

**Sedentary Behaviour in Patients with Peripheral Arterial Disease: Insights from a Systematic Review, Cross-Sectional Analysis and a Mixed Method Feasibility Study**

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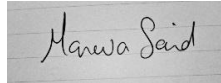
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## Declaration

I hereby declare that this thesis is entirely my own work and that I have not received a degree from University of Galway, or any other institution based on the content of this thesis.

Signed:

A rectangular box containing a handwritten signature in black ink on a light gray background. The signature reads "Marwa Said" in a cursive script.

Marwa Said

## **Statement of Contribution**

The PhD candidate was responsible for the design, data collection, analysis, and reporting of all research presented in this thesis. The study was conducted at vascular clinic-Galway University Hospital, with support from two PhD supervisors. The research was supported by the National Institute for Prevention and Cardiovascular Health (NIPC) and Croí, the West of Ireland Heart and Stroke Foundation. These organisations provided expertise, resources, and collaboration throughout the study.

## **Article-based PhD Requirements**

This PhD is structured as an article-based thesis, following the guidelines set by the University of Galway. These guidelines require the inclusion of three peer-reviewed articles, with the PhD candidate serving as the first author on the major part of the work.

## **Funding**

This research was conducted without any external funding. No financial support, grants, or sponsorships were received from any organisation or funding body.

## List of Works

The research conducted as part of this PhD has produced a number of publications and conference presentations, listed below:

### Published articles

**Said, M.**, Ghoneim, B., Jones, J., & Tawfick, W. 2023. The effects of sedentary behaviour on patients with peripheral arterial Disease: A systematic review. *Preventive medicine Reports*, 36, 102424. <https://doi.org/10.1016/j.pmedr.2023.102424>

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The feasibility study: “A Sedentary Behaviour Reduction Programme in Patients with Peripheral Arterial Disease: A Mixed-Method Feasibility Study” accepted for publication in the *International Journal of Vascular Medicine* - January 2026

### Oral presentation (International)

**Said, M.**, Tawfick, W., Edwardson, C. & Jones, J., 2023. Peripheral arterial disease and cardiac rehabilitation: A call to action in lifestyle and cardiovascular risk factor control – A cross-sectional study. *Heart (British Cardiac Society)*, 109(Suppl 5), pp. A13.2–A14. <https://doi.org/10.1136/heartjnl-2023-BACPR.23>

### Poster presentations (National)

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## **Abstract**

**Background:** Peripheral arterial disease (PAD) is associated with reduced mobility and elevated cardiovascular risk, yet the role of sedentary behaviour (SB) in this population remains underexplored.

**Aim:** This thesis aimed to assess SB in people with PAD, evaluate measurement approaches, and assess the feasibility and acceptability of an intervention to reduce sedentary time.

**Methods:** A systematic review, two cross-sectional studies, and a 12-week feasibility trial using the activPAL accelerometer were conducted.

**Findings:** The review highlighted high levels of SB across existing studies. Cross-sectional findings confirmed that individuals with PAD spend most waking hours sedentary, often in prolonged, uninterrupted bouts, and that self-reported measures substantially underestimate sitting time while overestimating moderate-to-vigorous physical activity. The intervention demonstrated that targeted behavioural strategies could reduce sitting time, though short-term functional gains were limited by PAD-related pain and barriers such as digital literacy. Device-based measurements provided reliable posture-specific data, highlighting the value of objective tools for future research.

**Conclusion:** Collectively, these findings emphasise the high prevalence and impact of sedentary behaviour in PAD, the importance of accurate measurement, and the potential for behavioural interventions to modify sedentary patterns. Future studies should integrate SB reduction with progressive walking, monitor both behavioural and functional outcomes, and incorporate long-term follow-up to determine sustained benefits for vascular health and overall well-being.

### **Keywords**

**Peripheral arterial disease; sedentary behaviour; sitting; physical activity; activPAL; self-report; feasibility; behavioural intervention**

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## **List of abbreviations**

6MWT	6 min walking test
ABI	Ankle Brachial Index
ACC	American College of Cardiology
AHA	American Heart Association
ALI	Acute Limb Ischemia
APAD	Asymptomatic Peripheral Arterial Disease
BCTs	Behaviour Change Techniques
BMI	Body Mass Index
BRC	Biomedical Research Centre
CCTs	Controlled Clinical Trials.
CLTI	Critical Limb–Threatening Ischaemia
COM-B	Capability, Opportunity, Motivation – Behaviour
CT	Computed Tomography
CVD	Cardiovascular Disease
CVDs	Cardiovascular Diseases
DM	Diabetes Mellitus
GUH	Galway University Hospital
HRQoL	Health Related Quality of Life
HTN	Hypertension
IC	Intermittent Claudication
ICC	Inter-Class Correlation
ICD	Implantable Cardioverter Defibrillator
IPAQ	International Physical Activity Questionnaire
IQR	Interquartile Range
LEAD	Lower Extremity Arterial Disease
LIPA	Low Intensity Physical Activity
LMICs	Low- And Middle-Income Countries
LRA	Lifetime Recreational Activity
MACE	Major Adverse Cardiovascular Events
MALE	Major Adverse Limb Events

MAPE Mean Absolute Percentage Error  
METs Metabolic Equivalent of Task  
MRC Medical Research Council  
MVPA Moderate to Vigorous Physical Activity  
NIPC National Institute for Prevention and Cardiovascular Health  
NOS Newcastle-Ottawa Scale  
PA Physical Activity  
PAD peripheral arterial disease  
PPI Public and Patient Involvement  
PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses  
RCTs Randomised Controlled Trials  
SD Standard Deviation  
SET Supervised Exercise Therapy  
SPAD Symptomatic Peripheral Arterial Disease  
SPSS Statistical Package for the Social Sciences  
ST Sitting Time  
SVS Society for Vascular Surgery  
TBI Toe Brachial Index  
TWD Total Walking Distance  
UHG University Hospital Galway  
WHO World Health Organisation  
WIQ Walking Impairment Questionnaire

## **Chapter 1. Introduction**

### **1.1 Overview**

This chapter reviews the background literature to the research conducted for this PhD thesis, focusing on sedentary behaviour in patients with peripheral arterial disease (PAD). It begins by examining PAD as a manifestation of cardiovascular disease (CVD) and explores whether sedentary time serves as a risk factor for PAD or exacerbates its progression. The potential role of reducing and interrupting sedentary behaviour in modifying PAD progression will be discussed. Finally, the chapter outlines the rationale for this research, presents the study's aims and objectives.

### **1.2 Global burden of PAD**

PAD is an atherosclerotic process in the peripheral vasculature that produces arterial stenosis or occlusion in the lower limbs, leading to intermittent claudication, ischemic pain, and functional limitation (1). Peripheral artery disease (PAD) is a common chronic occlusive disorder of the major systemic arteries, most frequently affecting the lower limbs. It is a progressive manifestation of atherosclerosis and serves as a marker of generalised vascular disease (2)

The likelihood of developing PAD increases in the presence of established cardiovascular risk factors such as smoking, diabetes, hypertension, and hyperlipidaemia. PAD is also strongly associated with increased cardiovascular morbidity and mortality, placing patients at high risk of both major adverse cardiovascular events (MACE) and major adverse limb events (MALE) (2) (3) . Within five years of diagnosis, approximately 20% of patients experience myocardial infarction or stroke, and mortality rates range from 10% to 15% (2). Peripheral arterial disease (PAD) affects over 230 million people worldwide and markedly increases the risk of major adverse cardiovascular and limb events (4). When confined to the legs, PAD is often referred to as lower extremity arterial disease (LEAD) (5) . Between 1990 and 2019, the global prevalence of peripheral arterial disease increased by 72.5%, outpacing overall population growth and highlighting a rising burden, particularly among older adults; these demographic shifts have driven much of the increased disease burden (6). A systematic review highlights that prevalence is climbing most rapidly in low- and middle-income countries (7).

Although PAD is recognised as a cardiovascular equivalent and has a growing global prevalence with substantial public health impact (4) , it often remains underdiagnosed and undertreated (4). As the third most common manifestation of atherosclerosis after coronary artery disease and stroke, PAD carries significant clinical consequences (4). Yet it continues

to receive relatively limited research attention and public awareness compared to the other major atherosclerotic conditions (4, 6).

Symptoms vary with the site of arterial obstruction. Clinical presentation ranges from impaired walking and intermittent claudication, the classical hallmark of PAD, to chronic limb-threatening ischaemia (CLTI), the most severe form, which may lead to limb loss or death (2). While intermittent claudication can often be detected via history or validated questionnaires, many patients present with atypical or no limb symptoms (8). Asymptomatic PAD (APAD) carries its own risks, poorer outcomes, reduced limb function and may go unrecognised when patients unconsciously limit activity to avoid discomfort (8). Such behaviour often delays diagnosis until the disease is advanced (5), by which time walking ability and quality of life have already declined (9).

