A study to assess the feasibility of implementing a supervised exercise programme for patients diagnosed with intermittent claudication

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The candidate confirms that the work submitted is their own and that appropriate credit has been given where reference has been made to the work of others.

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Abstract

Supervised exercise programmes (SEPs) have been demonstrated to improve the symptoms of intermittent claudication (IC) in individuals with peripheral artery disease (PAD) and are endorsed as a primary treatment approach by numerous national and international clinical guidelines. Nevertheless, the adoption of SEPs remains limited. This thesis describes a project aimed at implementing and evaluating a SEP for people with IC in York, England.

The York Claudication Exercise Service was launched in October 2023 as a collaboration between York St John University and York and Scarborough Teaching Hospitals NHS Foundation Trust. Eligible patients referred from York Hospital's vascular clinics participated in a 12-week programme with two, one-hour, group-based sessions per week. Baseline and exit assessments measured walking capacity, and quality of life. There was a descriptive analysis of the quantitative data, and a summary of the qualitative feedback gathered from participants to provide additional insights into patient experiences.

By May 2024, 109 IC patients had been identified; 40 had accepted the SEP option, and 29 had commenced exercise sessions. The exercises sessions were delivered as intended, and the median attendance was 19 of 24 sessions. Of 22 participants completing exit assessments, 59% reported improvement in IC symptoms. Pain-free walking distance (PFWD) increased by a mean of 97 metres (95% confidence interval (CI): 18 to 175). Most participants rated the SEP as "good" or "excellent". Barriers to implementation included inconsistent referral behaviour of vascular consultants, and logistical issues like transportation and distance to travel to the venue affecting participation.

Overall, the study demonstrated the service was delivered as intended in accordance with the National Institute for Health and Care Excellence (NICE) guidance. Participants were

satisfied with the service and valued playing an active role in managing their condition. Agreements have been made to continue the service for 2 years. During this time, funding will be sought to sustain the service, and it will be adapted to facilitate wider access and greater uptake.

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List of Abbreviations

ABPI, ankle brachial pressure index

ACPICR, Association of Chartered Physiotherapists in Cardiac Rehabilitation

ADL, activities of daily living

BMI, body mass index

CASP, Critical Appraisal Skills Programme

CI, confidence interval

CLI, critical limb ischaemia

GDPR, General Data Protection Regulations

GP, general practitioner

HR-QoL, health-related quality of life

HIC, high-income countries

IC, intermittent claudication

Kg, kilograms

LMIC, low-middle-income countries

MD, mean difference

MI, myocardial infarction

MID, minimal importance difference

MRA, magnetic resonance angiography

MWD, maximum walking distance

MWD/T, maximum walking distance/time

MWT, maximum walking time

NHS, National Health Service

NICE, National institute for Health and Care Excellence

NIHR, National Institute for Health and Care Research

PAD, peripheral artery disease

PFWD, pain free walking distance

PFWD/T, pain free walking distance/time

PFWT, pain free walking time

PIL, patient information leaflet

PROM, patient-reported outcome measure

QALY, quality adjusted life years

QoL, quality of life

RCT, randomised controlled trial

SEP, supervised exercise programme

SD, standard deviation

UK, United Kingdom

VAS, visual analog scale

VSNP, vascular specialist nurse practitioner

YHEC, York Health Economic Consortium

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Chapter 1: General Introduction

Peripheral artery disease (PAD) affects millions of people globally and is classified under the umbrella of cardiovascular disease, such as coronary heart disease, with overlapping management recommendations including risk factor modification and lifestyle changes (Gerhard-Hermann *et al*., 2017). The National Institute for Health and Care Excellence (NICE) (2020) reports that from the evidence found in population studies approximately 20% of the population aged over the age of sixty years have some degree of PAD.

PAD is characterised by a narrowing of the arteries due to a build-up of plaque on the artery walls; a process called atherosclerosis (Narula *et al*.,2020). The narrowed lumen leads to a reduction in blood flow to the limbs, usually the legs (Meru *et al*., 2006). PAD can differ significantly in its presentation of both physical and psychological symptoms depending on the severity of the disease. Harwood *et al.* (2022) indicates that an early typical physical presentation of PAD is intermittent claudication (IC). IC occurs when the muscle's demand for oxygen to sustain the activity is unmet due to the arterial narrowing (Tew *et al*., 2018). IC presents as a cramp-like muscle pain during exercise, usually in the calf due to occlusive disease in the femoral artery (Rose, 2000). However, it can be multilevel affecting different muscle groups including buttocks and thighs (de Vries *et al*., 2005). At rest the restricted blood flow still delivers enough oxygen to the muscles; however, during exercise, the demand for blood flow and oxygen is increased and cannot be met due to the narrowed lumen, resulting in ischemia and IC pain (Morley *et al.,* 2018). IC is often considered a benign level of PAD as only one in five people progress to develop more severe symptoms, and 1 in 20 continue to develop critical limb ischaemia (CLI), the level of disease when a limb becomes at risk of amputation. Ultimately, the lifetime risk of major limb

amputation of those people presenting with IC symptoms is 1-2% (Kannel *et al.,* 1970). The psychological impact that IC has on individuals is driven by functional decline, loss of independence and reduced quality of life (QoL) (NICE, 2012).

In healthcare, clinical practice is underpinned by evidence published as guidance and recommendations by NICE. The management of PAD is multifactorial; a one-size-fits-all approach is not always possible due to the heterogeneous nature of IC. The impact of the disease on day-to-day life needs to be considered and balanced against the chance of success versus the risk of treatment. NICE (2012) recommendations for people with IC are twofold. In line with all levels of PAD, NICE (2012) recommends that secondary prevention of cardiovascular events is managed with best medical therapy (an antiplatelet and statin tablet), which significantly reduces complications such as heart and strokes by around 30%. A secondary aim that is specific to people with IC is to improve walking distance. To address this aim, NICE's (2012) first-line recommendation, before invasive, high-risk interventions such as angiograms or surgery, is a low-risk treatment of exercise therapy. The exercise treatment should offer a minimum of 2 hours of supervised exercise per week for 3 months. A survey by Harwood *et al*. (2022) reported that despite the low-risks associated with a supervised exercise programme (SEP), this gold-standard recommendation is only accessible in approximately 48% of the National Health Service (NHS) Trust vascular hubs nationally which results in inequality, i.e., a SEP being available through the local vascular hub. There is an established and robust body of research on the benefits of SEP for improving walking for people with IC; however, the evidence as to why there is a low uptake of SEP by vascular hubs is limited.

This study aimed to determine the feasibility of implementing a SEP that met the NICE (2012) recommendations. The study was part of a service evaluation for people with IC

attending base-site vascular clinics in York. The York vascular service geographical region covers a population of 732,070 people, including coastal areas, which hold an aging population (North Yorkshire County Council, 2024). The study evaluated feasibility measures to recruit and retain participants over a 12-week time frame. Walking ability outcomes were measured both objectively and subjectively. Overall, findings were used to make recommendations and to support a business case to sustain and scale-up a SEP.

The new exercise service aimed to enhance the conservative management pathway for patients with IC at the local vascular hub, and hopefully help relieve pressure on the NHS Trust. It will enable the Trust to meet the NICE (2012) recommendations regarding SEPs for IC and may encourage surrounding vascular hubs to adopt a similar approach. Most significantly, it will put the patient at the centre of their care, improving their QoL and experience.

Chapter 2: Literature review- epidemiology, diagnosis and management of PAD

This chapter aims to provide a comprehensive exploration of PAD, with a specific focus on IC. The review will progress from an overview of the physiological mechanisms underlying IC, to diagnostic approaches, and then examine the broader impact of the disease on both affected individuals and wider society. Subsequently, the review will address the management strategies and care pathways for individuals with IC, with particular emphasis on the role of exercise as a therapeutic intervention.

2.1 Literature review searches and appraisal tool

Six electronic databases were used for this review: Medline, Amed, CINAHL, SPORTDiscus, the Cochrane Library, and digital dissertations via Ethos. The following keywords were used for the search: peripheral vascular/or arterial disease, exercise, supervised, supervised exercise programme or therapy, claudication, intermittent claudication, quality of life, ankle-brachial pressure index ABPI, diagnosis. The search was limited to the English language; no date limits were set. Cross-references supplemented electronic searches. From the search results, popular authors were noted and searched. Additional relevant material was identified through a review of the references and citations found within the articles discovered in the literature search.

Throughout the literature review, key studies were critiqued using the relevant Critical Appraisal Skills Programme (CASP) checklist. A CASP checklist is a tool that guides critical appraisal of a studies design. CASP checklists provide a systematic means to examine the validity, results, and relevance of research across different study types (CASP, 2023).

2.2 Definitions and *pathophysiology of PAD and IC .*

In its simplest definition, PAD is a buildup of plaque (atherosclerosis) within the inner wall of a blood vessel (Narula *et al*., 2020). PAD has a spectrum of symptoms; it can be asymptomatic, symptomatic, or atypical which can give present as burning or tingling symptoms (Narula *et al*., 2020). In its mildest form of symptom, PAD can present as pain when walking, known as IC (Yang *et al*., 2008). Hamburg and Creager (2017) reported IC to be present in only 10-20% of people with symptomatic PAD. IC occurs when the muscle's demand for oxygen to sustain the activity is unmet due to the arterial narrowing that limits blood flow increase (Morley *et al*., 2018). Although IC is a relatively benign level of PAD, McDermott *et al.* (2008) suggested IC has a profound impact on a person's QoL. The impact on people's QoL was supported by Treat-Jacobson and colleagues' (2002) grounded theory study, which identified seven significant themes through open-ended interviews of 38 participants, including limitation of physical, social, and role function in patients with PAD, and many participants, although not defined as quantifiable data, reported it directly impacting their ability to function in daily life. It is known that 20% of the IC population will progress to have worsening symptoms, and of these 5-10% will deteriorate to having CLI , which manifests as severe symptoms including night or rest pain and tissue loss placing their limb at risk of amputation (NICE, 2012).

The stages of atherosclerosis plaque development are complex and multifactorial. The process can be divided into six stages: intimal xanthomas/fatty streaks; fibroatheroma; thin cap fibroatheroma; plaque rupture; fibrous calcified plaque; and endothelial erosion (Fitridge, 2020). Throughout the six stages it has been recognised that an inflammatory response is fundamental in the progression of atherosclerotic lesions (Libby *et al.*, 2010). The atherosclerotic lesions rely on a dysfunctional endothelial lining expressing increased

levels of adhesive molecules in response to stimuli, whereas a usual lining would repel them from adherence (Libby *et al.,* 2010). Stimuli include hypercholesterolemia, smoking, diabetes, and hypertension (known risk factors for PAD associated with genetics and lifestyle factors) (Selvin and Erlinger, 2004). Chemokines (a protein acting as a key), create a passage for the molecules to pass into the intima (the innermost lining of an organ/blood vessel); once within the intima, the matured monocyte cells (macrophages) swell with lipids, causing damage to the arterial extracellular wall and form into foam cells, which accumulate. The process continues to collect waste products, including minerals (calcium), within the artery wall lining; as these increase in size, they obstruct the blood flow, inhibiting the delivery of oxygen and nutrients (Libby *et al.,* 2010).

Atherosclerotic plaques commonly develop near curves, or a bifurcation point in the arterial tree where blood flow turbulence occurs (Bentzon *et al.,* 2014). Commonly affected arteries include the iliac, femoral, and popliteal arteries. The location most frequently reported as being symptomatic from the buildup of atherosclerotic plaque are the calves (Schorr and Treat-Jacobson, 2013), however, the thighs and buttock regions may also be affected; particularly with proximal multilevel disease (NICE, 2022). The classification of the symptoms presented can be determined by the patient's clinical presentation of their symptoms and walking limitations (Norgren *et al.,* 2007).

2.3 Classification of PAD and IC

Fontaine *et al.* (1954) published a classification system for PAD that first emerged in 1952. The system classified PAD symptoms using numerical grading and staging, producing the first standardised method of classifying the clinical presentation of PAD in healthcare and research (Hardman *et al*., 2014). The so-called Fontaine classification became widely used

within the healthcare setting for its simple, easy-to-interpret method of classifying the severity and extent of PAD. Fontaine's *et al*. (1954) classification structure comprised 4-stage tier criteria based on the person's self-proclaimed pain-free walking distance (PFWD):

Stage I: asymptomatic PAD

Stage IIa: mild IC (PFWD >200 metres)

Stage IIb: moderate to severe IC (PFWD of 200 metres)

Stage III: ischaemic pain at rest

Stage IV: PAD with ulceration or gangrene.

Despite the simplicity of the Fontaine classification, making it easy to apply and interpret in clinical practice, it was recognised as being subjective owing to a lack of other diagnostic tests to support the degree of the disease being diagnosed (Hardman *et al.,* 2014). Rutherford (1997) built upon Fontaine *et al*.'s (1954) foundation staging criteria by including a further two categories specifically for defining CLI . For each stage he also added a clinical description and objective measures to ascertain a more precise definition of the level of disease (Rutherford *et al*., 1997). The objective criteria reduced the subjective limitations of relying on the patient's self-reported estimation of their PFWD as a stand-alone assessment. A patient's self-reported estimation, as used in Fontaine *et al*.'s (1954) measures, is enough to raise the suspicion of PAD, but not a reliable factor for categorisation (Norgren *et al.,* 2007). Rutherford *et al*. (1997) further strengthened his method by including physical measurements based on a 5-minute treadmill walk at 3.2 Km/hour on a 12% incline, ankle pressure, pulse volume recording trans-metatarsal and toe pressures. Rutherford's robust classifications are recognised and used widely to direct PAD patient management and for research purposes (Hardman *et al.,* 2014):

Grade 0/category 0 – Asymptomatic-no hemodynamically significant occlusive disease. Normal treadmill or reactive hyperemia test

Grade 0/category 1- mild IC. Completes treadmill exercise; ankle pressure after exercise >50mmHg but at least 20mmHg lower than resting value

Grade I/category 2- moderate IC. Between categories 1 and 3

Grade I/category 3- severe IC. Cannot complete standard treadmill exercise, and ankle pressure after exercise <50mmHg

Grade II/category 4- ischaemic rest pain. Resting ankle pressure <40mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording; toe pressure <30mmHg

Grade III/category 5- minor tissue loss-non healing ulcer, focal gangrene with diffuse pedal ischaemia. Resting ankle pressure <60mmHg, ankle or metatarsal pulse volume recording flat or barely pulsatile, toe pressure <40mmHg

Grade III/category 6- major tissue loss-extending above transmetatarsal level, functional foot no longer salvageable. Resting ankle pressure <60mmHg, ankle or metatarsal pulse volume recording flat or barely pulsatile, toe pressure <40mmHg.

In clinical practice, a patient's combined clinical history, including cardiovascular risk factors of hypercholesterolemia, smoking, diabetes, and hypertension, and a physical examination is undertaken. The physical examination is non-invasive, and there are various tests that can be carried out to confirm the diagnosis of PAD.

2.4 Detection and diagnosis of PAD and IC

Palpation of peripheral pulses is a common component of comprehensive peripheral arterial examinations. Although palpation is a useful method of examination for detecting some abnormalities, it can be less reliable for diagnosing PAD as the distal limb pulses can be

variable, resulting in an overestimation of the true prevalence of PAD (Norgren *et al*., 2007), thus should only be used to raise suspicion of PAD (Norganstig *et al*., 2023). In contrast, relying on self-reported symptoms alone can underestimate PAD diagnoses; hence, a reliable examination must be used in conjunction with the patient's presenting symptoms and risk factors to establish an accurate diagnosis (Norgren *et al*., 2007; NICE., 2023). The physical examination also visually checks the appearance of the integrity of the skin and pallor and identifies any areas of broken skin, changes to the visual appearance can be indicative of changes in the blood flow.

Norgren *et al*. (2007) suggest that ABPI is the most widely used and accurate noninvasive test to detect PAD. An ABPI measurement is a calculated ratio (Table 2.1) based on the highest systolic pressure of a patient's foot pulses, either the dorsalis pedis or posterior tibial pulse; this is the numerator, divided by the highest systolic pressure in either the right or left arm, the denominator (Norgren *et al*., 2007) (illustrated in Figure 2.1). Criqui *et al.* (2015) advocates that for the diagnosis of IC, the resting ABPI value has been shown to have a low sensitivity but a high specificity for an abnormal result. The Rotterdam study (Meijer *et al*., 1998), a population-based study with 7715 subjects , demonstrated sensitivity and specificity results for the use of ABPI in the diagnosis of IC. They reported of the 5,158 subjects without a confirmed diagnosis of PAD (ABPI of ≥0.9), 5125 (99.4%) subjects did not have IC symptoms, , and of the 1166 subjects confirmed as having PAD (ABPI of <0.9), 73 (6.3%) had IC symptoms. The findings from the Rotterdam study are referred to by a later study by Criqui *et al. (2015*) who found when using an ABPI as a diagnostic tool, asymptomatic PAD was several times more common in the population than people with IC. The validation of ABPI as a diagnostic tool in patients with IC symptoms was previously compared to angiography, finding the sensitivity and specificity of the ABPI to be between

97%-100%, although due to ethical reasons, these studies had limitations requiring them to use young participants, who the researchers presumed not to have artery disease to compare participants with confirmed PAD with angiography (Ouriel *et al*., 1982 and Yao *et al*., 1969).

Crawford *et al*. (2016) undertook a systematic review to estimate the diagnostic accuracy of the ABPI for the diagnosis of PAD in people who experience leg pain on walking that is alleviated by rest. The study obtained 746 full-text articles, only one study met the criteria. The included study by Vega (2011) compared the manual method of obtaining an ABPI with the automated oscillometric method in 85 patients. However, they did not report accuracy data at the participant level, meaning that Crawford *et al*. (2016) were unable to calculate estimates of sensitivity or specificity for individual patients. The main conclusion of the review of Vega's (2011) study by Crawford *et al (*2016) was the automated method of taking an ABPI may be more accurate when performed by individuals with no specialist training. Overall, there was little evidence of the value of using ABPI for the detection of patients with PAD with exertional leg pain.

Table 2.1 How should ABPI results be interpreted?

ABPI Ratio	Interpretation
Less than 0.5	Suggests chronic limb-threatening ischaemia
0.9 or less	Suggests the presence of arterial disease
Between 0.91 and 0.99	PAD may be present. Further investigation is necessary if there is any significant clinical suspicion
Between 1.0 and 1.4	Is considered normal
Greater than 1.4	May suggest the presence of arterial calcification. For values above 1.5 the vessels are likely incompressible.

(NICE,2024)

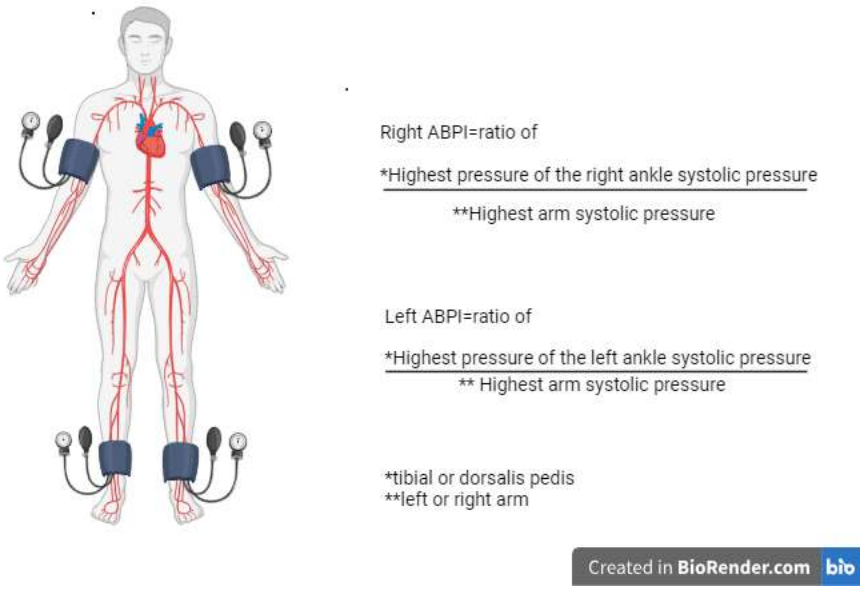

Figure 2.1 ABPI measurement: positioning of the blood pressure cuff

For diagnostic purposes, an ABPI reading should be repeated and recorded for each leg. The examination requires only a blood pressure cuff, a standard sphygmomanometer, and a digital handheld doppler. Historically, there have been many different techniques

used by healthcare professionals to measure an ABPI, including the patient's positioning, which pulse point to use, size, and position of the cuff, resulting in discrepancies, which have resulted in the production of test standardisation guidelines (Aboyans *et al*., 2012). Key points from these guidelines include positioning the patient in a supine position, ensuring sufficient resting time before the examination, in which NICE (2023) found no evidence to recommend a minimum rest period, only that it should be long enough for blood pressure to return to normal and to be practical in the running of clinics (e.g. 5-10 minutes), and using appropriately sized equipment. The cuff should be positioned above the malleolus on the leg with the Doppler probe held at a 45–60-degree angle to the skin's surface, and the method should be consistent (Aboyans *et al*., 2012) (illustrated in Figure 2.2) Notably, the potential influence of white coat syndrome should be considered when recording brachial pressure. This can be addressed by repeating the initial arm reading and calculating the average of the two measurements. However, if the first reading is more than 10 mmHg higher than the second, it should be disregarded to account for the effects of white coat syndrome (Aboyans *et al*., 2012). According to the recently revised guidance by NICE (2024), an ABPI reading of <0.9 is suggestive of the presence of arterial disease. These parameters reflect those of an earlier study by Norgren *et al*. (2007), who also defined the diagnosis of moderately large vessel disease (stenosis ≥50%) as being associated with an ABPI calculated result of ≤0.9 at rest. It is essential to acknowledge, however, that patients with chronic conditions such as diabetes may have incompressible vessels due to calcification, which can lead to falsely high ankle pressures and ABPI readings greater than 1.4. In such cases, alternative diagnostic methods would be needed to determine the diagnosis of PAD (NICE., 2024; Norgren *et al*., 2007). The greater adoption of tools such as ABPI to assess the

presence of PAD and the longer-living population has helped this chronic condition to be more commonly detected (Criqui *et al.*, 2015).

