Can a Nurse-led Intervention Program for people with peripheral arterial disease lead to sustained improvement in functional capacity and quality of life?

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Abstract
Peripheral arterial disease (PAD) is a manifestation of systemic atherosclerosis which causes significant morbidity and mortality affecting between 14% and 29% of individuals >70 years of age. Multiple studies have demonstrated an improvement in walking distance in people suffering from symptomatic PAD through exercise therapy. While most studies have examined the results of exercise and risk factor modification programs over a short-term this study sought to identify not only whether a nurse-led intervention program can improve functional capacity and quality of life, but if improvements could be sustained over a longer follow-up term.
There were 56 participants recruited from the Vascular Surgery Outpatients department at the Princess Alexandra Hospital, Brisbane. The nurse-led intervention program consisted of a 12-week supervised exercise program as well as a home walking prescription and fortnightly risk factor education sessions. A further 23 individuals who were unable to attend the intervention program due to geographical location agreed to complete quality of life-only follow-up and were given home exercise advice.
As predicted, participants in the nurse-led intervention program (NLIP) group demonstrated a statistically significant improvement in both functional capacity (p<.01) and all domains of a PAD specific quality of life questionnaire (Vascuqol) except social, directly following the program (p<.05).
Both treadmill assessment (claudication pain time and maximum walk time) and corridor walking assessment (6 minute walk) results continued to be significantly improved 12 months following the intervention program (p<.05) and at 30 months following intervention, claudication pain time remained significantly improved (p=.045).
Participants in the NLIP group also continued to have significantly improved quality of life in the domains of PAD symptoms and emotion. The quality of life only (QOLO) group demonstrated an improvement in the domain of pain at 12 months, however no further improvement was evident at either 12 or 30 months.
After a mean follow up time of 52 months, the NLIP group had sustained a 14% mortality rate. This is in keeping with the 5-year predicted mortality found amongst PAD sufferers.
The results from this study suggest that a nurse-led intervention program for people with PAD can have sustained improvement in pain free walking distance and emotional well-being. Further research is required to identify whether earlier intervention may lead to a reduction in mortality rates in PAD population.
Declaration by author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

I have clearly stated the contribution of others to my thesis as a whole, including statistical assistance, survey design, data analysis, significant technical procedures, professional editorial advice, and any other original research work used or reported in my thesis. The content of my thesis is the result of work I have carried out since the commencement of my research higher degree candidature and does not include a substantial part of work that has been submitted to qualify for the award of any other degree or diploma in any university or other tertiary institution. I have clearly stated which parts of my thesis, if any, have been submitted to qualify for another award.

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Publications during candidature

Conference Presentations/Abstracts Relating to Thesis


Invited Faculty Presentations

Nurse-led claudication rehabilitation programs- Liverpool Hospital (NSW) Aug 2014
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Publications included in this thesis

No publications included.
Contributions by others to the thesis

The data presented in this thesis is from the Targeted Disease Management Plans for People with Peripheral Arterial Disease (TEMPLATE) study which was a concept designed by Professor Thomas Marwick and Professor Simon Stewart.

Dr Brian Haluska- assisted with TEMPLATE study protocol revision

Ms Leah Wright- Supervised exercise program and assisted with data collection

Associate Professor Tony Stanton- Assisted with Statistical analysis

Statement of parts of the thesis submitted to qualify for the award of another degree

None
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Peripheral arterial disease, nurse-led, vascular, exercise, quality of life

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<td>PAD</td>
<td>Peripheral arterial disease</td>
</tr>
<tr>
<td>ACC/AHA</td>
<td>American College of Cardiology/American Heart Association</td>
</tr>
<tr>
<td>HDL</td>
<td>High density lipoprotein</td>
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<tr>
<td>LDL</td>
<td>Low density lipoprotein</td>
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<tr>
<td>HTN</td>
<td>Hypertension</td>
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<td>DM</td>
<td>Diabetes Mellitus</td>
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<td>ABI</td>
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<td>HRQOL</td>
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<td>BP</td>
<td>Blood pressure</td>
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<td>BMI</td>
<td>Body mass index</td>
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<td>CAD</td>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>PN</td>
<td>Practice Nurse</td>
</tr>
<tr>
<td>GP</td>
<td>General practitioner</td>
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<tr>
<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>MI</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>CHF</td>
<td>Chronic heart failure</td>
</tr>
<tr>
<td>AF</td>
<td>Atrial fibrillation</td>
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<tr>
<td>RCT</td>
<td>Randomised control trial</td>
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<td>PTT</td>
<td>Progressive treadmill test</td>
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<td>CPT</td>
<td>Claudication pain time</td>
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<td>MWT</td>
<td>Maximum walk time</td>
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Chapter 1

Introduction/Background

1.1 Peripheral Arterial Disease

Peripheral arterial disease (PAD) is a manifestation of systemic atherosclerosis which causes significant morbidity and mortality. It is defined by “atherosclerotic obstruction of the abdominal aorta and/or arteries to the legs that reduces arterial flow during exercise and/or rest” (Chi & Jaff, 2008).

Epidemiology

The prevalence of PAD in men and women ≥40 years of age is believed to be approximately 4% (Selvin & Erlinger, 2004). However, with increasing age the prevalence sharply increases to between 14% and 29% of individuals >70 years of age (Hirsch et al., 2001; Selvin & Erlinger, 2004). The pivotal Framingham Heart study reported a higher prevalence of PAD in men than in women (3.6%-men, 1.8%-women) (Kannel, Skinner, Schwartz, & Shurtleff, 1970). This gender-based difference has also been found in multiple subsequent studies including the Quebec Cardiovascular Study (Dagenais, Maurice, Robitaille, Gingras, & Lupien, 1991) and the Cardiovascular Health study (Newman et al., 1993).

The Australian Institute of Health and Welfare state that no national data exists to identify the exact prevalence of PAD in Australia, however they do note that PAD was responsible for over 25,000 hospitalisation in 2006-2007 and 2,163 deaths in 2006 (Australian Institute of Health and Welfare, 2010).

Associated Cardiovascular risk

It is the systemic nature of the atherosclerotic disease process which increases cardiovascular morbidity and mortality rates in people with PAD (Diehm et al., 2009). Within one year of presentation, 25% of patients with critical limb ischemia (CLI), the most advanced form of PAD die of cardiovascular causes and a further 25% suffer major limb amputation. Even individuals with stable or no symptoms of PAD have a
20% incidence of myocardial infarction or stroke and 15% to 30% mortality in 5 years of presentation (Figure 1) (Weitz et al., 1996).

**Figure 1** Reproduced with permission (Weitz et al., 1996)

**Risk Factors for PAD**
Risk factors for PAD can be defined as being either modifiable, or non-modifiable as outlined below.

**Non-modifiable risk factors**

**Genetics**

Family history has been shown to be a major determinant of risk for PAD (Valentine et al., 2004). Valentine, Guerra and Stephen et al found that 64% of people with a first degree relative with early-onset PAD (<50 years old) have documented arterial disease as determined by duplex ultrasound (Valentine et al., 2004). They were not
able to establish causality of this finding, however they were able to determine that family history was a major determinant of risk independent of smoking and when the two were combined, risk accelerated dramatically (Valentine et al., 2004).

Genetic defects in homocysteine metabolism resulting in hyperhomocysteinemia is also an independent risk for PAD and increases the risk of death from cardiovascular disease (Graham et al., 1997). Although reduction in serum homocysteine levels can be achieved quite simply through dietary supplements and vitamins, there is little evidence to suggest that this will produce a beneficial effect in people with PAD (Chi & Jaff, 2008).

**Ethnicity**

In the San Diego population study (2005) black ethnicity was shown to be a strong risk factor for PAD, even when adjusted for higher incidence of diabetes, hypertension and body mass index (Criqui et al., 2005). In Australia, there is also great disparity between the incidence of PAD in indigenous Australians and those of an Anglo-Celt heritage, with indigenous Australians being almost twice as likely to develop PAD (Davis et al., 2012). Results from the recent Fremantle Diabetes study show people of Indigenous background have not only a higher incidence of diabetes, but they are also diagnosed at a younger age and demonstrate poorer glycemic control (Davis et al., 2012). Overall, people of Indigenous background have an 18 year shorter life expectancy than their Anglo-Celt counterparts (Davis, McAullay, Davis, & Bruce, 2007).

**Modifiable Risk Factors**

**Cigarette smoking**

Cigarette smoking is the single most important modifiable risk factor for the development and advancement of PAD (Agarwal, 2009) (Willigendael et al., 2004). A 2004 meta-analysis of 17 studies found a 2.2-fold greater prevalence of symptomatic PAD in smokers compared with non-smokers (Willigendael et al., 2004). The incidence of symptomatic PAD has been shown to be directly proportional to the dose of exposure to nicotine, with an increase from 2.6% in never smokers to 9.8%
in heavy smokers (Price et al., 1999). Even passive tobacco exposure almost doubles the risk of development of PAD in non-smokers (He et al., 2008). The atherogenic effect of tobacco use has been linked to multiple etiologies, such as “activation of sympathetic system resulting in vasoconstriction, oxidation of low-density lipoprotein (LDL) cholesterol, inhibition of tissue plasminogen activator release from the endothelium, increased fibrinogen concentration, increased platelet activity, and increased expression of plaque tissue and endothelial dysfunction” (Chi & Jaff, 2008).

**Hyperlipidemia**

Hyperlipidemia initiates atherosclerosis by disturbing the normal homeostatic function of the endothelium and vascular wall (Kinlay, Libby, & Ganz, 2001). People with PAD tend to have a pattern of dislipidemia similar to those with metabolic syndrome including low high-density lipoprotein (HDL) levels and elevated triglyceride levels (Chi & Jaff, 2008). According to the PARTNERS (PAD Awareness, Risk and Treatment: New Resources for Survival) Program, the incidence of hyperlipidemia in PAD patients was as high as 77% (Hirsch et al., 2001). It has been shown to increase the likelihood of developing PAD by 10% for every 0.259mmol/L rise in total cholesterol (Hiatt, Hoag, & Hamman, 1995).

**Hypertension**

Hypertension (HTN) is another prominent risk factor for PAD and is present in as many around 55% of people with PAD (Lane & Lip, 2009). Atheromatous renal artery stenosis is a common primary cause of hypertension in people with PAD (Missouris, Buckenham, Cappuccio, & MacGregor, 1994). Other secondary causes of hypertension include endocrine disorders, such as primary hyperaldosteronism and diabetes mellitus (Beckman, Creager, & Libby, 2002).
**Diabetes mellitus**

The prevalence of PAD in people with diabetes mellitus (DM) has been estimated to be 20% to 30% greater than in any other matched population (Marso & Hiatt, 2006). DM increases the risk of complications to PAD sufferers through both microvascular and macrovascular dysfunction. “The metabolic abnormalities associated with hyperglycemia and insulin resistance alter endothelial function, smooth muscle vasomotor balance, and platelet aggregation, thereby promoting atherosclerosis and thrombus formation” (Gandhi, Weinberg, Margey, & Jaff, 2011). Macrovascular complications include coronary artery disease, hypertension, stroke, sensory, motor and autonomic neuropathy, wounds, infection, and gangrene of the lower/upper extremities and sexual dysfunction. Microvascular complications include damage to arterial supply of the eyes, leading to blindness/retina disease, and also the kidneys, which can lead to renal failure and even dialysis (Gibbons & Shaw, 2012). DM alters the distribution of the disease, and PAD in diabetic patients more often involves the arteries below the knee than in non-diabetic patients (Dosluoglu, Lall, Nader, Harris, & Dryjski, 2010). PAD is more commonly asymptomatic in diabetic patients because of the high association of sensory and autonomic neuropathy (Gibbons & Shaw, 2012). These patients are also more likely to present with tissue loss and are at higher risk for amputation (Jude, Oyibo, Chalmers, & Boulton, 2001). Due to the advanced presentation and diffuse disease often seen in diabetic patients, they also demonstrate reduced primary patency after endovascular interventions (DeRubertis et al., 2008).

### 1.3 Presentation and Diagnosis of PAD

**Physical assessment**

PAD is often underdiagnosed and undertreated (A. Simmons, Steffen, & Sanders, 2012). Intermittent claudication is the mildest symptomatic manifestation of PAD (Lauret et al., 2012). “Claudication is a word derived from the Latin word *claudicato*, meaning to limp” (Olin & Sealove, 2010). The discomfort which results is caused by reversible muscle ischemia. In people without PAD, exercise causes vasodilation, in order to deliver the higher volume of blood flow required by the muscles being used.
In patients with PAD exercise creates the same demand however the atherosclerotic narrowing limits the amount of blood and thereby oxygen which can be delivered to the periphery of the buttocks and/or lower extremities. This lack of oxygen causes an anaerobic state in which lactic acid and other metabolites are formed. This results in cramping or aching pain experienced one level distal to level of obstruction (eg, superficial femoral or popliteal obstruction causes calf pain and aortoiliac disease causes thigh, hip or buttock pain). In the resting state, the oxygen debt can be redeemed and symptoms are relieved (Olin & Sealove, 2010).