Two main clinical staging systems guide assessment and management for PAD(10). Fontaine's classification relies solely on symptoms, from mild claudication to rest pain and tissue loss. Rutherford's system originally described in 1986 and revised in 1997 distinguishes acute from chronic presentations but adds objective non-invasive data (Doppler waveforms, ankle-brachial index, pulse-volume recordings) to enhance diagnostic precision and inform treatment (11).

PAD is a significant public health concern due to its association with increased cardiovascular events, health complications, and reduced quality of life (12). Patients with PAD, particularly those in advanced stages or after amputation, have significantly reduced utility scores, reflecting impaired quality of life (13). Prospective cohorts and national surveys consistently demonstrate that individuals with PAD face substantially higher risks, making accurate prevalence estimates and risk-factor identification essential for effective screening, prevention, and targeted public health interventions (12).

The Framingham study reported that 75% of PAD patients died from cardiovascular causes, with those having intermittent claudication facing a two- to threefold higher mortality risk (14). PAD is therefore a strong predictor of poor long-term survival, with affected individuals approximately three times more likely to experience all-cause and cardiovascular mortality than those without the disease (15). Severity also influences prognosis, as lower ankle brachial index (ABI) values are linked to markedly higher mortality, underscoring the importance of early detection and management (2, 16)

### **1.3 Pathophysiology of PAD**

The underlying pathophysiology of PAD is driven by atherosclerosis, although vascular inflammation, trauma, or radiation exposure may also contribute (1). Major risk factors include diabetes, smoking, obesity, hypertension, dyslipidaemia, older age, and family history of cardiovascular disease contribute to lesion formation, progressive arterial narrowing, and reduced lower-limb blood flow (1, 2). While smoking and diabetes increase PAD worldwide, ageing populations and rising diabetes and tobacco use make its increase especially concerning in low- and middle-income countries (7).

Beyond structural changes, a combination of arterial stiffness, impaired endothelium-dependent vasodilation, and atherosclerotic progression disrupts normal physiological responses to exercise in PAD (17). This results in exertional leg pain, reduced skeletal muscle perfusion, and altered muscle metabolism. These physiological impairments are key contributors to decreased ambulatory capacity, increased sedentariness, and reduced health-related quality of life. Individuals with PAD often report greater disability and experience a faster physical decline compared to the general population (18)

PAD commonly involves large vessels (abdominal aorta, iliac, femoral arteries), where atherosclerotic plaques gradually narrow the vessel lumen. In early stages, arteries attempt to compensate by dilating (positive remodelling); however, as plaques progress, blood flow becomes increasingly restricted (1). A critical point occurs when arterial narrowing exceeds 50% of the diameter, resulting in significant flow limitation. Although collateral circulation may partially compensate, it is often insufficient to meet the increased metabolic demands during physical activity. This mismatch leads to intermittent claudication, which is relieved by rest (1, 19). In advanced cases, even resting metabolic needs are not met, causing ischaemic rest pain, typically a burning sensation in the feet. Chronic poor blood flow can result in non-healing ulcers, tissue loss, and, in severe cases, gangrene (1).

### **1.4 Diagnosis and clinical implications**

As most patients with PAD do not exhibit typical leg symptoms, objective diagnostic methods are essential. The resting ankle-brachial index (ABI) is recommended as the first-line diagnostic tool according to the 2016 American Heart Association (AHA) and American College of Cardiology (ACC) guidelines (20),(21). ABI is a non-invasive test comparing ankle to arm systolic pressure. It reflects vascular resistance, often affected by vessel narrowing from plaque, intimal damage, or external compression (22). ABI measurement involves assessing systolic blood pressure in both brachial arteries and in the dorsalis pedis and posterior tibial arteries using a sphygmomanometer and Doppler probe. The ABI is calculated by dividing the higher ankle pressure by the higher brachial pressure in each limb, with a value

of  $\leq 0.90$  considered diagnostic of PAD (22). The ABI, as a simple and cost-effective diagnostic tool, offers high specificity (83.3–99.0%) but variable sensitivity (15–79%). It is well-suited for use in both clinical practice and epidemiological research and remains the preferred initial test for detecting both symptomatic and asymptomatic PAD (5)

Advanced imaging techniques, such as duplex ultrasonography, CT angiography, and MR angiography, are often employed to assess arterial stenosis and inform revascularisation strategies (8). Invasive angiography, while still considered the gold standard for detecting arterial lesions, is typically reserved for procedural planning or cases with inconclusive non-invasive findings (8, 23). Additional modalities, like toe–brachial index, pulse-volume recordings, and transcutaneous oxygen measurements, can help evaluate patients suspected of critical limb–threatening ischaemia (CLTI) (8).

### **1.5 Sedentary behaviour, physical activity and PAD**

Recent advances in technology, changes in transport and occupational patterns, and shifts in leisure activities have contributed to a global rise in sedentary behaviour (24). The term “sedentary” originates from the Latin word *sedere*, meaning “to sit” (25). Sedentary behaviour (SB) refers to low-energy activities ( $\leq 1.5$  Metabolic Equivalent of Task (METs)) performed while sitting or reclining, such as television viewing, deskwork, or driving (26). This behaviour is distinct from physical inactivity: individuals can meet recommended levels of moderate-to-vigorous physical activity (MVPA) yet still spend most of their day sitting, which independently increases health risks (27).

Prolonged sedentary time is linked to higher risks of type 2 diabetes, cardiovascular events, and all-cause mortality, even after accounting for physical activity levels (24),(27). This unique physiological burden is further reflected in elevated inflammatory markers, adverse lipid and glucose profiles, insulin resistance, and impaired fibrinolysis (27).

Importantly, focusing solely on exercise time misses the substantial impact of light-intensity activity and the pattern of sitting accumulation (28). In one accelerometer study of 168 adults, frequently interrupting sedentary time was associated with lower adiposity, triglycerides, and two-hour plasma glucose independent of total sedentary and exercise time though further research is needed to confirm these “breaks” effects on cardio-metabolic biomarkers (29, 30).

These issues are magnified in peripheral arterial disease (PAD), where claudication pain limits walking and fosters prolonged sitting. In PAD patients, sedentary behaviour associates with impaired inflammatory and metabolic profiles (26),(31). Even asymptomatic individuals show lower ankle brachial indices with greater sitting time, whereas exercise time exhibits the

opposite relationship, indicating that sedentary behaviour itself may worsen peripheral circulation (32)..

Such a bidirectional cycle where sitting exacerbates PAD, which in turn promotes more sitting is supported by a recent systematic review (33). Wearable-monitor data reveal that people with PAD spend over half their waking hours sedentary, with most activity at light intensity (9). Although light activity benefits older adults without PAD, its effects in PAD remain unclear; nonetheless, many patients cannot achieve recommended moderate-to-vigorous physical activity (MVPA) due to symptoms, underscoring the importance of lighter activities in this group (34).

Low MVPA and high sedentary time are common independent risk factors: the harms of prolonged sitting persist even among those meeting or exceeding activity guidelines (29). Prolonged sitting may also contribute to endothelial dysfunction, a precursor to atherosclerosis and PAD and even asymptomatic PAD patients exhibit poorer systemic endothelial function than age-matched controls, suggesting vascular impairment precedes symptoms (18, 24).

Given these concerns, accurately measuring both total sitting time and interruptions is crucial. Self-reports often miss short breaks (<5 min), driving wider use of accelerometers to capture these patterns (35). Interrupting prolonged sitting with movement is now recognised as vital: PAD patients who engage in activity beyond light intensity experience significantly lower mortality, an effect that holds after adjusting for age, ABI, and BMI reinforcing that even modest movement improves prognosis (36). Accordingly, guidelines emphasise both increasing activity and reducing sedentary time (37). Each additional hour of sitting raises mortality risk by 12%, though this is attenuated to 5% after adjusting for MVPA; eight hours of sitting daily carries a 14% greater risk, and ten hours a 29% greater risk (38).

### **1.6 Physiological mechanisms linking sedentary time and cardiovascular disease**

Prolonged sitting and low physical activity each provoke distinct biological changes that contribute to cardiovascular risk (39). The absence of muscle contractions during extended sitting reduces skeletal muscle lipoprotein lipase activity, impairing triglyceride clearance and glucose uptake, and promoting elevations in total cholesterol and triglycerides (25). These metabolic disturbances foster insulin resistance and raise inflammatory markers such as C-reactive protein, which in turn damage the endothelium and increase vascular mortality. Repeated bouts of uninterrupted sitting also produce low shear stress in arterial walls, directly inducing endothelial dysfunction, a known precursor to atherosclerosis and cardiovascular events (25).