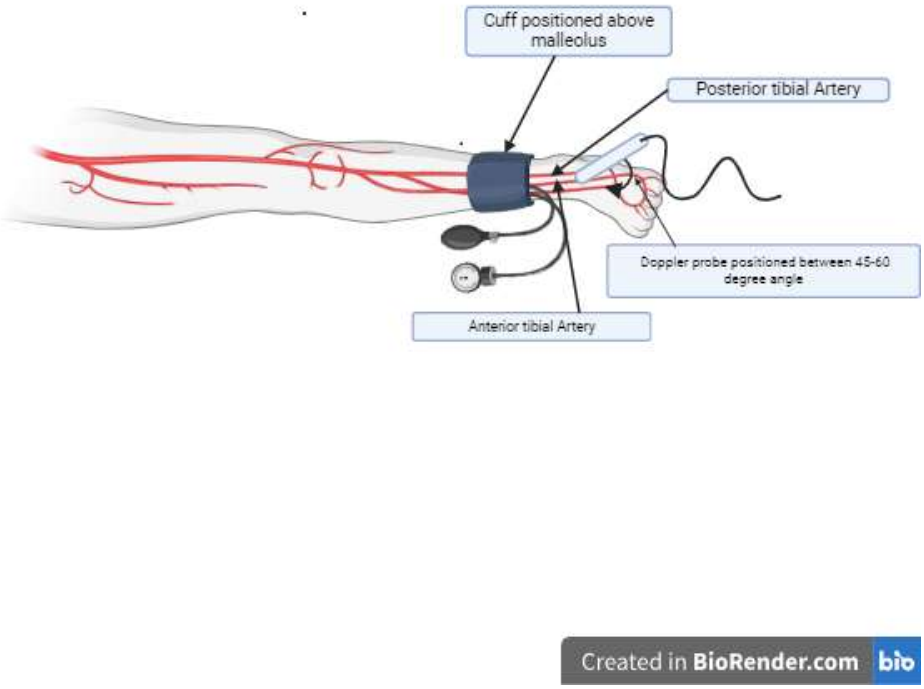

Figure 2.2 ABPI measurement: positioning of the doppler probe

2.5 Prevalence of PAD and IC

Historically, the prevalence of PAD has been underestimated and the condition has lacked research and public awareness despite it being the third most common manifestation of atherosclerosis disease, behind coronary artery disease and stroke (Song *et al*., 2019). PAD is a progressive, age-related, debilitating condition. The Global Burden of Disease study (2019) found PAD to affect around 1.52% of all ages ≥40 years globally, equivalent to 113 million people, with the highest prevalence figure of 20.7% in people between the age of 90-94

years old (Kim *et al.*, 2023). It is estimated that 13% of adults in the over-50 age group have PAD (Morley *et al*., 2018).

The low number of studies, especially in low-risk countries, has directly impacted on the accuracy of the diagnoses and reporting of the disease (Alzamora *et al*., 2010). The prevalence and incidence of PAD are estimated to be increasing by more than 10% among patients in their 60s and 70s (Criqui and Aboyans 2015). Crawford *et al.* (2016) suggested that symptomatic PAD affects about 5% of people in the Western world between the ages of 55 and 74 years. Many studies have reflected on the relationship between the ageing population and the increase in the prevalence of PAD (Golledge, 2022; Murabito *et al*., 2002.; Selvin and Erlinger, 2004). This relationship between age and the increased prevalence of PAD predominantly occurred in high-income countries (HICs). However, the relationship between age and increased prevalence has been more evident in both low and middle-income countries (LMICs) in recent years (Criqui and Aboyans, 2015). In addition, these findings often rely on other atherosclerosis disease research based in the western hemisphere, which has the same epidemiological transition (Fowkes *et al.,* 2017). Despite the general belief that men have an increased prevalence of PAD, in HICs the prevalence is slightly higher in females than males up to the age of 75, and no significant difference in prevalence between males and females in LMICs (Song *et al*., 2019). In contrast, among patients with IC, there has been research to suggest that men have a higher prevalence, but this is not consistent globally (Sigvant *et al*., 2007). Significantly in HICs, this correlates with an increase in age, as questionnaires undertaken in the USA and Europe concluded at 50 years old, <1% of men were found to have IC compared to men aged >65 years old at 6% (Norgren *et al.,* 2007). In addition to sex and age being identified factors in the prevalence of

IC, in PAD, it has been identified that men from LMIC have a much higher prevalence of risk factors for PAD (Golledge, 2022).

2.6 PAD and IC risk factors and comorbid conditions

There are many associated risk factors for PAD, and the development of PAD is multifactorial (Morley, 2018). Evidence suggests that over half of all PAD is attributed to smoking (Willigendael *et al*., 2004). People who smoke, when compared with those who do not smoke, are significantly more likely to develop PAD, at least doubling the risk (Criqui and Aboyans, 2015). The Edinburgh Artery Study (1991), a cross-sectional study of a sample size of 1500 people, aged between 55-74 years, found those who currently smoked versus non-smokers had up to four times the risk of developing asymptomatic PAD (Fowkes, 1991). Smoking can be modified without intervention, but smoking cessation is proven to be 50-60% more successful with nicotine replacement therapy and support (Hartmann-Boyce *et al.,* 2018).

Having diabetes results in a similar risk of developing PAD as smoking (Norgren *et al*., 2007). Diabetes mellitus is the risk factor with the highest complication rate and hospital admissions for treatment, especially for those with long-standing, poorly managed, raised blood glucose levels and insulin use (Criqui and Aboyans, 2015). Jude *et al*.'s (2001) comparative study of patients with PAD with diabetes (43%) or without diabetes, found that patients with diabetes were at a higher risk of limb loss (41.4 vs. 11.5%, odds ratio [OR] 5.4, $p < 0.0001$) and mortality (51.7 vs. 25.6%, OR 3.1, $p = 0.002$).

Other associated risk factors include hypertension and hypercholesterolemia (NICE, 2012). Hypertension has been associated with an increased risk of PAD across multiple studies (Newman *et al.,* 1993; Murabito *et al.,* 1997; Meijer *et al.,* 2000; Murabito *et al*.,

2002; Allison *et al.,* 2002). These studies found a significant link, with odds ratios ranging from 1.50 to 2.20; the lowest, 1.32 was reported in the Rotterdam Study (Meijer *et al*., 2000) which also adjusted for systolic blood pressure. The Rotterdam study by Meijer *et al.,* (2000) found that hypertension had an attribution fraction of 17%, while in the Framingham study by Murabito *et al.* (1997) and the Health Professionals Follow-up study by Joosten *et al*. (2012) it accounted for 30% and 41% of PAD risk, respectively. In all three latter studies hypertension was found to be the second most significant risk factor for PAD after smoking.

Criqui and Aboyans (2015) review found that the most studied lipid factor in relation to PAD is total cholesterol. They examined four key studies (Newman *et al.,* 1993; Murabito *et al.,* 1997; Meijer *et al.,* 2000; Murabito *et al.,* 2002) in the initial three of these studies, total cholesterol was significantly linked to PAD in multivariable analysis, in the fourth study although there was a link the analysis was simpler and was not as significant once other lipid measures were considered. Similar patterns were found by Criqui and Aboyans (2015) in other studies (Ingolfsson *et al.,* 1994; Bowlin *et al.,* 1994; Fowkes *et al*., 1992; Curb *et al*., 1996), total cholesterol is often associated with PAD, although its effect may weaken when other lipid factors are included in the analysis. According to the Health Professionals Follow up study by Joosten *et al.*, (2012) about 17% of PAD cases can be attributed to hypercholesterolemia.

Less considered risk factors include physical inactivity, alcohol, obesity, waist circumference, chronic kidney disease, ethnicity, and geographical locality, all found to contribute to an increased incidence of PAD and IC (Garg *et al*., 2009; Criqui *et al*., 2005; Golledge, 2022). People with PAD are found to be at a greater risk of a shorter life expectancy, and a significantly increased risk of cardio- and cerebrovascular morbidity and mortality than people without PAD (Golledge, 2022). A study by Nastasi (2021) reported

that over a 2.5-year follow-up period, patients with CLI experienced higher rates of myocardial infarction (MI) (13.4%), stroke (4.4%), and cardiovascular-related death (14.1%) compared to patients with IC, who demonstrated incidence rates of 7.8%, 3.1%, and 2.7%, respectively. Due to this, there is an emphasis on modifying the risk factors associated with PAD to reduce the population number developing PAD.

Physical activity has many known health benefits including improved sleep, maintaining a healthy weight, management of stress, and improved QoL. Physical activity is also proven to reduce the risk of developing several chronic health conditions, including cardiovascular disease by up to 35% (Department of Health and Social Care, 2019). It is recommended that adults and older people should aim for a weekly level of physical activity of at least 150 minutes (2 1/2 hours) of moderate-intensity activity (such as brisk walking or cycling), or 75 minutes of vigorous-intensity activity (such as running) (Department of Health, 2019). The Department of Health (2019) also recommends that strengthening activities to maintain or develop strength in the major muscle groups should be undertaken at least two days per week. However, people with IC fail to reach the lower threshold exercise limits to result in an improvement in their IC symptoms (McDermott *et al*., 2002).

It is not as profound as the subsequent risk factors, but it is important to acknowledge that there is an increased risk of PAD from genetic factors such as inherited thrombophilia, however, there is still little research into this link (Klarin *et al*., 2019). Risk factors left untreated may lead to a more significant burden on society with the association of other cardiovascular complications, including MI and stroke (Santoro *et al.*, 2018).

2.7 The burden of PAD and IC on patients and society

The lived experience and associated burden of PAD and IC for patients are greatly dependent on the severity of the disease. IC individuals are unlikely to progress to CLI, amputation, or death because of their diagnosis; it can be described as a lifelong debilitating condition that impacts their ability to function in their activities of daily living (ADL) (Leslie *et al.,* 2022). IC is associated with problems with pain, ambulation, and an increased risk of other cardiovascular health conditions, subjecting them to a deterioration in both physical and emotional well-being (Spronk *et al.,* 2007). Studies evaluating the impact of the burden that PAD and IC have on people's lives have mostly been conducted in Western countries (Fowkes *et al.,* 2017). 'Burden' is often measured in relation to an individual's QoL assessed using questionnaires or qualitative methods (Mays *et al.,* 2011).

A qualitative study by Treat-Jacobson *et al.'s* (2002) recruited participants from two major medical centres, allowing a broader geographical representative. However, the researchers deliberately selected the sample to include men and women and a wide range of PAD severity. They interviewed 38 individuals, and subsequent interviews were not included as no new information was contained (n=24 men; mean age 65 years). Participants reported seven significant themes, including: delay in diagnosis and frustration with the management of the disease; pain; limitation in physical functioning; limitation in social and role functioning; compromise of self; uncertainty and fear; and adaptation to the effects of the disease and demonstration of resiliency. Treat-Jacobson *et al.* (2002) concluded that existing QoL questionnaires failed to detect the significant range of debilitating effects of PAD, which may result in a failure to reveal changes in the disease severity or after an intervention, suggesting that an enhanced specific QoL tool would help measure PAD's effects more accurately, thus promoting more effective interventions and improving

outcomes for people with PAD. It is essential to acknowledge that the participants in Treat-Jacobson *et al*. (2002) study included a range of disease severity, CLI inclusive, which is not directly comparable to IC patients alone.

The interpretation from healthcare professionals of the impact of IC on an individual's QoL can be subjective and can impact the management and treatment offered (Pell *et al.,* 1995). Accurately assessing QoL is valuable when patients have indicated that they would trade life expectancy years for quality (Torrance, 1986). PAD and IC not only pose an individual burden, but they also have a significant impact on the NHS and the wider society, which are magnified globally through both HIC and LMIC.

The burden of PAD globally has an increased risk of cardiovascular incidents, with major amputation, and long-term health co-morbidities associated with it (Golledge, 2022), which inevitably leads to a burden on healthcare pressures worldwide with associated financial implications. The disability-adjusted life year measures population burden by calculating the years lost owing to premature death and years lived with a disability caused by PAD (Murray, 1994); IC accounted for most disability causes associated with PAD (Fowkes *et al.,* 2017). It is estimated that by 2045, there will likely be an increase of 30-50% of the population with PAD (Nordanstig *et al.,* 2023). The improvements in treatment for the associated complications and people living longer have placed an increasing demand on healthcare providers, such as the United Kingdom's (UK) NHS. The burden has also shifted to LMICs (that have little resources to manage and treat acute and chronic conditions) with greater increase rates of the disease compared to HICs (29% v 13%) between the years 2000 and 2010 with a continued upward trend (Song *et al*., 2019). This has mainly enforced the focus on preventing and managing PAD in LMIC, however, there is still a reliance on the

research from HIC to support this as there is a lack of published evidence available in LMIC areas (Fowkes *et al.,* 2017).

2.8 Management of IC

The management of IC has two main areas of focus: the secondary prevention of cardiovascular disease, and the reduction of symptoms. To reduce and prevent cardiovascular events, patients should continually be educated and provided with information about the associated risk factors, including quitting smoking, healthy eating, diabetes, hypertension, weight, exercise and medicines (Golledge, 2022). Two significant medical therapies in the secondary prevention of cardiovascular disease are statins (Mach *et al*., 2020) and anti-platelet agents (Committee, 1996). The Heart Protection Study (2002), a randomised placebo-controlled trial of 20,536 adults, found that people with a cholesterol level of over 3.5 mmol/l who took a statin daily had a reduction of 17.6% in subsequent cardiac events. A meta-analysis of 287 studies also found that anti-platelet therapy reduced cardiovascular events by 23% (Antithrombotic Trialists' Collaboration, 2002). Notably, the Caprie study (1996) found a statistically significant (p=0.043) relative-risk reduction of 8.7% in ischaemic events including stroke, MI or vascular death, in favour of Clopidogrel compared with aspirin as the anti-platelet agent. A more recent meta-analysis by Katsanos *et al*. (2015) demonstrated that six alternative antiplatelets were not superior to the benefits of Clopidogrel in the reduction of cardiovascular events; these findings agree with the previous recommendations by NICE (2012) on which clinical practice is based. Subsequently, the VOYAGER PAD study (Bonaca *et al*., 2020), a double-blind clinical trial, analysed the efficacy and safety of the use of rivaroxaban in patients who had undergone lower- extremity revascularisation. The primary efficacy outcome was a composite of acute

limb ischaemia, major limb amputation for vascular causes, MI, ischemic stroke, or death from cardiovascular causes. A total of 6564 patients were randomised in the VOYAGER PAD study (Bonaca *et al*., 2020) between two groups; rivaroxaban (2.5 mg twice daily) plus aspirin, or the placebo plus aspirin group. The VOYAGER PAD study (Bonaca *et al*., 2020) found that patients randomised to the rivaroxaban plus aspirin group were associated with significantly reduced incidence of major cardiovascular and limb events than those in the aspirin only group. The primary efficacy outcome occurred in 508 patients in the rivaroxaban group and 584 in the placebo group, with 3-year incidence rates of 17.3% and 19.9%, respectively (HR 0.85, 95% CI 0.76–0.96; P=0.009). The study's primary safety outcome was major bleeding according to the Thrombolysis in Myocardial Infarction classification; the International Society on Thrombosis and Haemostasis definition of major bleeding was the secondary safety outcome. The incident of major bleeding according to the primary safety outcome found no significant difference between the groups, the secondary safety outcome did find a significantly higher rate of major bleeding in the rivaroxaban group compared to the aspirin alone group.

Concomitantly, the second area of focus (reduction of symptoms) should be considered, with non-invasive intervention treatment options considered (NICE, 2012), this is discussed in the following sections.

2.8.1 Intervention (non-invasive and invasive) treatment aims for IC

The second focus is to treat the IC symptoms. Treatment of IC aims to improve the patient's walking, including maximum walking distance (MWD) and PFWD , improving overall health risks and positively impacting their QoL (Nordanstig *et al.,* 2023). Underpinning these aims, Norgren *et al.*'s (2007) earlier study voiced that the main aims of treatment for IC include:

- Improving symptoms, including pain;
- Improving walking performance, and;
- Improved daily functional ability.

2.8.2 The pathway of care for individuals with IC

According to NICE (2012), a SEP should be the first line of therapy for managing patients with IC (illustrated in Figure 2.3), involving 2 hours per week for 3 months; their recommendations include encouraging patients to walk to maximal pain and push through the pain threshold if possible. Evidence of early research into the conservative approach by Larsen and Larsen (1966) published in the Lancet, explored the effects of daily muscular exercise in patients with IC. This conservative management has continued to be studied and proven as a low-risk treatment for symptomatic PAD in helping improve walking ability (McDermott, 2018).

The offer of endovascular intervention, such as angioplasty and stenting, should only be considered following the completion of the hierarchy of processes (NICE, 2012). This includes risk factor modification reinforcement, unsatisfactory response to a SEP, and imaging confirmation that the endovascular option is suitable. A host of studies provide the foundation of the NICE (2012) recommendations. They compared the invasive endovascular intervention to supervised exercise, with the inclusion of the best medical therapy. The studies found that the invasive endovascular intervention, compared to supervised exercise, posed an increased risk of harm versus outcome benefit and was less cost-effective (Perkins *et al.,* 1996; Creasy *et al.,* 1990; Mazari *et al.,* 2010; Spronk *et al.,* 2009).

With the acceptance of severe lifestyle-limiting IC symptoms, surgical options, including bypass and grafting, should be avoided, and only considered as a revascularisation option if

the earlier methods have failed. Clinical trial data indicate that invasive procedures only have a short-term improvement in walking ability compared to conservative management, and they carry an increased risk to limb and life (Murphy *et al.,* 2012). A relevant study by Sorber *et al.* (2023) explored the association between early peripheral vascular interventions in people newly diagnosed with IC (≤6 months since diagnosis) and subsequent interventions. The study enrolled a total of 187,442 newly diagnosed patients with IC, among whom 6,069 (3.2%) underwent early peripheral vascular intervention. Over a median follow-up duration of 4.39 years, late peripheral intervention was performed in 22.5% of patients who had undergone early peripheral intervention, compared to 3.6% of those who had not (P<.001). An increase in subsequent interventions is not cost effective and would have an increased risk of harm to the patient.

A further consideration in the treatment of IC is the use of medication. A systematic review by Squires *et al*. (2011) assessed the effectiveness and cost- effectiveness of several vasodilators for the treatment of IC symptoms, compared to no vasoactive drugs; the review concluded there is evidence that drug treatment can improve walking distances when compared to a placebo; however, many are expensive, and the long-term effectiveness is uncertain. NICE guidance (2012) recommends that the use of medical management of IC with Naftidrofuryl, the cheapest vasodilator licensed for the treatment of IC in the UK, should be only considered once all other options have been explored (illustrated in figure 2.3) and should be reviewed at 3-6 months and discontinued if there has been no symptomatic benefit. It is the preferred vasodilator drug for treating IC.

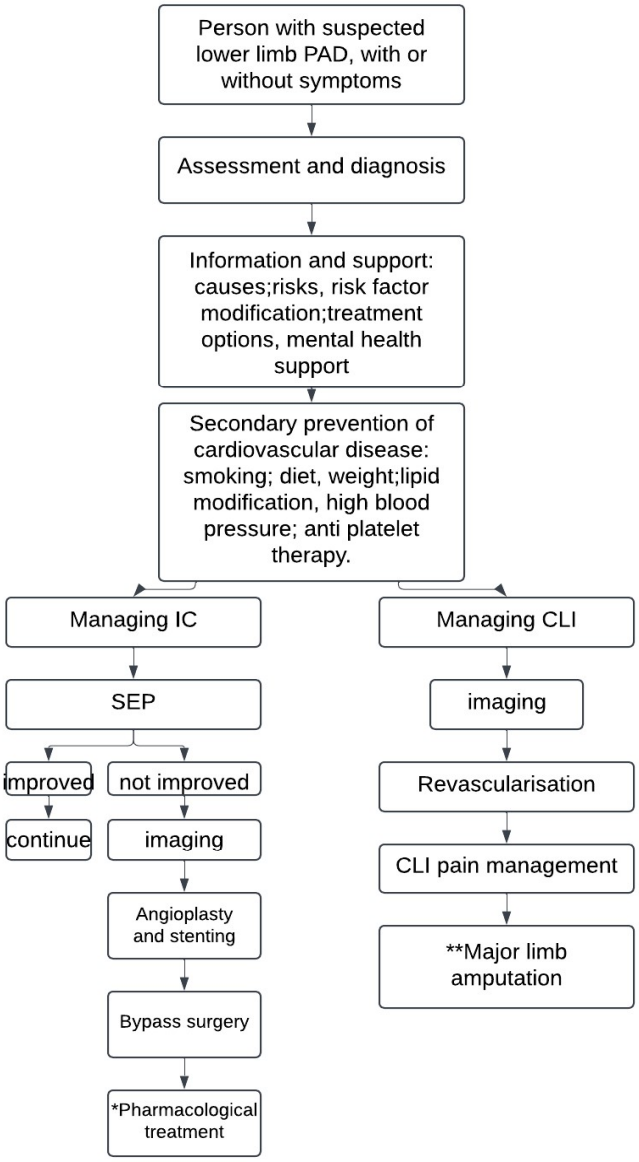

Figure 2.3 NICE (2012) PAD : diagnosis and management flow recommendations

2.8.3 Supervised exercise for IC

Physical exercise is proven to be efficacious for people with established cardiovascular disease (NICE, 2014) and can help improve symptoms for patients with IC (NICE,2012).

Exercise can be delivered in many alternative forms. For instance, exercise can be delivered as SEPs , home-based exercise therapy with an observational component, and walking advice alone which is commonly used (Bendermacher *et al.,* 2007). All methods of delivery have different levels of benefit across walking distance, QoL, and self-reported functional impairment outcomes. Hageman *et al.* (2018) conducted a systematic review of 21 randomised control trial (RCT) studies reviewing three main comparisons of exercise delivery across a range of outcomes: SEP versus home-based exercise therapy, SEP versus walking advice for IC, and home-based therapy versus walking advice. The primary outcome measure was maximum treadmill walking distance or time, and the secondary outcomes included: pain-free walking distance/time (PFWD/T), QoL, and self-reported functional impairment. The review is evidently valid; it is focused and contains relevant sourced papers from reliable databases; they covered potential data from unpublished work and searched all references from the relevant papers to ensure pertinent information wasn't overlooked. Hageman *et al.* (2018) tested the rigour of each RCT to identify any risk of bias; rating the studies as 'low', 'clear' or 'high' risk; this was taken into consideration in the categorising of the quality of the findings. Hageman *et al.* (2018) reported the findings of each of the three main comparisons at three intervals: 6 weeks, 12 weeks, and 6 months. The review concluded that overall SEP improved maximal and PFWD to a greater extent than home-based exercise, at 6 weeks the standardised mean difference (SMD) of 0.93 (95% confidence interval (CI) 0.15 to 1.70 p=0.02, low quality evidence in favour of SEP. At 12 weeks SMD was 0.37 (95% CI 0.12 to 0.62 p=0.004, moderate-quality evidence) and SMD at 6 months increased to 0.68 (95% CI 0.07 to 1.30 p=0.03, moderate-quality evidence). SEP compared to walking advice alone at 6 weeks had a SMD of 0.62 (95% CI 0.27 to 0.98; P=0.0006, moderate quality evidence) in favour of SEP. At 12 weeks, the SMD increased to 0.80 (95%

CI 0.53 to 1.07' P< 0.00001, high quality evidence) and at 6 months SMD remained stable at 0.75 (95% CI 0.44 to 1.05; P< 0.00001; high quality evidence) translating to a difference in favour of the SEP group of approximately 210 metres in increased MWD, maintained across all the time frames. However, in the secondary outcomes, the SEP had no greater effect than the home-based, but compared with the walking advice, it was found to have greater results across all the outcomes. Hageman *et al.'s* (2018) systematic review results are transferable and relevant to this feasibility study in how we approach the delivery of exercise to ensure the greatest outcome for the participants built on valid and reliable evidence.

There are several studies that have explored the role of exercise therapy in the routine management of IC, focusing on the perceptions, attitudes, perceived and practices of healthcare professionals and patients around exercise therapy for IC (Harwood *et al*., 2022; Makris *et al*., 2012; Shalhoub *et al*., 2009; Bartelink *et al*., 2005; Bartelink *et al*., 2004; Müller-Bühl *et al*., 2012; Kruidenier *et al.,* 2009; Lauret *et al*., 2012). Harwood *et al*. (2022) reported that in response to their most recent UK survey, 48% of vascular units reported having access to a SEP, which indicates a gradual increase over time considering results from previous surveys (24% in 2009, 36% in 2012, and 41.6% in 2017) (Shalhoub *et al.,* 2009; Makris *et al*., 2012; Harwood *et al.,* 2017), however the majority still did not have access to a SEP. This is reflected across Europe as it is indicated that less than one in three vascular surgeons reported having access to a SEP (Makris *et al*., 2012).