Approximately 50% of individuals with PAD however are asymptomatic (Steffen, Duprez, Boucher, Ershow, & Hirsh, 2008) and symptoms similar to intermittent claudication can be present in patients with musculoskeletal conditions which highlights the need for primary care screening of at-risk patients. One of the most accessible ways of screening for PAD in the primary care setting is ankle-brachial index (ABI) testing. This simple, inexpensive and non-invasive method of assessment can be helpful in the diagnosis of both symptomatic and asymptomatic PAD. ABI is measured using a continuous wave Doppler ultrasound device and a sphygmomanometer. The higher systolic pressure measured from either the posterior tibial or dorsalis pedis artery (in each leg) is then divided by the higher brachial artery pressure taken from either arm (figure 2). PAD can be diagnosed if ABI<0.90 (Olin et al., 2011). ABI can produce a falsely normal result in people with diabetes due to poorly compressible, calcified arteries (Arain & Cooper, 2008). If the ABI is greater than 1.30 then the ABI should be considered indeterminate and a normal ABI in a symptomatic diabetic should be treated as potentially inaccurate (Suominen, Rantanen, Venermo, Saarinen, & Salenius, 2008). In these cases further investigations such as duplex ultrasound can provide a more accurate diagnosis.
The Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) guidelines recommends ABI should be measured in:

- All patients who have exertional leg symptoms.
- All patients between the age of 50-69 and who have a cardiovascular risk factor (particularly diabetes or smoking).
- All patients ≥70 years regardless of risk factor status
- All patients with a Framingham risk score 10%-20%. (Norgren et al., 2007)
**Functional Assessment**

As one of the more limiting features of PAD is the reduction in functional capacity and this can greatly affect a person’s ability to carry out their activities of daily living, it is important to have a quantifiable mode of assessing function capacity. Treadmill testing is an established means to quantify walking ability in persons with PAD and is highly predictive of long-term morbidity and mortality outcomes (de Liefde et al., 2009). It is traditionally used to measure changes in walking performance following therapeutic interventions among PAD sufferers. It has been suggested however that the degree to which treadmill testing reflects functional capability in daily life is uncertain (McDermott et al., 2008). Treadmill testing is performed according to a set protocol which specifies walking speed and gradient and therefore may represent a relatively artificial measure of walking ability. Corridor-based functional performance measures such as the six-minute-walk are an important complement to treadmill assessment as they correlate better with physical activity during daily life, and studies of functional performance in persons with PAD should include both (McDermott et al., 2008).

**Quality of life assessment**

Chronic illness is the primary contributor to depression in the elderly (Pratt, Norris, & Kaufmann, 2005). The reduction in physical capacity in PAD can lead to a loss of independence and reliance upon others to perform everyday tasks. This may result in frustration or low self-esteem and in order to reduce what they see as burden upon others, people with PAD may withdraw from social activity leading to a reduction in their quality of life (Pratt et al., 2005). While treadmill and corridor walk testing are able to provide information regarding people with PAD’s walking ability, they do not address their perception of his or her walking ability or health related quality of life (HRQOL). In assessing the efficacy of an intervention for PAD it is important to not only investigate improvements in functional capacity but also note if the improvements correlate to an improvement in quality of life. The best way to assess mental health, emotional well-being, and social functioning, is through the use of specific questionnaires (Mays et al., 2011).
1.4 Treatment guidelines for PAD

Once a diagnosis of PAD has been made, appropriate treatment must address both the specific lower-extremity disability and the systemic impact of the disease (Norgren et al., 2007).

Both The current American College of Cardiology (ACC)/American Heart Association (AHA) and TASC II guidelines recommend aggressive management of atherosclerotic risk factors to reduce future cardiovascular events in all patients with PAD (Hirsch et al., 2006) (Norgren et al., 2007). Risk factor management includes cessation of smoking, control of diabetes, hypertension, and hypercholesterolemia, along with dietary restrictions aimed at reducing low-density lipoprotein cholesterol and obesity (Table 1). In addition, treatment options for PAD are geared towards medical therapy which includes antiplatelet agents such as aspirin and clopidogrel, exercise rehabilitation, surgical therapy such as endovascular interventions, or surgical bypass. It is recommended that management of patients through medication and exercise should be attempted prior to the more aggressive approaches of endovascular intervention or surgical bypass (Gardner & Afaq, 2008).

Table 1- ACC/AHA guidelines for cardiovascular risk factor reductions in patients with PAD

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Smoking cessation</strong></td>
</tr>
<tr>
<td>Quit smoking</td>
</tr>
<tr>
<td><strong>Weight reduction</strong></td>
</tr>
<tr>
<td>Counselling to reduce weight if BMI &gt;25</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
</tr>
<tr>
<td>HBA1C goal of &lt;7% or as close to 6% as possible</td>
</tr>
<tr>
<td><strong>Hyperlipidemia</strong></td>
</tr>
<tr>
<td>LDL &lt;2.59mmol/L for all patients and &lt;1.81mmol/L in patients with PAD and disease in other vascular beds</td>
</tr>
<tr>
<td><strong>Antiplatelet therapy</strong></td>
</tr>
<tr>
<td>Aspirin for all patients with symptomatic PAD. Clopidogrel may be an effective alternative to aspirin.</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
</tr>
<tr>
<td>BP &lt;140/90 or &lt;130/80 in patients with diabetes mellitus or renal failure</td>
</tr>
</tbody>
</table>

Hirsch et al (Hirsch et al., 2006)
Exercise therapy for PAD

Exercise therapy has historically been prescribed for patients with intermittent claudication. In 1898, Wilhelm Erb a German neurologist described the successful results of exercise therapy for a patient with IC (Erb, 1898). More recently, in a 2008 Cochrane review of 22 trials involving exercise for intermittent claudication, the authors noted that compared with usual care or placebo, exercise significantly improved maximal walking time with improvements ranging from 50% to 200% (C. J. Watson, Ellis, & Leng, 2008). Both pain-free walking distance and maximum walking distance also improved significantly, with pain-free walking distance increasing by a mean of 82.19 metres (95% CI 71.73 to 92.65) and maximum walking distance increasing by a mean of 113.20 metres (95% CI 94.96 to 131.43) (C. J. Watson et al., 2008).

The exact mechanism by which this improvement occurs is yet to be proven conclusively. “There is inadequate evidence to attribute the functional benefit from exercise, as is often believed, to the growth of new arterial collaterals (angiogenesis); in contrast, clinical improvement is more likely to be due to alterations in skeletal muscle metabolism, muscle hypertrophy, improvements in endothelial function, improved cellular or subcellular function, or altered gait” (Gandhi et al., 2011).

ACC/AHA guidelines recommend a supervised exercise-training program as the initial treatment modality for patients with intermittent claudication. Supervised exercise programs have in fact been shown to be as effective as endovascular revascularisation in their effectiveness to improve functional capacity and do so at a much lower cost (Spronk et al., 2008). It is also recommended that the training program should be performed for a minimum of 30-45mins, in sessions performed at least three times per week for a minimum of 12 weeks (Hirsch et al., 2006). These recommendations have been made based upon evidence derived from randomised controlled trials which have shown supervised exercise programs to be superior to home-based exercise programs (see table 2) (Hirsch et al., 2006). It should be noted however that the trials cited in the 2005 ACC/AHA guidelines are from a range of
years, beginning with Larsen et al in 1966. The most recent trial cited, was Petersen et al in 1997. All of the trials were of relatively small sample size (n=7-25) and questionnaires were the only tool used to assess community-based functional capacity. Even though there have been multiple other trials and meta-analyses since (Degischer et al., 2002; Gardner, Katzel, Sorkin, & Goldberg, 2002; Lee et al., 2007; C. J. Watson et al., 2008), the 2011 update to the ACC/AHA guidelines again refer to the evidence cited in the 2005 guidelines.
<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>No. of Patients</th>
<th>Intervention</th>
<th>Duration, Months</th>
<th>Change in ACD (%)</th>
<th>Functional Assessment*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Larsen</td>
<td>1966</td>
<td>7</td>
<td>Daily Walks</td>
<td>6</td>
<td>183*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7</td>
<td>Placebo Tablet</td>
<td></td>
<td>-6</td>
<td></td>
</tr>
<tr>
<td>Holm</td>
<td>1973</td>
<td>6</td>
<td>Exercise</td>
<td>4</td>
<td>133*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6</td>
<td>Placebo Tablet</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Dahllof</td>
<td>1974</td>
<td>11</td>
<td>Exercise</td>
<td>6</td>
<td>117*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6</td>
<td>Placebo Tablet</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Dahllof</td>
<td>1976</td>
<td>8</td>
<td>Exercise</td>
<td>4</td>
<td>135*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>Placebo Tablet</td>
<td></td>
<td>75*</td>
<td></td>
</tr>
<tr>
<td>Lundgren</td>
<td>1989</td>
<td>25</td>
<td>Surgery + Exercise</td>
<td>6</td>
<td>263*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25</td>
<td>Surgery</td>
<td></td>
<td>173*</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>25</td>
<td>Exercise</td>
<td></td>
<td>151*</td>
<td></td>
</tr>
<tr>
<td>Creasy</td>
<td>1990</td>
<td>13</td>
<td>Exercise</td>
<td>6</td>
<td>442*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20</td>
<td>Angioplasty</td>
<td></td>
<td>57</td>
<td></td>
</tr>
<tr>
<td>Hiatt</td>
<td>1990</td>
<td>9</td>
<td>Supervised exercise</td>
<td>3</td>
<td>123*</td>
<td>Improved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>Control</td>
<td></td>
<td>20</td>
<td>No Change</td>
</tr>
<tr>
<td>Mannarino</td>
<td>1991</td>
<td>10</td>
<td>Exercise + Antiplatelet</td>
<td>6</td>
<td>105*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>Exercise</td>
<td></td>
<td>86*</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>Antiplatelet</td>
<td></td>
<td>38*</td>
<td></td>
</tr>
<tr>
<td>Hiatt</td>
<td>1994</td>
<td>9</td>
<td>Supervised exercise</td>
<td>3</td>
<td>74*</td>
<td>Improved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8</td>
<td>Strength Training</td>
<td></td>
<td>36*</td>
<td>No Change</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>Control</td>
<td></td>
<td>-1</td>
<td>No Change</td>
</tr>
<tr>
<td>Regensteiner</td>
<td>1997</td>
<td>10</td>
<td>Supervised exercise</td>
<td>3</td>
<td>137*</td>
<td>Improved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>Home exercise</td>
<td></td>
<td>5</td>
<td>No Change</td>
</tr>
<tr>
<td>Patterson</td>
<td>1997</td>
<td>19</td>
<td>Supervised exercise</td>
<td>6</td>
<td>195*</td>
<td>Improved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19</td>
<td>Home exercise</td>
<td></td>
<td>83*</td>
<td>Improved</td>
</tr>
</tbody>
</table>

ACD - Ambulatory claudication Distance *Use of questionnaire to evaluate community-based functional status
* p less than 0.05 compared with baseline; ≠ p less than 0.05 for difference between groups
1.5 The increasing cost of PAD

Atherothrombotic disease, which encompasses coronary artery disease, ischemic stroke and PAD, is the most common cause of morbidity and mortality worldwide and as such carries great economic burden (Ademi et al., 2010) (Watkins, 2004). In 2004 the total direct health costs in Australia for peripheral vascular disease was $240m, $162m of which can be attributed to in-patient Hospital services in both the public and private sector (National Heart Foundation Australia, 2005). In the United States, census data for the same year estimated total annual costs associated with vascular-related hospitalisations to be in excess of $21 billion (Mahoney et al., 2008). The international REACH (Reduction of Atherothrombosis for Continued Health) registry was designed to obtain long-term follow-up information on participants having or at high risk for atherothrombosis. Between December 2003 and June 2004, a total of 67,888 participants were recruited from 44 countries including 2873 participants from Australia (Ohman et al., 2006). Based upon the findings of this registry in 2010 Mahoney et al (on behalf of the REACH registry investigators) concluded that prospective studies of the effectiveness and cost-effectiveness of secondary prevention strategies aimed specifically at reducing PAD-related events seem warranted because effective interventions may curb the otherwise impending clinical and economic burden of PAD in the aging population (Mahoney et al., 2008).

1.6 Rationale

It has been documented, that primary care physicians have been less diligent in treating atherosclerotic risk factors in patients with PAD than in patients with other manifestations of atherosclerosis. In 2008 Welten et al found that patients with PAD are indeed at increased risk for long-term mortality when compared with a risk factor matched population of coronary artery disease (CAD) patients primarily due to PAD patients receiving less cardiovascular medical therapy including beta-blockers, statins, ACE inhibitors, calcium antagonists, nitrates and aspirin than CAD patients (Welten et al., 2008). The above mentioned ACC/AHA guidelines on exercise therapy can also prove difficult to translate into practice in an acute clinical setting. The availability of gymnasium space and appropriately trained staff to supervise three times a week is challenging from an institutional perspective, and for patients,
commuting to hospital frequently can incur great transportation costs. This results in supervised exercise programs being underused or unavailable to most PAD patients (Gandhi, Weinberg, Margey, & Jaff, 2011).

The key to improving long term management of people with PAD may lie in the creation of nurse-led intervention programs. This involves the appointment of an appropriately trained nurse who not only develops a rapport with patients, but is then able to co-ordinate the multidisciplinary team to ensure PAD patients are provided the risk factor modification, supervised exercise and education necessary for both the short and long term management of their chronic disease.