Evidence consistently links higher total sitting time with lower HDL cholesterol across diverse populations. Both accelerometer-based and self-report studies demonstrate this inverse

relationship, and these associations persist after adjusting for moderate-to-vigorous physical activity (25). Television viewing, a common sedentary behaviour has been linked in large cohorts and meta-analyses to higher incidence of type 2 diabetes (25). Longer TV time also correlates with higher blood pressure, lower HDL, and raised glucose, again reflecting both direct metabolic effects of sitting and indirect lifestyle influences (40). Importantly, interruptions to sitting are associated with lower triglycerides and C-reactive protein, underscoring that even brief muscle activity can reduce some of the harmful cardiovascular consequences of prolonged sedentary time (25).

### **1.7 Drivers of sedentary behaviour in PAD**

Sedentary lifestyles worsen the prognosis of PAD. Individuals who remain inactive have a significantly higher risk of mortality compared to those who engage in physical activity (36),(41). Addressing the psychological, social, and physical barriers that restrict mobility is therefore critical to reducing sedentary behaviour and improving health outcomes in this population.

A range of causes contribute to sedentary behaviour in individuals with PAD. Claudication-related pain, physical limitations, and reduced motivation are frequently reported challenges. A notable but often unspoken factor is fear of falling (41). This fear, linked to poor balance and higher fall risk in people with PAD and diabetes, often leads to reduced activity and further functional decline (41). Embarrassment about walking ability also hinders participation, particularly in public or unfamiliar settings (42). This highlights the potential benefit of group-based exercise programmes, where individuals facing similar challenges may feel more comfortable and supported. Creating environments that foster psychological safety is key to encouraging participation (41). Conversely, several factors can help reduce sedentary time. Social support, programme accessibility, and structured interventions such as supervised walking therapy were highly valued. These not only provide motivation but also create a sense of community (41).

### **1.8 Measuring sedentary patterns and physical activity in PAD**

Sedentary behaviour is typically assessed using self-report questionnaires, accelerometers, or direct observation. While direct observation offers the most accurate data, its high cost limits its use in large studies (43). Traditionally, questionnaires were used in epidemiological research, with accelerometers mainly applied in small trials. However, falling costs have led to wider use of accelerometers in large studies (25).

Traditionally, physical activity in patients with intermittent claudication has been assessed through indirect methods such as self-report questionnaires and performance-based tests like

the six-minute walk test (9). However, these approaches may not reflect habitual daily activity. Self-reported methods tend to overestimate moderate-to-vigorous physical activity (MVPA) and underestimate sedentary time by approximately 1.74 hours per day when compared to device-based measures (44). Thus, recent studies emphasise the need for objective, posture-based monitoring to provide more accurate assessments and evaluate the effectiveness of interventions (45),(46).

In response to these limitations, advanced activity monitors like activPAL (PAL Technologies, Glasgow, Scotland), have been increasingly used to capture physical behaviour in detail recording step count, step rate, and time spent sitting or standing (47). Accurately measuring sedentary time is essential for understanding its link with health outcomes and mortality. The activPAL device worn on the thigh, is widely used in research to distinguish between sitting/lying and standing, offering a valid, posture-based tool for capturing sedentary behaviour (48). Edwardson et al. (48) highlighted over 50 studies employing activPAL, reinforcing its reliability. As sedentary behaviour has now been integrated into 24 hour movement guidelines, accurate monitoring of posture and movement is increasingly important (45),(48).

The activPAL is regarded as an accurate accelerometer for measuring sedentary time. Worn on the thigh, it uses an inclinometer to more effectively distinguish between sitting/lying and upright postures (49). A validation study compared activPAL and ActiGraph GT3X accelerometers against direct observation. The activPAL showed a very strong correlation with observed sitting time whereas the ActiGraph accelerometer demonstrated only moderate correlation (25).

Research shows that claudication limits movement, but detailed data on activity timing, duration, and intensity remain limited (46). Typically, patients with PAD demonstrate a consistent daily pattern: activity increases in the morning, peaks in late morning to early afternoon, and declines thereafter. On average, they take around 3,586 steps per day at a low energy expenditure of 1.77 METs, with very few episodes exceeding light intensity. About seven hours of their waking day are spent sedentary, mostly in short bouts interrupted by brief light activity (46).

Thus, objectively measured sedentary time was associated with PAD, even after adjusting for leg symptoms, physical function, and cardiovascular risk factors (24). Importantly, this association persisted even after controlling for MVPA levels, suggesting sedentary behaviour may independently contribute to the development and progression of lower extremity atherosclerosis (24). Accelerometers and self-reports each have strengths and limitations in measuring sedentary behaviour. Accelerometers objectively capture total sedentary time but

do not provide details about specific activity domains. Self-report questionnaires can identify domains but often fail to accurately measure sitting breaks or light-intensity activities and are subject to considerable measurement error (25).

### **1.9 Interventions to reduce sedentary time**

The relationship between sedentary time and mortality showed a gradual increase as sedentary hours rose, with a more significant effect observed for sedentary time exceeding 9.5 hours (28). Spending 10 hours per day sedentary was associated with a 48% higher risk of death, while 12 hours per day was linked to nearly a threefold higher risk (28).

Given the clinical burden of PAD, increasing physical activity (PA) is a key management strategy (42). Supervised exercise therapy (SET) has been shown to enhance walking capacity and quality of life (50). However, limited access and resources often restrict its implementation. Similarly, home-based programmes incorporating activity monitors show promise but remain underutilised, leaving general advice to increase physical activity as the most common approach in routine clinical care (42).

In contrast to the widely studied benefits of physical activity, sedentary behaviour particularly prolonged sitting has only recently gained recognition as an independent health risk. It is now associated with increased cardiovascular and all-cause mortality, cardiovascular events, and heart failure (32). Although an inverse relationship between physical activity and PAD is established, the independent contribution of sedentary behaviour to PAD onset and progression remains underexplored (32). Physical activity contributes to improved endothelial function by increasing laminar shear stress on vascular walls, yet it remains uncertain whether modifying daily activity patterns such as increasing standing or walking time while reducing sedentary time can provide similar benefits, particularly in those with asymptomatic PAD (APAD) (18).

Although most interventions target individuals with symptomatic PAD (SPAD) due to overt walking impairments and high sedentary time, a considerable proportion of people with PAD are asymptomatic (51). Despite lacking classic claudication symptoms, these individuals often show impaired mobility, reduced calf muscle mass, and lower quality of life compared to age-matched peers. Moreover, APAD is also associated with higher risks of premature mortality and vascular events (18). A recent 12-week intervention aimed at reducing sedentary time and increasing lifestyle physical activity in individuals with APAD led to modest improvements in microvascular reactivity and reductions in sedentary time, although it did not significantly impact arterial stiffness. These findings suggest that behavioural interventions, even in the early, subclinical stages of PAD, may still yield meaningful benefits (18).

In individuals with SPAD, exertional leg symptoms often limit daily PA. Nevertheless, increasing activity in this group improves not only vascular function and arterial structure but also broader cardiovascular outcomes such as blood pressure, lipid profiles, and body composition (18). Furthermore, those who engage in activity beyond light intensity demonstrate lower mortality, even after adjusting for age, ankle-brachial index (ABI), and body mass index (BMI), reinforcing the importance of promoting at least moderate-intensity activity (52).

Despite the growing body of evidence supporting physical activity in PAD, interventions specifically targeting sedentary behaviour remain limited. At the time this study was designed, evidence on interventions targeting sedentary behaviour in people with PAD was very limited. Only one randomised controlled trial in 38 individuals with asymptomatic PAD had examined this approach. Participants were randomised to a 12-week home-based physical activity and sedentary reduction programme or an attention control group. The intervention significantly reduced daily sitting time ( $-0.80 \pm 0.87$  vs  $0.18 \pm 0.77$  hours/day;  $P = 0.001$ ) and improved walking performance, with six-minute walk distance increasing from  $354.5 \pm 98.5$  m to  $467 \pm 100.6$  m compared with minimal change in the control group.

After our feasibility study had been designed, new evidence became available from the BREAK-UP study, a single-centre before-and-after study evaluating an 8-week personalised intervention encouraging short activity breaks to interrupt prolonged sitting. The study reported significant reductions in sitting time and improvements in walking ability, along with reductions in prolonged sitting bouts and improvements in standing, stepping, anxiety, depression, and vascular quality of life. As this evidence was not available during the development of our study, it did not inform the intervention design but provides important context for future refinement.

