signs will include pretibial edema, skin induration, hyperpigmentation, redness, venous ectasia, and pain on calf compression.

5

http://vasocare.com/wp-content/uploads/2014/07/Claudication-limb-pain-image1.jpg

Evidence-Based Significance

- Better QOL for patients
- Decrease the burden of costly treatments and procedures done to this population of patients
- Decreased hospitalizations
- Decreased use of medications
- Fewer physician office visits
- Less use of clinic resources

6

Social Change

- The collaborative effort of these elements can lead to improved patient care and better patient outcomes.
- According to Simmons (2010) clinical reasoning is a "complex cognitive process that uses formal and informal thinking strategies to gather and analyze patient information, evaluate the significance of this information and weigh alternative actions" (p. 1155).
- The evaluation of what information is relevant and essential in the coordination of patient care helps to guide treatment options within the vascular practice that I work within.

7

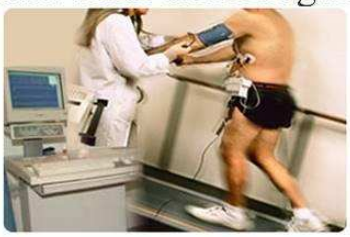
Inclusion Criteria

- The population sample will include patients with unilateral symptomatic DVT diagnosed at least six months prior to enrollment and current ipsilateral manifestations in the leg consistent with PTS.
- Patients with unilateral symptomatic DVT diagnosed at least 6 months prior to enrollment with current ipsilateral manifestations in the leg consistent with PTS.
- Potential subjects who sign consent will be required to undergo a supervised treadmill exercise stress test. If the participant reports any symptoms during the exercise test that that may put the patient at risk, the patient will be excluded from the study.
- Score of 5 or above on Villalta scale
- Successfully complete pre-program Supervised Exercise test to gauge baseline level of exercise capacity

8

Exclusion Criteria

- Contraindications to exercise
- Pregnant or plans on becoming pregnant
- Open venous ulcers
- Documented Pulmonary Embolism (PE)
- Patients who stop pre-program exercise stress test due to any reason other than fatigue



http://www.bing.com/images/search?q=Exercise+stress+test&view=detailv2&id=E421056C74668C3C5C688D514E6B958DA5459A9D&selectedindex=18&ccid=arkBOfsA&simid=608079387443180488 1&thid=HN.607993874431804881&mode=overlay&first=1

Literature Review Strengths

- Patient outcomes regarding exercise and PTS was positive documenting the need for further studies
- The relationship between PTS and an exercise program showed the promise of improvement in a similar study conducted.
- An exercise program is a useful tool for the promotion of self-care behaviors in the PTS population.

http://www.buyselltreadmills.com/wp-content/uploads/2013/01/CYBEX-750T-IFI-Total-Access-treadmill.jpeg

10

Literature Weaknesses

- The lack of exercise programs in relationship to treating PTS remained a large gap within current literature.
- The only available study regarding exercise and PTS was the randomized controlled two-centre trial conducted by Kahn et al., (2011) which demonstrated effectiveness and the need for further research.
- The size of the sample populations was small and evident of the need for further research.

Conceptual Models, Theoretical Frameworks

The Stetler Evidenced-Based Practice (EBP) Model

- Phase I: Preparation
- Phase II: Validation
- Phase III: Comparative Evaluation/Decision Making
- Phase IV: Translation/Application
- Phase V: Evaluation

The Stetler Evidenced-Based Practice Model will guide the potential pilot study in implementing structure and evaluating successful completion of the trial.

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Design/Methods

- Feasibility study
- 20 patients
- Quasi-experimental control group pretest-posttest design
- Pre and post test data will be collected via a convenience sample due to the time limitations of the project
- Open, comparative, single center study
- Screening Visit: Villalta score
- Baseline assessment of muscle strength, flexibility and walking endurance
- Baseline assessment of edema, venous ectasia, hyperpigmentation, eczema, pain scales, and varicose collateral veins
- Individualized exercise program will be prescribed
- The subject will perform this exercise prescription for a total period of three months and advanced to their capacity as warranted.

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Design/Methods (continued)

- Patients will be asked to submit their home exercise records at the end of the three month program
- After the three months of exercise has been completed the subjects will complete a second Villalta score
- Repeated assessments of strength, flexibility and walking endurance
- Assessment of symptoms of PTS compared to baseline will be assessed
- The control group will undergo and complete all assessments but will maintain their own normal exercise routine
- The data obtained will be compared to determine whether there is a significant difference between the control and interventional group

Data Collection

- ICF
- Quality of Life Questionnaires (Baseline/3months)
  - -VEINES
  - -SF-12
- Patient diary of exercise
- Outcomes evaluated will include patient-rated venous symptoms: Pain, cramps, heaviness, paresthesia, and puritis
- Clinician-rated venous signs of PTS will include: Pretibial edema, skin indurations, hyperpigmentation, redness, venous ectasia, and pain on calf compression.

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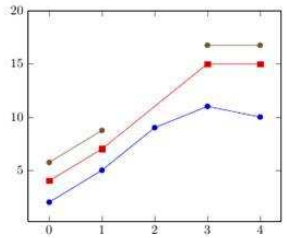
Data Analysis

- Statistical analysis of the results will be conducted following the second exercise stress test at month three.
- Enrollment of 20 patients is expected in the study.
- Successful data capture and analysis will be considered with 60% compliance with patient exercise program and diaries.
- Analysis will be completed using SPSS statistical software.



Project Evaluation

- Short term goals:
  - Assessment of protocol feasibility
  - Enrollment of study subjects
  - Maintenance of those subjects who are enrolled
  - Financial feasibility
- Long term goals:
  - Evaluation of the data to determine efficacy of the exercise program
  - Overall effect that it had on symptoms of PTS and QOL

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Summary

- The development of a new standard of care for PTS will assist in better QOL and symptom control for patients who suffer from this lifelong condition.
- This proposal within the vascular area could assist in defining measurable outcomes and data that could assist in managing this chronically debilitating disease.
- If symptoms are manageable and patients are able to assist in their own care expected outcomes would include decreased hospitalizations, use of medications, physician office visits, and clinic resources.
- All of the outcomes would effectively save the hospitals, insurance companies, Medicare and Medicaid, as well as the consumer's money that is spent on expensive treatments.

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