1.7 Aim/Hypothesis

While there is sufficient evidence to demonstrate functional improvement directly following the completion of a vascular exercise program, there is a paucity of evidence relating to the sustainability of this improvement. The following literature review will explore the evidence relating to current programs for PAD which are more commonly coordinated from within an exercise or physiotherapy discipline and identify how nurse-led programs may provide a more holistic approach. It will also examine the evidence base behind nurse-led intervention programs for other conditions and how their introduction has shaped both patient care and outcomes.

The aim of the research contained in this thesis is to identify if a nurse-led intervention program for patients with peripheral arterial disease can demonstrate a sustained improvement in functional capacity and quality of life 12 months following a 12-week program. This evidence has the potential to significantly contribute to the evidence base required for ongoing funding of such programs to allow for more effective care and improved outcomes for people with PAD.
Chapter 2

Literature Review

2.1 Nurse-led intervention programs

Within aging populations, there is mounting pressure to find cost-effective ways to manage increasing numbers of individuals with chronic illness who are frequently hospitalised (Dai, Wu, & Weng, 2002; Pearson et al., 2006; Stewart, Maclntyre, et al., 2001). A wide range of nurse-led multidisciplinary programs have been developed to manage chronic diseases and provide continuity of care from the hospital to home. It has been proven that these nurse-led programs improve disease management, (Weingarten et al., 2002) reduce mortality, (Elkan et al., 2001) and decrease recurrent hospitalisation rates (Stewart, Pearson, Luke, & Horowitz, 1998).

In 2012, the Australian Medicare Local Alliance defined nurse-led care as;

‘patient care that is primarily coordinated by nursing staff with support from the general practice team. Nurse-led care in this context includes, but is not limited to, health education, promotion and disease prevention, and psychological support such as listening to and discussing patients’ concerns. It also includes the provision of clinical care and monitoring patients’ health conditions. The level of care provided varies and is determined by the scope of practice of each nurse.’ (Australian Medicare Local Alliance, 2012)

The primary care setting has been one of the leading fields in the development of nurse-led care and the above definition and document from which it has been sourced, is a significant advancement in outlining the role of, and providing a framework of care, for general practice nurses in Australia. While the role of the practice nurse (PN) has been well defined and utilised in the United Kingdom since the 1990’s, Australia has lagged behind due to multiple factors which will be discussed in greater detail in the following section (Hoare, Mills, & Francis, 2012).

2.2 Nurse-led interventions in Primary Care

The earliest publication regarding the use of practice nurses was in 1967 in which two British doctors in general practice employed a nurse to triage calls, provide first visits, immunise, and routinely visit elderly patients (Smith & Mottram, 1967). After
further studies in 1969 and 1974 highlighted the potential gain of employing practice nurses, more general practitioners (GPs) began to do so (Dixon, 1969; Reedy, Philips, & Newell, 1976). In the early 1990’s in the UK, following the development of a contract arising from the National Health System and Community Care Act (OPSI, 1990) and the Health of the Nation White Paper (Department of Health, 1992), GPs received payment for introducing services to provide health promotion, manage chronic disease and additional payments for childhood immunisation and cervical smear tests. These financial incentives led to greater expansion of the practice team as GPs employed more practice nurses to reach these targets (Gemmell, Campbell, Hann, & Sibbald, 2009). The election of the Labour Government in 1997 led to further developments which would accelerate the use of nurse-led care. This included the creation of Primary Care Groups which brought together GPs, practice nurses, community nurses and other primary care professionals to increase clinical leadership, and the creation of a quality improvement system, clinical governance (Allen, 2000). Clinical governance was a novel initiative which provided a system of accountability for the delivery of quality care as all previous government reporting had been strictly financially based (Hoare et al., 2012). This system evolved into the Quality and Outcome Framework (QOF) which uniquely assessed GP clinics according to five domains; clinical, organisational, patient experience, additional services and access. GP clinics were awarded points for their achievements in each domain which greatly increased the government funding provided to the clinic (Ashworth, Seed, Armstrong, Durbaba, & Jones, 2007).

Following the introduction of the quality framework nurses were found to be absorbing more of the workload than GPs, however nurses believed patients to be receiving improved continuity of care (Gemmell et al., 2009; McGregor, Jabareen, O’Donnell, Mercer, & Watt, 2008). Practice nurses also identified that the increased level of autonomy improved their sense of job satisfaction (Maisey et al., 2008).

In Australia, although facing similar issues with growing numbers of individuals with chronic disease, the extension of the practice nurse role is still an emerging specialty when compared to the United Kingdom (UK) (Halcomb, Davidson, Griffiths, & Daly, 2008). One of the major issues causing this delay may be the different government funding practices. In the UK government funding is provided to GP clinics based upon capitation of enrolled patients along with incentive programs for quality of care as previously described (Hoare et al., 2012). In Australia, general practice is
predominantly self-employed medical practitioners who receive government funding on a ‘fee-for-service’ basis from Medicare. The Australian system has been described as ‘complex’ as around 85% of the scheduled fee is covered by Medicare and then individual practices determine whether or not the consumer will pay an additional fee (Halcomb, Davidson, & Patterson, 2008). Between 2004 and 2007 the Australian Government approved eight new item numbers under the Medical Benefits Schedule (MBS) for remuneration of certain services provided by a practice nurse including immunisation and cervical screening (Keleher et al., 2007). The number of nurses working in general practice during this period of time increased by 23% presumably in response to this initiative (Australian General Practice Network, 2007). However, a study by Mills and Fitzgerald (2008) identified some key obstacles practice nurses encountered in implementing these services (Mills & Fitzgerald, 2008). Their action research study involved the creation of a small reflective group of practice nurses who were credentialed to complete cervical screening. They identified that the nurses frequently encountered problems due to the fact that the GPs were not only their colleagues but, as business owners, they were also often their employer. Female GPs were also seen to be providing resistance to this evolution as cervical screening had historically been seen as their domain which created power struggles and obstructed collaborative practice (Mills & Fitzgerald, 2008). In Australia the MBS benefit for immunisation provided by a nurse is considerably less than when performed by a GP and it has been suggested that in some practices, although the PN is performing the task, the GP claims for the service on behalf of the PN in order to receive a greater benefit (Hoare et al., 2012). Practice of this kind clearly undermines the professional role of the PN and could lead to inaccurate government reporting of the usage of nurse-led care in the primary care setting (Mills & Hallinan, 2009).

A survey of 284 practice nurses in Australia in 2008 found that the most cited barrier to role extension of the practice nurse for cardiovascular disease management was legal implications (n=144, 51%). These respondents identified GPs as being hesitant to allow practice nurses to perform tasks without direct supervision due to fear of litigation (Halcomb, Davidson, Griffiths, et al., 2008). Although not specified in the article, it is clear from the data presented that respondents were able to select more than one barrier. Other barriers cited included lack of space/equipment (n=86, 30.8%), a belief by respondents that their current role is appropriate (n=83, 29.7%)
and GP attitudes (n=80, 28.7%). Only four (1.4%) respondents identified inadequate remuneration to encourage role extension and fifteen (5.3%) identified deficient funding models that impede the provision of additional services (Halcomb, Davidson, Griffiths, et al., 2008). Most of the respondents were female (99%), registered Nurses (86%) with a mean age of 45.8 years. More than half (63%) indicated that their highest level of qualification was a hospital nursing certificate (Halcomb, Davidson, Griffiths, et al., 2008).

Such findings suggest that despite the evidence of successful implementation of models of nurse-led care in the primary care setting (Eley et al., 2013), Australia is still progressing and may require intervention by means of legislative, educational and funding revision in order to allow nurse-led or collaborative care to fulfill it’s potential.

2.3 Nurse-led interventions in Hypertension

While hypertension is a key risk factor for not only PAD but cardiovascular disease also, it is estimated that in more than one third of people with hypertension, it is uncontrolled (McAlister et al., 2011). Reduction of elevated blood pressure (BP) has been associated with a decreased incidence of stroke (35-40%), MI (20-25%) and heart failure (>50%) (Chobanian et al., 2003). Reduction of blood pressure requires an organised approach which may include lifestyle modifications and appropriate dosing and/or combining of antihypertensive medication (Chobanian et al., 2003; Clark, Smith, Taylor, & Campbell, 2010). Hypertension is most often managed in the primary care setting, however doubt persists as to which members of the primary care team provides the most effective management (Clark et al., 2010). Barriers to effective hypertension management may be patient or clinician related. Patients issues may include cultural beliefs, financial burden which can impact upon medication compliance, GP contact, and dietary intake, and lack of education regarding hypertension management and the associated risks and potential benefits from antihypertensive therapy (Chobanian et al., 2003). For clinicians, a lack of knowledge of the current management guidelines may lead to under-prescribing of antihypertensive therapy and a shortage of time during patient consults can result in less than thorough patient education.

In one of the earlier trials comparing nurse and doctor management of hypertension, 457 participants were enrolled to compare hypertension management provided by
specially trained nurses at the participants workplace and that of GPs (Logan, Milne, Achber, Campbell, & Haynes, 1979). Nurses were permitted to prescribe and adjust medication without doctor approval after having completed an education program in which they were taught to manage hypertension according to a set protocol. The results indicated that people with hypertension who were managed by a nurse were more likely to be prescribed antihypertensive medication (94.7% v 62.7%), to achieve target blood pressure in six months (48.5% v 27.5%) and be compliant in taking their prescribed medication (67.6% v 49.1%) (Logan et al., 1979).

In a 2010 systematic review and meta-analysis (Clark et al., 2010) which included 33 studies spanning 30 years (1979-2009), it was found that in comparison to usual care, nurse-led interventions that included a stepped treatment algorithm demonstrated a significantly greater reduction of both systolic and diastolic blood pressure. However this did not translate into a greater achievement of blood pressure targets. Studies which included nurse-led prescribing were found to demonstrate an even greater reduction of systolic and diastolic blood pressure, while telephone monitoring was found to be associated with greater achievement of blood pressure targets.

2.4 Nurse-led intervention programs for chronic heart failure

Chronic heart failure (CHF) is a deadly and disabling syndrome which affects an estimated 10% of people aged 65 years and over, and greater than 50% of people aged 85 and over (Krum & Abraham, 2009). The incidence of CHF continues to rise due to an ageing population, increased survival rates from coronary artery disease and increased incidence of diabetes and obesity (Najafi, 2007). Hospital admissions remain common occurrences for people with CHF and mortality rates remain high despite improved pharmacological interventions (Dickstein et al., 2008). In a similar evolution to the management of CAD, awareness of the increasing burden CHF places on the health system has led to the creation of heart failure management programs (Boyde, Turner, Thompson, & Stewart, 2011).

In 1995 Rich et al conducted an innovative prospective randomised control trial which demonstrated a 56% reduction in hospital readmissions for CHF patients who took part in a nurse-led heart failure management program (Rich et al., 1995). This
nurse-led intervention program lead to improved quality of life, reduced hospital readmissions and health care cost (Rich et al., 1995). Subsequent systematic reviews have demonstrated similar efficacy of nurse-led intervention programs for CHF (Gonseth, Guallar-Castillon, Banegas, & Rodriguez-Arteago, 2004; Holland et al., 2005; McAlister, Stewart, Ferrua, & McMurray, 2004; Phillips, Singa, Rubin, & Jaarsma, 2005).

In 2011, the National Benchmarking and Evidence-Based National Clinical Guidelines for Heart Failure Management Programs (BENCH) study examined the results of nurse-led titration of beta-blockers in 48 Australian Heart Failure Management Programs (Driscoll, Krum, Wolfe, & Tonkin, 2011). The study found that patients participating in a nurse-led titration program were more commonly prescribed the target dose of beta-blocker and suffered fewer hospitalisations or death than those in programs with no nurse-led titration of medications. Participants in nurse-led CHF programs have identified that they were satisfied with the content provided by their program and that even the more intensive program was not a burden. This is significant as it has also been proven that people with severe heart failure may require a high level of support including home visits in order to achieve educational goals (Hoekstra, Lesman-Leegte, van der Wal, Luttik, & Jaarsma, 2010).

Nurse-led multidisciplinary CHF management programs have now become the gold standard treatment in guidelines for the management of people with CHF (Davidson, 2010; Krum et al., 2006) and are becoming increasingly incorporated into the clinical setting to reduce re-admissions and improve the quality of life and survival of people with CHF (Lambrinou, Kalogirou, Lamnisos, & Sourtzi, 2012).

2.5 Nurse-led intervention programs for atrial fibrillation

Atrial fibrillation (AF) is the most common cardiac arrhythmia (Heeringa et al., 2006) and, it’s incidence markedly increases with age from around 1% in people aged 50 years to almost 10% in people aged 80 years or more (Wolf, Mitchell, Baker, Kannel, & D’Agostino, 1998). The management of AF poses significant strain on health care resources in a similar manner to CHF (Carrington et al., 2013). Without effective management to reduce the risk of thromboembolic events and tachycardia-induced cardiomyopathy, chronic AF can lead to heart failure or stroke (Stewart, Hart, Hole, &
McMurray, 2001). Following the successful implementation of nurse-led CHF programs, trials of nurse-led multidisciplinary AF programs began to emerge. In 2004, a nurse-led multidisciplinary home-based intervention for people with chronic AF found that overall home-based intervention was associated with a 25% reduction in recurrent hospital stay compared to “usual care” post discharge (Inglis et al., 2004). It also identified a strong statistical trend towards improved survival for those receiving home-based intervention during the 5 year follow-up. A more recent randomised control trial (RCT) of nurse-led versus usual care for patients with atrial fibrillation found nurse-led care to be superior to usual care provided by a cardiologist in terms of hospitalisation rates and cardiovascular mortality (J. Hendriks et al., 2012). In a subsequent economic analysis of the same trial, it was determined that nurse-led care is a cost-effective management strategy when analysed in terms of quality-adjusted life-year (J. Hendriks, Tomini, van Asselt, Crijns, & Vrijhoef, 2013).