A study from the Netherlands by Lauret *et al.* (2012) found a positive attitude around the use of SEP for the treatment of IC. Lauret *et al*. (2012) reported that all the vascular surgeons that they surveyed agreed that SEPs should be part of the rehabilitation for IC, and that 97% believed that they should be used as the primary treatment if IC, agreeing that

they are more effective than walking advice alone. However, this attitude is not reflected in the number of eligible patients referred to SEPs in the UK, as 46% of UK surgeons reported referring less than 50% of eligible patients to the SEP (Shalhoub *et al*., 2009).

Furthermore, patient engagement and adherence to exercise therapy have been found to be low (Bartelink *et al.*, 2004; Harwood *et al.,* 2022; Muller-Buhl *et al.,* 2012; Shalhoub *et al*., 2009). A German study by Muller-Buhl *et al*. (2012) reported that 69% of the patients either declined the offer of an exercise programme or did not attend training.

This, if anything, strengthens the evidence for further research. There is a hesitance for healthcare professionals to refer into SEPs, patients to accept and adhere to SEPs, a healthcare system that is reluctant to fund and have access to SEPs despite the overwhelming evidence for the clinical and cost effectiveness of SEPs.

A questionnaire survey by Harwood *et al.* (2018) (the PREFER study) surveyed 30 patients with confirmed and stable IC, aimed to identify and incorporate patient preferences for exercise delivery (excluding anyone who couldn't understand written English or who did not have the capacity to understand the health-service evaluation). Harwood *et al.* (2018) used an online survey tool to collect and record the data ensuring that it was anonymised using unique and confidential participant identifiers. Although it was unclear to identify the relationship between the researcher and participant adequately, Harwood *et al.'s* (2018) results acknowledged a clear statement of findings that despite SEP being a proven method of improving overall walking, most patients in their study preferred home exercise (50%). Harwood *et al.* (2018) reported contributing factors to these findings were 'financial,' 'time,' and 'transport' concerns. These findings are important to consider in how exercise is delivered for IC patients, ensuring a patient-centred approach is taken. As strong as the

evidence is for SEPs, if the limitations prevent patients from participating, then the benefits will not be reaped.

In consolidation, SEPs are the most beneficial method to deliver exercise to improve walking distance for people with IC, and home-based exercise is the preferred delivery method by participants. The modality of exercise is not discussed, weighing up the considerations and impacts that different types of exercise may have on improving walking outcomes, this is examined in greater detail in the next section.

2.8.4 Exercise modality for SEP

The NICE (2012) guidance recommends that a SEP should involve 2 hours of supervised exercise per week for three months. The programme should encourage people with IC to exercise to the point of maximal pain. The guidance is not specific regarding the choice of exercise modality. A systematic review by Tew *et al.* (2016) to evaluate the completeness of intervention descriptions in 58 RCTs of SEP (reporting on 76 interventions) in people with PAD found that most studies (59%) used walking, making it the most tested and proven modality. Overall, all the studies reviewed by Tew *et al.* (2016) failed to describe their interventions sufficiently to be replicated.

A later Cochrane review including 32 RCTs, of which data for 10 of the studies were included in a meta-analysis, exposed participants to exercise, usual care, or a placebo as a treatment for IC, it showed that the exercise group compared to the non-exercise group had an overall improvement in the mean MWD (mean difference (MD) 120.36%, 95% CI 50.79 to 189.92, $p < 0.0007$) (Lane *et al.,* 2017). In the exercise group, however, the participants were involved in other modes of exercise, which incorporated strength training,

cycle ergometry, and pole striding, making it difficult to isolate the effects of walking exercise.

As alternative modes to walking, studies have compared the efficacy of arm-ergometry versus treadmill exercise (Treat-Jacobson *et al.,* 2009), cycling (Zwierska *et al*., 2005), resistance training (Parmenter *et al*., 2019), Nordic walking and strengthening (Kropielnicka, 2018) on the effects of walking distance for people with IC.

Treat-Jacobson *et al.* (2009) conducted a pilot RCT of 41 participants comparing the relative efficacy of arm ergometry, treadmill exercise, combination training (arm and treadmill) and usual care on measured outcomes including MWD and pain-free walking distance (PFWD). The study had some weaknesses. The assisting staff supervising the physicians in the exercise laboratory pre, and post-intervention tests were not blinded, however; to mitigate this, the testing was standardised to avoid deviation from the measured outcomes. Furthermore, the average age of the participants in both the combined group and usual care group were an average of 6-8 years older than those in the arm ergometry or treadmill group which may have put them at a disadvantage, although this along with the other documented baseline demographics were found to have no statistical difference. The pilot study reported the effects of the intervention comprehensively using P values, the Bonferroni test and ANCOVA tests were applied to reduce the risk of making statistical errors when making multiple comparisons, and to statistically equate the groups for one or more variables that may vary across the groups. After 12 weeks of intervention MWD was increased most in the treadmill group +69% (p=0.001), the arm-ergometry group improved by +53% (p=0.002), and the combined group by +68% (p=0.001) versus the usual care group. The study reported no significant difference between the interventional groups; however, the pilot acknowledges that the findings may

have clinical importance and could be statistically significant if the study were to be repeated on a larger population. The PFWD results found that the arm-ergometry group improved the most walking 82% further than their baseline tests, the treadmill group improved by 54% and the combined group by 60%, although the difference between groups were not significantly different from one another (p=1.0). In comparison, the usual control group only improved their PFWD by 1%.

Treat-Jacobson *et al.'s* (2009) study directs the choice of the modality of exercise to walking to offer to participants in this thesis's feasibility study to give the best possible improvements in MWD and PFWD. However, it is important to acknowledge that the 'dose' of intervention in the Treat-Jacobson *et al.* (2009) was higher (3 sessions per week) than the NICE (2012) guidance of 2 sessions per week, that this study will adopt. There may be greater benefits in the study outcome from Treat-Jacobson *et al.* (2009) compared to studies adopting the NICE (2012) guidance of two sessions per week due to several factors, including increased exposure to the stimulus, enhanced adaptation to the higher volume of physical activity, and consistency and habit formation. Having said this Treat-Jacobson *et al*. (2009) provided a valid, methodologically sound study to support an alternative mode of exercise to walking for those patients who are unable to sustain walking for any reason, such as unwillingness to walk, deconditioning or injury, that arm-ergometry could also be effective in improving walking capability for individuals with lifestyle limiting IC. They also touched upon the reasons that participants reported non-attendance, this strongly relates to this thesis's purpose in determining the feasibility of establishing a SEP, such as transport and scheduling of the programme.

A narrative review by Parmenter *et al*. (2019) examined different exercise modes, including resistance and circuit-based training. This review found a lack of high-quality

evidence to support these alternative modes of exercise (to walking) as primary interventions in the treatment of IC, advocating walking as the primary modality; however, emerging evidence supports the use of them in a complementary role (Parmenter *et al.,* 2019). This conclusion was supported by the systematic review by Jansen *et al.* (2020), who found no clear evidence between alternative exercise modes (including a greater range of alternative modes compared to Parmenter *et al*. (2019), such as Nordic walking, leg strengthening and cycling) and supervised walking exercise in improving the MWD and PFWD in patients with IC, however, the evidence was judged to be of low quality due to clinical inconsistency, small sample size and risk of bias.

Subsequently, Harwood *et al.* (2020) have published an overview of authors and organisational published guidance and recommendations for healthcare practitioners based on the relevant underpinning evidence. Overall Harwood *et al.* (2020) encapsulate the varying guidance, providing a clear and detailed guideline for the prescription and training for IC patients which can be interpreted worldwide.

To summarise, there are a range of exercise modalities that have been found to benefit people with other forms of cardiovascular disease and address some of the limitations of walking programmes, including deconditioning and unwillingness to walk (Hirsch *et al.,* 2006). However, the highest quality evidence in improving walking distance for people with IC are walking programmes (Jansen *et al.,* 2020). Despite the known benefits of SEPs, and national guidance recommendations by NICE, the number of vascular centres that report having access to an exercise programme would suggest that the use of SEP remains surprisingly under-utilised in clinical practice (Harwood *et al.,* 2018).

2.8.5 Implementation of a SEP

A survey conducted by Harwood *et al*. (2022) determined the provision of SEPs within vascular units in the UK, following the publication of the NICE (2012) diagnosis and management of PAD guidelines, stood at a mere 48% that had access to a SEP, compared to 24% before the guideline's publication (Shalhoub *et al*., 2009). Harwood *et al.'s* (2022) survey identified that the majority of the SEPs were hospital based (62%); the sessions were predominately group-based (73%), running one session per week (n=15; 50%), and lasted 12 weeks (n=15; 50%). The survey by Harwood *et al* (2022) also acknowledged that there is likely to be an underestimation of vascular hubs that offer a SEP due to the survey response figures and thus missing data especially in the Northeast of England. In an earlier survey undertaken by Harwood *et al.* (2017) it was reported that all the SEP home-based programmes (n=3) that were recorded in the survey failed to record commencement and compliance formally, and 'best guess' data was used for all data; the absence of accurate data invalidates the reported findings in this area of the survey. In the latest survey by Harwood *et al.* (2022), they found that most home-based programmes were managed through exercise booklets and pedometers. Harwood *et al*. (2022) survey highlighted many barriers to the implementation of SEPs including lack of funding, facilities and the lack of detail provided within the NICE guidelines despite the demonstration of cost-effectiveness being an integral part of the NICE (2012) guideline's recommendation for practice. Multiple other factors included poor patient compliance, lack of motivation from patients, and the unwillingness of senior staff to change practice, which may be challenging to overcome (Popplewell and Bradbury., 2014), were also reported barriers in the earlier Harwood *et al.* (2017) survey discussion. Harwood *et al.'*s (2022) later survey did address other mitigating circumstances that may lead to patient compliance and motivation, such as transportation,

time, work, and social needs. There remains a gap in the research around barriers and recommendations to overcome them in practice.

Pearson *et al.* (2020) conveyed that 'to improve the likelihood of impact, factors that may impede intervention should be considered' (P2). Bauer *et al*. (2015) suggested there is a failure to implement effective treatment in healthcare; this has been recognised as a priority internationally (Craig *et al.,* 2008., Eccles *et al*., 2009., Peters *et al*., 2013., Neta *et al*., 2015). Addressing uncertainties through pilot and feasibility studies can effectively integrate evidence-based intervention into practice (Pearson *et al*., 2020), allowing the opportunity to identify and refine potential barriers and limitations to deliver the intervention effectively (Eldridge *et al*., 2016). Pearson *et al*.'s (2020) guidance on conducting feasibility and pilot studies for implementing trials highlights several factors to explore, including adoption, fidelity, reach, sustainability, adaptability, feasibility, compactivity, complexity, context, culture, and self-efficacy.

2.9 Summary of the literature review

A broad overview of the literature review denotes that as the ageing population increases, the prevalence of PAD will continue to rise, and the associated risk of cardiovascular morbidity and mortality will follow, leading to a greater burden on society. IC, although perceived as a relatively benign level of arterial disease, is debilitating, impacting individuals' physical and mental health (Spronk *et al.,* 2007).

Exercise delivered in different modalities has been proven to improve the walking distance/time of individuals with IC (Parmenter *et al*., 2019) and is cost-effective with low risk of harm. This has led to published guidance advocating SEP as the first-line treatment for people with IC, but the guidance does not distinguish the modality. However, there is the

strongest evidence for walking (Jansen *et al.,* 2020). Despite this, nationally, there is a low uptake of the SEP by vascular centres. The justification for low uptake and the under-utilisation of established SEP are poorly evidenced.

2.9.1 Aims and objectives of the study

With consideration of the main findings in the literature review and the identified gaps in current research, this study aims:

To determine the feasibility of implementing a SEP for people with IC in York, England.

The study's objectives are:

a) To establish and deliver a SEP that meets the NICE (2012) guidance.
b) To measure and evaluate patient outcomes including: MWD/T, self-reported pain scores, QoL.
c) To identify and evaluate the barriers to service implementation and delivery during the different stages of the study including recruitment, assessment, delivery, and evaluation.

Chapter 3: Methods

In this chapter, an overview of this study will be presented, followed by a detailed step-by-step breakdown of the methods used. This includes a comprehensive discussion of key aspects such as ethics, participant eligibility criteria, recruitment and assessment procedures, the SEP, and the evaluation process. The structure of this chapter is designed to ensure clarity and transparency, facilitating the potential replication of the study. By outlining each methodological step in a systematic manner, this chapter provides the necessary framework to understand how the study was conducted and the rationale behind the chosen methods.

3.1 Overview of study

It is recognised that a mixed-method study, combining quantitative and qualitative methodology provides an overarching approach, fostering creativity and adaptability in research (Hesse-Biber and Johnson, 2013). This approach was adopted into the methodology of this feasibility study using quantitative data collection from the four stages of patients' participation (recruitment, pre-assessment, SEP delivery, exit assessment), with the addition of qualitative feedback using a questionnaire during the exit assessment of the study. The outset was to recruit patients to the SEP attending vascular clinics at one NHS site as part of their normal care. During recruitment data was collected and evaluated including referral numbers and patient demographics. Following recruitment data was collected over a 12-month timeframe from the pre and post assessments and intervention. After the 12-month timeframe the SEP continued as the normal pathway of care. Following recruitment, participants attended an entry assessment to record baseline measurements, including

stature, body mass, HRQoL scores, ABPI readings, and pain-free and maximum walking distances/times during an incremental treadmill test.

After completing the entry assessment participants were enrolled in a 12-week SEP (staggered start dates) with twice-weekly face-to-face sessions, with a maximum of 104 exercise sessions to be delivered across the 12-month evaluation period if sessions were held every week. However, due to holiday breaks (Christmas and Easter) and unforeseen building problems on one occasion, the total number of exercise sessions that were delivered and had data to collate from was 97. Each session included a 10-minute warm-up, followed by six-minute bouts of forced pace walking repeated five times with a two-minute passive rest between each bout. The session finished with a 10-minute period of bodyweight resistance exercises, static stretching and recovery. Data collected in each session included distance walked, and maximum pain scores that occurred in each bout of walking. Attendance and reasons for missed sessions were also recorded. If sessions were canceled by the facilitators, then these sessions were not included in the participants' attendance, sessions missed through participant cause were included in their attended session numbers.

After completing the exercise programme, participants were invited to return for an exit assessment. This repeated the structure of the initial assessment tests to provide comparative data. Additionally, at this stage, participants were asked to complete an evaluation questionnaire about the stages of the SEP. Similarly to the study by Matthews *et al.* (2016), this feasibility study asked the participants to self-report if their symptoms had improved, stayed the same, or become worse during their involvement; if the participant's symptoms were self-reported as 'worse' or 'the same', then they were given the

opportunity to discuss potential alternative treatment options with their named consultant. If their self-reported symptoms were 'improved' they were discharged to primary care.

3.2 Cost-effectiveness

Cost-effectiveness should be measured by the expected cost of an intervention or treatment compared to its health benefit rather than the overall cost or resource implications of their implementation, in essence, if there is evidence that an intervention offers substantial health benefits at a reasonable cost per patient treated, it should be endorsed even if its widespread implementation would be costly (NICE, 2009). Health benefits are commonly assessed using quality-adjusted life years (QALYs). A QALY represents a person's lifespan adjusted by the value assigned to their health-related quality of life (HRQoL) during that time (NICE, 2012). NICE (2012) guidance reported the calculated cost per patient to attend a SEP at £288, and although the cost of a SEP compared to unsupervised is greater, the health benefit outweighed the financial cost.

The York Health Economic Consortium (YHEC) was commissioned to produce a local cost calculator of treatment pathways for patients with PAD, particularly focusing on IC; this work was part of the overall service evaluation, but the outcomes will be reported elsewhere.

3.3 Ethical approval and governance

The study recruited participants diagnosed with IC who were under the care of York and Scarborough Teaching Hospitals NHS Foundation Trust. Data collection and storage of patient details were all carried out in accordance with local and national General Data Protection Regulations (GDPR) guidelines, to ensure patient safety and confidentiality. From

the Trust's perspective, the SEP project was considered a service evaluation, meaning ethical approval was not required from an NHS Research Ethics Committee. However, it was a requirement for the service evaluation to be registered within the Hospital Trust surgical care group, and this was actioned on 19th June 2023 (Appendix 2). Similarly Ethical approval was not required from York St John University perspective either, however it was sought and approved on 30th June 2023 by York St John University (Ethics reference: STHEC0072) (Appendix 1) after advice to provide some scrutiny. A Service Level Agreement was approved between The Hospital Trust and the University on 12th October 2023 (Appendix 3). A combined participant consent form to participate in the exercise programme, and to routinely collect data for service evaluation (Appendix 4) was completed for each participant and then scanned into the Hospital's electronic record system.

Initially, a written patient information leaflet (PIL) (Appendix 5) to be provided at the recruitment stage was approved by the PIL team in May 2023 prior to participant recruitment. A systematic review by Susteric *et al*. (2016) concluded that using PILs can enhance patients' understanding and contentment in both acute and chronic situations. Additionally, Susteric *et al*. (2016) highlighted that the effect on adherence to treatment of chronic conditions fluctuated based on the circumstances, the method of providing the PILs, and the invasiveness of the treatment. The findings from Susteric *et al.'s* (2016) study is pertinent to this feasibility study as it found that when effectively crafted and administered in a timely manner, PILs have the potential to enhance patients' understanding and satisfaction regardless of the medical scenario, and promote improved compliance with treatment, especially in the near future. Susteric *et al.* (2016) reviewed 24 studies, having a clear objective to propose recommendations and suggestions for improving the quality of PILs, how to use them, and methods to evaluate them. The review searched relevant health

databases and used a theoretical model as a robust method of data extraction rating the studies as either 'low' good' or 'high' quality.

The PILs team fast-tracked the approval due to the intended use within a feasibility study without ratification or Healthwatch input (a board of people who provide readability input of any proposed patient written information), as this could be implemented later. However, when the PILs team was later approached for permission for two related PILs to be produced: home exercise (Appendix 6) and exercise log (Appendix 7) in October 2023, ahead of the SEP start date, permission was denied. On this occasion, the team rejected the fast-track approval (November 2023) and requested that all PILs to be given to participants during the service moving forward were to undergo the full ratification process. All the PILs were submitted, presented, and ratified by the surgical governance team on 31st of January 2024 after several months of delay. Once approved by the governance team in January, the three PILs were returned to the PILs team to be presented to the Healthwatch team for review- this process was completed on the 3rd of April 2024. The recommended amendments made by the Healthwatch panel were implemented, and then the PILs were once again returned to the PILs team on 5th April 2024 for final approval. The PILs to support home exercise (Appendices 6 and 7) and the new version of Appendix 5 were withheld from participants until final approval was obtained on 23rd May 2024. The PILs were sent for print, with a turnaround of 2 months before the PILs were available to hand out. As initial approval was granted for the first PIL (Appendix 5) this PIL was provided throughout the duration of the study. The contents of the PILs are explained in more detail under the relevant subheadings, which also indicates when they were provided to the participants.

3.4 Participant recruitment

3.4.1 Inclusion criteria

Patients were included in this study based on:

1. Being under the care of York and Scarborough Teaching Hospital NHS Foundation Trust
2. Having attended a vascular clinic at York Hospital
3. Being ≥18 years old
4. Having a clinical diagnosis of IC due to PAD
5. Reporting that their ADL's were limited, with IC the main limiting factor
6. To walk independently without walking aids (except a stick for reassurance)

3.4.2 Exclusion criteria

Patients were excluded based on:

1. Patient unwilling or unable to participate
2. Unable to provide informed consent
3. Walking impairment for a reason that is not related to PAD
4. Asymptomatic patients (no symptoms of IC)
5. CLI
6. Major surgery within previous 3 months
7. Unstable cardiac disease
8. Evidence of coronary ischaemia during initial graded exercise test
9. Any other factors that may prevent safe exercise participation.

3.4.3 Sample size

The sample size for the feasibility study was determined by considering several factors:

1. Data collection timeframe: The study planned to collect and evaluate data over 12 months, from September 2023 to August 2024.
2. SEP duration: The duration of the SEP was 12 weeks.
3. Session manageability: It was agreed that 10 participants would be the maximum number per session, considering safety and manageability.

Based on these factors, the timeframe would accommodate 4 x complete 12-week SEPs, with a maximum of 10 participants enrolled in each SEP. Equating to a maximum sample size of 40 participants. According to Totton *et al.* (2023) the sample size for this feasibility study is consistent with typical sample sizes for pilot and feasibility studies conducted in the UK.

3.4.4 Participant selection

Participants for this study were recruited from York and Scarborough Teaching Hospitals NHS Foundation Trust. To identify potential participants, the outpatient vascular clinic records in the hospital's electronic Core Patient Database were manually screened. This process focused on reviewing new patient referrals to find individuals showing symptoms of IC for inclusion in the study. Referrals detailing information about the patient that did not meet the study's criteria were excluded at this stage and not considered. Once potentially eligible patients were identified, if available, the vascular specialist nurse practitioner (VSNP) would attend the clinic appointment in person, or if unable to attend in person, a written prompt was placed on the electronic clinic list to identify to the consultant that the patient may be suitable for the SEP.

If a patient was diagnosed with IC during the clinic appointment, the consultant or registrar determined the treatment pathway. Options included SEP, imaging, discharge with verbal advice (best medical therapy advice and walking advice to the primary care team), or a combination of treatments such as SEP with pending imaging. The outcome for each patient was recorded based on these variables. Vascular consultants could also refer suitable patients to the study from follow-up appointments by copying the VSNP into the clinic letter.

Patients who were offered the SEP, satisfied the eligibility criteria, and were seen in the clinic face-to-face by a vascular nurse specialist during their appointment, received verbal details of the SEP detailing the background of the study. Some patients at this stage declined the SEP, and their reasons were recorded, and the consultant was informed.

If the patients accepted the SEP, they were given written information about the SEP (Appendix 5). As recommended by Susteric *et al.'s* (2016) systematic review of effective PILs (discussed in section 3.3), written information provided at the recruitment stage of the feasibility study explained IC, why a SEP is offered, and what a SEP involves. In addition, the PIL provided details of the assessments and the SEP, including duration, time, location, and structure of the sessions. The PIL also incorporated a brief explanation of what to expect after the SEP. It featured advice on how the patient can help themselves (risk factor modification), including smoking cessation advice, and keeping active, as shown in an infographic (Tew *et al.,* 2018) (Appendix 6). A PIL sourced from the Circulation Foundation was also provided (Appendix 8) to help participants better understand IC and the alternative treatment approaches. If the patient stated that they currently smoke, they were provided with a separate stop smoking postcard with local contact details for free advice on stopping smoking. If the patient was happy with the information provided, they were given a consent

form (Appendix 4) to read, time to ask questions, and sign the consent if they agreed to the consent statements.

Patients referred by the consultant from follow-up appointments or new patient referrals (if the VSNP was not present in the clinic) for consideration to participate in the SEP were brought to the VSNP attention through being copied into the clinic letter, the patient was then contacted by telephone usually within 2 weeks of their appointment with the consultant. The same verbal discussion was held as if seen face to face in the clinic, and if they met the criteria and agreed to the SEP, then the same written information was sent via the post. The consent form was completed when they attended their entry assessment.