### **1.10 Aim**

Sedentary behaviour has not been well studied in individuals with peripheral arterial disease (PAD). This study aimed to explore the relationship between sedentary behaviour and PAD, assess sedentary time in this population, and evaluate the feasibility and acceptability of an intervention designed to reduce sitting time in this cohort.

## Chapter 2: Methodology

### 2.1 Overview

This chapter outlines the methodological approach used in this thesis, summarising the methods employed to address its aims and objectives. It also highlights the role of public and patient involvement and ethical considerations.

### 2.2 Aim and Objectives

The overall aim of this research was to assess sedentary behaviour in individuals with peripheral arterial disease (PAD) and to evaluate the feasibility and acceptability of an intervention adapted to reduce sedentary time in this population. The programme of research was structured around four interconnected studies, each with specific objectives, guided by the UK Medical Research Council (MRC) framework for developing and evaluating complex interventions. This framework emphasises systematically understanding the problem, identifying intervention components, and assessing feasibility before progressing to full-scale evaluation (53).

#### Study 1 – Systematic Review

- **Objective:** To synthesise existing literature on sedentary behaviour in PAD and identify key evidence gaps.
- **Rationale:** A thorough understanding of current evidence was required to clarify the limitations of previous studies, particularly the reliance on self-reported sedentary behaviour and underrepresentation of PAD populations. This aligns with the MRC guidance to understand the problem fully before designing an intervention.

#### Study 2 – Cross-Sectional Study 1

- **Objective:** To objectively quantify sedentary time in individuals with symptomatic peripheral artery disease (PAD) using the activPAL accelerometer, which distinguishes between sitting, reclining, and upright postures.
- **Rationale:** At the time this study was designed, no studies had evaluated activPAL-measured sedentary behaviour in symptomatic PAD. Only one study had used activPAL in a PAD population, but this was limited to asymptomatic individuals. Before developing a feasibility and acceptability intervention to reduce sedentary behaviour, it was essential to first objectively characterise sedentary and physical activity patterns in this population and determine whether the activPAL method would be feasible and acceptable to participants. This information provides a foundation for designing targeted interventions and informs clinical and research applications

### Study 3 – Cross-Sectional Study 2

- **Objective:** To compare objective measurements obtained from the activPAL accelerometer with self-reported sedentary behaviour and physical activity measured using the International Physical Activity Questionnaire (IPAQ) – long form.
- **Rationale:** The IPAQ is a widely used questionnaire that includes measures of sitting time and moderate-to-vigorous physical activity (MVPA). However, its accuracy in individuals with symptomatic peripheral artery disease (PAD) has not been well established. This study aimed to evaluate whether self-reported sedentary behaviour and physical activity measured by the IPAQ accurately reflect objectively measured behaviours captured by activPAL. Establishing this relationship is important to determine whether the IPAQ can be reliably used in clinical and research settings for patients with symptomatic PAD

### Study 4 – Mixed-Methods Feasibility Intervention Study

- **Objective:** To evaluate the feasibility, acceptability, and preliminary changes of a 12-week behaviour change intervention designed to reduce sedentary time in people with PAD.
- **Rationale:** Guided by the MRC framework, this feasibility study allowed testing of intervention components in a real-world context before a potential full-scale trial. Integrating objective outcomes (activPAL), qualitative feedback (semi-structured interviews), and behaviour change theory (COM-B model and Behaviour Change Wheel) ensured the intervention was evidence-informed, feasible, and acceptable to participants (54).

## 2.3 Approach to the Research

To achieve these objectives, the research followed a **layered methodological approach** aligned with the MRC framework.

- **Systematic Review:** Synthesised evidence identified methodological limitations, and highlighted gaps in sedentary behaviour research in PAD. This step informed the design of subsequent observational and interventional studies.
- **Cross-Sectional Studies:** Provided detailed, PAD-specific insights into sedentary behaviour using objective (activPAL) and self-report (IPAQ) measures. These studies justified the need for an intervention by highlighting behavioural patterns and measurement discrepancies.

- **Feasibility Intervention Study:** Tested the feasibility and acceptability of a 12-week programme combining online education, weekly health coaching, and wearable prompts to reduce sitting time in people with PAD.

Collectively, the four studies provided a clear, evidence-based pathway from problem identification to a feasibility-tested intervention, with the cross-sectional studies addressing key gaps in PAD-specific sedentary behaviour and aligning with the MRC framework. The findings were integrated through a review, identifying themes and overlaps across quantitative and qualitative data. The systematic review highlighted evidence gaps, the cross-sectional studies provided robust PAD-specific sedentary behaviour data, and the feasibility study evaluated intervention acceptability and preliminary effectiveness. This synthesis informed intervention targets, practical implementation considerations, and overall research conclusions.

## **Chapter 3, Systematic Review**

### **The Effects of Sedentary Behaviour on Patients with Peripheral Arterial Disease: A systematic review**

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#### **Abstract**

Sedentary behaviour has recently emerged as a risk factor for cardiometabolic diseases. The objective of this review was to assess the relationship between sedentary behaviour and peripheral arterial disease (PAD). Using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines, we performed an electronic search across databases including Cochrane Central Register of Controlled Trials, Embase, MEDLINE (Ovid), CINHAL and PubMed to identify studies focusing on sedentary behaviour and PAD. A total of 678 records fulfilled eligibility; 166 duplicates were removed, 487 were excluded at the title and abstract level and 15 studies were excluded at the full article level. Thus, our review comprised 10 studies of 20,064 patients with mean age 67.4 years. The average sedentary time was 544.9 min/day. The current review findings indicate that patients with PAD exhibited prolonged periods of sedentary behaviour. Furthermore, sedentary behaviour among patients with PAD was associated with lower survival rates. The included studies also reported varied outcomes regarding walking distance with some showing an association between reduced sedentary behaviour and increased total walking distance. A randomised controlled trial in this review highlighted that reducing sedentary time among patients with PAD improved walking distance. Therefore, the connection between sedentary behaviour and PAD seems to be bidirectional. Sedentary time could contribute to PAD development, and PAD-related symptoms may lead to prolonged sedentary behaviour. A call for research investigating the link between PAD and sedentary time. Additionally, intervention studies are needed to target the reduction of sedentary time in patients with PAD.

### 3.1 Introduction

Worldwide, peripheral arterial disease (PAD) is a major public health challenge affecting more than 200 million patients (1). Being an atherosclerotic disease, many risk factors have been identified for PAD including age, smoking, dyslipidemia, hypertension, diabetes and physical inactivity. Sedentary behaviour has been identified as an independent risk factor for cardiovascular diseases (CVDs) including PAD. Sedentary behaviour refers to sitting or reclining postures and activities characterised by energy expenditures  $\leq 1.5$  Metabolic Equivalent of Tasks (METs) (55).

According to the World Health Organisation (WHO), physical activity incorporates any movement performed by skeletal muscles that necessitates energy expenditure. For individuals aged 18–64 years, WHO recommends engaging in either 150–300 min of moderate-intensity aerobic physical activity, 75–150 min of vigorous-intensity aerobic physical activity, or a balanced mix of both throughout the week (56). Whereas physical inactivity is defined as performing an insufficient amount of moderate to vigorous physical activity (55). Hence, individuals can be physically active according to recommended guidelines while still spending a considerable amount of time in sedentary behaviour.

Mechanistically, sedentary behaviour links to the development and worsening of PAD (32),(24). High levels of sedentary time are associated with increased inflammation, high blood glucose, and high lipid profiles (26). Accordingly, sedentary behaviour has a negative impact on metabolic disorders such as diabetes mellitus, hypertension, and dyslipidaemia, which all or individually and collectively lead to PAD (57).

Being a chronic disease, PAD has a great impact on lifestyle (58). Individuals with PAD had an increased 1-year relative risk of adverse events, stroke, heart failure, cardiovascular mortality and all-cause mortality compared to those without PAD (59) . Despite its significant impact on morbidity and mortality, PAD has received relatively less research or public attention (7). The current available literature lacks a standardised definition of sedentary behaviour, leading to variations in how it is measured and reported across studies. Also, many studies use cross-sectional designs and limited longitudinal studies tracking individuals over time. Few intervention studies focus on reducing sedentary time among PAD patients (43, 60).