2.6 Nurse-led intervention programs for Diabetes

Every day in Australia approximately 280 people are diagnosed with diabetes (NDSS, 2012). It is the fastest growing chronic disease in the country with almost one million individuals diagnosed and an estimated one million more who are yet to be diagnosed. According to Diabetes Australia;

‘there is an urgent need for increased understanding of the economic, and societal seriousness of diabetes and its complications, and of the escalating costs to individuals, families, workplaces, society and governments. We need sustained, nationally consistent programs to prevent, detect and manage diabetes in Australia. Too many plans have been designed and not properly implemented or evaluated….We need to ensure funding for quality treatment is available and accessible to all to prevent or delay the onset of diabetes and its complications.’ (Diabetes Australia)

People with diabetes benefit from frequent regular contact with health professionals regardless of the level of intervention (Woodward, Wallymahmed, Wilding, & Gill, 2005). However nurse-led case management of diabetes has demonstrated a clinically significant improvement in mean blood glucose management as measured
by HbA1c when compared with physician-led outpatient services (Welch, Garb, Zagarins, Lendel, & Gabbay, 2010). Structured nurse-led counselling based on motivational interviewing has not been shown to alter HbA1c or lifestyle related to diet and physical activity (Jansink et al., 2013). Therefore while nurse-led care for diabetes has indeed demonstrated efficacy (McLoughney, Khan, & Ahmed, 2007; Welch et al., 2010), there are limitations to the extent of this improvement, which could possibly be improved with the implementation of a multidisciplinary approach.

2.7 Nurse-led intervention programs for PAD

The American College of Cardiology/American Heart Association (ACC/AHA) and Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC II) guidelines for the management of PAD include both supervised exercise and aggressive risk factor modification in order to reduce cardiovascular risk (Hirsch et al., 2006; Norgren et al., 2007). PAD intervention programs (both nurse-led and non-nurse-led) have demonstrated improvements in functional capacity, quality of life and some cardiovascular risk factors (table 1). However examination of this evidence identifies areas within the field requiring further investigation.

Nurse-led Studies

While there have been multiple studies examining the optimal modality, length and level of supervision required for a PAD exercise program (Gardner, Montgomery, & Parker, 2012; Hiatt, Wolfel, Meier, & Regensteiner, 1994), there is a paucity of evidence regarding nurse-led intervention programs which incorporate both supervised exercise and risk factor modification which have been assessed through multiple outcome measures over a sustained time period. With evidence demonstrating improved walking distance in people with claudication through exercise (Skinner & Strandness, 1967), and following the successful introduction of structured rehabilitation programs for Coronary Artery Disease, vascular rehabilitation programs for people with PAD began to emerge in the United States (US) in the early 1980’s (Williams, Ekers, Collins, & Lee, 1991). Whilst they have become common in the US and Europe, only a handful of vascular units in
Australia have embraced these programs. Additionally very few are currently nurse-led (personal communication).

The main aim of an intervention program for people with PAD is to reduce the associated cardiovascular risk and so having vascular nurses involved in the supervision of these programs is important (Hirsch et al., 2006; Spronk, Dolman, Boelhouwer, Veen, & den, 2003).
<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>Study type</th>
<th>Participants (n)</th>
<th>Intervention</th>
<th>Follow-up, Months</th>
<th>Functional Assessment Method</th>
<th>Additional Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nurse-led Programs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Braun</td>
<td>1999</td>
<td>Retrospective analysis</td>
<td>22</td>
<td>12 week supervised Exercise + risk factor modification education</td>
<td>24</td>
<td>Treadmill Test</td>
<td></td>
<td>Increased °</td>
</tr>
<tr>
<td>Spronk</td>
<td>2003</td>
<td>Prospective study</td>
<td>104</td>
<td>8-16 week Home-based exercise program + risk factor modification</td>
<td>4</td>
<td>Corridor walking assessment</td>
<td></td>
<td>Increased °</td>
</tr>
<tr>
<td>Sillesen</td>
<td>2007</td>
<td>Prospective cohort study</td>
<td>693</td>
<td>Exercise advice + risk factor modification</td>
<td>12</td>
<td>Questionnaire</td>
<td>Risk Factors (mean TC, LDL, BP)</td>
<td>Increased** Improved**</td>
</tr>
<tr>
<td>Hatfield</td>
<td>2008</td>
<td>Prospective study</td>
<td>78</td>
<td>Exercise advice + Structured risk factor modification</td>
<td>3</td>
<td></td>
<td>Framingham Risk</td>
<td>Improved**</td>
</tr>
<tr>
<td>Simmons</td>
<td>2013</td>
<td>Quality improvement project</td>
<td>17</td>
<td>Home-based exercise</td>
<td>1</td>
<td>Questionnaire</td>
<td></td>
<td>Increased frequency of exercise^</td>
</tr>
</tbody>
</table>

| **Non-Nurse-led Programs** | | | | | | | | |
| Franz | 2010 | Prospective study | 47 | 12 week supervised exercise program + risk factor modification | 3 | Treadmill Test & 12 Minute Walk | Risk Factors (Mean BMI, BP, Lipids) | Increased** Improved^ |
| Fakhry | 2011 | Comparative longitudinal cohort study | Group 1 142 | 24 Week structured home exercise program | 12 | Treadmill | QOL | Increased** Increased** |
| | | | Group 2 75 | 24 Week supervised exercise program | | Treadmill | QOL | Increased** Increased** |
| Guidon | 2013 | Randomised control trial | Group 1 17 | 12 week supervised exercise program | 12 | Questionnaire | QOL | Increased^ |
| | | | Group 2 12 | Exercise advice | | Questionnaire | QOL | Decreased |

^ = not statistically significant  ** = p<0.001 ° = p value not stated QOL = Quality of Life assessment
It is imperative that patients are provided with education regarding risk factor modification. It must also be clearly explained to the patient that the objective is not only to improve walking distance but, more importantly, to reduce the risk of atherosclerotic disease progression. Vascular nurse supervision provides the opportunity for patients to develop a rapport with a health professional and to continue to feel supported and motivated to establish routines which involve positive lifestyle changes which may otherwise be difficult to achieve (Spronk et al., 2003). While the current evidence regarding nurse-led intervention programs for PAD is minimal, improvement in functional capacity and cardiovascular risk through optimising certain cardiovascular risk factors has been clearly demonstrated (table 3).

**Non-Nurse-led Studies**

Although non-nurse-led intervention programs may lack the intensive risk factor modification of a nurse-led program, they have demonstrated efficacy in improving functional capacity and quality of life (Fakhry, Spronk, de, den, & Hunink, 2011; Franz, Garwick, & Haldeman, 2010; Guidon & McGee, 2013). (Table 3) Fakhry et al’s comparative longitudinal cohort study (2011) compared the results of a non-nurse-led structured home exercise program and a non-nurse-led supervised exercise program. The participants in the latter group were also enrolled in a concurrent RCT comparing supervised exercise to peripheral stenting. Due to the extensive inclusion criteria for the RCT, the structured home-program enrolled twice as many participants. Both groups demonstrated statistically significant improvement in functional capacity and quality of life at 12 months. However, the supervised exercise group demonstrated a far greater improvement in functional capacity than those in the structure home program group (Fakhry et al., 2011).

**Limitations of existing studies**

The number of participants in studies regarding PAD intervention programs are generally lower than those of other disciplines; with only 20-59 participants, on average, due to advancing age and extensive co morbidities (C. J. Watson et al., 2008). While the study by Sillesen et al (2007) recruited 693 participants over four years, they also reported an attrition rate of greater than 50% by 12 months.
Similarly, the second largest nurse-led study (Spronk et al., 2003) which recruited 104 participants suffered a 30% attrition rate in just 16 weeks.

In addition, the Sillesen study, as with much of the PAD literature, assessed functional capacity through questionnaire alone. A potential weakness of this approach is that it is simply measuring changes in patient-perceived functional capacity. Assessing functional capacity by questionnaire alone can lead to inaccuracies as it has been shown that participants frequently make errors when completing the self-reporting tools (Mahe et al., 2011). and when estimating walking distances (L. Watson & Collin, 1998). It can also be the case that, following an intervention program, participants may feel an obligation to report an improvement or may even perceive that there has been an improvement when, in fact, their functional capacity has not improved (Enright, 2003).

Functional testing by means of treadmill testing may also represent a relatively artificial means of quantifying walking capacity as it is performed according to a protocol which automatically specifies walking speed and gradient. For this reason, it is recommended that studies evaluating functional capacity should include both a treadmill and a corridor-based functional assessment, such as the six-minute walk, which few of the existing studies do (McDermott et al., 2008).

A further, and critical, limitation of the existing research is the lack of randomised control trials. This is a challenge for researchers due to the specific recommendations of the ACC/AHA guidelines which recommend a supervised exercise program as initial treatment for all people with PAD (Hirsch et al., 2006).

Many of the published studies also suffer from a lack of long-term follow-up. It is important to determine whether or not the functional improvements the participants have experienced during the study are still evident after a long follow-up term.

In all nurse-led interventions, the nurse can play a vital role in coordinating care, providing education and establishing a trust that can have a meaningful impact upon people’s health and quality of life (Lovell, Myers, Forbes, Dresser, & Weiss, 2011). For nurse-led interventions in the field of PAD, further research is required in order to address some of the shortfalls identified in the existing evidence.
Chapter 3
Methodology
The following chapter will describe the research methodology used for this study, including the recruitment and inclusion/exclusion of participants. It will describe in detail the nurse-led intervention program and the parameters used for analysis. In order to address the research question:

$Can$ $a$ $nurse$-led $intervention$ $program$ $for$ $people$ $with$ $peripheral$ $arterial$ $lead$ $to$ $sustained$ $improvement$ $in$ $functional$ $capacity$ $and$ $quality$ $of$ $life$?
section 3.5 will address how functional capacity was measured followed by 3.6 which will describe the tools which were used to measure quality of life in the participants.

3.1 Sample & Setting
Participants were recruited from both the Vascular Outpatients department and Vascular Ward at the Princess Alexandra Hospital in Brisbane, Australia between March 2009 and December 2011. Eligible participants were identified through chart review and contacted by a research nurse to discuss involvement in the study. All potential participants were informed that participation was voluntary and declining to participate would not alter their ongoing medical management.
Ethical clearance was obtained for the study from both Metro South Human Research Ethics Committee (HREC/08/QPAH/221) and University of Queensland Human Research Ethics committee (2009000187). All participants gave written informed consent.

3.2 Inclusion Criteria
Participants had to be aged between 18 and 80 years of age and have a diagnosis of peripheral arterial disease confirmed by either:

- Positive Edinburgh claudication questionnaire (Leng & Fowkes, 1992)
- Ankle-brachial index ≤0.8 (Hirsch et al., 2006)
- Previous diagnostic examination including duplex or angiogram

3.3 Exclusion Criteria
Participants were excluded if they were:

- Clinically unfit to take part in the vascular intervention program due to conditions such as class III-IV angina, severe heart failure or end stage renal failure
• Scheduled for major vascular surgery
• Found to have critical limb ischemia
• Pregnant
• Unable to present for follow-up testing
• Unable to provide written informed consent

3.4 Data Collection

Past Medical History
Participants were interviewed by the research nurse for a full medical/surgical history including current medications and cardiovascular risk factors, including:
• History of cardiovascular disease
• Smoking status and number of pack years
• Hypertension
• Family history of cardiovascular disease
• History of diabetes mellitus/metabolic syndrome
• Previous surgeries/interventions
• Current exercise and activity levels

Clinical Examination
All participants underwent a full vascular assessment which included:
• Systolic and Diastolic blood pressure
• Heart rate
• Height
• Weight
• Body Mass index
• Waist and Hip Measurement
• Assessment of pulses (femoral, popliteal, posterior-tibial, & dorsalis-pedis) by manual palpation or hand-held Doppler when impalpable.
• ECG
Pathology

The following blood tests were obtained:

- fasting lipids (total cholesterol, HDL, LDL & Triglycerides)
- HBA1C for diabetic participants.

Ankle-Brachial Index

Ankle-brachial index (ABI) is a simple non-invasive method of assessment which can be helpful in the diagnosis and severity scoring of both symptomatic and asymptomatic PAD (Norgren et al., 2007). A reduced ABI has been shown to be a strong predictor of future cardiovascular events, with the level of risk correlating to the degree of reduction in ABI, independent of other risk factors (Figure 3.1)(Resnick et al., 2004). PAD can be diagnosed if ABI ≤ 0.90 (Olin et al., 2011). A ratio of greater than 1.30 suggests poorly compressible, calcified arteries (Arain & Cooper, 2008) which can be a common occurrence in the diabetic population.