All patients who initially agreed to attend the SEP were placed on an electronic waiting list. At this stage, participants were allocated a participant number to anonymise their data. Data from recruitment recorded various outcomes, including:

- Number of clinics attended in person/reviewed retrospectively by the VSNP
- Name of consultant clinic the patient attended
- Number of patients from the new patient referrals with potential IC symptoms diagnosed with IC
- Number of patients identified as having IC offered the SEP as first-line treatment
- Reasons for the patient declining the offer of SEP (if offered)
- Alternative investigation/treatment offered
- Other relevant notes

Demographic data collected at recruitment included:

- Age
- Ethnicity
- Sex Employment (based on the following categories: employed, unemployed, retired, not stated).
- Locality (postcode and region)
- Deprivation score (calculated using an online tool, decile range one to ten, one represents the most deprived area, ten represents the least deprived (area) (GB Postcode Deprivation Finder, 2021).

All participants were later contacted by telephone and vetted to ascertain that they still met the study criteria and to arrange their entry assessment appointment. The assessment appointment was recorded on a Hospital Trust clinic template, and a formal appointment letter was sent with directions and parking information attached. The clinic template was formatted as part of the service evaluation. It provided a professional and official record for the participant, which also linked to the NHS alert system for a text reminder of their appointment. A clinic template also provided a record of attendees and outcomes to the SEP in preparation to present to the Trust for a business case to continue the SEP as usual care at a later date.

3.4.5 Medical examination and history

Participants attended a standard consultant appointment with a duration of between 10-15 minutes. During their consultation, all participants underwent a medical examination, including a detailed medical/surgical history identifying any associated risk factors of PAD and a medication history. Some patients had previously undergone investigations and/or

interventions for PAD, including Magnetic Resonance Angiography (MRA) and/or invasive angiography. Mazzolai *et al.* (2024) promote accurately identifying cardiovascular risk factors during the initial assessment to improve preventative measures and reach preventive goals before starting exercise training rehabilitation.

In contrast to the evidence discussed in section 2.4, the preferred method of physical examination observed in clinical practice was the palpation of pulses to support the diagnosis of IC. ABPI's were not routinely performed as part of the examination within the consultant clinics. On the occasions when ABPIs were observed, there was no standard practice followed; commonly, the patient did not lay supine for any length of time prior to the procedure and the position of the cuff was variable. However, during the entry and exit assessments of this study the ABPIs were performed under standardized conditions, this is explained in greater depth in section 3.5.4.

3.5 Assessments

Assessments were conducted at the York St John University campus in a clinical research room. There was allocated free parking on site, requiring pre-submission of the participant's car registration plate to avoid parking charges. The distance from the parking area to the clinic room was approximately 150metres. The order and method in which the assessments were performed were standardised. Mazzolai *et al*. (2024) actively encourage reproducible conditions; they also acknowledge that if a treadmill is used as part of an assessment, patients should be given the opportunity to familiarise themselves with the equipment. To address this, the participants were allowed to walk on the treadmill before the assessment commenced to experience the pace and feel the initial gradient they would undergo later during the treadmill test. The recording of the data during the assessments was inputted

directly into a prewritten Google form using only the participant's research number to maintain confidentiality.

3.5.1 Stature and body mass

The first measures recorded during the assessment were stature and body mass. Participants removed shoes and any heavy clothing or items from their pockets before these were recorded. Stature was taken using a free-standing stature measure device (make: Seca, model: 217), recorded in centimetres rounded to the nearest 1 decimal place, then the participant's mass was taken in kilograms (Kg) using digital floor scales (make: Seca, model: 877 class III). The participant's body mass index (BMI, in Kg/m^2) (body mass-to-height ratio tool) was then auto-calculated using the formula- body mass in Kg divided by statue in m squared by the Google form. A high or low BMI ratio is a modifiable health risk factor (Department of Health, 2022). The importance of calculating, interpreting, and investigating the underlying cause of a person's raised BMI in healthcare is advocated by the Department of Health and Social Care (2022), who highlight the associated development of obesity-related health conditions such as type 2 diabetes, stroke, ischaemic heart disease, and mental health-related issues. A systematic review by Cronin *et al*. (2013) found that obesity was an independent risk factor for people with PAD who experienced a cardiovascular event. Furthermore, evidence suggests that the association between obesity (people with a raised BMI) and PAD is found to be markedly stronger amongst women although the reasons for this are unclear (Heffron *et al*., 2020).

3.5.2 Relevant medical history

The VSNP confirmed details about the participants' IC symptoms including the affected limb/s, duration of symptoms, and self-reported PFWD . The participants' smoking status was also recorded, and if applicable, current cigarette consumption or years since cessation if they were an ex-smoker. Co-morbidities, including associated risk factors (hypertension, diabetes, hyperlipidemia, MI , stroke) and current medication taken, including hypertensive, antiplatelet, and statins medications, were also recorded.

3.5.3 HR-QoL questionnaires

To ascertain the response to exercise training on a participant, an assessment of QoL should be incorporated at the beginning and end of the intervention, providing a holistic approach to functional status (Mazzolai, 2024). Participants were asked to self-interpret and independently complete two HR-QoL questionnaires- the VascuQoL-6 and the EQ-5D-5L on an electronic device to capture the outcomes related to both a PAD-specific perspective and a generic health perspective, retrospectively. As this decision alludes, there are different types of HR-QoL questionnaires used within PAD, generic and disease-specific, with a lack of standardisation and little consensus on which is more reliable in interpreting QoL (Broadbent *et al.,* 2017); considering this the decision was made to incorporate both types of questionnaires within the feasibility study. The VascuQoL-6 is a disease-specific questionnaire for patients with PAD (Appendix 10), and the EQ-5D-5L is a generic questionnaire (Appendix 11). Permission to use the VascuQoL-6 was requested, but no response was received; the email request is included in Appendix 9. Permission to use the EQ-5D-5L in digital form is included in Appendix 11. Self-reported functional impairment and QoL assessment are subjective; however, it's recognised that to measure the impact of

health-related issues, there needs to be an objective method of measuring QoL for patients with IC (Pell *et al.,* 1995). The HR-QoL questionnaires are formatted to have a numerical rating attached to the responses, allowing a score to be calculated based on the participant's response, thus allowing a comparative measure.

The VascuQoL-6, a shortened version of the VasculQoL-25 disease-specific questionnaire was designed to alleviate the reluctance to complete long questionnaires (Larsen *et al.,* 2017). The revised VascuQoL-6 questionnaire by Nordanstig *et al.* (2014) comprises of 6 questions, each with 4 answer options scored 1-4; the total score is achieved by adding the total value of each question (scoring between 6-24); higher values indicate better health status. Larsen *et al.* (2017) studied 171 participants (86% IC, 14% CLI) and compared the VasculQoL-6 questionnaire to the Short Form-36 and clinical measures as anchors. Larsen *et al.'s* (2017) study concluded that the VascuQoL-6 is a reliable and valid tool for assessing QoL in PAD patients. A further anchor-based study by Hageman *et al*. (2022) used the VascuQoL-6 questionnaire on 124 patients with IC prior to, and after attending a 12-week SEP, their VascuQoL-6 scores increased from 16.3 ±4.4 to 18.7 ± 3.8, resulting in 32%-41% of the patients achieving a clinically meaningful improvement in HR-QoL using the VascuQoL-6 questionnaire ($p<.001$). The minimal importance difference (MID) ranged from +2.0 to +3.8, and substantial clinical benefit ranged between +3.7 to 5.0 points, giving a benchmark for a successful SEP.

The EQ-5D-5L is a generic QoL questionnaire designed to measure health status across five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain has five levels, each level having a corresponding value attached: no problems (1), slight problems (2), moderate problems (3), severe problems (4) and extreme problems (5). The five numbers are then combined into a five-digit number

that can be used to summarise the participant's health state, for example, 11234 (EuroQol, 2019). Additionally, the 5-digit health state figure can be converted into a single utility index value using a formula that attaches weight to each value given for the domain level. The utility index is calculated by deducting the appropriate weights from 1, the value for full health. The calculated single-digit figure reflects how good or bad a health state is according to the preference of the general population of a specific country/region (EuroQol, 2019). A mapping method devised by Van Hout *et al.* (2012), referred to as the 'crosswalk' approach, enabled 5Q-5D-5L value sets to be obtained using the available existing values from the EQ-5D-3L. The utility index scores for this feasibility study are based on the crosswalk model values, the UK scores range between -0.594 and +1.0 (higher scores representing better health status) (Van Hout *et al.,* 2012). The EQ-5D-5L questionnaire also incorporates a visual analogue scale (VAS) to measure the participant's self-rated health. The scale uses a Likert numerical scale between 0-100 (0 representing 'worst health' and 100 representing 'best health'). The EQ-5D-5L questionnaire has been developed to replace the original EQ-5D questionnaire to address the ceiling effects of the first version, which proved to have issues in measuring small changes in health (Herdman *et al.,* 2011). De Vries *et al.* (2005) study reported that before the changes to the EQ-5D questionnaire, it was compared along with another generic QoL questionnaire to the VascuQoL-25. De Vries *et al.* (2005) concluded that although both types of questionnaires could detect severe from mild disease at the baseline equally, the disease-specific questionnaire was better at discriminating between a large versus a small change in disease severity at the point of follow-up. However, using a VAS scale can make it easier for older people to interpret, and aid in determining the degree of disability caused by their IC symptoms (Peräkylä *et al*., 2008).

Further reinforcement for the informed selection of both the VascuQoL-6 and EQ-5D-5L HR-QoL questions in this feasibility is evidenced by Rymer *et al.'s* (2021) review of Patient-Reported Outcome Measures (PROMs). Rymer *et al*. (2021) reviewed twenty-four PROMs used within 157 studies along a continuum of validation within the classic test theory framework, based on whether they met specific criteria for (1) content validity, (2) psychometric validation, and (3) further expansion of the evidence base for validation, in people with PAD without CLI. The review identified that both the VascuQoL-6 and EQ-5D-5L questionnaires were among the top five PROMs to have the most extensive evidence of validation in this population of people.

3.5.4 ABPI

The participant's ABPI measurements were recorded in both limbs following the measurement guidance discussed in section 2.4. The doppler used in the feasibility study was a Huntleigh DMX digital doppler. For those participants who trialed the treadmill, this was performed soon after arrival at the assessment, the participant completed the other assessments including QoL questionnaires, statue and body mass measurements to allow for the participants blood pressure to return to normal (between 15-20 minutes). Before the ABPI examination all participants rested in the supine position for between 5-10 minutes to allow for the blood pressure in the brachial and lower limb system to equalise (NICE, 2012) as discussed in section 2.4. Measuring ABPI in participants with known media calcinosis (calcification) is likely impossible due to the hardening of the arteries, resulting in incompressible vessels and inaccurate results (Aboyans *et al*., 2017). As per NICE guidance (2023), the participant's ABPI was recorded as incompressible if the ABPI reading was > 1.5. It was also recorded if the procedure was abandoned if the participant reported it to be too

painful to continue. The mean entry ABPI results are determined using the lowest calculated reading from both legs of each participant. This approach minimised potential data distortion by excluding results from asymptomatic limbs with normal ABPI values of those participants with unilateral symptoms.

3.5.5 Graded Treadmill Test

ABPI diagnostics alone are a poor predictor of walking performance in patients with PAD (Szuba *et al*., 2006). Therefore, a graded treadmill test based on the Treat-Jacobson *et al.* (2009) protocol was used to measure exercise performance and functional ability of the participants objectively. To minimise measurement error, the participants were given an opportunity to familiarise themselves with treadmill walking before the start of the assessment, as many older adults may not have experience using a treadmill. Treat-Jacobson *et al.* (2009) protocol was designed specifically to assess IC symptoms. The protocol measures PFWD, MWD, and corresponding times.

The protocol followed 3-minute progression stages, starting at a speed of 2 mph and a 0% gradient; the gradient increased by 3.5% every three-minute interval until a maximum of 10.5%; then the speed increased by 0.5 mph for the remaining intervals (Treat-Jacobson *et al*., 2009). A maximum time of 21 minutes of walking was used. Participants were stopped if they could not progress to the increased walking increment, and that distance and time were recorded as their MWT and MWD. If a participant was unable to start the treadmill test in the entry assessment at the required minimum pace the pace was reduced, this was then replicated at the exit assessment. Any participant's treadmill test that was adjusted was not included in the result analyses and will be mentioned in the results and discussion summary.

Participants were asked to only lightly hold the grab rails for balance, which were positioned both laterally and adjacent to participants on the treadmill. During the graded treadmill test, the participants were asked to verbally indicate when they started to experience the onset of IC pain, and when they had reached their maximum walking distance/time (MWD/T). At these points and at every 3-minute interval reached, they were asked to score the pain using a simplified IC pain scale, a visual copy was displayed for reference in the assessment, see below:

0- No pain,

1- Mild pain, very tolerable,

2- Moderate pain, bothersome but tolerable,

3- Intense pain, barely tolerable,

4- Unbearable pain cannot continue.

(Liguori *et al.,* 2021; and Treat-Jacobson *et al.,* 2011).

Participants were questioned at the end of the test to ensure that halting the test was solely attributed to intolerable IC pain, rather than other co-morbidities like breathlessness or joint pain unrelated to their IC symptoms. Instances where the cessation was due to alternative causes were noted in the outcomes.

At the end of the entry assessment, participants were provided with written directions and times of the SEP and information such as parking. A start date was agreed which aimed to be within a week of their assessment unless there were exceptional circumstances. A standard letter was sent electronically to their General Practitioner (GP) and recorded on their electronic hospital records.

3.6 SEP

The SEP was conducted at York St John University's Haxby Road Sports Park, situated near the York Hospital (approximately 1 mile by road). The facility had ample free parking and was on a main bus route from the city centre. The car park had active automatic number plate recognition onsite, requiring the participants to log their car registration plates on arrival to avoid being issued a parking fine. The closest bus stop was less than 100m away.

The sports hall was spacious, and the basic equipment required, including chairs and cones, was readily available. A television screen to play music during the sessions was also available. York St John University also supplied the hand counters needed for documenting distance walked during each walking interval.

Following the guidance outlined by NICE (2012) for individuals with IC, the programme provided two hours of supervised exercise per week over a twelve-week duration. The sessions were initially scheduled on Tuesdays from 2.30pm until 3.30pm, and Thursdays from 8.45am until 9.45am. The days chosen for the SEP were determined due to several factors. Firstly, to avoid missed sessions associated with bank holidays Mondays and Fridays were purposefully avoided, the two days were split to allow for a rest day, and finally, the availability of the venue. The timing of the sessions was due to the availability of the venue. The sessions were conducted in groups, accommodating up to ten participants of either sex on a rolling basis. Data was recorded each session for class utilisation, the reason for absence and for leaving the programme early. The chosen mode of exercise is detailed in the following section.

Guided by the evidence explored within the literature review, the main mode of exercise delivered in the SEP was walking; this is in line with current PAD management

guidelines, which recommend walking as the preferred exercise modality (Hirsch *et al*., 2006; Norgren *et al*., 2007).

3.6.1 SEP- interval-based walking

As concluded by the outcomes of Tew *et al.'s* (2016) systematic review and Treat-Jacobson's (2009) pilot study discussed under the earlier heading 'exercise modality for SEP', walking-based exercise is the modality found to have the strongest level of evidence to improve outcomes for patients with IC. Historically, the most utilised mode of walking exercise has been treadmill walking within a hospital setting (Regensteiner and Hiatt, 1995).

The service adopted an interval-based walking approach, involving five intervals of 6-minutes' duration. Previous interval walking protocols have used intervals of between three-and ten-minutes' duration. Overground walking had to be done due to a lack of treadmills, but this has advantages of being similar and more natural form of walking.

During each walking interval, participants were instructed to walk back and forth over a marked 30-metre length, which was marked out in the sports hall. The participants were encouraged to perform as many lengths as possible during the 6-minute timeframe to achieve the greatest distance possible, being able to rest if required, but the clock continued to run. Participants were able to talk to each other, music was played, and the exercise instructor gave occasional non-standardised instructions and motivational phrases for example, 'try to walk through the pain as much as tolerated'. At the end of each interval the participant's maximum pain score for 6-minute period was recorded using the same pain scale used in the graded treadmill assessment (see heading 3.5.5). The participants used a handheld counter to record the total number of 30m lengths completed within the 6-minute timeframe. If the patient failed to complete the total 30m length in the 6-minute time, that

length was not included. This process was repeated five times with a two-minute rest between walking (i.e. 30 minutes of walking accumulated in total).

3.6.2. SEP warm up/cool down

A pre-exercise warm-up is crucial to prevent health complications; a warm-up ensures that the cardiac system can adequately meet the demands of physical exertion; it does this by promoting sufficient blood flow to prepare key organs optimally for the controlled stresses of a productive exercise session (Association of Chartered Physiotherapists in Cardiac Rehabilitation (ACPICR)., 2023). The ACPICR (2023) recommends that a warm-up should last for 15 minutes, mobilising joints and warming-up large muscle groups. Due to time restrictions and the nature of the main exercise component (i.e., walking), a 10-minute warm-up was adopted at the start of each SEP session, and a 10-minute cool-down was conducted at the end of the session. Given that a significant number of PAD patients show signs of cardiovascular disease, placing them at a heightened risk of experiencing additional cardiovascular events such as stroke and MI, one of the main aims of PAD care is the secondary prevention of these life-threatening outcomes (NICE, 2012). On the background of the strong evidence between PAD and secondary cardiovascular disease, both the warm-up and cool-down protocols of the SEP were modeled on the cardiac rehabilitation practices outlined below. In addition to cardiovascular, the warm-up incorporates strengthening, flexibility, balance, and coordination exercises to produce a training effect to prepare for the duration, intensity, and mode of the exercise (ACPICR,2023).

Research has shown that implementing a gradual cooldown component can decrease the occurrence of complications such as hypothermia and ischaemia, it should mirror the warm-up in most aspects, with the goal of gradually bringing the

cardiorespiratory system back down to nearly resting levels within a timeframe of 10-15 minutes (American College of Sports Medicine, 2014; Fletcher, 2001; Pina, 2003; and Vincent, 2003).

Harwood *et al.* (2020) highlight the growing evidence supporting the benefits of progressive resistance training, emphasising that patients should be encouraged to incorporate strength-based exercises alongside a walking programme. In line with this evidence, a home-based exercise supplement (Appendix 6) was created that integrates strengthening exercises, cardiovascular training, and active recovery. The exercises include standing dead bugs, wall press-ups, lunges, sit-to-stands, standing calf raises, bent-over rows, shoulder presses, standard step-ups, and seated lateral raises. Participants were advised to complete 30 minutes of these exercises at least twice per week. They were instructed to select up to eight of the recommended exercises, perform each one for 20 seconds followed by a 10-second rest, and repeat each exercise eight times. To ensure proper technique, these exercises were demonstrated during the warm-up and cool-down components of the SEP sessions. This approach is designed to help participants integrate strength training into their routines safely and effectively.

3.7 Participant experience feedback

All participants who attended the exit assessment were asked to complete an experience feedback form of the SEP. Those who did not finish the SEP but attended at least one session were attempted to be contacted retrospectively to complete the form. The experience feedback form, recorded electronically, included questions about whether their GP had contacted them since starting the SEP and a self-report on whether their IC symptoms had ‘improved,’ ‘stayed the same,’ or ‘worsened.’ Participants were asked to rate

each stage of the SEP (recruitment, assessment, exercise sessions, home exercise advice, and overall) using the adjectives ‘excellent,’ ‘good,’ ‘fair,’ ‘poor,’ or ‘very poor’, they were given an opportunity to expand on the rating given in their own words to support the rating. They were also asked if they would recommend the SEP to others with IC. Additionally, participants could suggest improvements or provide further comments, and those who did not complete the SEP were asked for their reasons for leaving.

3.8 Analysis method

This feasibility study employed a descriptive analysis approach to identify trends, relationships, and characteristics within the specific population. Methods included calculating means, standard deviations (SD), percentages, and CIs using Excel software to compare entry and exit results. A summary was conducted for the qualitative feedback to identify overarching themes and patterns.

Chapter 4: Results

4.1 Patient recruitment and flow through the SEP

Figure 4.1 shows patient recruitment and flow throughout the study. Recruitment data collection ran over a 12-month timeframe, between June 1st, 2023, and May 31st, 2024. During this time a total of 181 patient referrals with IC symptoms were accepted and appointed to a York vascular clinic. The most common route of referral was via the GP referrals (n=169). Of these referrals, the majority were vetted as 'new patient routine' (n=154); the rest were vetted as 'urgent' (n=15). The remaining appointments were follow-up patients (n=11) and a VSNP referral (n=1).

Of the total number of referrals (n=181), 72 patients (40%) received an alternative diagnosis and were ineligible for the service; the remaining 109 patients received a diagnosis of IC. Of these 109 patients, 44 (40%) were not offered the SEP as a treatment option. The recorded outcomes for the patients not offered the SEP were cross-sectional imaging (n=20), discharge with verbal advice (n=23), and podiatry (n=1).

Of the 65 patients offered the SEP, 25 (38%) declined. The most common reason for declining the SEP was transport (n=9), followed by distance (n=6), work (n=4), cross-sectional imaging (n=3), alternative treatment (n=2), and inability to contact (n=1). The most frequent outcome for the patients who declined the SEP was discharge with verbal advice (n=14), followed by cross-sectional imaging (n=9), Naftidrofuryl (n=1), and surgery (n=1).

Of the 40 patients who accepted the SEP, 8 withdrew before attending the entry assessment. Reasons given for withdrawal included, postponing (n=3), transport (n=2), availability (n=1), inability to contact (n=1), and death (n=1). Outcomes for these patients were postponed SEP (n=3), discharged (n=3), returned to a pre-arranged consultant clinic

(n=1), and referred to a consultant clinic (n=1). A total of 32 patients completed an entry assessment, three of which withdrew before starting the SEP sessions due to personal health (n=1), injury (n=1) and transport (n=1).

Twenty-nine patients attended at least one SEP session. However, there was a 17% (n=5) dropout rate, leaving a total of 24 patients who completed the programme. Of the 24 completers, a couple did not complete the exit assessment (n=2) due to being lost to follow-up (n=1) and physical health (n=1).

Thirteen of the of the 22 completers 59% reported an improvement in their IC symptoms. Among these, 10 patients were discharged, while 3 opted to consult with their named consultant again. Seven patients (31.8%) reported no change in their symptoms; of these, 5 requested a follow-up with their named consultant, and 2 were discharged. The remaining 2 patients (9%) reported a worsening of symptoms compared to their condition prior to starting the SEP, and both sought further consultation with their named consultant.