We hypothesised that increased sedentary behaviour is associated with a higher prevalence and severity of PAD among individuals. Therefore, the aim of this review was to evaluate sedentary time among patients with PAD and the effects of prolonged sedentary time on PAD

## **3.2 Methods**

This systematic review was performed and reported in adherence with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (61) following the PICOST structure (Population, intervention, Comparator, Outcome). The search was conducted between 20th of March 2022 and 29th of May 2022. We registered the study at PROSPERO International prospective register of systematic reviews (study ID: CRD42023408729).

### **3.3 Ethics approval and consent to participate.**

Since this is a systematic review, the acquisition of data from human subjects was not necessary, and therefore, ethical approval was not required. Given the nature of this study written informed consent was not considered necessary.

### **3.4 Search strategy:**

We conducted searches in the following electronic databases: Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane library, Embase, MEDLINE (Ovid), CINHALL and PubMed. We utilised Medical Subject Headings (MeSH) descriptors during our search, modifying them accordingly for each database. The terms used included, but were not restricted to “peripheral arterial disease,” “sedentary time,” “sedentary behaviour,” “prolonged sitting,” and “intermittent claudication” (Appendix 1). We searched all databases from their inception to May 2022. Search results were downloaded and imported into Rayyan. Rayyan (<https://rayyan.ai>) is a free web and mobile application designed to help and speed up the initial process of screening and selecting studies (62).

## **3.5 Eligibility criteria**

### **3.5.1 Population**

Our review considered studies involving adults ( $\geq 18$  years) with PAD. Patients were considered to have confirmed PAD if they had any of the following: an ankle-brachial index (ABI) of less than 0.90 in one or both lower extremities, a toe brachial index of less than 0.60, or if arterial occlusive disease was detected in one lower extremity by duplex ultrasonography, computed tomographic angiography, or magnetic resonance angiography (63).

### **3.5.2 Interventions**

We included studies that investigated interventions aimed at improving sedentary time among patients with PAD, such as behavioural interventions, advice and coaching, remote interventions using computer-based prompts to stand or walk, software programmes

incorporating self-monitoring and personal goal setting, or wearable devices. These studies were included because they directly evaluated approaches to modifying sedentary behaviour in PAD, providing evidence on the effectiveness of existing interventions.

### **3.5.3 Comparator**

No intervention or minimal intervention. In the context of this review minimal intervention could include online videos containing health recommendations related to PAD or covering topics like general PAD facts.

### **3.5.4 Outcome measures:**

#### **3.5.4.1 Primary outcome**

- Sedentary time in patients with PAD.

#### **3.5.4.2 Secondary outcomes**

- Major Adverse Cardiovascular Events [MACE]
- Walking distance.

### **3.5.5 Study designs:**

We included all types of studies that report on sedentary behaviour/time and PAD among adults ( $\geq 18$  years). In our systematic review, we included different study designs such as randomised controlled trial (RCT) design, controlled clinical trials (CCT) and observational studies concentrating on the reporting of sedentary behaviour in patients with PAD. No language restrictions were applied in the search strategy

### **3.5.6 Timing:**

The search was performed without restrictions on publication date.

## **3.6 Screening process**

We imported titles and abstracts identified from the search strategy into Rayyan (<https://www.rayyan.ai>). Titles and abstracts of identified studies were screened by two review authors (M.S. and B.G.) to detect their eligibility to be included in the review. Any conflicts were solved by discussion between the two authors. If disagreement persisted, two further authors (J.J. and W.T.) were invited to arbitrate. A similar process was conducted to screen full-text articles.

## **3.7 Data extraction and management**

Independently, two review authors (M.S. and B.G.) extracted the data from the incorporated studies. Any disagreement was dealt with by discussion or by asking the other reviewers (J.J.

and W.T.). According to general recommendations for dealing with missing data, we reached out to the investigators who had conducted the original research to request the missing data. Data from the selected articles was recorded in a Microsoft Excel spreadsheet by two separate authors (M.S. and B.G.). This data encompassed details about the study, such as the country where it was conducted, the sample size, methods for measuring sedentary time and the main outcomes.

### 3.8 Assessment of bias in conducting the systematic review

Two review authors (M.S. and B.G.) separately evaluated the quality of risk of bias for all included studies using the Newcastle-Ottawa Scale [NOS] (64). The NOS is one of the most widely used and recommended tools for evaluating the quality of observational studies in systematic reviews and meta-analyses. The NOS was employed to assess methodological quality, as most of the included studies were observational in design. The NOS was specifically developed for non-randomised studies, making it well-suited for cohort and case-control designs. In contrast, risk-of-bias tools (ROB) are primarily designed for randomised controlled trials and may not adequately capture methodological limitations unique to observational research (64, 65). The NOS assesses studies based on three main criteria: selection of study groups, comparability of groups, and outcome of interest as described in Table 3.8.1. Each study is awarded a number of stars, with a higher star count indicating higher methodological quality. In our analysis, the NOS scores ranged from four to six stars suggesting varying levels of methodological consistency among the included studies

**Table 3.8.1 The Newcastle- Ottawa Quality Assessment Scale of the included studies.**

Author, year	Selection			comparability	outcome		Study quality	
		*	*			*		*
<b>Gerage et al, 2019 (42)</b>		*	*	*	-	*	*	Good
<b>Hernandez et al, 2019 (46)</b>			*	*	-	*	*	Fair
<b>Whipple et al, 2019 (41)</b>			*	*	-	*	*	Fair
<b>Whipple et al, 2020 (31)</b>			*	*	-	*	*	Fair
<b>Parson et al, 2016 (66)</b>		*	*	*	-	*	*	Good
<b>Laslovich et al, 2019 (18)</b>	*		*	*	*	*	*	Good

<b>Delaney et al, 2013 (16)</b>	*	*	*		-	*	*	Good
<b>Kulinski et al,2015 (32)</b>	*	*	*	*	-	*	*	Good
<b>Gardner et al,2021 (34)</b>		*	*	*	-	*	*	Good
<b>Unkart et al, 2020 (24)</b>	*	*	*		-	*	*	Good

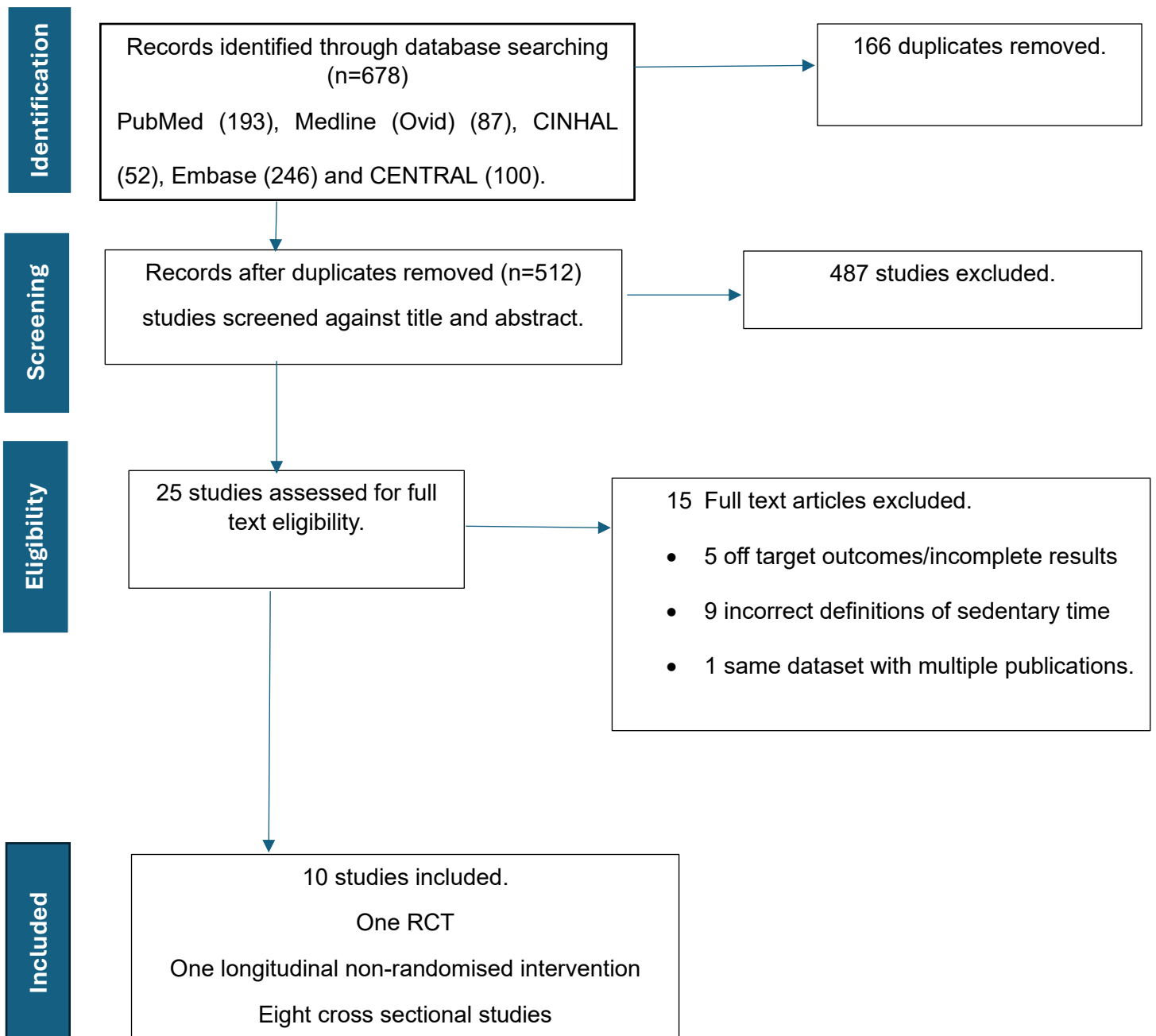
Table 3.8.1 presents the Newcastle-Ottawa scale [NOS] assessing risk of bias in 3 domains (selection, comparability, and outcome) with an overall judgment of study quality (poor, fair or good). An increased number of stars can imply decreased bias.