Figure 3.1

Reproduce with permission (Resnick et al., 2004)
For this study ABI was measured using a handheld continuous wave Doppler ultrasound device (5mhz) and a manual sphygmomanometer. The higher systolic pressure measured from either the posterior tibial or dorsalis pedis artery (in each leg) was divided by the higher brachial artery pressure taken from either arm (figure 3.2) as per the TASC II guidelines (Norgren et al., 2007).

**Figure 3.2** Reproduced with permission (Hiatt, 2001)

<table>
<thead>
<tr>
<th>Right ABI</th>
<th>Left ABI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher right ankle pressure</td>
<td>Higher left ankle pressure</td>
</tr>
<tr>
<td>Higher arm pressure</td>
<td>Higher arm pressure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpretation of ABI</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1.30</td>
<td>Noncompressible</td>
</tr>
<tr>
<td>1.00 – 1.29</td>
<td>Normal</td>
</tr>
<tr>
<td>0.91 – 0.99</td>
<td>Borderline (equivocal)</td>
</tr>
<tr>
<td>0.41-0.90</td>
<td>Mild-to-moderate peripheral arterial disease</td>
</tr>
<tr>
<td>0.00 – 0.40</td>
<td>Severe peripheral arterial disease</td>
</tr>
</tbody>
</table>

Right-arm systolic pressure  
Right-ankle systolic pressure  
Left-arm systolic pressure  
Left-ankle systolic pressure
3.5 Function Assessment

Six Minute Walk

The six-minute walk test is a method of assessing walking capacity which has demonstrated excellent test re-test reliability in people with PAD (Montgomery & Gardner, 1998). Corridor-based functional performance measures such as the six-minute-walk are an important complement to treadmill assessment as they have been shown to correlate better with physical activity during daily life, and it is recommended that studies of functional performance in persons with PAD should include both (McDermott et al., 2008).

Participants performed the six minute walk test according to a set protocol which instructed participants to walk up and down a measured and marked 25 metre lap of a corridor as many times as they could in a six minute time frame. All participants received identical instructions. The distance they were able to walk was recorded in metres as well as the number of times they had to stop within the six-minute timeframe.

The Progressive Treadmill Test

Treadmill testing is also an established means to quantify walking ability in persons with PAD and is highly predictive of long-term morbidity and mortality outcomes (de Liefde et al., 2009). Treadmill walking is frequently used to measure changes in walking ability following interventions in people with PAD (McDermott et al., 2008). It has potential advantages including ease of direct comparison of results due to a tightly controlled setting and use of a standardised protocol. However it has also been criticised as creating a more “artificial” environment when compared to corridor-based testing and baseline tests may in fact be limited by anxiety and the persons inexperience with walking on a treadmill rather than actual functional limitation (McDermott et al., 2008).

In cardiology the Bruce protocol is used as a standardised protocol for exercise stress testing (table 1) (Bruce, Kusumi, & Hosmer, 1973). It increases speed and incline every 3 minutes in order to elevate heart rate to near age-correlated-maximum to identify possible signs of cardiac ischemia.

In PAD assessment, there are a wide variety of treadmill protocols which are used, and have been validated, however no protocol in particular has been universally
accepted. The two main types of treadmill protocols used are continuous, where speed and incline are not adjust throughout the test, or graded where speed and incline are commenced at a lower workload and then both are increased at set times throughout the test. Continuous protocols have proved difficult to use in the PAD population due to the wide variety in walking abilities and comorbidities amongst sufferers. The high initial workload of a continuous test is also not well tolerated by persons with severe PAD. Graded treadmill protocols have also demonstrated a greater reliability than continuous protocols when using maximum walking time as the primary outcome measure (Nicolai et al., 2009).

The progressive treadmill test (PTT) is a graded treadmill test which was devised specifically for people with PAD and was the treadmill test used in this study (table 3.1) (Braun, Colucci, & Patterson, 1999). Although both the PTT and Bruce are graded treadmill tests, the PTT has a more gradual increase in speed an incline which is better tolerated in the PAD population than the Bruce protocol.

To perform the Progressive Treadmill Test, participants were commenced at stage 1.6 km/hr with a 5% incline and continued along the protocol increasing speed and incline at the set times until they felt they could not walk any further. The participants were asked to alert staff when they began to experience claudication pain during the test and this time was noted as claudication pain time (CPT). When they could no longer continue, the time was documented as maximum walk time (MWT). Both measures were documented in minutes and seconds.

CPT and MWT have been used in multiple studies demonstrating improvements in both pain-free and total walking time post intervention for PAD (Gardner et al., 2001; Gardner, Parker, Montgomery, Scott, & Blevins, 2011; Haluska, 2013).
Table 3.1

<table>
<thead>
<tr>
<th>MINUTES</th>
<th><strong>Progressive Treadmill Test</strong></th>
<th><strong>Bruce Protocol</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Speed (km/hr)</td>
<td>Incline (%)</td>
</tr>
<tr>
<td>1</td>
<td>1.6</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td>2.4</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
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<td>6</td>
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<td>24</td>
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<tr>
<td>25</td>
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</tbody>
</table>

(Braun et al., 1999; Bruce et al., 1973)

3.6 Quality of Life assessment

All participants were asked to complete both an SF12 and Vascuqol quality of life questionnaire both prior to commencing the Nurse led intervention program and again at intervals of 12 months, 24 months and 30 months. While treadmill and corridor walk testing are able to provide information regarding a PAD sufferer’s walking ability, they do not address their perception of their walking ability or health related quality of life (HRQOL). In addition, other elements of health status, such as mental health, emotional well-being, and social functioning, can only be assessed by questionnaires (Mays et al., 2011).
General Quality of Life Assessment Tools
The Short Form 36 (SF-36) Questionnaire is a general HRQOL tool which provides a brief yet comprehensive assessment of HRQOL (J. E. Ware, Jr. & Sherbourne, 1992). It measures eight domains: physical, role and social functioning, mental health, patient health perceptions, vitality, bodily pain, and change in health (Mays et al., 2011) and has been extensively validated for assessing HRQOL in symptomatic PAD patients (Turner-Bowker, 2002). The Short Form 12 (SF-12) questionnaire (J. E. Ware, Jr. & Sherbourne, 1992) extracts select items from all eight domains of the SF-36 and includes the same physical and mental component (Mays et al., 2011). It was designed to be a simpler version of the SF-36 and because it is a relatively short questionnaire compared with other general health questionnaires, it can be a more practical option for use in clinical settings (Mays et al., 2011). It is due to this practicality that the SF12 was chosen as the general quality of life tool for this study (Appendix 1). The SF12 consists of 12 questions which are scored from 1 to 3 or 1 to 5, with the lowest scores representing the higher QOL response. The advantage of generic questionnaires is that they can be used for evaluating QOL for various types of diseases and for calculating utility values in cost-effectiveness analysis. However, they are considered to be less sensitive to detect small but clinically significant differences in treatment effects because they do not focus on specific effects of disease (Mehta, Venkata, Chetter, & McCollum, 2003).

PAD Specific Quality of Life Assessment Tool
The Vascular Quality of Life (VascuQol) (Morgan, Crayford, Murrin, & Fraser, 2001) questionnaire is a disease-specific tool which measures more specific elements of PAD and thus it is more sensitive to measuring more subtle effects after treatment. The VascuQol contains 25 questions subdivided into 5 dimensions: pain, symptoms, activities, social, and emotional. Each question has a 7-point response option with the lowest mark (1) being assigned to the answer representing the poorest QOL and the highest mark (7) assigned to the answer representing high QOL (Appendix 2) (Morgan et al., 2001).
The domains in each tool were analysed to identify if an improvement was evident not only following the nurse led intervention program, but if any improvement was in fact sustained over a 30 month time period. Participants who underwent revascularisation or major amputations during the study period were eliminated from analysis as it would not be possible to identify which intervention led to any improvements or decline in their quality of life.

Quality of life only Group
A sub-group of people who were unable (due to geographical location) to attend the Vascular Intervention Program were sent exercise and risk factor modification information. They then completed quality of life questionnaires and gave consent for access to their medical record and telephone follow up for 30 months. Due to a lack of randomisation, this group cannot act as a true “control” group for the study.

3.7 Nurse-led Intervention Program
After completing baseline testing all participants began the Nurse-led intervention program which included:

- Attending a 12 week nurse-led exercise and risk factor modification program
- Contacting participants GP to inform them of participants inclusion in study as well as communicate suggestions for medical therapy optimisation.
- Referring participants for additional education/intervention where indicated (smoking cessation and diabetic education)
- Setting a home walking program for participants to continue with once they had completed the supervised exercise program

Supervised Exercise Program
This 12 week program took place at the Princess Alexandra Hospital one day per week and consisted of:

- 1 hour exercise sessions, comprised of warm up stretches, followed by six 5-minute circuit stations and cool down stretches. The circuit training was tailored for individual ability and included:
  - Exercise bike
  - Rowing machine
  - Arm ergometry
- Free weights
- Step ups

All participants also completed 2 treadmill stations per session as published evidence suggests that walking is the preferable mode of training for improvement in functional capacity in people with PAD (Gardner & Poehlman, 1995; Hiatt et al., 1994). Circuit stations alternated upper and lower body exercises to allow claudication pain to subside while keeping heart rate up to improve cardiovascular fitness.

Exercise sessions were supervised by both an experienced Vascular Nurse and Physiotherapist. Vital signs including blood pressure, pulse, and blood glucose level for diabetics were assessed both before and after exercise.

**Risk Factor Modification Education**

The ACC/AHA guidelines for the management of PAD recommends aggressive risk factor modification in order to reduce the extreme associated cardiovascular risk (Hirsch et al., 2006). Consequently, education and assistance with risk factor modification was an essential element of the nurse-led intervention program. On 5 of the 12 week visits for the nurse-led intervention program, participants attended education lectures regarding risk factor modification. They included:

<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter/Educator</th>
<th>Educational Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Peripheral Arterial Disease”</td>
<td>Vascular Nurse</td>
<td>• What is PAD?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Causes, Symptoms and treatment options</td>
</tr>
<tr>
<td>“Hypertension &amp; Salt Skip”</td>
<td>Hypertension Clinical Nurse Consultant</td>
<td>• What is ‘optimal’ blood pressure?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Benefits of home BP monitoring</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Salt reduced diet</td>
</tr>
<tr>
<td>“Dietary Management of PAD”</td>
<td>Dietician</td>
<td>• Good fats/Bad Fats</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• What makes a balanced diet?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Portion control</td>
</tr>
<tr>
<td>“PAD Medications”</td>
<td>Pharmacist</td>
<td>• Anti-platelet drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Warfarin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Statins</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Possible side effects and necessary precautions</td>
</tr>
</tbody>
</table>
Diabetic participants were referred to the diabetic education program run by the hospital endocrine department to increase their understanding of dietary choices for improved diabetic management as well as other important associated complications including neuropathy, and foot care. Participants who continued to smoke were referred to the hospital alcohol and drug dependency unit for support with smoking cessation.

### 3.8 Statistical Analysis

Continuous variables are expressed as mean +/- SD or as median (interquartile range); categorical variables are expressed as percentages. Student's t tests were used to compare differences between two groups for continuous variables. Chi-square tests were used to determine significant differences between two groups of categorical variables. Analysis of variance with Bonferroni post hoc analysis was used to determine differences across and between groups when >2 groups were present. A p value <0.05 was considered significant. Pearson correlation coefficient was calculated to measures the strength of the linear relationship between normally distributed variables. The Spearman rank correlation method was used when variables where not normally distributed. Linear regression analysis was used to identify univariate predictors. Variables with statistical significance on univariate analysis of >0.1 were selected for inclusion in the model.

All statistical analysis was performed using the Statistical Packages for Social Sciences software (SPSS Inc, Chicago, Il).
Chapter 4

Research Findings

4.1 Introduction

This chapter will discuss the findings from the research conducted. Section 4.2 will discuss the participant demographics and clinical outcomes, while 4.3 and 4.4 will present the results pertaining to functional capacity and quality of life respectively.

4.2 Participant Demographics

137 potential participants with symptomatic Peripheral Arterial Disease were identified for the study. Of this group, 56 people consented to taking part in the nurse-led intervention program and a further 23 individuals who were unable to attend the intervention program agreed to complete quality of life-only follow-up.

The baseline demographics for both the nurse-led intervention program (NLIP) group and the quality of life-only (QOLO) group are detailed below (Table 4.2.1). As the QOLO group were unable to attend for physical testing, some data was unable to be collected. The only statistically significant difference between the groups was the male/female ratio, with the NLIP group comprising around 80% male and the QOLO group only 47.8% male. The prevalence of PAD in men and women has been reported differently in many studies, however most studies identify a higher prevalence of symptomatic PAD in the male population with ratio’s varying between 2:1 and 3:1 (Norgren et al., 2007).