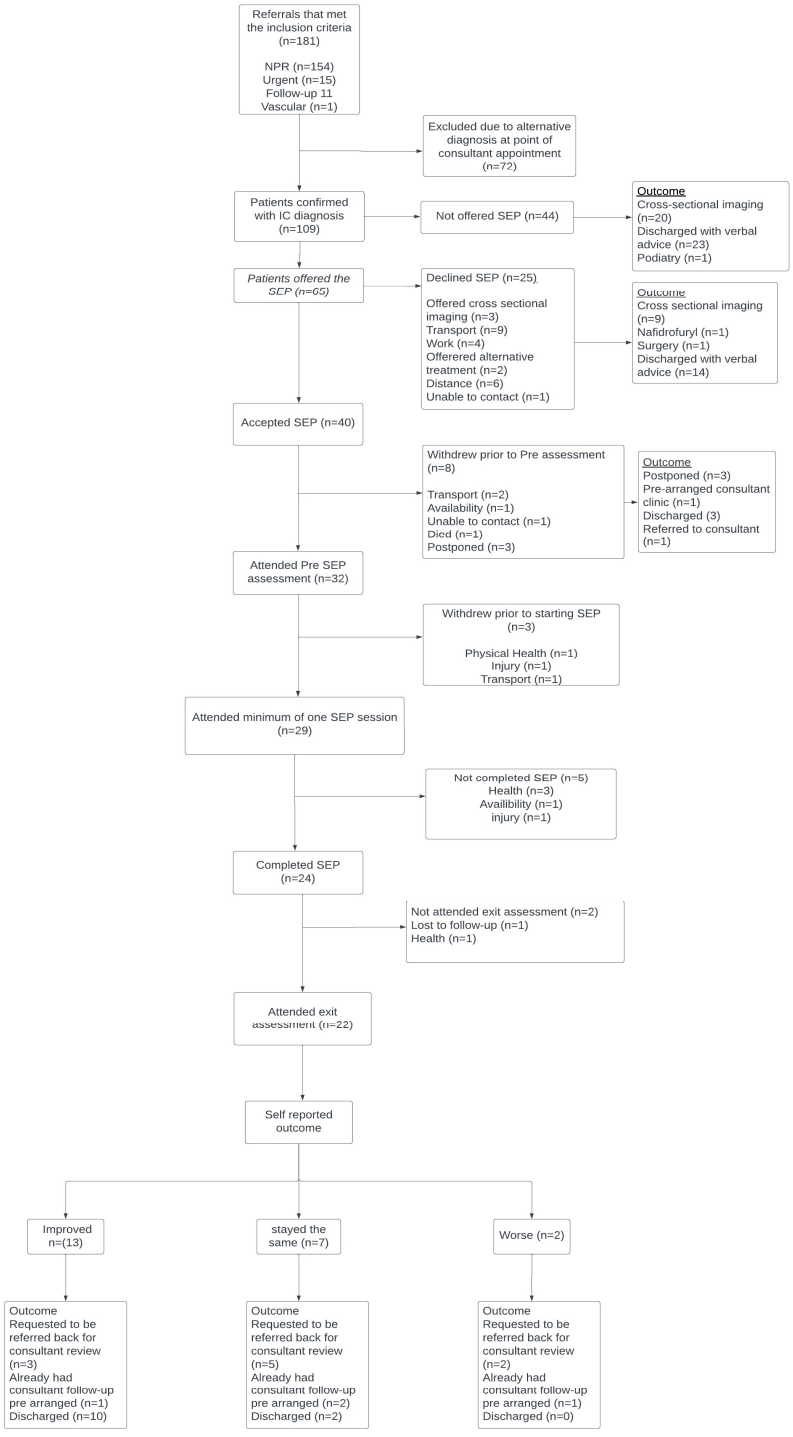

Figure 4.1 Flow of participants through the feasibility study

4.2 Reasons for withdrawal and participants lost to follow-up

Figure 4.2 illustrates the reasons for withdrawal given at each stage of the service from the 40 patients who initially accepted the SEP offer. A total of 18 participants (45%) withdrew before completing the exit assessment. Eight of these withdrawals occurred between accepting the offer and attending the entry assessment. Three participants withdrew after completing the entry assessment, while an additional five participants withdrew during the SEP sessions. Two participants completed the SEP sessions but did not attend the exit assessment, with one lost to follow-up and one withdrawing due to health reasons.

The primary reason for participant withdrawal from the SEP was health-related, which accounted for five participants. Transportation difficulties and postponement each led to the withdrawal of three participants. Additionally, two participants withdrew due to injury, and another two withdrew due to personal availability. Two withdrew as they were lost to follow-up, and one participant withdrew due to death.

4.3 Adverse events

No adverse events were found to be linked to the SEP. Two participants experienced minor cerebral incidents during the 12-week programme; however, these were deemed unrelated to the SEP and both participants were able to complete the programme after receiving medical clearance.

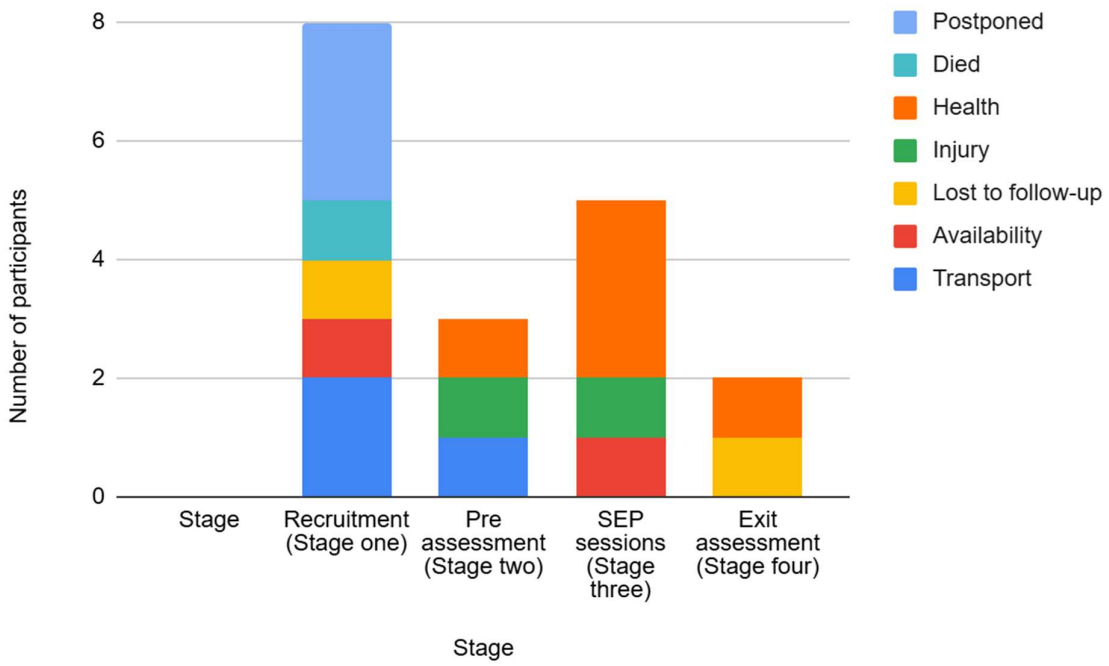

Figure 4.2 Reason and stage of Figure withdrawal from SEP

4.4 Participant characteristics and demographics at service entry

Table 4.1 presents the characteristics and demographics of participants who accepted the SEP offer, categorised into four groups: participants who accepted the SEP offer (n=40, group one); all participants who attended the pre-assessment (n=32, group 2); participants who attended at least one SEP session (n=29, group 3); and participants who completed both the SEP and the exit assessment (n=22, group 4). Most participants at service entry were seen in person by the VSNP, participants in group 4 were seen the most by the VSNP (73%) at the point of entry.

The mean age of participants across all groups was over 65 years, group 4 had an average age of 71.6 years, most were male (91%), white British (82%), and retired (91%). Across all groups, the range of distance traveled from home to the SEP remained the same,

between 1.5 miles and 42 miles, in group 4 the mean (SD) traveled 10.13 miles (10.25) to the SEP site. The favoured mode of transportation across all groups was too self-drive, with 91% reporting that they self-drive to the SEP in group four. The number of participants who reported using public transport (13%) in group 1 decreased in those who completed the SEP in group 4 (5%). The participants' mean deprivation score increased from 7.6 in group 1 to 8.05 in group 4, with the highest mean in group 3 (8.1). The range of deprivation scores was static across all domains between 3 and 10.

The participant health and IC symptom characteristics at service entry are also shown in Table 4.1. However, these characteristics are not reported in the category of 'participants who accepted the SEP' (group 1) as the data was collected later in the entry assessment. Health status data showed that BMI remained consistent across the three groups (means of 27.51, 27.94, and 28.88), all within the 'overweight' range. The ABPI measures are reduced by two participants in each group due to missing data. The baseline ABPI of the lowest leg mean scores presented no difference across the three groups (0.67, 0.67, 0.67). Participants frequently had multiple comorbidities, with hypertension being the most reported across the three groups. Although of those with hypertension, fewer participants reported the condition in group 4 (77%) than those who initially attended the pre-assessment (94%). A history of MI was more prevalent than stroke, with both conditions showing a slight decrease across the groups. In group 2, 19% (n=6) reported a previous MI, and 6% (n=2) reported a stroke, compared to 18% (n=4) for MI and 5% (n=1) for stroke in group 4. The majority of participants were former smokers, comprising 69% (n=22) in group 2, which increased to 73% (n=16) in group 4. Participants who had never smoked were more numerous than current smokers, with 19% (n=6) in group 2 and 23% (n=5) in group 4,

compared to 12.5% (n=4) and 5% (n=1) who were current smokers in group 2 and 4, respectively.

Table 4.1 Participant characteristics at service entry.

	Participants who accepted the SEP (n=40) (Group 1)	**All participants who attended the pre-assessment SEP (n=32) (Group 2)**	**Participants who attended a minimum of one SEP session (n=29) (Group 3)**	**Participants who completed the SEP and exit assessment (n=22) (Group 4)**
Seen by the VSNP in the consultant clinic, n (%)	23 (58)	20 (63)	18 (62)	16 (73)
Age, mean (SD) Range	71.8 (7.39) 54-86	70.9 (7.46) 54-82	70.9 (6.77) 54-82	71.6 (6.99) 54-82
Sex n (%) Male Female	 34 (85) 6 (15)	 27 (84) 5 (16)	 25 (86) 4 (14)	 20 (91) 2 (9)
Ethnicity n (%) White British White mixed Not stated	 35 (88) 2 (5) 3 (8)	 27 (84) 2(7) 3(9)	 25 (86) 1 (4) 3 (10)	 18 (82) 1 (4) 3 (14)
Employment status n (%) Employed Unemployed Retired	 2 (5) 2 (5) 36 (90)	 2 (7) 1 (3) 29 (91)	 2 (7) 0 27 (93)	 2 (9) 0 20 (91)
Home to SEP distance (miles) to travel, mean (SD) Range	10.2 (10.5) 1.5-42	8.4 (8.4) 1.5-42	8.8 (9.4) 1.5-42	10.1 (10.3) 1.5-42
Mode of travel to SEP n (%) Car (self-drives) Car (lift) Public transport Mobility scooter	 31 (76) 3 (8) 5 (13) 1 (3)	 25 (78) 1 (3) 5 (16) 1 (3)	 25 (86) 1 (4) 3 (10) 0	 20 (91) 1 (5) 1 (5)
Deprivation score, mean (SD) Range	7.6 (2.5) 3-10	7.8 (2.6) 3-10	8.1 (2.4) 3-10	8.1 (2.4) 3-10
Body mass (Kg) mean (SD)		82.6 (16.3)	84.6 (15.1)	86.9 (12.1)

Stature (centimetres), mean (SD)		172.9 (7.7)	173.8 (6.9)	173.5 (6.6)
BMI Kg/m², mean (SD)		27.5 (4.8)	27.9 (4.6)	28.9 (3.8)
ABPI, mean (SD)		**(n=30) 0.67 (0.13)	**(n=27) 0.67 (0.12)	**(n=20) 0.67 (0.12)
Duration of IC symptoms, n (%) < 6 months 6-12 months 1-2 years 2 or more years		 1 (3) 8 (25) 6 (19) 17 (53)	 1 (3) 7 (24) 6 (21) 15 (52)	 1 (5) 5 (23) 4 (18) 12 (55)
Self-reported PFWD n (%) <50 yards 50-200yards >200 yards		 3 (9) 20 (63) 9 (28)	 3 (10) 18 (62) 8 (28)	 2 (9) 15 (68) 5 (23)
Previous MI n (%)		6 (19)	6 (21)	4 (18)
Previous Stroke n (%)		2 (6)	2 (7)	1 (5)
Diabetes n (%)		8 (25)	8 (28)	6 (27)
Hypertension n (%)		30 (94)	22 (76)	17 (77)
Other medical conditions n (%)		3 (9)	2 (7)	1 (5)
Smoking status n (%) Yes No, never smoked No, ex-smoker		 4(12.5) 6 (19) 22 (69)	 2 (7) 6(21) 21(72)	 1 (5) 5 (23) 16 (73)

* Percentage rounded to the nearest whole number

** number of participants reduced due to missing data

4.5 SEP delivery: Occupancy and reasons for missed sessions.

Table 4.2 presents data on the SEP classes conducted between November 7th, 2023, and September 10th, 2024. The table includes several key metrics: the total class occupancy as a percentage (where 10 participants represent 100% occupancy), the mean number of participants enrolled in the programme each month, the attendance rate of enrolled participants as a percentage, the number of missed sessions per month, and the most reported reasons for missed sessions.

The data in Table 4.2 indicates that November had the highest-class occupancy, with a mean of 76%, while September had the lowest, with only 33% occupancy. The average monthly occupancy remained above 49% until August 2024, which saw a notable decrease of 26% compared to the previous month. The mean number of participants enrolled in the SEP remained relatively stable between November 2023 and May 2024, fluctuating between 8.4 and 10.9 participants. The higher-than maximum participant recruitment mean number was due to 4 sessions in May that were oversubscribed, these sessions had 12,13,12, and 11 participants enrolled to offset an increased number of absences at that time. However, a decline was observed in June 2024, with enrolment dropping to 7.1, and further declining to 3.7 participants in September.

Participant attendance varied throughout the study, with November 2023 recording the highest average attendance rate of 92%, while April 2024 saw the lowest attendance at 53%. More than half of the months (54.5%) had an average attendance rate above 80%, with attendance rates ranging from 82% to 92%. The reasons for participant absences are illustrated in Figure 4.3, with the most frequently reported cause being illness, accounting for 27.5% of missed sessions. As shown in Table 4.2, illness was the leading factor

contributing to absences during several months, including December (3 sessions), March (9 sessions), April (16 sessions), May (8 sessions), and September (1 session). Holidays were the primary reason for absences during three consecutive months—June, July, and August—resulting in a total of 20 missed sessions, or 12.5% of all absences. Additionally, venue temperature significantly affected attendance in January and February, contributing to 8 missed sessions (6.4%). In total 160 absences were recorded. The most common reason for missed sessions was illness, accounting for 44 absences (27.5%), followed by holidays having 29 absences (18.1%) and unreported reasons 19 absences (11.9%). Additional reasons, each contributing to less than 10% of absences, were as follows: injury 14 absences (8.8%), work commitments 13 absences (8.1%), session timing 11 absences (6.9%), venue temperature 8 absences (5%), family commitments 7 absences (4.4%), transport issues 5 absences (3.1%), communication problems 4 absences (2.5%), medical appointments 3 absences (1.9%), personal reasons 2 absences(1.3%), and attending a funeral 1 absence (0.6%). These findings are visually represented in Figure 4.3 for further clarity.

Table 4.2 Average monthly occupancy of SEP class, average number of participants enrolled, and average participant attendance from all participants who attended at least one SEP session (n=29)

	Nov' 2023	Dec' 2023	Jan' 2024	Feb' 2024	Mar' 2024	Apr' 2024	May 2024	June 2024	July 2024	Aug' 2024	September 2024
Mean occupancy of sessions % (SD)	76% (10)	67% (6)	73% (13)	71% (16)	64% (12)	53% (11)	64% (19)	49% (7)	60% (10)	34 % (5)	33% (15)
Number of participants assigned to SEP mean n (SD)	8.4 (1.4)	9.3 (6)	9(0)	8.6 (1.2)	9.6 (0.7)	10 (0)	10.9 (1.2)	7.3 (0.8)	7(0)	4 (0.5)	3.7 (1.2)
Participant attendance % (SD)	92% (10)	76% (15)	82% (16)	83% (14)	66% (11)	53% (11)	59% (16)	68% (5)	86% (14)	88% (15)	89% (19)
Number of missed sessions Including 'not reported' reasons (n)	7	8	11	13	21	31	38	16	9	5	1
Most reported reasons for a missed session (n)	Medical Appointments (n=2)	Unwell (n=3)	*Temp (n=5)	*Temp (n=3)	Unwell (n=9)	Unwell (n=16)	Unwell (n=8)	Holiday (n=10)	Holiday (n=5)	Holiday (n=5)	unwell (n=1)

*Temp is referring to the temperature of the sports hall

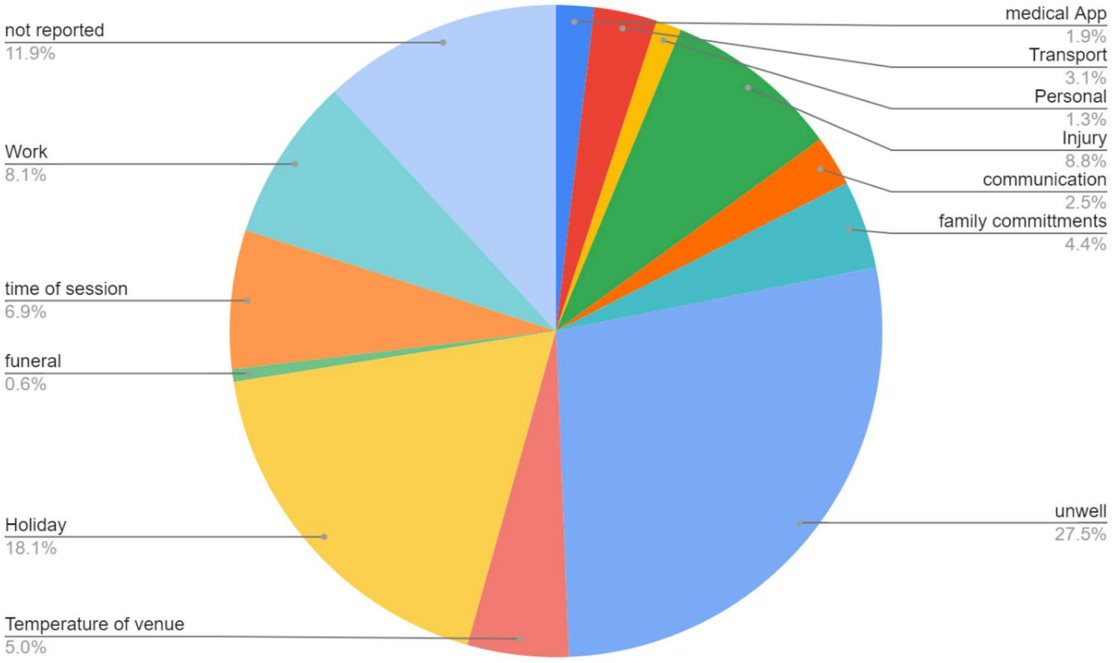

Figure 4.3 Reasons for missed SEP sessions in %

Table 4.3 illustrates that among the participants who completed the SEP (n=22), the majority—12 participants (55%)—attended 21 or more SEP sessions. This figure surpasses the combined attendance of participants across the lower attendance ranges, where 10 participants (45%) attended fewer than 21 sessions. Notably, no participants attended fewer than 6 sessions.

Table 4.3 Total number of SEP sessions attended of those who completed the SEP and exit assessment (n=22)

Number of sessions attended out of a maximum of 24	Number of participants	Percentage (%)
0-5	0	0
6-10	2	9
11-15	2	9
16-20	6	27
21-24	12	55

4.6 Walking distances and pain scores recorded during the SEP

The walking distance and IC pain scores were recorded throughout the 12-week programme for participants who completed the SEP (n=22). To measure exercise progression, the mean values and SD were calculated from the first, mid-point, and final sessions of the SEP. The values were typically taken from week 1 session 1, week 6 session 11, and week 12 session 24. If the participant was absent from these sessions, the data was taken from the other session recorded that week, if this session was also missed, the data from the next attended session was used. The results presented in Table 4.4 below demonstrate that on average participants reported an increased level of IC pain from week 1 (2.98), to the midpoint (3.61), this plateaued at the final session (3.53). The participant's mean walking distance had a steady increase as the duration of the SEP progressed: 1,920m in week one; 2,107m at the midpoint and 2,146m at the final session. The MD walked during the SEP sessions comparing the first and last sessions was 226m.

Table 4.4 Average IC pain scores (0-4) and distance walked (m) from the exercise sessions of participants who completed the SEP and attended the exit assessment (n= 22)

	Week 1 (session 1)	**Midpoint- 6 weeks (session 11)**	**Week 12 (session 24)**
IC Pain score (0-4), mean score over the session (SD)	2.98 (1.20)	3.61 (0.47)	3.53 (0.58)
***Total distance walked (m) over session, mean (SD)**	1920 (538)	2107 (525)	2146 (576)

*total distance walked in metres rounded to nearest whole number

4.7 Health-related outcomes

Table 4.5 summarises the service outcome data for the 22 participants who completed both entry and exit assessments. Several outcome measures had missing or incomplete data. At entry, the VascuQoL-6 results for two participants were not fully saved on the electronic device, one participant was unable to provide a score on the EQ-5D-5L VAS, and two participants had ABPI measurements that could not be recorded due to incompressible vessels. Data from these participants were excluded from all analyses, with adjusted participant numbers indicated in the result tables.

Similarly, in the treadmill test, three participants were unable to walk at the minimum pace and were excluded from the analysis. Additionally, two participants were unable to increase their walking speed at one of the pace increments, continuing instead at the previous pace. As a result, their MWD/T was excluded due to incompatibility with the wider dataset, but their pain-free walking distance/time (PFWD/T) was retained, as these values were below the critical increment point in the protocol.

One participant's feedback also failed to save on the electronic device due to connectivity issues, reducing the number of evaluations completed by those who completed both entry and exit assessments (n=21).

As seen in Table 4.5 the mean values for the health status and disease-specific QoL outcomes improved slightly between entry to exit assessments, however the 95% CI's for the change scores spanned zero, VasculQoL-6 MD of 0.6 (-0.82 to 2.55), EQ-5D-5L utility index MD of 0.07 (-0.02 to 0.17), and the EQ-5D-5L VAS 4.62 (-1.44 to 10.66).

The results of the treadmill test were contrasting between the pain-free and maximum walking measures. The entry to exit mean PFWD/T were found to have moderate increases, with a PFWD MD (95%CI) of 97m (18-175), and pain free walking time (PFWT) MD (95% CI) 119s (10 -228). However, the mean MWD and MWT both only had small differences from the entry to exit, with both MD (95% CI spanning zero), of 103m (-1.88-209) for MWD, and 92s (-12-197) for MWT.

Table 4.5 Entry and exit assessment results for participants who completed both entry and exit assessments

	N	**Service entry**	**Service exit**	**Entry to exit difference** **Mean (95% CI)**
VasculQoL-6 score	**20**	14.8 (3.2)	15.4 (2.9)	0.6 (-0.8 to 2.6)
*EQ-5D-5L utility index score	**22**	0.70 (0.20)	0.76 (0.12)	0.07 (-0.02 to 0.17)
**EQ-5D-5L VAS	**21**	60.86 (17.08)	64.77 (16.14)	4.62 (-1.44 to 10.66)
***Graded treadmill (distance-m/time-seconds)	**20**			
PFWD		228 (176)	325 (285)	97 (18 to 175)
PFWT		267 (201)	369 (321)	119 (10 to 228)
MWD	**18**	498 (353)	602 (419)	103 (-2 to 209)
MWT		546 (347)	638 (400)	92 (-12 to 197)

Data are presented as mean (SD) or mean (95% CI)
*EQ-5D-5L utility index calculated using the 'crosswalk method' range between -0.594-1, higher scores indicating a better health status (see section 3.4.3)
**EuroQoL VAS (EQ-VAS) scores range from 0-100, with higher scores indicating a better health status.
*** Distance in metres and time in seconds rounded to the nearest whole number.