### 3.9 Data synthesis

We had intended to pool multiple studies with similar enough data to perform a *meta*-analysis to identify this common effect. We had planned to use the random-effects model (67). Unfortunately, only two studies focused on interventions aimed at improving sedentary time among patients with PAD. The first study was a randomised controlled trial by (18), while the second study was a pilot study that used a single-group, repeated-measures design without a control group, conducted by (31).

### 3.10 Results

The database searches according to our search strategy, resulted in 678 records, of which 166 were removed due to duplication as shown in the PRISMA flowchart (Figure 3.10.1). A total of 512 title and abstract records were screened, out of which 487 records were excluded. Twenty-five studies were assessed for full-text eligibility. A total of 15 reports were excluded, resulting in 10 studies being included in the current systematic review.



**Figure 3.10.1 PRISMA flowchart of the selection process.**

A PRISMA flowchart (Figure 3.10.1) illustrates a total of 512 titles and abstract records were screened, out of which 487 records were excluded. Twenty-five studies were assessed for full-text eligibility. A total of 15 reports were excluded, resulting in 10 studies being included in the current systematic review.

### **3.10.1 Excluded studies.**

As our primary focus was sedentary time, we excluded 15 reports for various reasons: Mattioli et al. (68), Gardner et al. (69) and Lanzi et al. (70) did not provide information on sedentary time. Ritti-Dias et al. (71) and Peri-Okonny (72) reported on the percent of sedentary patients. Germano-Soares et al. (9) utilised the same patient dataset presented by Gerage et al. (42) leading to their inclusion as a single study.

Amidou et al. (5) defined sedentary behaviour as < 150 min of moderate-intensity activity per week or equivalent. Berger et al. (12) classified those engaging in vigorous leisure time exercise at least once a week as active; others were sedentary. Krishnan et al. (73) categorised the sedentary group as those individuals not meeting the criteria of 30 min/day for 5 days/week of physical activity. Wilson et al. (74) defined sedentary time to involve behaviours such as sitting, sleeping, or reclining, while also specifying that it excludes any form of lifetime recreational activity (LRA). Some studies incorporated sleep in sedentary time definition. Farah et al. (26) and Farah et al. (27). McDermott et al. (75) and McDermott et al. (76) showed no distinction between reclining during wakefulness, nap time, and sleep time. finally, Gardner et al. (36) calculated sedentary time by combining sedentary time and light intensity activity. Therefore, none of these studies fulfilled the criteria for defining sedentary time, which involves sitting/lying behaviours or activities with energy expenditure of 1.5 METs or less (57).

### **3.10.2 Included studies:**

A total of 10 studies were included in this review. They varied in study design and outcome measures. Two studies used interventions to modify sedentary time among patients with PAD. One was a randomised controlled trial Laslovich et al. (18), The other was a prospective cohort study Whipple et al. (31). The time for the intervention in both was 12 weeks. The remaining eight studies were all cross-sectional in design Gerage et al. (42); Hernandez et al. (46); Whipple et al. (41); Parsons et al. (66); Kulinski et al.(32); Unkart et al. (24); Gardner et al. (34); and Delaney et al (16). An additional study by Germano-Soares et al. (9) will also be discussed. Germano-Soares et al. (9) and Gerage et al. (42) utilised the same patient dataset, leading to their inclusion as a single study due to multiple publications by the same group. Gerage et al. (42) was considered the primary study, while both are mentioned for different outcomes.

Detailed descriptions of the included studies' basic characteristics and summary of results are presented in Table 3.10.2.1 The included studies were published between 2013 and 2022. The total number of individuals included was 20,064 patients. The range of individuals

included in the studies covered in this review varied from 10 to 7,609 individuals with an overall mean age of 67.4 years (range 40–96). One study included men only Parsons et al.(66) and the remaining nine included both genders, with females representing 39.6%. The current review involved population from a range of countries. One study was conducted in the United Kingdom, one in Brazil, and eight in the United States

**Table 3.10.2.1 Descriptive characteristics of studies included in the review with main outcome(s)**

Reference Author(s)/year	Study design	Population	Sedentary time measurement	Main outcome(s)
<b>Gerage et al,2019 (Brazil) (42)</b>	Cross sectional study.	174 patients (43-96 years) with intermittent claudication	ActiGraph GT3X+ triaxial accelerometer.	<p><b>Sedentary time</b></p> <ul style="list-style-type: none"> <li>• Sedentary time was on average 640 ± 121 minutes/day.</li> </ul> <p><b>Waking distance:</b></p> <ul style="list-style-type: none"> <li>• Using the walking impairment questionnaire (WIQ), the mean (score) walking distance (m) was 22.7 (22.2).</li> <li>• The 6MWT (m) was 326.6 (92.7).</li> <li>• total walking distance was not associated with adherence to PA in PAD patients (OR 1.01 95%CI (0.99; 1.02) (p &gt; 0.05)).</li> </ul>
<b>Hernandez et al., 2019 (USA) (46)</b>	Cross sectional study.	44 Patients with PAD	ActiGraph GT1M accelerometer	<p><b>Sedentary time</b></p> <ul style="list-style-type: none"> <li>• Sedentary time was on average 433.45 ± 29.9 minutes/ day</li> </ul>

<p><b>Whipple et al,2019 (41) (USA)</b></p>	<p>A concurrent mixed methods design</p>	<p>Convenient sample of 10 adults aged 65 years and older with PAD and diabetes</p>	<p>ActiGraph wGTX3-BT accelerometer</p>	<p><b>Sedentary time</b></p> <ul style="list-style-type: none"> <li>Participants spent 66.9% (range 53–78%) of their time in sedentary behavior.</li> </ul> <p><b>Walking distance:</b></p> <ul style="list-style-type: none"> <li>WIQ mean (SD) was 35.7 (34.7) ranging from 4.3 – 100. The 6MWT (feet) ranging from 480-1615 with sedentary participants achieved lower 6MWT distances;77% sedentary was associated with 480 feet and 61% sedentary was associated with 1615 feet 6MWT.</li> </ul>
<p><b>Parsons et al,2016 (UK) (66)</b></p>	<p>Cross sectional</p>	<p>945 men from the British Regional heart study, mean age 78.4 years. The British Regional Heart Study is a prospective, population-based cohort study following 7735 men recruited from primary care in 24 British towns</p>	<p>Actigrap GT3X accelerometer.</p>	<p><b>Sedentary time</b></p> <ul style="list-style-type: none"> <li>Sedentary time was on average 640 ± 84 minutes/day among low ABI patients.</li> <li>The percentage of time spent sedentary among low ABI patients was 75.9% vs 71.2 % in normal/borderline ABI patients.</li> </ul>