Although the participants in the NLIP group had a high rate of hypertension and hyperlipidaemia, baseline mean blood pressures and lipid markers were within the ACC/AHA target limits demonstrating reasonable management of these risk factors (Hirsch et al., 2006). HbA1C was only marginally above the target limit of 7%, which again suggests the diabetic participants were managing their diabetes moderately well.
### Table 4.2.1

<table>
<thead>
<tr>
<th></th>
<th>NLIP N=56</th>
<th>QOLO N=23</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>45 (80.4%)</td>
<td>11 (47.8%)</td>
<td>.003</td>
</tr>
<tr>
<td>Age</td>
<td>66.5±10.1</td>
<td>66.8±7.8</td>
<td>ns</td>
</tr>
<tr>
<td>BMI</td>
<td>29±5.2</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>132±18.6</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>69.6±10.4</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>ABI (mean)</td>
<td>0.68±0.16</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Total Chol (mmol/L)</td>
<td>4.2±1.2</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>2.2±0.8</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>1.05±0.38</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>HbA1C (%)</td>
<td>7.06±1.2</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>History</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>49 (87.5%)</td>
<td>18 (78.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>27 (48.2%)</td>
<td>9 (39.1%)</td>
<td>ns</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>30 (53.6%)</td>
<td>8 (34.8%)</td>
<td>ns</td>
</tr>
<tr>
<td>Hyperlipidaemia</td>
<td>47 (84 %)</td>
<td>20 (87%)</td>
<td>ns</td>
</tr>
<tr>
<td>CVA</td>
<td>10 (17.9%)</td>
<td>5 (21.7%)</td>
<td>ns</td>
</tr>
<tr>
<td>Current Smoker (within 12 months)</td>
<td>27 (48.2%)</td>
<td>7 (30.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Previous peripheral Bypass</td>
<td>8 (14.3%)</td>
<td>4 (17.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Previous peripheral stent/plasty</td>
<td>7 (12.5%)</td>
<td>3 (13%)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Medications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statin</td>
<td>56 (100%)</td>
<td>19 (82.6%)</td>
<td>ns</td>
</tr>
<tr>
<td>Antiplatelet therapy</td>
<td>45 (80.3%)</td>
<td>18 (78.3%)</td>
<td>ns</td>
</tr>
<tr>
<td>Warfarin</td>
<td>9 (16%)</td>
<td>2 (8.7%)</td>
<td>ns</td>
</tr>
<tr>
<td>ACE inhibitor</td>
<td>26 (46.4%)</td>
<td>6 (26.1%)</td>
<td>ns</td>
</tr>
<tr>
<td>Beta Blocker</td>
<td>24 (42.9%)</td>
<td>9 (39.1%)</td>
<td>ns</td>
</tr>
</tbody>
</table>

n/a= not available    ns=not statistically significant

### Clinical Outcomes

Participants in both groups were followed up for a mean time of 52 ± 9 months for number of cardiac admissions, peripheral angioplasty or stent, peripheral arterial bypass, major lower limb amputations and all-cause mortality (Table 4.2.2). Six participants in the NLIP group and 4 in the QOLO group were lost to follow up. The QOLO group did undergo a statistically significantly higher rate of peripheral arterial bypass than that of the NLIP group over the follow-up time.
4.3 Functional Capacity Assessment Results

3 Months

The functional capacity assessment results following the 12 week Nurse-led Intervention program were indeed consistent with improvements noted in other PAD studies (C. J. Watson et al., 2008) with both Claudication Pain Time (CPT), and Maximum Walk Time (MWT) demonstrating a statistically significant improvement (Table 4.3.1). Also consistent with other studies in the PAD population, was a moderate attrition rate with only 37 of the original 56 participants completing the 12-week Intervention Program (Silleesen, Madelung, Eldrup, & Roed, 2007; Spronk et al., 2003). All of the 19 people who did not complete the program cited medical reasons for non-completion.

Table 4.3.1

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>3 Months</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT (seconds)</strong></td>
<td>264±199</td>
<td>612±749</td>
<td>.005</td>
</tr>
<tr>
<td><strong>MWT (seconds)</strong></td>
<td>541±310</td>
<td>854±437</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

12 Months

12 Months following their baseline testing, all participants were asked to return for follow-up physical testing, however only 25 participants were able to return to perform a six-minute walk test, and of them only 19 were able to complete a progressive treadmill test. This was due to physical limitations they were experiencing such as knee, hip or back concerns which would render them unfit to safely attempt the treadmill test. As corridor testing is able to be performed at an
individual’s own pace, they were able to perform a six-minute walk test. The functional assessment results of the group remained statistically significantly improved when compared to their baseline assessment results (Table 4.3.2).

**Table 4.3.2**

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Baseline</th>
<th>12 Months</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT (seconds)</strong></td>
<td>19</td>
<td>259±177</td>
<td>517±315</td>
<td>.004</td>
</tr>
<tr>
<td><strong>MWT (seconds)</strong></td>
<td>19</td>
<td>569±319</td>
<td>688±334</td>
<td>.043</td>
</tr>
<tr>
<td><strong>6 Min Walk (metres)</strong></td>
<td>25</td>
<td>308±97</td>
<td>349±97</td>
<td>.03</td>
</tr>
</tbody>
</table>

**30 Months**

The final assessment for functional capacity was performed 30 months following the commencement of the Nurse-led Intervention Program and while 35 of the 37 people who completed the program returned for final testing, only 13 were able to perform a progressive treadmill test. The improvement in functional capacity which had been evident up until the 12 month time-point, had at this stage begun to show signs of decline. (Table 4.3.3)

Claudication pain time continued to be statistically significantly improved when compared to baseline results, and while the means of the maximum walk time and six-minute walk time appear to show a continued improvement, the reduction in the sample size has meant a loss of statistical significance. This is most likely due to the fact that those who were able to perform the treadmill test at 30 months were indeed the participants who were more physically fit and could walk a considerable distance, even at baseline.

**Table 4.3.3**

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Baseline</th>
<th>30 Months</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT (seconds)</strong></td>
<td>13</td>
<td>257±158</td>
<td>507±333</td>
<td>.045</td>
</tr>
<tr>
<td><strong>MWT (seconds)</strong></td>
<td>13</td>
<td>658±318</td>
<td>716±399</td>
<td>.526</td>
</tr>
<tr>
<td><strong>6 Min Walk (metres)</strong></td>
<td>35</td>
<td>317±107</td>
<td>321±107</td>
<td>.838</td>
</tr>
</tbody>
</table>
Figure 4.3.1- Functional Assessment Results

![Bar chart showing Functional Assessment Results](chart.png)

**Functional Capacity Correlations**

Both measures of functional capacity (Treadmill and six-minute walk) were found to correlate significantly, at baseline and 30 months (Table 4.3.4), suggesting that treadmill testing may not be as inaccurate a representation of functional capacity in daily life as has been suggested in some literature (McDermott et al., 2008).

### Table 4.3.4

<table>
<thead>
<tr>
<th></th>
<th>r</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MW &amp; CPT (Baseline)</td>
<td>.59</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>6MW &amp; MWT (Baseline)</td>
<td>.65</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>6MW &amp; CPT (30 Months)</td>
<td>.53</td>
<td>.06</td>
</tr>
<tr>
<td>6MW &amp; MWT (30 Months)</td>
<td>.76</td>
<td>.003</td>
</tr>
</tbody>
</table>

Predictors of functional measures (6MWT, CPT, MWT) were sought, however due to the reduced participant numbers at follow-up visits [start = 56, 12 months = 19, 30 months = 13] only analysis at baseline was feasible. Univariate predictors are shown in table 4.3.5 below.
Table 4.3.5

<table>
<thead>
<tr>
<th>Functional Measure</th>
<th>Variable</th>
<th>β</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MW</td>
<td>BMI</td>
<td>-0.321</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>Total Chol</td>
<td>-0.275</td>
<td>0.048</td>
</tr>
<tr>
<td></td>
<td>Mean ABI</td>
<td>0.279</td>
<td>0.043</td>
</tr>
<tr>
<td>CPT</td>
<td>BMI</td>
<td>-0.342</td>
<td>0.017</td>
</tr>
<tr>
<td></td>
<td>Total Chol</td>
<td>-0.316</td>
<td>0.021</td>
</tr>
<tr>
<td></td>
<td>Mean ABI</td>
<td>0.275</td>
<td>0.044</td>
</tr>
<tr>
<td>MWT</td>
<td>Total Chol</td>
<td>-0.285</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>Mean ABI</td>
<td>0.332</td>
<td>0.01</td>
</tr>
</tbody>
</table>

No significant predictors were found in multivariate models to predict 6MW and CPT, however in a multivariate linear regression model to predict MWT [overall $R^2=0.18$, $p<0.01$], both total cholesterol [$R=-0.289$, $p=0.032$] and mean ABI [$R=0.312$, $p=0.021$] were found to be significant predictors (figures 4.3.2 and 4.3.3 below).
Figure 4.3.2- Total Cholesterol as a predictor for Baseline MWT

Figure 4.3.3- Mean ABI as a predictor for Baseline MWT
Ankle-Brachial Index

Ankle-brachial index (ABI) did not demonstrate any significant change throughout the intervention program. (Table 4.3.6) This was not unexpected as ABI is a measure of macrovascular perfusion and although the exact mechanism responsible for exercise-related improvements in walking distance in people with PAD has yet to be proven conclusively, the evidence to date suggests that it is the result of improved endothelial function and muscle-utilisation of available perfusion, both of which would not be detected by ABI (Hamburg & Balady, 2011).

Table 4.3.6

<table>
<thead>
<tr>
<th></th>
<th>12 Months</th>
<th>30 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ABI</td>
<td>0.73±0.25</td>
<td>0.67±0.19</td>
</tr>
<tr>
<td><em>p</em> (compared to Baseline ABI 0.69±0.16)</td>
<td>.332</td>
<td>.263</td>
</tr>
</tbody>
</table>

4.4 Quality of Life Assessment Results

The assessment of quality of life in this study was performed using both a general quality of life tool (SF12- Appendix 1) and a PAD specific validated tool (Vascuqol-Appendix 2).

Short Form 12 (SF12) Quality of Life Assessment tool (J. E. Ware, Kolinski, M., Keller, S.D.,, 1995) is a validated shortened version of the SF36 which assesses both mental and physical domains. Participants in the NLIP group were asked to complete this survey at baseline (pre-intervention program), 3 months (post-intervention program) and again at 12 and 30 months.

Participants in the QOLO group were asked to complete at Baseline, 12 and 30 months.

The results of the QOLO group’s SF12 questionnaires showed no significant change throughout the study (Table 4.4.1). Those in the NLIP group did not show any significant change directly following the 12-week program, however they were
significantly improved in both domains at the 12 month time-point. However, this improvement was no longer evident by 30 months (Table 4.4.2).

Table 4.4.1- SF12 results

<table>
<thead>
<tr>
<th>QOLO Group</th>
<th>Baseline n=23</th>
<th>12 Months n=9</th>
<th>30 Months n=7</th>
<th>p 12 Months</th>
<th>p 30 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental</td>
<td>45.4±9.7</td>
<td>44.2±7</td>
<td>49.2±6.5</td>
<td>.778</td>
<td>.159</td>
</tr>
<tr>
<td>Physical</td>
<td>35.3±12</td>
<td>39.7±9</td>
<td>38.8±12.5</td>
<td>.117</td>
<td>.824</td>
</tr>
</tbody>
</table>

Table 4.4.2- SF12 results

<table>
<thead>
<tr>
<th>NLIP Group</th>
<th>Baseline n=56</th>
<th>3 Months n=31</th>
<th>12 Months n=35</th>
<th>30 Months n=31</th>
<th>p 3 Months</th>
<th>p 12 Months</th>
<th>p 30 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental</td>
<td>49.6±13.4</td>
<td>49.5±11.6</td>
<td>46.5±10.1</td>
<td>46.9±6.3</td>
<td>.978</td>
<td>.010</td>
<td>.963</td>
</tr>
<tr>
<td>Physical</td>
<td>31.1±8.4</td>
<td>32.7±8.5</td>
<td>33.9±11.4</td>
<td>34.4±8.6</td>
<td>.232</td>
<td>.030</td>
<td>.102</td>
</tr>
</tbody>
</table>

While the SF12 is a validated tool to assess quality of life, the Vascuqol is a PAD specific quality of life assessment tool which examines 5 domains including Activity, PAD symptoms, Pain, Emotion, Social as well as an overall total (Morgan et al., 2001). The Vascuqol questionnaires were administered to both the QOLO and NLIP group at the same time-points as the SF12 questionnaire.

Again the QOLO group showed almost no significant change throughout the study (Table 4.4.3). The only significant improvement was seen in the domain of pain at the 12 month mark. Due to the high attrition rate, it is possible that the QOLO group did experience improvement in QOL which was undetectable due to the reduced sample size.
Table 4.4.3

<table>
<thead>
<tr>
<th>Vascuqol- QOLO Group</th>
<th>Baseline n=23</th>
<th>12 Months n=17</th>
<th>30 Months n=11</th>
<th>p 12 Months</th>
<th>p 30 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity</td>
<td>4.02±1.3</td>
<td>4.28±1.4</td>
<td>4.5±1.3</td>
<td>.261</td>
<td>.881</td>
</tr>
<tr>
<td>Symptoms</td>
<td>5.08±1.2</td>
<td>5.28±1.1</td>
<td>5.73±1</td>
<td>.503</td>
<td>.427</td>
</tr>
<tr>
<td>Pain</td>
<td>4.09±1.5</td>
<td>4.93±1.4</td>
<td>4.93±1.6</td>
<td>.003</td>
<td>.362</td>
</tr>
<tr>
<td>Emotion</td>
<td>5.04±1.5</td>
<td>5.32±1.3</td>
<td>5.87±1.2</td>
<td>.390</td>
<td>.577</td>
</tr>
<tr>
<td>Social</td>
<td>4.72±1.6</td>
<td>4.78±1.6</td>
<td>5.2±1.4</td>
<td>.769</td>
<td>.726</td>
</tr>
<tr>
<td>Total</td>
<td>4.52±1.3</td>
<td>4.88±1.2</td>
<td>5.22±1.2</td>
<td>.154</td>
<td>.578</td>
</tr>
</tbody>
</table>

The NLIP group demonstrated significant improvement in all domains except social, at the 3 month time-point, which was directly following the 12 week intervention program (Table 4.4.4). The group sustained this significant improvement in the domains of PAD symptoms and emotion throughout the 30 months of the study.