4.8 Evaluation feedback

Twenty-three participants completed the evaluation in total, the majority of whom had completed the SEP and exit assessment (n=21), the other two participants attended at least one SEP session. The remaining participants who had participated in at least one SEP session were unable to be contacted retrospectively. One participant who completed the SEP and exit assessment did complete an evaluation; however, the software failed to save their responses. Most participants (n=22, 95.7%) reported that their GP had not contacted them since enrolling in the SEP. Twelve participants (52.2%) self-reported that their IC symptoms had improved since the start of the programme, nine (39.1%) reported their symptoms had not changed, and two (8.7%) reported their symptoms to have worsened.

Table 4.6 shows participant experience ratings for each stage of the service, including recruitment, assessment, exercise sessions, home exercise advice, and their overall experience of the service using a Likert scale with the adjectives good, fair, poor, or very poor. The assessment stage was found to have the best rating with 14 (60.9%) participants rating their experience as 'excellent.' The majority of the stages, recruitment; SEP sessions; and overall ratings had the highest proportion of rating of 'good,' with only the home exercise advice scoring the highest rating in the 'fair' category with 10 (43.5%). Only one participant rated 'very poor', which was for the home exercise advice.' Overall, most participants thought that the SEP experience was either 'good' (n=13, 56.5%), or 'excellent' (n=9,39.1%). Nearly all the participants (n=22, 95.7%) who completed the evaluation said that they would recommend the service to others in a similar situation, with only one participant (4.3%) stating that they would not.

Table 4.6 Participant experience rating of the SEP stages (n=23)

Question **How would you rate your experience with…..**	**Excellent**	**Good**	**Fair**	**Poor**	**Very Poor**
…the recruitment process?	9	12	2	0	0
…the assessment sessions?	14	8	1	0	0
…the exercise sessions?	9	12	1	1	0
…the home exercise advice?	4	6	10	2	1
…the programme overall?	9	13	0	1	0

In summary the feedback on the recruitment stage was largely positive, with participants frequently highlighting its informative and timely nature. One participant described the recruitment process as an opportunity to gain "control" over their condition. However, another participant expressed a contrasting view, feeling that it was another instance of being "told" what to do.

The assessment stage revealed themes similar to those of the recruitment stage, with "informative" being the most frequently mentioned. One participant noted, "everything [was] explained, giving each other better insight and understanding of my individual symptoms." Another prominent theme was participants' appreciation for the comparison of their walking abilities before and after the SEP. Comments included: "good to be able to see the difference before and after the SEP", "better than I was the first time", and "gave [an] opportunity to compare". Only one negative response was reported, stating, "no expectations at first and no feedback from the second".

Feedback on the SEP sessions highlighted several positive themes, including the benefits of group sessions, an enjoyable experience, and a strong connection with the instructor. One participant remarked, "It was fun, met some good people", while others noted, "enjoyed the group aspect, talking to people with the same condition", "the instructor was the right person for the job—aware, motivating, and reassuring", and "attending as a group helped encourage walking further". However, negative feedback centered on the venue's temperature, with comments such as "the venue was not appropriate, too cold", and "temperature cold in the morning". Additionally, one participant mentioned difficulties with the timing of a session, stating, "overall good, but the early session was difficult to get too due to traffic".

Unlike the previous stages, feedback on the home exercise advice was primarily negative and focused on its availability. Participants expressed a desire for more comprehensive guidance, with comments such as “not expected home exercise advice, but would have been useful”, “maybe advice on how everyday activities like gardening can be used as exercise”, and “some limited advice given, could have been more”. However, some participants acknowledged receiving advice in either verbal or written form, as reflected in comments like “some information given; it’s up to the individual to act on it”, “I have done the warm-up exercises at home”, and “advised to continue at home”.

Although the question about overall experience of the SEP had the lowest number of participant responses (n=16), the feedback generally suggested that the SEP fostered a strong sense of connection between participants and the instructor. Feedback also emphasised a supportive and inclusive atmosphere, with participants noting that they were "made to feel part of the programme, not just a number", and appreciated the "great group community and support", and "relaxed feel". One participant stated, "very good, everyone

was nice, helped being in a group and meeting other people. A reason to get out". Participants also reported other perceived benefits, including feeling "fitter", "healthier", and experiencing weight loss.

When asked if they would recommend the service to others with IC symptoms, participants emphasised the programme's diverse benefits. Illustrative comments included, "because it helped with my symptoms and made me fitter and healthier", and "it can help with the pains in your legs and general health".

Twenty-two participants provided feedback on potential improvements to the service. The primary theme centered on the facility and the scheduling or location of sessions. Suggestions included having a "warmer facility" and considering "other health conditions" when setting session times, as well as noting that "timing of the sessions [was] too early due to other health needs". One participant recommended offering "alternative locations" to reduce travel time and costs, particularly for those coming from the east coast. Other feedback focused on programme structure, with suggestions such as using a "visual timer for each session" and marking a "halfway point" during exercises, and a recommendation to "tailor the program more to individual assessments".

Chapter 5 Discussion

5.1 Do the results answer the aims and objectives?

The SEP was established and delivered in accordance with the recommendations outlined in the NICE (2012) guidelines. There were initial delays in the approvals process, mainly with obtaining sign-off of the Service Level Agreement from the York Trust, but this turned out to be a minor hinderance to the establishment of the service. Overall, the implementation of the SEP was successful.

The feasibility study was able to measure and evaluate objective measures including MWD/T, PFWD/T, as well as more subjective measures such as QoL. The findings for these objectives were not reflective of the total pool of participants due to study limitations resulting in missing data, which reduced the analytical sample size in some of the outcome measures. However, the delivery of the SEP and data collection were feasible; these aspects were mainly delivered as planned, resulting in little data being missing. The qualitative feedback provided an opportunity to summarise participants' experiences, collating both positive and negative feedback to discuss, and importantly gave them an opportunity to say if they thought their symptoms had improved.

The study identified several barriers to service implementation and delivery across all stages including recruitment, assessment, delivery, and evaluation. Grol and Grimshaw (2003) suggest that the challenges to implementing healthcare interventions can be observed across five levels: the patient, the healthcare provider, the healthcare team, the organisation, and the broader environment. An early barrier identified during the recruitment process was the number of patients not offered the SEP as a treatment option at recruitment by the diagnosing consultant (40%). This is relevant as the study found that

most patients who were offered the SEP accepted (61.5%), which highlighted the missed number of potential patients that may have accepted the SEP if they were offered it. Although the change to practice is not a complex one, it does require significant collaboration and a new organisational structure initially (Murgitroyd *et al.,* 2019). Rogers (2002) suggested that adherence to change tends to be higher when addressing acute conditions, likely because of the immediate feedback resulting from such changes, in contrast, to implementing chronic care guidelines, partly due to the "delayed rewards from adoption"(P.989). Murgitroyd *et al.* (2019) recognised that to successfully implement a chronic care intervention, it is essential to identify and address potential obstacles to commitment.

A barrier within the assessment stage resulting in a reduction of usable data was the treadmill assessment test. Several participants reported the initial treadmill speed to be too fast, so reasonable adjustments were made for these patients, which excluded their treadmill data from being included in the main data analyses. However, this did provide an individual entry/exit comparison for the individual participant providing positive reinforcement which may be important for patient compliance (Murgitroyd *et al.,* 2019).

McDermott *et al.* (2014) argued that the six-minute walk test offers superior outcome measures compared to treadmill testing, primarily due to its stronger correlation with daily walking activities (Greig *et al.,* 1993; Swerts *et al*., 1990; Peeters *et al.,* 1996), the test related phenomenon associated with treadmill walking (Gardner *et al.,* 1991), and the availability of a defined minimal clinically important difference (Perera *et al.,* 2006). Moreover, changes in six-minute walk performance have been shown to predict mortality and mobility loss in patients with PAD, a predictive validity not established for treadmill testing (McDermott *et al*., 2007; McDermott *et al.,* 2008). Treadmill walking was used in this

feasibility study due to space constraints for the assessments and ultimately the outcome measures, however, the delivery of the exercise was structured similarly to the six-minute walk test, thereby retaining many of its functional and clinical advantages mentioned. The limitations of using a treadmill have been acknowledged but felt to be offset by the use of the interval-based walking as the main dose of therapy within this study.

Staff cover was found to be a barrier in delivering the SEP on several occasions due to covering annual leave with another staff member with the relevant level of training. Also, problems with the facility contributed to several sessions being cancelled, including condensation from the roof and the sports hall being too cold over the winter months. On several occasions double booking of the sports hall resulted in the hall either being shared, the session being cancelled or moved to tennis courts located onsite.

The highest withdrawal rate was recorded in the recruitment stage of the study of those who accepted the offer of the SEP. Contributing barriers were health, transport, availability and postponement that led to these withdrawals, with the highest number been associated with health reasons. This correlates with the highest mean scores of the participants characteristics demonstrating that the majority were over the age of 65 years, had multiple comorbidities including hypertension and MIs, and were overweight. The number of withdrawals from the SEP almost halved at the intervention delivery stage, and further reduced in the final stages.

5.2 How do the findings support/relate to the evidence?

The findings of this study support those studies discussed in the literature review which found that walking as an exercise modality improved both MWD and PFWD in people with IC symptoms (Hageman *et al.,* 2018; Treat-Jacobson *et al*., 2009; Lane *et al*., 2017; and

Jensen *et al*., 2020). The improvements found in both PFWD/T and MWD/T means from entry to exit change in this feasibility study were consistent with that of the Cochrane review undertaken by Lane *et al.'* (2017). Also, according to Gardner *et al*. (2018) the entry to exit changes in PFWD in this feasibility study can be categorised as 'moderate' in magnitude. The presence of a defined MID for PFWD and MWD in walking tests enhances the clinical interpretability of these results. In the context of this service evaluation, demonstrating changes that meet or exceed the MID provides strong evidence that the intervention delivered not only statistically significant but also clinically meaningful benefits. This underscores the value of the SEP in improving functional mobility and quality of life in patients with IC, thereby justifying its continued implementation and potential scale-up within clinical practice. The findings of this feasibility study will be used within local cost analyses to support the future of the SEP as a treatment option within our area. Despite the large body of evidence that SEPs improve IC symptoms, studies exploring the implementation and outcomes of routine exercise services for this population are rare, with only three UK-based evaluations identified (Leslie *et al*., 2022; Matthews *et al.,* 2016; Murgitroyd *et al*., 2024). Leslie *et al.'*s (2022) retrospective analysis of data from a Wolverhampton service did not report about the implementations factors of feasibility, fidelity or acceptability, but their walking distance results did support the use of SEP rather than basic advice in improving IC symptoms. Matthews *et al.'s* (2016) evaluation of an initiative based in Salford found that most participants who completed the exercise programme reported improved IC symptoms (72%), however this study did not report the characteristics of their participants, or anything about the fidelity or acceptability of the SEP. Lastly, Murgitroyd *et al.* (2024) study based in Edinburgh reported on the experiences and outcomes of implementing a SEP. The initiative involved the local council and the vascular

service, offering multiple venues and times for the classes including evenings to accommodate patients who worked. Murgitroyd *et al*. (2024) found that on average patients improved their distance walked over 6 minutes by 21%, the programme was a 12-week programme, encouraging the patients to attend three sessions per week.

The use of QoL questionnaires at the entry and exit assessments provided the opportunity to provide a holistic approach toward patients with IC symptoms, as Mazzoli (2024) recommended in the literature review. The results for the health status and disease-specific QoL outcomes in this feasibility study were not found to be as clinically meaningful between entry to exit such as the findings reported by Hageman *et al.* (2022) as the 95% CIs spanned zero. The effect difference could be because of small participant numbers in this feasibility compared to the 124 participants in Hageman *et al.'s*. (2002) study. Despite this there were slight improvements in both the VasculQoL-6 and EQ-5D-5L utility index score including the EQ-5D-5L VAS. In contrast to Peräkylä *et al*. (2008), the feasibility study observed that participants appeared "unsure" about how to interpret the EQ-5D-5L VAS on several occasions. While this was not formally recorded or included in the results, this uncertainty could have influenced the findings of the study.

The findings of this feasibility study support some of the interventional design challenges discussed in the literature review. A key similarity to Popplewell and Bradley's (2014) quotation cited in Harwood *et al.'* (2017) discussion, was that there was an "unwillingness at senior staff level to change practice" (p209), to move away from invasive intervention. However, in contrast to Harwood *et al.'s* (2022) findings that the majority (50%) of SEPs only delivered one session per week, this study delivered the recommended two sessions per week. Harwood *et al.* (2017) survey also reported that there was poor compliance from participants without further explanation of the reasons behind those

findings. This study found compliance of participants to be good overall, with most of participants (55%) who attended entry and exit assessment attending between 21-24 sessions of the maximum 24. Participants in this study were also found to readily offer their reasons for missed sessions, which were mainly due to being unwell (the main reason across five months of the study), similarly to that of the highest reason for withdrawal from the SEP. In relation to practice there needs to be an awareness of the physical demands of participating in a SEP, and that preexisting health conditions may impact an individual's ability to successfully complete the programme. In light of these findings, there may be reasonable adjustments that can be made in these circumstances, or that patients may need other health issues stabilising prior to enrolling onto a SEP.

5.3 Implications for practice and research

The main implication for practice from these findings is the culture around the change in practice, and the need for a 'team approach' in the establishment of a new service. A strength of this study was the ability to provide good communication and enable the participant to feel 'informed', this may have had a positive effect in patient compliance and rapport between the service provider and the participant. A limitation in establishing the SEP in this study was again the lack of 'teamwork' at the hospital, with colleagues refusing to take phone messages from participants; this, at times, led to a delay in communication between the service and participant. Favorably for implementation into clinical practice both quantitative and qualitive findings from this study suggested that the modality of walking is feasible to continue, with improved self-reported outcomes and feedback that the simplicity of walking was welcomed. However, a limitation of the treadmill test, as alluded to by Treat-Jacobson *et al.* (2009), was that many older participants had no prior

experience walking on a treadmill and struggled to adjust, especially given the short "trial" period before completing the test. The limitations of the treadmill overall may need some revision moving forward in continued assessments.

Participants' self-reported outcomes in this study also support the findings of the objective measures in the relevant studies critiqued in the literature review, that most people improved their walking. This 'real life' measure was feedback in the exit assessment to the VSNP by participants referring to comparisons in their everyday living, such as: now being able to walk the entire length of the supermarket, whereas before they could only manage one isle; able to walk the around the block, before they had the stop at the corner of the street. This emphasises the importance of ensuring that the patient can relate to 'real life' situations as the treadmill test does not simulate 'real' life. The qualitative participant feedback was invaluable in terms of discussing barriers of the SEP. However, this also had its limitations as the participants fed back to the VSNP who had been closely involved in the SEP, this may have influenced some of the answers given. Despite these limitations of the method of collecting the feedback, Harwood *et al.* (2018) recognised in their study that gaining insight into barriers that affect how exercise is delivered for patients with IC will help deliver a patient-centred approach and acknowledges that no matter how strong the evidence is for SEPs, if the limitations prevent patients from participating, then the benefits will not be reaped. Furthermore, the qualitative feedback in this study has drawn attention to not only the barriers, but the long-term implications of the SEP, as many participants reported 'feeling their overall health had improved', the SEP helped with "social anxieties" and "overall wellbeing", also participants voiced improved "general fitness", the benefits of a SEP far exceeds of just improving walking, it has a positive effect across social, physical and

mental health. Patients will engage in exercise treatment and feel empowered when informed discussions are given to them regarding the management of their health.

5.4 Limitations

There were several main limitations in the study evaluation. The generalisability of the University-Hospital collaboration may pose a limitation to other vascular hubs to replicate this model. The model worked well within this service evaluation due to the proximity of both parties and the willingness to collaborate. There is potential as demonstrated in Matthews *et al.* (2016) evaluation for other vascular hubs to incorporate SEP into pre-existing rehabilitation exercise programmes, or into schemes managed by local leisure centres (Caldow *et al*., 2019).

The treadmill assessment was limited in that it did not reflect everyday walking and several participants were unable to manage the pace from the start of the protocol resulting in their results been excluded from the study. McDermott *et al.* (2014) acknowledge the need for good balance and a consistent rhythmic gait at a fixed pace is required on a treadmill, since slowing would end the test. However, as an objective measure the treadmill test provided a direct comparison for entry to exit walking, and most participants managed the protocol. Availability of space also weighted the use of the treadmill within the assessments, although the use of treadmills within the delivery of the sessions would pose limitations with cost and limit the number of participants (Harwood *et al.,* 2022). The exercise prescription delivered in the classes did allow individualisation as the participants were encouraged to walk at their own pace, stopping as required during the walking cycles. The only feedback that challenged the individualisation was one participant felt he could

have managed to continuously walk without the 2-minute rests between walking cycles, this could be considered in future sessions.

Although the service evaluation provided some home-based exercise advice, it was delayed due to obtained approval to use the PILs through the hospital vetting process so not all participants received the written PILs. Furthermore, this service evaluation did not measure the effects of the home exercise information on interventional outcomes.

Finally, this service evaluation is limited in that long term outcomes were not assessed as the participants were not followed up at any later interval after attending the exit assessment.

5.5 Recommendations

The main recommendation drawn from the results of this service evaluation is that funding should be sought to safeguard the future of the SEP. The embedding of a SEP would provide an integral and holistic service as part of the routine care for patients diagnosed with IC, in line with NICE (2012) guidance. There needs to be support and education for clinicians in the adoption of a change in practice, and this should involve the whole team. There needs to be a robust, easy to use referral process into the SEP, ensuring that eligible patients are triaged appropriately. The SEP needs to have the ability to scale-up, offering multiple localities, to reduce the number of patients unable to access the service due to transport and travel, with venues that are fit for purpose. Some adjustments to the entry and exit assessments are needed to address the limitations found mainly around the use of a treadmill. The SEP delivery needs to have a team to provide the service to avoid any gaps in delivery. For those patients who are unable to attend a SEP, a home exercise plan should be available with the support of a clinician. Research and clinical practice need to work more cohesively together

to mitigate the reluctance to use exercise in healthcare. Furthermore, primary and secondary care, and local authorities working in collaboration would be beneficial. There remains scope for repeat service evaluations, with the potential involvement of longer-term follow-up and a health economic component to aid robustness.

5.6 Conclusion

The key finding of this service evaluation is that it was feasible to implement a NICE compliant SEP for people with IC within the usual care pathway of a vascular unit in England. The findings of the interventional outcomes are beneficial and in line with the body of evidence by NICE (2012). There remain multiple barriers to accessing, establishing and maintaining a SEP. However, this study suggests that healthcare professionals are one of the main barriers to establishing a service that is financially viable for the NHS. Patients, when given support and are well informed are willing, engaging and feel empowered from exercise programmes. This study has shown that the benefits of a SEP are multidimensional, including patients reporting improved social, physical and mental wellbeing.

The Service Level Agreement has been extended for an additional 12 months until September 2026, giving the opportunity for the identified barriers to be refined, and to hopefully sustain and expand the service.

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Appendices

Appendix 1: Ethical approval, York St John University (Ethics reference: STHEC0072)

Est. 1841 | YORK ST JOHN UNIVERSITY

York St John University,
Lord Mayors Walk,
York,
YO31 7EX

30/06/2023

School of Science, Technology, and Health Research Ethics Committee

Dear Lisa,

Title of study: A study to assess the feasibility of implementing a supervised exercise programme for patients diagnosed with intermittent claudication
Ethics reference: STHEC0072
Date of submission: 20/06/2023

I am pleased to inform you that the above application for ethical review has been reviewed by the School of Science, Technology, and Health Research Ethics Committee and I can confirm a favourable ethical opinion on the basis of the information provided in the following documents:

Document	Date
Application for ethical approval form, participant information sheet and consent form, questionnaires and protocol documentation	30/06/2023

Please notify the committee if you intend to make any amendments to the original research as submitted at date of this approval, including changes to recruitment methodology or accompanying documentation. All changes must receive ethical approval prior to commencing your study. You are now free to begin data recruitment and collection for the above approved study.

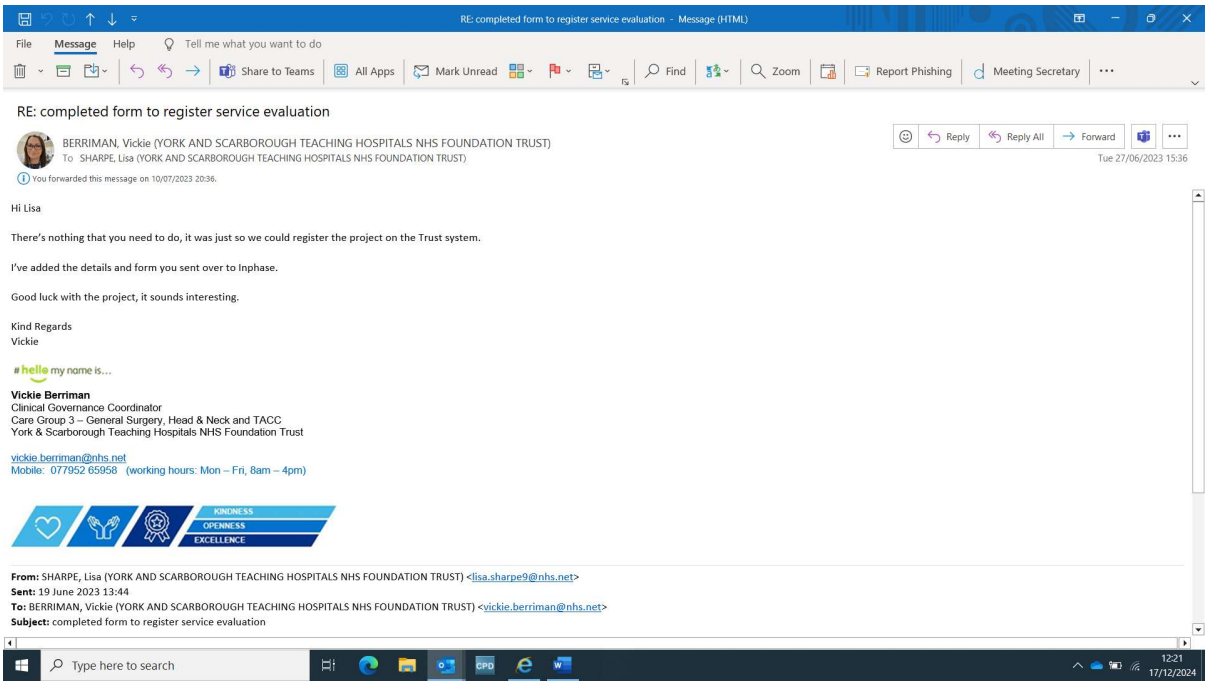
Yours sincerely,

Dr Sophie Carter
Chair of the School of Science, Technology, and Health Research Ethics Committee

Appendix 2: Surgical care group service evaluation registration form and email confirmation

Care Group 3 Clinical Audit Registration Form *(Please complete sections below)* **Please send completed forms to: CG3GovernanceFacilitators@york.nhs.uk**					
Site(s)	☐ Trustwide ☒ York ☐ Scarborough ☐ Community				
Care Group Audit Priority *(please identify as appropriate)*					
External 'Must do' e.g. national audits	Internal 'Must do' e.g. contract requirement, NICE guidance	*If applicable, state which NICE Guidance*	High local priority Service line / Trust (*see below for Quality Goals*)	Medium local priority Service line interest	
Audit Title	A feasibility study in the implementation of a supervised exercise programme for patients diagnosed with intermittent claudication				
Audit Objectives	To identify barriers to implementing a supervised expercise programme				
Audit Start Date	July 2023	**Proposed Completion Date**	Sept 2024		
Lead Auditor for this project	First Name: Andrew	Surname: Thompson			
Lead Consultant	First Name: Andrew	Surname: Thompson			
Team Members *(List name & job title for all)*					
Lisa Sharpe, vascular specialist nurse. Garry Tew, professor of clinical exercise science and academic					
Report Findings To Be Presented *(findings must not be externally shared until reviewed by your Care Group Governance Team)*					
Proposed date of presentation	Feb 2025 ☐ Internally ☐ Externally ☒ Both				
Agreement & Disclosure					

Ethics & Confidentiality	Clinical audits must be conducted within an ethical framework. This means ensuring patient confidentiality at all times and complying with legislation, guidance and
IG Confirmation	I confirm I have attended the Trust Information Governance Training ☐
Audit Approval	I confirm I have discussed and agreed this audit with the Audit Lead ☐
	I confirm I have discussed and agreed this audit with the Governance Lead ☐
Publication Approval	I confirm I understand that no findings from this audit can be published / presented externally until the results have been presented to the Care Group Governance
Agreement	I hereby agree to complete the audit as detailed on this form, share the audit results with relevant Trust staff and return an Audit Report which includes an action plan (with re-audit date if applicable) to the Care Group Governance Team on



Appendix 3: Service level agreement

AGREEMENT FOR THE PROVISION OF SERVICES FOR THE CLAUDICATION EXERCISE SERVICE – WITH YORK ST JOHN UNIVERSITY

This **Agreement** is made with effect from *1st September 2023*.