				<ul style="list-style-type: none"> <li>Each extra 30 min of SB was associated with an OR of 1.19 (95% CI 1.07, 1.33) for a low ABI.</li> </ul>
<p><b>Laslovich et al,2019 (USA) (18)</b></p>	<p>RCT</p> <p>Intervention: PA sedentary reduction (PASR) (n = 19). received bimonthly online video series and a 12-wk interactive homebased online sedentary activity reduction programme (GRUVE). The GRUVE software programme incorporates self-monitoring, personal goal setting, real-time feedback, problem solving, and planning to facilitate increases in daily lifestyle PA and reductions in sedentary behaviour.</p> <p>Control: Attention control group (n = 19) received</p>	<p>38 participants with asymptomatic PAD (APAD)</p>	<p>ActivPAL-3™ Micro activity monitor.</p>	<ul style="list-style-type: none"> <li><b>Sedentary time</b></li> <li>Sedentary time was on average in control= 9.46 ± 0.82 hours/day vs 9.70 ± 0.68 hours/day in intervention group.</li> <li>The intervention group significantly decreased daily sit/lie hours (-0.80 ± 0.87 vs 0.18 ± 0.77 P = 0.001).</li> <li><b>Walking distance:</b></li> <li>Mean± SD 6MWT (m) was 358.2 ± 89.8 in control group vs intervention 354.5 ± 98.5 at base line. After 12 weeks of intervention the mean 6MWT (m) was 364.6 ± 85 in control vs 467 ± 100.6 in intervention (P &lt;0.001).</li> </ul>

	<p>bimonthly online videos involving health recommendations related to PAD (general PAD facts and figures, hypertension, diabetes, cardiovascular disease prevention, tobacco cessation, and nutrition). Participants were asked to continue normal daily activities and routines during the 12-wk study period</p>			
<p><b>Gardner et al,2021 (USA) (34)</b></p>	<p>Observational study</p>	<p>386 patients were eligible (Fontaine II/Rutherford grade I PAD)</p>	<p>The Johnson space centre (JSC) physical activity scale</p>	<p><b>MACE</b></p> <ul style="list-style-type: none"> <li>• The sedentary group represented 12.4%</li> <li>• During follow up, 66.6% died consisting of 83.3% from the sedentary group, 64.3% from the light-intensity physical activity group, and 64.0% from the moderate- to vigorous-intensity physical activity group.</li> </ul>

<b>Kulinski et al., 2015 (USA) (32)</b>	Descriptive data from the National Health and Nutrition Examination Survey (NHANES)	1443 participants. aged 40 years and older.	ActiGraph accelerometer.	<b>Sedentary time</b> <ul style="list-style-type: none"> <li>• Sedentary time was on average 454 ± 144 minutes/day.</li> <li>• Sedentary time was positively associated with a low ABI ((OR) 1.22, (95% CI, 1.03–1.43); P=0.02)</li> </ul>
<b>Whipple et al, 2020 (USA) (31)</b>	A concurrent mixed methods design. Patients completed 2-3 supervised exercise therapy (SET) sessions per week for 12 weeks consisting primarily of repeated bouts of treadmill walking exercise. Sessions broadly followed an established protocol for patients with PAD but were individualised according to patient needs.	44 patients newly enrolled in SET programmes having PAD and DM	A wrist-worn ActiGraph wGTX3-BT accelerometer	<b>Sedentary time</b> <ul style="list-style-type: none"> <li>• Sedentary time was on average 444.2 ± 101.8 minutes/day.</li> <li>• After 12 weeks of SET participants had a 2.8% increase in the average minutes of sedentary time.</li> <li>• Although there was substantial variability, ranging from a 40% decrease to a 38% increase in average minutes of sedentary time per day. There were no statistically significant changes in sedentary activities from baseline to 6 weeks or from baseline to 12 weeks.</li> </ul> <b>Walking distance</b> 6MWT total distance mean (SD) at baseline was 315.5 (94.4) m vs

				344.5 (85.1) m after 12 weeks (P=0.002; (95% CI =11.4 - 46.6)). In addition, improvements in the distance of the WIQ was noted 30.4 (25.7) at baseline vs 38.8 (27.7) after 12 weeks (P= 0.008; (95% CI= 2.3 -14.5)).
<b>Unkart et al,2020 (USA) (24)</b>	Observational the Hispanic Community Health Study/Study of Latinos (HCHS/SOL)	7,609 eligible Hispanic/Latinos individuals aged 45–74 years old.	Actical accelerometer	<p><b>Sedentary time</b></p> <ul style="list-style-type: none"> <li>• The median sedentary time was 12.2 (IQR, 11.1–13.3) hr/day.</li> <li>• The prevalence of PAD was 5.4%</li> <li>• Sedentary time had a significant overall (p= 0.048) association with PAD.</li> </ul> <p>Sedentary time was associated with higher odds of PAD, with the highest sedentary time had (OR=1.49; 95% CI=1.02,2.18) times higher odds of PAD than patients with the lowest sedentary time.</p>
<b>Delaney et al, 2013 (16)</b>	Observational study.	5656 patients (ABI between 0.90 and 1.40) out of the Multi-Ethnic Study of	The typical week physical activity survey'	<ul style="list-style-type: none"> <li>• The incidence of PAD was (n=161). PAD patients were more sedentary,</li> </ul>

		Atherosclerosis (MESA sample 6,814)		<p>performed less vigorous and moderate activity.</p> <ul style="list-style-type: none"> <li>• An association between physical activity/ sedentary behaviour and the progression to low ABI among the sedentary group unadjusted RR=1.20, 95%CI (0.94, 1.52).</li> <li>• Greater intentional exercise reduced the risk of incident PAD (RR=0.85, 95% CI 0.74, 0.98).</li> </ul>
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Table (77): The table provides a comprehensive overview of the design, population, sedentary time assessment and outcome(s) of the included studies (10 studies). It highlights the specific outcome(s) under investigation, including sedentary time, walking distance, and the presence of Major Adverse Cardiovascular Events (58) where applicable.

Studies reporting on the primary outcome could be sub-grouped into categories as follows:

### **Studies reporting on the association between sedentary time and ABI/PAD**

**1. Studies report on sedentary time (min/day or percentage) among patients with PAD:**

Gerage et al., (42), Hernandez et al., (46), Whipple et al., (41), Whipple et al., (41), Parson et al., (66) and Laslovich et al., (18),

**2. Studies comment on the association between sedentary time and low ABI regardless of symptoms:**

Delaney et al., (16), Whipple et al., (31), Laslovich et al., (18), Hernandez et al., (46), and Gerage et al., (42).

**3. Studies report on sedentary time and odds of having PAD:**

Kulinski et al., (32), Parsons et al., (66) and Unkart et al., (24).

**4. Studies aim at reducing sedentary time among patients with PAD.**

Laslovich et al., (18) and Whipple et al., (31)

### **Studies reporting on MACE.**

- Gardner et al., (34).

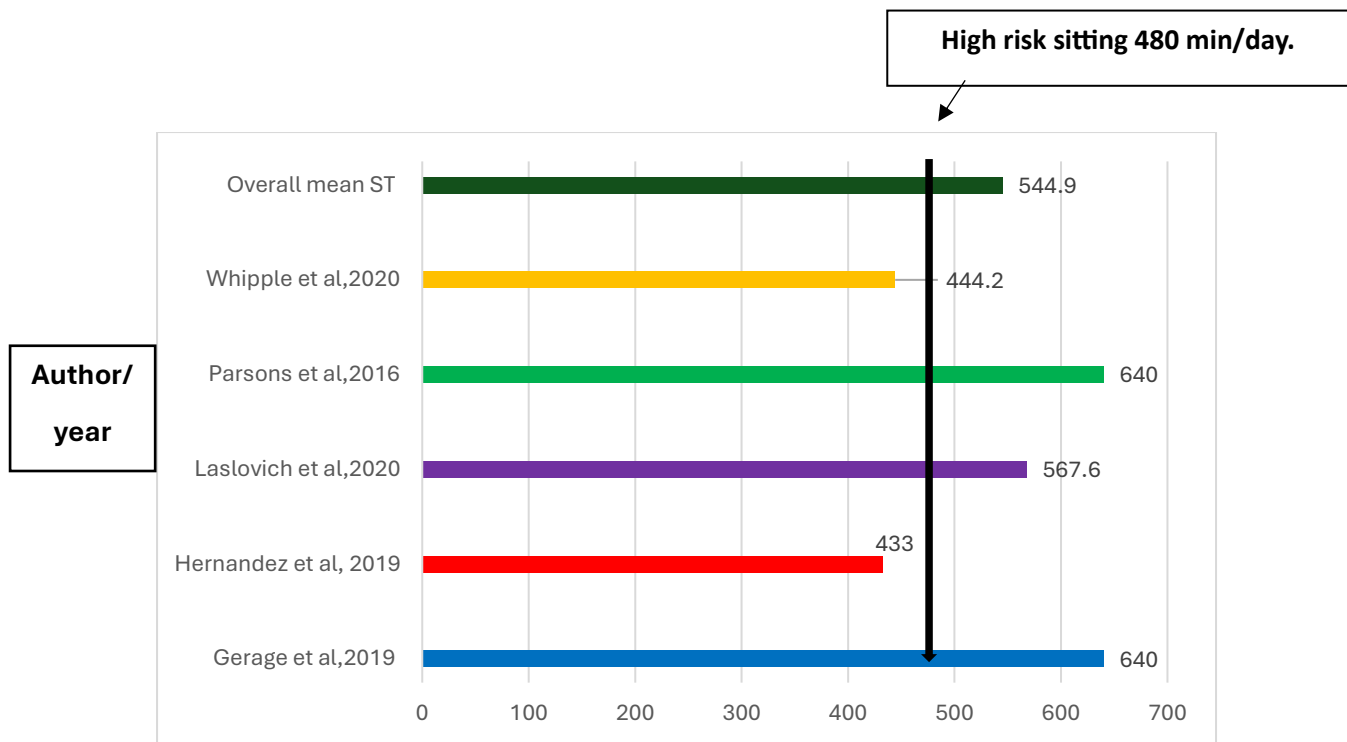
### **Studies reporting on walking distance.**