Table 4.4.4

<table>
<thead>
<tr>
<th>Vascuqol- NLIP Group</th>
<th>Baseline n=56</th>
<th>3 Months n=37</th>
<th>12 Months n=42</th>
<th>30 Months n=36</th>
<th>p 3 Months</th>
<th>p 12 Months</th>
<th>p 30 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity</td>
<td>3.79±1</td>
<td>4.18±1.3</td>
<td>3.9±1.3</td>
<td>3.86±1.3</td>
<td>.019</td>
<td>.896</td>
<td>.760</td>
</tr>
<tr>
<td>Symptoms</td>
<td>4.34±1.4</td>
<td>5.19±1.2</td>
<td>4.88±1.4</td>
<td>4.89±1.2</td>
<td>.001</td>
<td>.035</td>
<td>.014</td>
</tr>
<tr>
<td>Pain</td>
<td>3.81±1.4</td>
<td>4.46±1.4</td>
<td>4.19±1.4</td>
<td>3.96±1.5</td>
<td>.008</td>
<td>.187</td>
<td>.299</td>
</tr>
<tr>
<td>Emotion</td>
<td>4.35±1.6</td>
<td>4.82±1.6</td>
<td>4.82±1.7</td>
<td>4.67±1.8</td>
<td>.041</td>
<td>.041</td>
<td>.043</td>
</tr>
<tr>
<td>Social</td>
<td>4.30±1.6</td>
<td>4.66±1.6</td>
<td>4.72±1.6</td>
<td>5.22±1.7</td>
<td>.165</td>
<td>.507</td>
<td>.334</td>
</tr>
<tr>
<td>Total</td>
<td>4.08±1.1</td>
<td>4.62±1.3</td>
<td>4.43±1.3</td>
<td>4.33±1.3</td>
<td>.004</td>
<td>.145</td>
<td>.114</td>
</tr>
</tbody>
</table>

Table 4.4.5

Baseline quality of life comparison

<table>
<thead>
<tr>
<th>Vascuqol</th>
<th>NLIP group</th>
<th>QOLO group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity</td>
<td>3.51±0.8</td>
<td>3.89±1.3</td>
<td>.296</td>
</tr>
<tr>
<td>Symptoms</td>
<td>3.89±1.3</td>
<td>5.12±0.9</td>
<td>.011</td>
</tr>
<tr>
<td>Pain</td>
<td>3.61±1.4</td>
<td>4.15±1.4</td>
<td>.300</td>
</tr>
<tr>
<td>Emotion</td>
<td>3.89±1.5</td>
<td>4.89±1.5</td>
<td>.052</td>
</tr>
<tr>
<td>Social</td>
<td>4.19±1.7</td>
<td>4.64±1.6</td>
<td>.395</td>
</tr>
<tr>
<td>Total</td>
<td>3.74±1</td>
<td>4.43±1.2</td>
<td>.090</td>
</tr>
</tbody>
</table>
Table 4.4.6

<table>
<thead>
<tr>
<th>SF12</th>
<th>NLIP group</th>
<th>QOLO group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental</td>
<td>52.96±10.7</td>
<td>48.91±12.8</td>
<td>.403</td>
</tr>
<tr>
<td>Physical</td>
<td>29.51±8.5</td>
<td>33.94±9.4</td>
<td>.284</td>
</tr>
</tbody>
</table>

When comparing both the NLIP and QOLO groups quality of life results at baseline it can be seen that a significant difference did exist in the results of the Vascuqol in the domains of PAD symptoms and Emotion. The QOLO group identified as having significantly worse PAD symptoms and almost significantly poorer emotional well-being than those in the NLIP group at baseline. No significant difference was identified between the two group in either domains of the SF12 questionnaire. Both groups did also encounter a reasonable attrition rate, and as such it should be noted that QOL analysis was performed on an “intention to treat” basis.
Chapter 5
Discussion and Recommendations

5.1 Introduction

The final chapter of this thesis will discuss the results from the previous chapter in detail and identify what they have added to the body of knowledge in this field of study. It will also identify challenges encountered and recognise limitations of this study. Finally, it will identify recommendations for how this knowledge may be used to guide patient care as well as highlight areas requiring further investigation.

5.2 Background

Peripheral arterial disease is known to have a significantly high morbidity and mortality rate with sufferers demonstrating a significantly reduced functional capacity, accelerated rates of functional decline and reduction in quality of life (McDermott et al., 2001; Pratt et al., 2005).

Nurse-led intervention programs for PAD provide the opportunity to combine both supervised exercise and risk factor modification as recommended in the ACC/AHA and TASC II guidelines (Hirsch et al., 2006; Norgren et al., 2007). Even so, nurse-led intervention programs for PAD are known to be an under-utilised resource (Shalhoub, Hamish, & Davies, 2009). While there have been multiple studies examining the optimal modality, length and level of supervision required for a PAD exercise program (Gardner et al., 2012; Hiatt et al., 1994), there is a paucity of evidence regarding nurse-led intervention programs which incorporate both supervised exercise and risk factor modification which have been assessed through multiple outcome measures over a sustained time period.

This study sought to identify whether improvements in functional capacity and quality of life following participation in a nurse-led intervention program could be sustained over a longer-term follow up period. This not only supplements existing evidence regarding short-term efficacy of such programs but also the long-term benefits they can provide for PAD sufferers and an increasingly overburdened health system.
5.3 Functional Capacity

Following the nurse-led intervention program, both claudication pain time and maximum walk time were significantly improved when compared to baseline assessment (both p<.01) which was expected and is congruent with existing research results directly following intervention programs (C. J. Watson et al., 2008).

The aim of this study however, was to determine the sustainability of functional improvements following a nurse-led intervention program so of greater interest was the discovery that both treadmill and corridor test results remained significantly improved above baseline 9 months later, at the 12 month follow-up point (p<.05).

It is also essential to note that only one person in the intervention program underwent a peripheral arterial stent within their first 12 months of participation and this person did not return for 12 month testing so this can be excluded as a potential factor in sustaining these functional improvements.

At the final follow up (30 months) claudication pain time remained significantly improved compared to baseline (p<.05) however both maximum walk time and six minute walk were no longer significantly improved. This not only shows that people who took part in the nurse-led intervention program were in fact able to sustain significantly improved pain-free walking distance, but also given the functional decline expected for people with PAD (McDermott et al., 2004) it would be reasonable to suggest that even a lack of functional decline in this population may in fact be as optimal an outcome as one can expect.

Again at the 30 month time point it must be noted that of the 5 people who had undergone peripheral stent or angioplasty since the 12 month follow up visit, none of them were able to perform the treadmill test (due to physical limitations other than worsening claudication). Similarly, of the 2 participants who had undergone peripheral arterial bypass surgery since the 12 month visit, one did not return for final testing. The other did return however their treadmill results were reduced and their six-minute walk results unchanged when compared to their baseline. This may have been due to remaining disease in the contralateral limb which continued to cause claudication, Therefore, surgical or endovascular intervention can be excluded as a potential contributor to the sustained improvement in claudication pain time.
It has been suggested in some studies that when using the treadmill as a functional assessment tool, it is essential to perform a test, re-test method so as to eliminate unfamiliarity with equipment as a potential factor for reduced initial performance (Askew, Green, Hou, & Walker, 2002). This requires participants to perform a treadmill test and then return the following day to perform it again, with the second results being regarded as baseline. This was not feasible for this study as it was felt that participants would be unwilling to do so. The correlations which were found between the treadmill scores and six-minute walk at both baseline and 30 months (Table 4.3.4) suggests that the test, re-test method may in fact be unnecessary. Both CPT and MWT were found to significantly correlate to six-minute walk at baseline (p<.001) and even at 30 months MWT significantly correlated to six-minute walk (p<.05) and CPT trended towards correlating (p=.06). As it is not suggested that a person should test-retest when performing a corridor walk test these results suggest that it should not have been a factor contributing to the improvements in treadmill scores.

Modelling for predictors of functional measure was difficult due to the unequal participant numbers at the follow up time points. Both Mean ABI and total cholesterol were found to be significant predictors of baseline MWT. It is not surprising that mean ABI would predict baseline MWT as it would be expected that people with a lower ABI would have a reduced MWT. This finding does however validate the sample group. The finding of total cholesterol as a predictor for baseline MWT was more of a surprising discovery. This finding validates the need for strict lipid management for people with PAD, not only for the reduction of cardiovascular risk but also for improvement of walking distance. This may in fact be a more tangible incentive for people with PAD than simply improvement in risk.

5.4 Quality of Life

When examining the quality of life results it is important to bear in mind that the QOLO (quality of life only) group cannot represent a true "control" group due to a lack of randomisation process. The group consisted of people who were eligible to participate in the program however were unable to due to geographical distance or travel issues, not simply because they did not want to participate. This group also
identified as having significantly worse PAD symptoms at baseline. This is another reason why the two groups are not directly comparable and may be the reason for the increased number of peripheral arterial bypasses (compared to the NLIP group) being performed on this group during the 52 month follow up time period. Interestingly however, regardless of the higher rates of surgical intervention, no improvement was evident in any domains of either QOL assessment tool in the QOLO group at the 30 month follow up.

Taking into account the physical limitations experienced by the NLIP (nurse-led intervention program) group which prevented many of them from performing follow up treadmill testing (including severe musculoskeletal, balance issues or amputations) it is evident why a disease specific tool would be more accurate in this population. Given the extensive comorbid conditions this population are plagued with, the ability to discern between claudication pain and other bodily pain is essential.

The SF12 being a general quality of life tool, examined only overall physical and mental domains. Although it did show a significant improvement in both domains 12 months following the intervention program no further improvement were seen in either group at any time point.

The disease specific quality of life tool, the Vascuqol was able to identify improvements at a more specific level by addressing both pain and PAD symptoms individually. While the NLIP group statistically improved all domains except social following the intervention program, the improvement in “pain” was no longer evident at 12 months, yet “PAD symptoms” remained significantly improved compared to baseline (p=.035). This is consistent with the ailments identified as preventing people from performing treadmill testing at 12 months and similarly at the 30 month time point also.

Participants in the NLIP group also demonstrated sustained improvement (compared to baseline) in the domain of “emotion” at both the 12 and 30 month time points (p=.041 and p=.043 respectively).
The results from the quality of life assessments demonstrate that a nurse-led intervention program can lead to sustained improvement in both PAD symptoms and emotional wellbeing.

5.5 What this study has added to the body of evidence

When compared to other studies on nurse-led and non-nurse led intervention programs for PAD (Table 5.5.1) it can be seen that this study is of comparable sample size with studies of longer duration. This study provides one of the longest follow-up terms when compared to the existing literature and by using treadmill and corridor assessment, it provides “harder” endpoints than some of the studies which assess functional capacity using questionnaires only.