BETWEEN: York and Scarborough Teaching Hospitals NHS Foundation Trust (The Trust)

(the **"Commissioner"**)

AND: York St John University

(the **"Provider"**)

Together referred to as the **"Parties"** or individually a **"Party"**.

Term. This Agreement will commence (on the Effective Date) and will continue until *1 February 2025*, unless extended by the Commissioner on giving the Provider not less than three months written notice prior to *1st February 2025* or terminated in accordance with clause 7 of the Conditions (**"the Term"**).

Services. The services to be provided by the Provider to the Commissioner shall be as set out in Schedule 1 (**"the Services"**).

Entire Agreement. This Agreement comprises;

(i) This signature page
(ii) The attached Conditions
(iii) Schedule 1 – Services
(iv) Schedule 2 – Services Fee
(v) Schedule 3 – Data Protection Protocol

which in the event of any conflict shall take precedence in the order in which they appear above. The Agreement, effected by the signatures of the Parties below, constitutes the entire agreement between the Parties relating to the Services and supersedes all prior negotiations, representations or understandings whether written or oral. This Agreement may only be amended in writing in accordance with clause 6 of the Conditions.

Signed on behalf of **Commissioner**	Signed on behalf of **Provider**
Name: Andrew Bertram	Name: Karen Bryan
Title: Finance Director	Title: Vice Chancellor
Signature:	Signature:
Date: 12/10/2023	Date: 12:10:2023

Appendix 4: Participant consent form

York and Scarborough Teaching Hospitals NHS Foundation Trust

Supervised exercise programme for patients with intermittent claudication

CONSENT FORM

York and Scarborough Teaching Hospitals NHS Foundation Trust (the Trust) is working with York St John University to offer a supervised exercise programme to patients with intermittent claudication. We would like to invite you into this programme as we think it will help to improve your symptoms, fitness and health. Full details of the programme are outlined in the patient information leaflet (Reference PIL1618 v1).

The Trust requires consent from each patient who agrees to participate in the programme.

Consent to participate in the exercise programme

	Please initial box
I have read the patient information leaflet and have had the opportunity to ask questions about the exercise programme.	
I understand that my participation in the exercise programme is voluntary and that I can withdraw by speaking to a member of the programme team.	
I agree that it is my responsibility to inform the programme team of any changes in my health or treatments that may occur during my participation in the exercise programme.	
I agree to participate in the exercise programme.	

Consent for routinely collected data to be used in service evaluations

	Please initial box
I understand that relevant sections of my medical records and data collected during the exercise programme may be looked at by individuals from the programme team, regulatory authorities or from the Trust for the purpose of service evaluation. I give permission for these individuals to have access to my records.	
I understand that if I withdraw from the exercise programme, any data collected about me up to the point I withdraw will be retained and may be used in service evaluations.	
I understand that any information given by me may be used in anonymised form in future reports, publications, articles, or presentations by the programme or service evaluation teams.	

Your name…….…….....

Date……..…

Your e-mail address and/or phone number (if you consent to be contacted this way)

…….…….....……..

Your signature……..……...…

[one copy to the participant, one copy to be filed in the medical records]

Appendix 5: Patient information leaflet: supervised exercise programme

NHS
York and Scarborough Teaching Hospitals
NHS Foundation Trust

Information for patients with intermittent claudication symptoms

Supervised exercise programme (SEP)

What is intermittent claudication?

Intermittent claudication pain is one of the first symptoms of peripheral arterial disease (PAD). It is caused by a narrowing or a blockage of one of the arteries taking blood to your leg, reducing the flow of blood it gets. At rest your leg is getting enough blood flow, but when you start to walk, your body cannot supply enough blood to the muscles to provide the oxygen it requires to sustain the activity. This results in a cramping, aching, tightness or a pain in your leg.

The symptoms quickly resolve once you have stopped walking for a few minutes and the oxygen demand has reduced.

Although there is no cure for PAD, moderate exercise has been proven to improve intermittent claudication symptoms. Exercise encourages smaller arteries in the leg to enlarge and help manage the blood flow when there is more demand. For example when you walk, which is known as collateral circulation.

Why a supervised exercise programme (SEP)?

Research has shown that participating in supervised exercise is more effective in improving your symptoms than just giving you advice to exercise (unsupervised) and improves your quality of life. The National Institute for Health and Care Excellence (NICE) is the governing body that provides the NHS with clinical practice recommendations. As a first-line treatment for your diagnosis of intermittent claudication, NICE recommends that you have the chance to take part in a supervised exercise programme.

What is a supervised exercise programme (SEP)?

In brief, a SEP is an organised programme where you will participate in structured exercise classes. These are delivered by a qualified exercise instructor over a specified time frame. For example they could be walking or strengthening exercises.

Assessment

Before starting your SEP, you will be invited to attend a face-to-face appointment with a vascular specialist nurse who will take some basic measurements which are explained below. You should allow two hours for this assessment.

You will be asked to complete a consent form in order to participate in the SEP.

These are the basic measurements that the nurse will take:

- A pressure, similar to taking your blood pressure in your arm, will be taken on both legs. This measurement is a way to assess the degree of arterial disease in your legs. It can give an indication of the amount of blood flow to your feet. This is called an Ankle Brachial Index (ABPI).

- Using a quality-of-life questionnaire, the nurse will also ask a few questions about your symptoms and how they affect your daily life.

- You will then be asked to walk on a treadmill to assess your baseline pain-free and maximum walking distance.

This assessment will take place at York St John University, **Lord Mayor's Walk site**. Directions and parking instructions are available at the end of this booklet.

Your supervised exercise programme

The programme is free and will run over 12 weeks on a Tuesday afternoon at 14.30 and a Thursday morning at 08.45.

The classes are group-based, with a maximum of ten participants (mixed sex) per session.

At each session, there will be a warm-up followed by shuttle walking. Shuttle means walking as far as possible in six-minute blocks, at a speed

that causes you to have claudication symptoms and trying to walk through the pain. This is repeated five times. The class ends with a cool down.

The sessions are held at York St John's University, **Haxby Road site Sports Barn**. There is an onsite café serving drinks and snacks.

Directions and parking instructions are available at the end of this booklet.

Please arrive on time to allow the class to start prompt

What happens after the exercise programme?

If you complete the programme, you will be invited to attend a similar assessment to the one you undertook before starting the SEP. This will compare your pre- and post measurements.

Whether or not you completed the entire 12-week programme (if your symptoms remain the same or are worse) you can be referred back to the vascular consultant clinic to discuss any alternate treatment options.

If your symptoms have improved and you are satisfied with the outcome, we will write to your GP and discharge you from the SEP. A telephone follow-up will be arranged in six to eight weeks with the vascular specialist nurses to provide you with support and advice.

What can I do to help myself?

Stopping smoking is the most important thing you can do to prevent your disease from getting worse and reduce your risk of heart attack or stroke. These are some of the available stop smoking services:

- **Call the free National Smokefree Helpline** on **0300 123 1044** (England only). Talk to a trained adviser for advice and support.
- Or access help via the internet:

www.nhs.uk/better-health/quit-smoking/

- Or join through social media by joining **the Quit Smoking Support Group on Facebook**

- Further support is available by downloading the free NHS Quit Smoking app on the Google Play Store and Apple App Store.

- York City council health trainers, a free stop-smoking service are available on 01904 553377.

- Alternatively, speak to your GP about local stop-smoking services.

Keep active

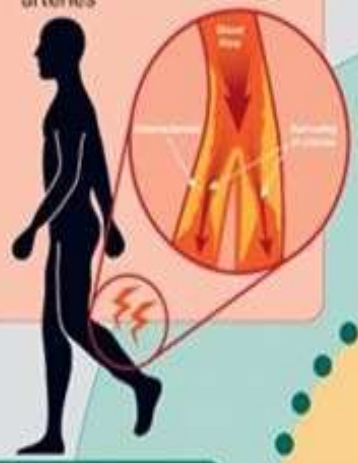
The other important thing you can do to help is to start or increase exercise. The Circulation Foundation has developed the following information (infographic) that might help you try to exercise (page 5).

More information about exercise and intermittent claudication from the Circulation Foundation is available online at: www.circulationfoundation.org.uk or you can ask the vascular nurse for a paper copy.

Exercise for Intermittent Claudication

What is intermittent claudication?

- Leg muscle pain or discomfort during walking
- Usually caused by narrowed arteries



NICE National Institute for Health and Care Excellence

RECOMMENDS EXERCISE

Supervised exercise classes produce the greatest benefits - ask your doctor or specialist if these are available locally

Benefits of exercise

- Reduces pain
- Reduces the need for vascular procedures
- Improves heart and vascular health
- Improves mood
- ZZ Improves sleep
- Maintains healthy weight

Key recommendations

- Aim to complete 30-60 minutes of walking per session
- Follow the walk-rest-walk pattern (central diagram)
- 3-5 sessions per week

Further guidance

- **Do not fear walking with leg pain** – it will not harm you
- **Build up gradually** – your walking speed and time
- **Be patient** – it usually takes several weeks of exercise to improve symptoms

General tips

- Wear comfortable clothing, keep hydrated
- Choose routes with resting places
- Build in variety, involve others, keep it fun
- Do not exercise if you are unwell
- Seek medical advice if you experience chest pain, dizziness or sickness

Do strengthening and balance activities as well

... on at least 2 days per week
... to stay strong and reduce the risk of falling

Where can I find out more information about this condition?
The Circulation Foundation: *www.circulationfoundation.org.uk*

Source:
Based on the BASES Expert Statement by Tew, Harwood, Ingle, et al. in The Sport and Exercise Scientist, Issue 57 (Autumn 2018). *https://www.bases.org.uk/imgs/autumn_2018_7601_bas_expert_statement_v2_569.pdf*

Thanks:
To the reviewers who helped to produce this infographic, which was co-funded by The Circulation Foundation and Northumbria University.

CIRCULATION FOUNDATION
The Vascular Charity

Take the right medication

Your consultant will have discussed with you whether certain medications are appropriate for you. They will also tell your GP. These normally include a blood thinning tablet and a cholesterol tablet. A combination of these tablets are known to prevent the risk of cardiovascular complications including heart attack or stroke in the future.

Your GP will manage other risk factor medication including diabetes and blood pressure tablets. The nurse at your assessment can discuss these medications with you if you wish.

Other lifestyle considerations:

1. Healthy balanced diet.
2. Lose weight if you are overweight or obese.

York St John University directions and parking

Lord Mayor's Walk Site- assessment site

York St John University, Lord Mayor's Walk, York, YO31 7EX

The campus is located to the north of York City Centre. It can be accessed from the south by the A19, from the east by the A1036. From the north it can be accessed by Haxby Road or Huntingdon Road.

The Lord Mayor's Walk Site has Automated Number Plate Recognition (ANPR). The vascular nurse will ask for your car registration in advance of your assessment to allow you to park without inccurring any fee. There is Blue Badge parking at this site but there are designated parking spaces available for the assessment.

Parking arrangements will be sent to you with your appointment date.

First bus routes 1,5,5A and 6 stop at Clarence Street bus stop close to the assessment site.

Building location

The vascular nurse will arrange to meet you at the parking location sent with your appointment. The building where your assessment will take place is the

Foss building, coded FS

Haxby Road- SEP site

York St John University Sports Fields, Haxby Road, New Earswick, York, YO31 8TA.

The Sports Park is located off Haxby Road to the north east of the York City Centre. Haxby Road links the City Centre with the A1237 Outer Ring Road to the north.

Haxby Road Sports Park has a large car park with Automated Number Plate Recognition (ANPR). On arrival use the screen in the main reception to log your car registration plate, which will allow four hours of free parking. The exercise instructor can assist with this if required.This must be completed on each visit to the facility upon arrival.

The car park has Blue Badge parking available near to the entrance, you will still need to register your car registration plate on arrival if you park in one of these.

First Bus service number 1 provides the closest bus stop for Haxby road- SEP site. The number 1 service runs between Wigginton and Chapelfields. Traveling towards town the stop is Foss Park. Traveling out of town towards Wiggington, the closest stops are either Bowling Green or Mille Crux.

Building location

The reception point is located just inside the main entrance. On your first session one of the team will meet you at the reception to direct you to room for your exercise programme.

ⓘ For more information, please contact the assistant vascular secretaries on: 01904 724165 or 01904 725540

Alternatively, you can email the vascular nursing team at:

yhs-tr-vascularnurseservice@nhs.net with the subject heading SEP.

Patient Advice and Liaison Service (PALS): We can listen to feedback (positive or negative), answer questions and help resolve any concerns about Trust services. PALS can be contacted on 01904 726262, or email pals@york.nhs.uk An answer phone is available out of hours.

Leaflets in alternative languages or formats: If you require this information in a different language or format, for example Braille, large print, Easy Read or audio, please ask the staff who are looking after you.

Date this version published	June2023 (Pilot Scheme)
Review Date	June 2024
Document Reference	PIL1618 v1, Supervised Exercise Programme (SEP)

www.yorkhospitals.nhs.uk

Appendix 6: Patient information leaflet: home exercise

NHS
York and Scarborough Teaching Hospitals
NHS Foundation Trust

Home-based exercise supplement for people with intermittent claudication.

This home-based exercise supplement is provided in addition to the supervised exercise programme (SEP). These exercises can be completed at home and are a combination of cardiovascular (CV) and active recovery (AR) exercises devised by a trained physical fitness instructor. The exercises will be demonstrated in the exercise classes.

You should aim to complete 30 minutes of these exercises at least twice a week. Choose up to eight of the suggested exercises from the guide below. You could use the ‘Tabata timer’ method for each of the exercises in this supplement. The Tabata timer method is simply performing the exercise for 20 seconds then resting for 10 seconds, repeating each exercise eight times. The Tabata timer is available to download as a free App from most android or Apple devices to help you manage your time.

Alternatively, you can work through the exercises at an intensity that you can sustain for at least 3-10 minutes, resting when required.

Wear comfortable and supportive footwear while exercising, and make sure you have adequate space to exercise safely. If you are prescribed an inhaler and/or GTN (angina) spray, keep them with you whilst exercising. Ensure you have a drink available to maintain hydration.

The table on the next page shows a warm-up exercise to start, followed by nine further exercises on the subsequent pages. Each exercise is named in the first column of the table. There is a visual illustration in the second column, and a description for each exercise in the third column. Except for one exercise, they have different variations available. **EV**- is for easier variations of that exercise, and **AV**- is for advanced variations of that exercise. We have also suggested alternative exercises in the fourth column. If there are any exercises that you find difficult to perform, see if there is an easier option suggested under the ‘Variations’ column or skip to the next one.

If you have any questions about these exercises, please ask your exercise instructor at your next SEP class.

Exercise	Visual illustration	Description	Variations **EV**- easier variation **AV**-advanced variation	Alternatives
Standing dead bugs (warm-up)		Stand tall, chest proud. Feet together, arms by your hips. Then raise the opposite knee and arm. The aim is to reach as high as possible with your knee and hand. Repeat on the other side. Go nice and slowly. Think of this as quality over quantity.	**AV**- karate variation. Start with hands by hips. As the knee rises, both hands go over your head. 	Walking on the spot.

Wall press up	  	Start by facing a wall. Place palms against the wall at shoulder height. Maintaining pressure on the wall, bend your elbows so your body goes toward the wall. Keep your face clear of the wall. Then press against the wall until your arms are fully extended again.	**AV**- visual not shown. As you get more advanced you may go towards a kneeling press up or full press up.	Chest presses in a gym environment. (Ask an instructor for demonstration)

Lunges/ pushbacks		Stand tall. Chest proud. Feet shoulder width apart. Take a stride forward with one leg, both feet facing forward. Allow both knees to bend, the back knee going towards the floor aiming to be parallel. Push through the front foot and return to standing position.	**EV**- No visual. Stand tall, chest proud, and look forward. With one foot, tap behind. Return to starting position. Repeat on the other leg. Once you have got the rhythm you can then bring both arms up into a forward raise as the leg goes back. Imagine that you are pushing yourself back. **AV**- if you want to advance then raise both arms overhead and aim not to allow your knee to touch the floor.	If in a gym environment, leg press, leg extension/curl. (Ask a gym instructor to demonstrate). Alternatively, at home – standing knee raises or if seated it would be leg extensions.

Sit to stand		Sit upright, chest proud. Feet shoulder width apart. Right angle bend at the knee. Push weight through the soles of your feet. Stand up, not using your arms to help you and push your hips forward. Push your hips back as you sit back into the chair slowly.		Any leg exercise in a gym. Or seated leg extensions at home.

Standing calf raises	 	Stand tall. Feet slightly apart. Press your toes into the floor and raise your heels. Raise both arms above your head if possible. Return to starting position. Aim to be slow and controlled with this exercise.	**EV**- standing with a chair for balance.  **EV**- seated. 	Walking. Calf raise machine at a gym.

Bent over rows	 	Stand tall. Chest proud. Feet shoulder width apart. Hands by side of hips. Keeping chest proud, looking forward, pushing hips back allowing knees to bend, pivoting forward from the hips bending over. Keeping chest up, looking forward pull arms up squeezing shoulder blades together. Then extend arms and repeat.	**EV**- Sit upright. Feet shoulder width apart. Lean  forward, keeping chest up, head looking forward while pushing hips into the  back of the chair. Then return to your upright position by placing  hips forward, chest up.	Seated row at a gym. (Ask an instructor to demonstrate). **AV**- you can use the addition of resistance such as tins of food or dumbbells.

Shoulder press	 	Stand tall. Chest up. Feet shoulder width apart. Place hands above shoulders, making a fist with both hands. Push elbows to be in line with your shoulders, then extend your arms in a vertical path above your head. Return hands to in line with your ears, then repeat.	**EV**- seated. Follow the instructions above from a seated position. 	Lateral raises, or shoulder press machine at a gym.- (Ask an instructor to demonstrate). **AV**- you can use the addition of resistance such as tins of food or dumbbells.

Standard step-ups (small step required, or use bottom stair) If you are using a small step take care not to overbalance.	  	Stand tall. Chest proud. Feet slightly apart. Stand close to the step. Lift your leg and place one foot on the step, then stand on the step bringing the other foot up. Step down with the leading foot. Try to alternate which foot leads.	**EV-** If unable to step up, simply just tap with the toe of the foot then repeat with the other leg.  **EV**-Seated- (step optional) Start both knees at right angles, extend one leg at a time returning to the start position 	Walking. Walking up and down stairs. **AV**-as you step up one knee raises to 90 degrees.  Take care not to overbalance.

Seated Lateral raises	 	Sit straight. Chest proud. Hands by side of hips. Feet shoulder width apart. Knees 90-degree angle. Extend both arms out to the side parallel to the floor. Return hands back to the start position then repeat.	**AV**- No visual. Same as seated but in a standing position. **AV**-Add light weights such as tins of food or dumbbells.	Shoulder press at a gym

Appendix 7: Patient information leaflet: Exercise log

NHS
York and Scarborough Teaching Hospitals
NHS Foundation Trust

Supervised exercise programme (SEP) information for intermittent claudication patients.

Home exercise log

Exercise log

This booklet provides log sheets to record exercise completed at home during your 12-week supervised exercise programme (SEP).

Regular exercise is the recommended treatment of intermittent claudication. People often worry about the pain that exercise, such as walking, brings on. However, exercise is known to reduce your symptoms and can increase how far you are able to walk, which can help improve your quality of life.

A key target is to do 30 minutes of purposeful exercise eg. a brisk walk at least three to five days per week. Each supervised exercise session at Haxby Road involves 30 minutes of walking exercise, so these sessions contribute to this weekly target. Other moderate aerobic activities can be substituted for walking such as swimming or cycling.

In addition, you should aim to complete a home-based strength and balance exercise routine at least two days per week. Ask your supervised exercise programme instructor for a home-based exercise supplement. See the infographic on page 3 for more guidance.

The Circulation Foundation also provides information about different types of exercise suitable for people with intermittent claudication. The following link provides alternative home exercises:

https://www.circulationfoundation.org.uk/news/covid-19-special-configure

Alternatively, scan the QR code below to directly access the site via your smartphone or tablet:

Helpful tips

Try to schedule your exercise into your daily routine and plan ahead.

Prior to starting each week's log, take time to consider your goals for that week.

Remember goals should be **SMART: S**pecific **M**easurable **A**chievable **R**ealistic **T**imely.

Some things to consider to help you achieve your **SMART** goals are:

- What am I going to do?

- Where am I going to do it?

- When am I going to do it?

- Who am I going to do it with?

Overcoming barriers to change

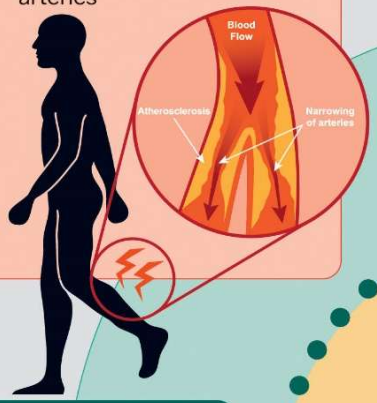
Introducing exercise or increasing the amount of exercise you do can present you with barriers or obstacles, which could prevent you from achieving your goals. It is important to recognise any barriers or obstacles and to think about solutions to overcome them. Use the table below to write any barriers and possible solutions.

Barrier or obstacle	Ideas to overcome this difficulty
Example: walk outside and it's raining	*Check the weather forecast ahead of time and schedule to walk outside on a day that has a dry forecast*

Exercise for Intermittent Claudication

What is intermittent claudication?