The results of this study contribute to the evidence surrounding the efficacy of nurse-led intervention programs for PAD and the need for greater implementation and access to such programs. In Queensland there are over 60 cardiac rehabilitation programs, while there are still only a handful of PAD programs Australia wide. Evidence from this study suggests that nurse-led intervention program can provide sustained improvements for people suffering from PAD and such programs should not necessarily be seen as an alternative to surgical intervention, but more an essential part of the long-term management of this chronic disease, which can complement any required surgical or endovascular intervention.
<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>Study type</th>
<th>Participants (n)</th>
<th>Intervention</th>
<th>Follow-up, Months</th>
<th>Functional Assessment Method</th>
<th>Additional Outcome Measures</th>
<th>Results</th>
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<tr>
<td>Nurse-led Programs</td>
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<td>Braun</td>
<td>1999</td>
<td>Retrospective analysis</td>
<td>22</td>
<td>12 week supervised Exercise + risk factor modification education</td>
<td>24</td>
<td>Treadmill Test</td>
<td>Increased °</td>
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<td>8-16 week Home-based exercise program + risk factor modification</td>
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<td>Prospective cohort study</td>
<td>693</td>
<td>Exercise advice + risk factor modification</td>
<td>12</td>
<td>Questionnaire</td>
<td>Risk Factors (mean TC, LDL, BP)</td>
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<td>78</td>
<td>Exercise advice + Structured risk factor modification</td>
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<td>Framingham Risk</td>
<td>Improved**</td>
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<tr>
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<td>Quality improvement project</td>
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<td>Home-based exercise</td>
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<td>12 Week supervised exercise program &amp; risk factor modification education &amp; Exercise advice</td>
<td>30</td>
<td>Treadmill &amp; Six minute walk</td>
<td>QOL</td>
<td>Increased</td>
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<td>Group 2 23</td>
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<td>Not avail</td>
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<td>Improved QOL</td>
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<td>Franz</td>
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<td>Treadmill Test &amp; 12 Minute Walk</td>
<td>Risk Factors (Mean BMI, BP, Lipids)</td>
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<td>Fakhry</td>
<td>2011</td>
<td>Comparative longitudinal cohort study</td>
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<td>12</td>
<td>Treadmill</td>
<td>QOL</td>
<td>Increased**</td>
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<td>Group 2 75</td>
<td>24 Week supervised exercise program</td>
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<td>Treadmill</td>
<td>QOL</td>
<td>Increased**</td>
</tr>
<tr>
<td>Guidon</td>
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<td>Randomised control trial</td>
<td>Group 1 17</td>
<td>12 week supervised exercise program</td>
<td>12</td>
<td>Questionnaire</td>
<td>QOL</td>
<td>Increased^</td>
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<td></td>
<td></td>
<td>Group 2 12</td>
<td>Exercise advice</td>
<td></td>
<td>Questionnaire</td>
<td>QOL</td>
<td>Decreased</td>
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</tbody>
</table>

^= not statistically significant    **=p<0.001    °=p value not stated    QOL=Quality of Life assessment
5.6 Research Challenges

Recruitment can prove challenging for any interventional study in PAD (C. J. Watson et al., 2008) and this study did undergo initial difficulties in recruitment. The original TEMPLATE trial excluded people who had undergone peripheral arterial bypass, stent or angioplasty within the past 12 months. However, this did not allow for the fact that people still may have been suffering from claudication due to disease in the contralateral limb, or even more distal disease in the ipsilateral limb. In a revision of the protocol after 9 months due to lower-than-expected recruitment numbers this exclusion criteria was removed, and the only inclusion criteria became symptomatic PAD as determined by Edinburgh Claudication Questionnaire (Leng & Fowkes, 1992). This improved recruitment numbers and is also an important factor to be taken into consideration when coordinating a nurse-led PAD program. Peripheral arterial bypass, stent or angioplasty are performed for management of symptoms or for limb salvage but they obviously cannot cure the systemic disease process of PAD. Therefore, exercise and risk factor modification must remain an ongoing part of the chronic disease management for PAD, regardless of symptoms.

Another obstacle encountered not only for recruitment but the general management of people with PAD, is the need to wait for review from a member of the Vascular Surgical team before a referral to a nurse-led intervention program can occur. In the public hospital setting where this study was conducted it is evident that people have been symptomatic of PAD for sometimes years before being seen as a non-urgent outpatient. This delay is not only due to public hospital outpatient waiting lists, but also the time it has taken for the patient to mention their symptoms to their primary care physician who can then make referrals for vascular investigations and reviews. When PAD is known to have a 15-30% 5-year mortality rate, this is time that really cannot afford to be lost (Hirsch et al., 2006). Community awareness of PAD, its signs, symptoms and progression as well as greater community screening are things that could help to reduce this wait. Access to nurse-led intervention programs from the primary care setting could also alleviate some burden from the extensive public hospital outpatient waiting lists.
5.7 Limitations

There are some limitations to this study which we have identified. The lack of a true control group through a randomisation process is certainly a limitation. As the current guidelines (ACC/AHA and TASCII) recommend supervised exercise as optimal initial treatment for PAD it was felt that to deny willing participants access to such a program would be unethical (Hirsch et al., 2006; Norgren et al., 2007).

Another limitation is the lack of physical and functional assessment form the quality of life only group. This was simply not feasible as the people in this group were not able to attend the nurse-led intervention program due to geographical distance from the hospital and some had no knowledge of when or if they might be returning to the hospital for further appointments.

It is also disappointing that not all participants in the intervention program group were able to perform a graded treadmill test at follow up visits. This is due to the nature of the progressive treadmill test and its set speed and incline. It would have posed a significant safety threat for participants of declining physical function to have attempted it and thus they were only able to perform corridor walking test (six minute walk). People with worsening claudication were not omitted from treadmill testing, only those with severe balance, musculoskeletal complaints or amputations.

5.8 Conclusion

Peripheral arterial disease, as an atherothrombotic disease, contributes to the number one killer of all Australians (Ademi et al., 2010). While existing guidelines recommend supervised exercise and strict risk factor reduction for the management of PAD, nurse-led intervention programs which provide the opportunity to do both remain scarce and underutilised in Australia.

This study demonstrates that nurse-led intervention programs for people with peripheral arterial disease can lead to sustained improvements in pain-free walking distance, PAD symptoms and emotional well-being.

Greater community awareness of PAD and creation of more programs which are accessible from the primary care setting could further improve outcomes for people with PAD and reduce hospital outpatient waiting lists. Further investigation is required to identify if increasing access to programs and community education could
lead to a reduction in the high mortality and morbidity rates associated with this condition.
References


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The NHS and Community Care Act (1990).


Appendix 1- SF12
**Health and Well Being (6-12)**

**INSTRUCTIONS:** This survey asks for your views about your health in general. For each of the following questions, please fill in the circle of the best possible answer.

1. In general, would you say your health is:
   - [ ] Excellent
   - [X] Very good
   - [ ] Good
   - [X] Fair
   - [ ] Poor

2. Does your health now limit you in moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf?
   - [ ] Yes
   - [ ] No
   - [ ] Not sure

3. Does your health now limit you in climbing several flights of stairs?
   - [ ] Yes
   - [ ] No

4. During the past 4 weeks, how much of the time have you accomplished less than you would like with your work or other regular daily activities as a result of your physical health?
   - [ ] Most of the time
   - [X] Some of the time
   - [ ] A little bit
   - [ ] Not at all

5. During the past 4 weeks, how much of the time were you limited in the kind of work or other activities as a result of your physical health?
   - [ ] Most of the time
   - [X] Some of the time
   - [ ] A little bit
   - [ ] Not at all

6. During the past 4 weeks, how much of the time have you accomplished less than you would like with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?
   - [ ] Most of the time
   - [X] Some of the time
   - [ ] A little bit
   - [ ] Not at all

7. During the past 4 weeks, how much of the time were you limited in the kind of work or other activities as a result of any emotional problems (such as feeling depressed or anxious)?
   - [ ] Most of the time
   - [X] Some of the time
   - [ ] A little bit
   - [ ] Not at all

8. How much of the time during the past four weeks have you felt calm and peaceful?
   - [ ] Most of the time
   - [X] Some of the time
   - [ ] A little bit
   - [ ] Not at all

9. How much of the time during the past four weeks did you have a lot of energy?
   - [ ] Most of the time
   - [X] Some of the time
   - [ ] A little bit
   - [ ] Not at all

10. How much of the time during the past four weeks have you felt downhearted and depressed?
    - [ ] Most of the time
    - [X] Some of the time
    - [ ] A little bit
    - [ ] Not at all

11. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?
    - [ ] Most of the time
    - [X] Some of the time
    - [ ] A little bit
    - [ ] Not at all

12. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
    - [ ] Not at all
    - [ ] A little bit
    - [X] Moderately
    - [ ] Quite a bit
    - [ ] Extremely
Appendix 2- Vascuqol questionnaire

Researcher Initials: ______________  Date: ______________

VASCUQOL

The following questions are about how you have been affected by the poor circulation in your legs in the past two weeks. You will be asked about the symptoms you have had, the way that your activities have been affected, and how you have been feeling.

For each question please read all of the answers and then check the one that applies best to you.

1. During the past two weeks, I have had pain in my leg (or foot) when walking...
   - O All of the time
   - O Most of the time
   - O Much of the time
   - O Some of the time
   - O A little of the time
   - O Hardly any of the time
   - O None of the time

2. During the past two weeks, I have been worried that I might injure my leg...
   - O All of the time
   - O Most of the time
   - O Much of the time
   - O Some of the time
   - O A little of the time
   - O Hardly any of the time
   - O None of the time

3. During the past two weeks, cold feet have given me...
   - O A very great deal of discomfort or distress
   - O A great deal of discomfort or distress
   - O A moderate amount of discomfort or distress
   - O Some discomfort or distress
   - O Very little discomfort or distress
   - O No discomfort or distress

4. During the past two weeks, because of the poor circulation to my legs, my ability to exercise or to play sports has been...
   - O Totally limited, couldn't exercise at all
   - O Extremely limited
   - O Very limited
   - O Moderately limited
   - O A little limited
   - O Only very slightly limited
   - O Not at all limited

5. During the past two weeks, my legs felt tired or weak...
   - O All of the time
   - O Most of the time
   - O Much of the time
   - O Some of the time
   - O A little of the time
   - O Hardly any of the time
   - O None of the time

6. During the past two weeks, because of the poor circulation in my legs, I have been restricted in spending time with my friends or relatives...
   - O All of the time
   - O Most of the time
   - O Much of the time
   - O Some of the time
   - O A little of the time
   - O Hardly any of the time
   - O None of the time

7. During the past two weeks, I have had pain in the foot (or leg) after going to bed at night...
   - O All of the time
   - O Most of the time
   - O Much of the time
   - O Some of the time
   - O A little of the time
   - O Hardly any of the time
   - O None of the time

8. During the past two weeks, pins and needles or numbness in my leg (or foot) have caused me...
   - O A very great deal of discomfort or distress
   - O A great deal of discomfort or distress
   - O A moderate amount of discomfort or distress
   - O Some discomfort or distress
   - O Very little discomfort or distress
   - O No discomfort or distress
9. During the past two weeks, the distance I can walk has improved...
   - Not at all
   - A little
   - Somewhat
   - Moderately
   - A good deal
   - A very great deal

10. During the past two weeks, because of the poor circulation in my legs, my ability to walk has been...
    - Totally limited, couldn't walk at all
    - Extremely limited
    - Very limited
    - Moderately limited
    - A little limited
    - Only very slightly limited
    - Not at all limited

11. During the past two weeks, being (or becoming) housebound has concerned me...
    - A very great deal
    - A great deal
    - A good deal
    - Moderately
    - Somewhat
    - A little
    - Not at all

12. During the past two weeks, I have been concerned about having poor circulation in my legs...
    - All of the time
    - Most of the time
    - Much of the time
    - Some of the time
    - A little of the time
    - Hardly any of the time
    - None of the time

13. During the past two weeks, I have had pain in the foot (or leg) when I am resting...
    - All of the time
    - Most of the time
    - Much of the time
    - Some of the time
    - A little of the time
    - Hardly any of the time
    - None of the time

14. During the past two weeks, because of the poor circulation in my legs, my ability to climb stairs has been...
    - Totally limited, couldn't climb stairs at all
    - Extremely limited
    - Very limited
    - Moderately limited
    - A little limited
    - Only very slightly limited
    - Not at all limited

15. During the past two weeks, because of the poor circulation in my legs, my ability to participate in social activities has been...
    - Totally limited, couldn't socialise at all
    - Extremely limited
    - Very limited
    - Moderately limited
    - A little limited
    - Only very slightly limited
    - Not at all limited

16. During the past two weeks, because of the poor circulation in my legs, my ability to do routine household work has been...
    - Totally limited, couldn't do housework at all
    - Extremely limited
    - Very limited
    - Moderately limited
    - A little limited
    - Only very slightly limited
    - Not at all limited
17. During the past two weeks, ulcers or sores on my leg (or foot) have caused me pain or distress...
   - All of the time
   - Most of the time
   - Much of the time
   - Some of the time
   - A little of the time
   - Hardly any of the time
   - None of the time (select this option if you do not have leg ulcers)

18. Because of the poor circulation in my legs, the range of activities that I would have liked to do in the past two weeks has been...
   - Severely limited (most activities not done)
   - Very limited
   - Moderately limited (several not done)
   - Slightly limited
   - Very slightly limited (very few not done)
   - Not at all limited (have done all activities)

19. During the past two weeks, problems caused by poor circulation in my legs has made me feel frustrated...
   - All of the time
   - Most of the time
   - Much of the time
   - Some of the time
   - A little of the time
   - Hardly any of the time
   - None of the time

20. During the past two weeks, when I have had pain in the leg (or foot) it has given me...
   - A very great deal of discomfort or distress
   - A great deal of discomfort or distress
   - A good deal of discomfort or distress
   - A moderate amount of discomfort/distress
   - Some discomfort or distress
   - Very little discomfort or distress
   - No discomfort or distress

21. During the past two weeks, I have felt guilty about relying on friends or relatives...
   - All of the time
   - Most of the time
   - Much of the time
   - Some of the time
   - A little of the time
   - Hardly any of the time
   - None of the time

22. During the past two weeks, because of the poor circulation in my legs, my ability to go shopping or carry bags has been...
   - Totally limited, couldn't go shopping at all
   - Extremely limited
   - Very limited
   - Moderately limited
   - A little limited
   - Only very slightly limited
   - Not at all limited

23. During the past two weeks, I have worried I might be in danger of losing a part of my leg or foot...
   - All of the time
   - Most of the time
   - Much of the time
   - Some of the time
   - A little of the time
   - Hardly any of the time
   - None of the time

24. During the past two weeks, the distance I can walk became less...
   - A very great deal
   - A great deal
   - A good deal
   - Moderately
   - Somewhat
   - A little
   - Not at all (select this option if the distance is unchanged or increased)
25. During the past two weeks, I have been depressed about the poor circulation in my legs.

   O All of the time
   O Most of the time
   O Much of the time
   O Some of the time
   O A little of the time
   O Hardly any of the time
   O None of the time