- Leg muscle pain or discomfort during walking
- Usually caused by narrowed arteries



NICE National Institute for Health and Care Excellence

RECOMMENDS EXERCISE

Supervised exercise classes produce the greatest benefits - ask your doctor or specialist if these are available locally

Benefits of exercise

- Reduces pain
- Reduces the need for vascular procedures
- Improves heart and vascular health
- Improves mood
- ZZ Improves sleep
- Maintains healthy weight

Walk at a speed that you can maintain for 3-10 minutes

to reduce pain and improve fitness

Walk regularly for exercise

some is good, more is better, make it a habit

Rest until the pain subsides then walk again

Continue until moderate-to-strong leg pain develops

Key recommendations

- Aim to complete 30-60 minutes of walking per session
- Follow the walk-rest-walk pattern (central diagram)
- 3-5 sessions per week

Further guidance

- **Do not fear walking with leg pain** – it will not harm you
- **Build up gradually** – your walking speed and time
- **Be patient** – it usually takes several weeks of exercise to improve symptoms

General tips

- Wear comfortable clothing, keep hydrated
- Choose routes with resting places
- Build in variety, involve others, keep it fun
- Do not exercise if you are unwell
- Seek medical advice if you experience chest pain, dizziness or sickness

Do strengthening and balance activities as well

... on at least 2 days per week
... to stay strong and reduce the risk of falling

Where can I find out more information about this condition?
The Circulation Foundation: *www.circulationfoundation.org.uk*

Source:
Based on the BASES Expert Statement by Tew, Harwood, Ingle, et al. in The Sport and Exercise Scientist, Issue 57 (Autumn 2018), *https://www.bases.org.uk/imgs/autumn_2018_7601_bas_expert_statement__v2_569.pdf*

Thanks:
To the reviewers who helped to produce this infographic, which was co-funded by The Circulation Foundation and Northumbria University.

CIRCULATION FOUNDATION
The Vascular Charity

Use this log to record all physical activity you do each week. This includes walking and other physical activities (eg, cycling, swimming, hoovering, washing the floor or other *heavy* housework, exercise classes). Record all activities for each day.

Week 1

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 2 Date: Goals:

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 3

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 4

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 5

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 6

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain

Week 7

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section on the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 8

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 9

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 10

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 11

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

Week 12

Date: **Goals:**

	Physical activity	Duration of exercise	*Total number of steps	Claudication symptoms or other notes
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

In the notes section of the exercise log, you may want to note any claudication symptoms experienced during the exercise; this might include the time before you experienced any pain or how far you walked before experiencing any pain.

*An activity tracker such as a smartphone or watch can be used to count steps. If you have a device that can monitor your steps, please ask your fitness instructor about how to access this function.

This information leaflet is one of three. The complete set includes:

- Supervised exercise programme: patient information
- Supervised exercise programme: home exercise log
- Supervised exercise programme: exercise supplement

They provide information about the supervised exercise programme and a guide of exercises you can do at home. The log provides a place to record your supervised exercise and home exercises. Your exercise log is a personal record. If you choose it can be shared with your fitness instructor and health care professionals involved in your care.

Appendix 8: Circulation Foundation leaflet

Intermittent Claudication

Whilst we make every effort to ensure that the information contained in this patient information sheet is accurate, it is not a substitute for medical advice or treatment. The Circulation Foundation recommends consultation with your doctor or health care professional. The information provided is intended to support patients, not provide personal medical advice. The Circulation Foundation cannot accept liability for any loss or damage resulting from any inaccuracy in this information or third-party information, such as information on websites to which we link.

What Is Intermittent Claudication?

Intermittent Claudication is caused by narrowing or blockage in the main artery taking blood to your leg (femoral artery). This is due to hardening of the arteries (atherosclerosis). The blockage means that blood flow in the leg is reduced.

Blood circulation is usually sufficient when resting, but when you start walking, the calf muscles cannot obtain enough blood. This causes cramp and pain, which gets better after resting for a few minutes. If greater demands are made on the muscles, such as walking uphill, the pain comes on more quickly.

Claudication usually occurs in people aged over 50 years; however, it can occur much earlier in people who smoke and those who have diabetes, high blood pressure, or high levels of cholesterol in the blood.

Unfortunately, the blockage which causes the claudication will not clear itself, but the situation can improve. Smaller arteries in the leg may enlarge to carry blood around the block in the main artery. This is called collateral circulation.

Many people notice some improvement in their pain as the collateral circulation develops. This normally happens within six to eight weeks of the start of the claudication symptoms.

How is Claudication Detected?

A blockage in the circulation can be detected by examining the pulses and blood pressure in the legs. A blockage will lead to the loss of one or more pulses in the leg.

The blood pressure in your feet is measured using a handheld ultrasound device called a continuous wave Doppler. The blood pressure in the foot can be measured and compared with arm blood pressure (which is usually normal).

This measurement is called the ABPI (ankle brachial pressure index) and is expressed as a ratio. The ABPI provides an objective measure of the lower limb circulation.

Sometimes an arteriogram may be performed. An arteriogram is an x-ray of the arteries performed by injecting contrast (dye) into the artery at groin level. The contrast outlines the flow of blood in the arteries as well as any narrowings or blockages.

Treatments

Claudication is not usually limb-threatening, and it is not necessary to treat it if the symptoms are mild.

Claudication often remains stable with no deterioration in walking distance over long periods.

Less than one in ten patients will notice any reduction in walking distance during their lifetime. However, if your symptoms worsen, there are treatments available which you can discuss with your vascular surgeon.

General measures to improve walking distance include stopping smoking, taking more exercise, and making sure you are not overweight.

Blood tests to rule out other causes of atherosclerosis are often done. These will include a blood sugar test to exclude diabetes, thyroid and kidney function tests, and a cholesterol test.

There are a number of drugs on the market which claim to improve walking distance. These are not used by vascular surgeons as the evidence for their effectiveness is very limited. There is evidence that taking Aspirin or an antiplatelet medication is generally good for people with circulation disorders. Please consult either your GP or vascular surgeon for more information.

Treatment Options

Exercise

Exercise has been shown to more than double walking distance. Some hospitals can offer an exercise programme with structured exercises. If this is not available, a brisk walk three times a week lasting 30 minutes will normally noticeably improve walking distance over 3-6 months.

Angioplasty

Angioplasty (stretching the artery where it is narrowed with a balloon) may help to improve walking distance for some people. Overall, it is less effective in the longer term than simple exercise. Angioplasty is usually limited to narrowings or short complete blockages (usually less than 10 centimetres) in the artery.

Surgery

Bypass surgery is usually reserved for longer blockages of the artery when the symptoms are significantly worse. There may be very short-distance claudication, pain at rest, ulceration of the skin in the foot, or even gangrene in the foot or toes.

Is Treatment Successful?

The simple exercise program is very successful at increasing the walking distance. It provides a long-term solution for the majority of people, and most importantly, it is safe.

Because surgery (and to a lesser extent angioplasty) is not always successful, it can normally only be justified when the limb is threatened. There will usually be pain keeping you awake at night, or ulceration or gangrene of the foot or toes.

How Can I Help Myself?

There are several things you can do which can help. The most important is to stop smoking and take regular exercise.

If you are a smoker, you should make a determined effort to give up completely. Tobacco is particularly harmful to claudicants for two reasons:

- Smoking speeds up the hardening of the arteries, which is the cause of the trouble.
- Cigarette smoke prevents the development of the collateral vessels, which get blood past the blockage.

The best way to give up is to choose a day when you are going to stop completely rather than trying to cut down gradually. If you do have trouble giving up, please ask your doctor, who can give you advice on additional help or put you in touch with a support group.

It is also important not to be overweight. The more weight the legs have to carry around, the more blood the muscles will need. If necessary, your doctor or dietician will give you advice about a weight-reducing diet.

What is the Risk of Losing My Leg?

Very few patients with intermittent claudication will ever be at risk of losing a leg through gangrene. It is the vascular surgeon's job to prevent this outcome at all costs.

If there is thought to be any risk to the limb, a vascular surgeon will always act to save the leg if at all possible.

You can minimize the risk of progression of your symptoms by following the advice provided.

It is the simple measures which are the most effective. The vast majority of patients do not need x-ray or surgical procedures to treat their symptoms.

Maintenance Procedures

Half of the bypasses performed will need some "maintenance" procedure to keep them going. This may be an x-ray procedure or might involve further surgery.

Appendix 9: Permission request via email and VascuQoL-6 questionnaire

Email requesting permission

From: LISA SHARPE
Sent: Wednesday, March 22, 2023 9:48 AM
To: mark.morgan@bopdhb.govt.nz <mark.morgan@bopdhb.govt.nz>
Subject: permission to use the vascuqol-6 questionnaire

Dear Mark Morgan,

I'm writing to you as a masters in research student to ask for your permission to use the Vascuqol-6 tool as part of our research. The project is a feasibility study between the Vascular hub at York Hospital and York St John University. It aims to establish a supervised exercise programme for patients with intermittent claudication symptoms as directed by the NICE guidance. The tool is intended to be used at the beginning and end of a 12-week time frame to assess if the patients QoL has changed as a direct consequence of undertaking the exercise program.

Please do not hesitate to ask further questions about the research and our intentions for the use of the vascuQoL-6, the above is a brief outline,

kind regards

Lisa Sharpe
vascular specialist nurse and masters student

VascuQoL-6 questionnaire

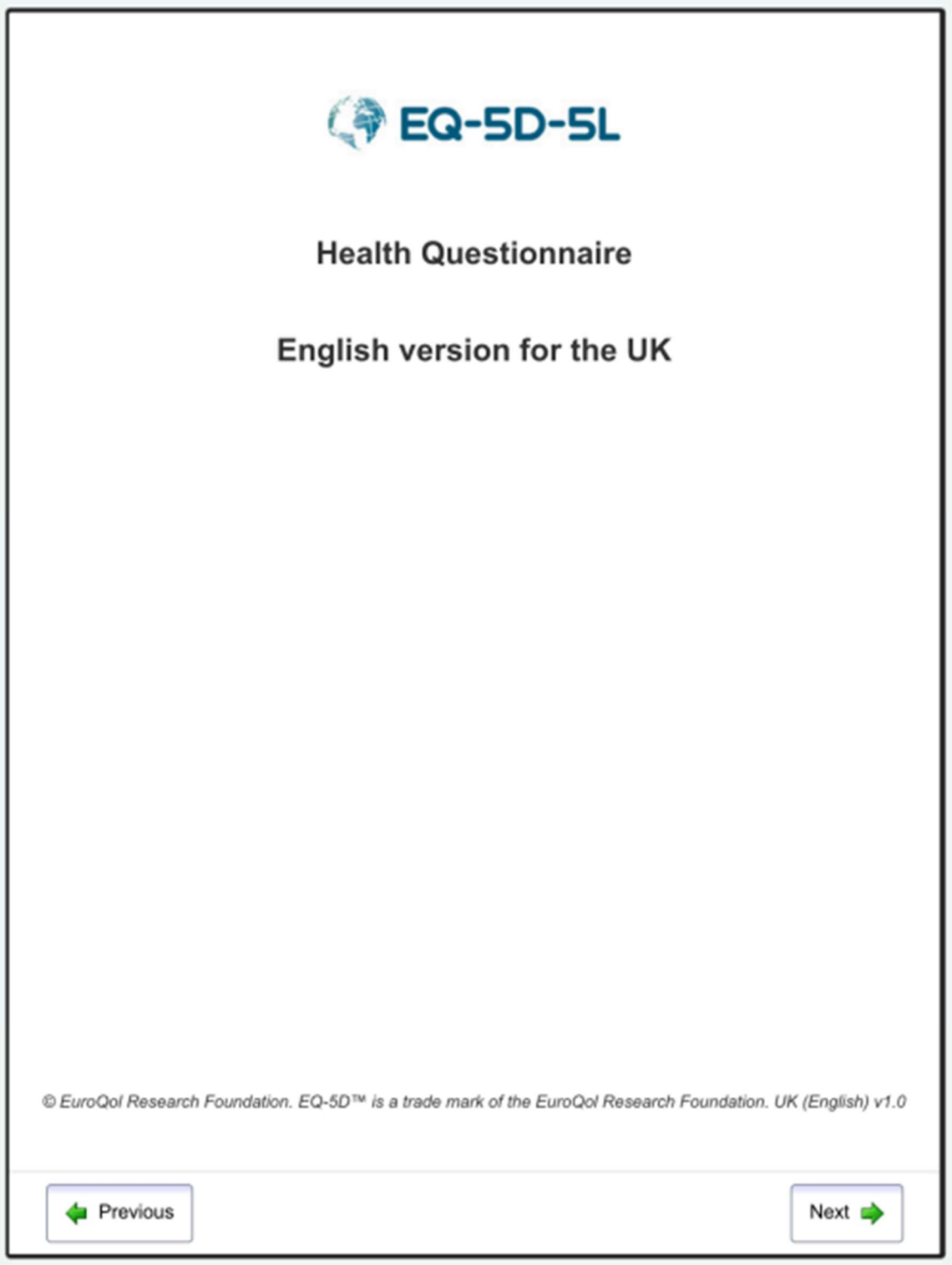
The six-item Vascular Quality of Life *(VascuQoL-6)* health-related quality of life (HRQoL) instrument

- 1.
  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…
    - 1.
      Severely limited—most activities not done
    - 2.
      Very limited
    - 3.
      Very slightly limited
    - 4.
      Not limited at all—have done all the activities that I wanted to
- 2.
  During the past two weeks, my legs felt tired or weak…
    - 1.
      All of the time
    - 2.
      Some of the time
    - 3.
      A little of the time
    - 4.
      None of the time
- 3.
  During the past two weeks, because of the poor circulation in my legs, my ability to walk has been…
    - 1.
      Totally limited, couldn't walk at all
    - 2.
      Very limited
    - 3.
      A little limited
    - 4.
      Not at all limited

- 4.
  During the past two weeks, I have been concerned about having poor circulation in my legs…
  - 1.
    All of the time
  - 2.
    Some of the time
  - 3.
    A little of the time
  - 4.
    None of the time
- 5.
  During the past two weeks, because of the poor circulation in my legs, my ability to participate in social activities has been…
  - 1.
    Totally limited, couldn't socialize at all
  - 2.
    Very limited
  - 3.
    A little limited
  - 4.
    Not at all limited
- 6.
  During the past two weeks, when I have had pain in the leg (or foot) it has given me…
  - 1.
    A great deal of discomfort or distress
  - 2.
    A moderate amount of discomfort or distress
  - 3.
    Very little discomfort or distress
  - 4.
    No discomfort or distress

Each question is scored 1-4. The total score is achieved by summarizing the score on each question, resulting in a score between 6 and 24. Higher value indicates better health status.

Appendix 10: EQ-5D-5L questionnaire (representation of digital form)



Please select the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ☐

I have slight problems in walking about ☐

I have moderate problems in walking about ☐

I have severe problems in walking about ☐

I am unable to walk about ☐

Previous Next

Please select the ONE box that best describes your health TODAY.

SELF-CARE

I have no problems washing or dressing myself ☐

I have slight problems washing or dressing myself ☐

I have moderate problems washing or dressing myself ☐

I have severe problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

Previous Next

Please select the ONE box that best describes your health TODAY.

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐

I have slight problems doing my usual activities ☐

I have moderate problems doing my usual activities ☐

I have severe problems doing my usual activities ☐

I am unable to do my usual activities ☐

Previous Next

Please select the ONE box that best describes your health TODAY.

PAIN / DISCOMFORT

I have no pain or discomfort ☐

I have slight pain or discomfort ☐

I have moderate pain or discomfort ☐

I have severe pain or discomfort ☐

I have extreme pain or discomfort ☐

Previous Next

Please select the ONE box that best describes your health TODAY.

ANXIETY / DEPRESSION

I am not anxious or depressed ☐

I am slightly anxious or depressed ☐

I am moderately anxious or depressed ☐

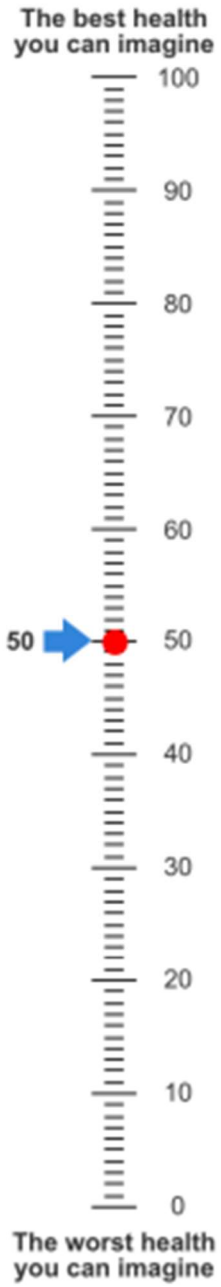
I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

Previous Next

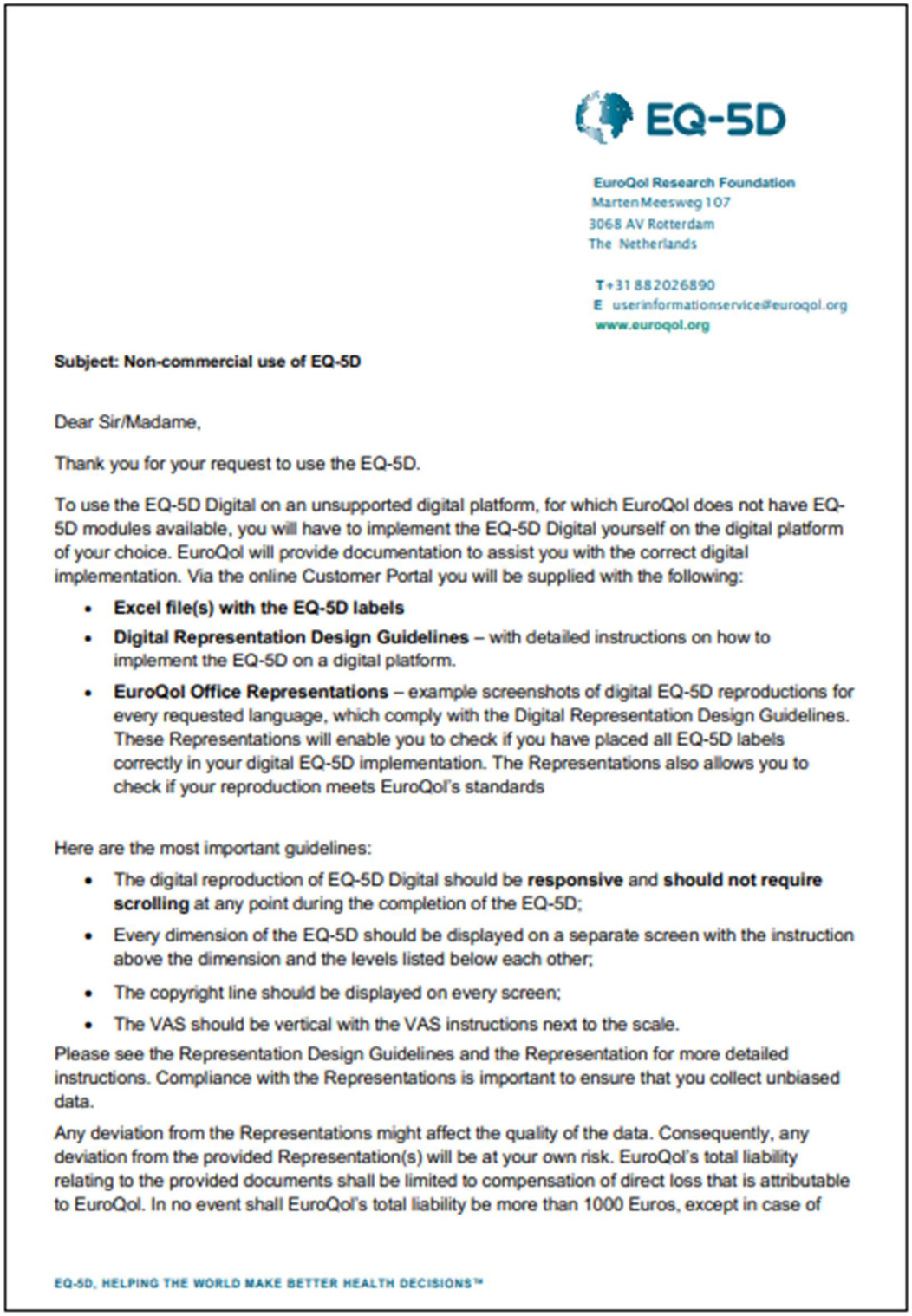
- We would like to know how good or bad your health is TODAY.
- You will see a scale numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Please indicate on the scale how your health is TODAY.

YOUR HEALTH TODAY = **50**



Previous Next

Appendix 11: EQ-5D-5L Digital permission



EQ-5D

EuroQol Research Foundation
Marten Meesweg 107
3068 AV Rotterdam
The Netherlands

T +31 88 2026890
E userinformationservice@euroqol.org
www.euroqol.org

Subject: Non-commercial use of EQ-5D

Dear Sir/Madame,

Thank you for your request to use the EQ-5D.

To use the EQ-5D Digital on an unsupported digital platform, for which EuroQol does not have EQ-5D modules available, you will have to implement the EQ-5D Digital yourself on the digital platform of your choice. EuroQol will provide documentation to assist you with the correct digital implementation. Via the online Customer Portal you will be supplied with the following:

- **Excel file(s) with the EQ-5D labels**
- **Digital Representation Design Guidelines** – with detailed instructions on how to implement the EQ-5D on a digital platform.
- **EuroQol Office Representations** – example screenshots of digital EQ-5D reproductions for every requested language, which comply with the Digital Representation Design Guidelines. These Representations will enable you to check if you have placed all EQ-5D labels correctly in your digital EQ-5D implementation. The Representations also allows you to check if your reproduction meets EuroQol's standards

Here are the most important guidelines:

- The digital reproduction of EQ-5D Digital should be **responsive** and **should not require scrolling** at any point during the completion of the EQ-5D;
- Every dimension of the EQ-5D should be displayed on a separate screen with the instruction above the dimension and the levels listed below each other;
- The copyright line should be displayed on every screen;
- The VAS should be vertical with the VAS instructions next to the scale.

Please see the Representation Design Guidelines and the Representation for more detailed instructions. Compliance with the Representations is important to ensure that you collect unbiased data.

Any deviation from the Representations might affect the quality of the data. Consequently, any deviation from the provided Representation(s) will be at your own risk. EuroQol's total liability relating to the provided documents shall be limited to compensation of direct loss that is attributable to EuroQol. In no event shall EuroQol's total liability be more than 1000 Euros, except in case of

gross negligence or willful misconduct by EuroQol.

Please sign this letter digitally or by printing and signing with a pen. You are then kindly requested to upload the signed letter via the online Customer Portal. After receipt of the signed letter, the documents will be made available in the online Customer Portal, and you are allowed to use the EQ-5D Digital for the duration of the registered Study or ROM/PROMs Project.

Please be advised that separate permission is required if:

- the Study or ROM/PROMs Project is funded by a pharmaceutical company, medical device manufacturer or for profit stakeholder;
- the intention is to charge a fee for third party access to the collected EQ-5D data in the Study or ROM/PROMs Project.

Further, please note that the following is **not allowed**:

- Making the EQ-5D Digital available on paper.
- Using the EQ-5D Digital in a new study/project without a new registration.
- Distributing the EQ-5D Digital to third parties (other than clinical sites, regulatory commissions, respondents, involved digital vendors) without prior approval of EuroQol.
- Modifying, altering, or amending the provided EQ-5D Digital.
- Developing any new language of the provided versions without permission of EuroQol.
- Reproducing the EQ-5D Digital in a publication or on the internet without permission.

If you have also requested the EQ-5D Paper or EQ-5D Modules, please be advised that the Terms of Use Non-Commercial attached in the Appendix are applicable to the use of the EQ-5D Paper.

If any dispute arises out of or in connection to this Letter, parties shall strive to amicably settle the dispute.

If you have any questions related to this Letter, please reach out to userinformationservice@euroqol.org. Please refer to the registration ID number and Study or ROM/PROMs Project title (both can be found on the Registration Confirmation email you received from EuroQol).

As agreed for Registration ID:	57090
Your name:	Garry Tew
Your position:	
Signature:	Type text here Garry Tew
Date:	13/06/2023