Gerage et al., (42), Laslovich et al., (18), Whipple et al., (41) and Whipple et al., (31)

## **3.10.3 Outcomes**

### **3.10.3.1 Studies reporting on the association between sedentary time and ABI/PAD**

The included studies defined sedentary time as any waking behaviour such as sitting or lying with an energy expenditure of 1.5 METs or less (57). The 10 included studies used various tools, subjective or objective, to measure the sedentary time outcome. Eight studies used motion sensors/accelerometers as objective measurement tools. Across these eight studies, devices varied widely as shown in Figure **3.10.3.1.1**



Average sedentary time in

Activpal	
ActiGraph GT3X	
ActiGraph GT1M	
ActiGraph wGTX3-BT	
ActiGraph GT3X+	
Overall mean ST	
8 hr/day (high risk sitting)	

**Figure 3.10.3.1.1 The mean sedentary time (min/day) among studies using accelerometer for sedentary time assessment.**

A bar chart illustrates the various types of accelerometers utilised in the studies that were included in the current review to objectively measure sedentary time in relation to high-risk sitting (480 min/day), with the high-risk sitting being represented by the colour black.

### 3.10.3.2 Studies report on sedentary time (min/day or percentage) among patients with PAD

Six studies reported on sedentary time (min/day) in patients with PAD using accelerometer (Gerage et al., (42); Hernandez et al., (46); Whipple et al., (41); Whipple et al., (31); Parsons et al (66); and Lastovich et al., (18). Whipple et al., (41) reported on percentage of sedentary time during waking hours. They reported that patients with PAD spent 66.9% (range 53–78%)

of their time in sedentary behaviour. The remaining five studies reported on mean sedentary time minutes/day. The overall mean sedentary time across these five studies was 544.9 mins/day ranging from 433 to 640 mins/day (Figure 2)

### **3.10.3.3 Studies comment on the association between sedentary time and ABI regardless of symptoms**

Five studies reported on sedentary time and ABIs. Delaney et al., (16) noted an association between sedentary behaviour and the progression to low ABI among the sedentary group unadjusted RR = 1.20, 95 %CI (0.94, 1.52). Four studies investigated the association between sedentary time and low ABI: Whipple et al., (31), Laslovich et al., (18), Hernandez et al., (46) and Gerage et al., (42). The mean sedentary time across these studies was 521.2 min/day.

High sedentary time (>480 min/day) (78),(37) was reported in two studies with low ABIs Laslovich et al., (18) and Gerage et al.,(42) with mean sedentary time of 605 min/day. Both used triaxial accelerometers to assess sedentary time.

Whereas moderate sedentary time (240–480 min/day) was reported in two studies with low ABIs Whipple et al., (31) and Hernandez et al., (46) with mean sedentary time of 438.9 min/day. One study used a triaxial wrist accelerometer Whipple et al., (31) while the other utilised a uniaxial accelerometer Hernandez et al., (46)

### **3.10.3.4 Studies report on sedentary time and odds of having PAD**

Three studies reported on the sedentary time and odds of having PAD/low ABI: Kulinski et al., (32); Parsons et al., (66) and Unkart et al.,(24). Kulinski et al., (32) revealed an odds ratio (OR) of 1.22 (95% CI: 1.03–1.43) for a low ABI with high sedentary time. Similarly, Parsons et al., (66) showed that each additional 30 min of sedentary time was linked to an OR of 1.19 (95% CI: 1.07, 1.33) for a low ABI. Unkart et al., (24) indicated an OR of 1.16 (95% CI: 1.02–1.31) for PAD with sedentary time.

### **3.10.3.5 Studies aim at reducing sedentary time among patients with PAD**

Laslovich et al., (18) and Whipple et al., (31) assessed the impact of interventions aiming at modifying sedentary time among patients with PAD. Laslovich et al., (18) conducted an RCT to assess the effect of sedentary time reduction on patients with PAD. The intervention involved a 12-week interactive homebased online sedentary activity reduction programme, which incorporated self-monitoring, personal goal setting, real-time feedback, problem solving, and planning. The intervention significantly decreased daily sit/lie minutes ( $-48 \pm 52$  vs  $11 \pm 46$ ;  $P = 0.001$ ).

Whipple et al., (31) conducted a pre/post longitudinal prospective study. Patients were asked to complete 2 to 3 Supervised Exercise Therapy (SET) sessions per week for 12 weeks. In contrast to Laslovich et al., (18) the authors of this study reported a 2.8% increase in the average minutes of sedentary time per day from baseline at 12 weeks, following SET. However, there was substantial variability, ranging from a 40% decrease to a 38% increase in average minutes of sedentary time per day.

### **3.10.3.6 MACE**

One study Gardner et al., (34), reported on mortality and sedentary time among patients with PAD. Of the 386 patients included, 257 (66.6%) died during the follow-up period. Survival rate was lowest in the sedentary group. Mortality rate was 83.3% in the sedentary group, 64.3% in the light-intensity physical activity group, and 64.0% in the moderate to vigorous-intensity physical activity group.

### **3.10.3.7 Walking distance**

Four studies reported on walking distance Gerage et al., (42), Laslovich et al., (18), Whipple et al., (31) and Whipple et al., (41). Two of these studies reported on walking distance, however, did not report on an association with sedentary time. Gerage et al., (42) and Whipple et al., (31).

Following a 12-week intervention to reduce sedentary time, Laslovich et al., (18) noted a significant improvement in walking distance. The mean (SD) 6MWT (m) improved from 354.5 (98.5) to 467 (100.6) in the intervention group, compared to a change from 358.2 (89.8) to 364.6 (85) in the control group ( $P < 0.001$ ).

In a cross-sectional study, Whipple et al., (41). reported on the association between sedentary time and walking distance. Using the 6MWT (feet) as a measurement of walking distance, persons with greater sedentary time percentage tended to report lower 6MWT distances. Individuals with sedentary time of  $> 70\%$  had a 6MWT distance of  $< 1000$  feet. Whereas Individuals with sedentary time  $< 70\%$  had 6MWT distance of  $> 1000$  feet.

Germano-Soares et al., (9) utilised the same patient dataset as Gerage et al. (42) and used a compositional *iso-temporal* substitution to detect the effect of reallocating 30 min per week from sedentary to MVPA. This allocation was associated with higher total walking distance (TWD) in men and women. The authors denoted that reducing sedentary time may lead to greater walking distance in patients with PAD.

### **3.10.3.8 Key findings from observational and interventional studies in the review**

#### **3.10.3.8.1. Interventional studies**

Laslovich et al. (18) conducted a 12-week RCT, significantly reducing sedentary time by 48 minutes/day compared with an 11-minute/day increase in the control group ( $P = 0.001$ ). Whipple et al. (31) performed pre/post supervised exercise therapy (SET) sessions for 12 weeks, with sedentary time showing an average 2.8% increase, although individual responses varied widely.

### **3.10.3.8.2. Observational studies**

Several observational studies have examined sedentary behaviour in patients with PAD (Gerage et al., (42); Whipple et al., (41); Hernandez et al., (46); Parsons et al., (66); Delaney et al., (16); Kulinski et al., (32); Gardner et al., (34) and Unkart et al., (24)). These studies found that patients with PAD spend prolonged periods in sedentary behaviour. Associations between sedentary time and walking distance were variable, with some studies reporting that lower sedentary time was linked to greater total walking distance. In addition, Gardner et al., (34) found that participants in the most sedentary groups were found to have the lowest survival rates (34).

## **3.11 Discussion**

To our knowledge this is the first systematic review that highlights the association between sedentary time and PAD. The results from the current review from eight observational studies, one cohort and one RCT based on 20,064 persons revealed concerning levels of sedentary time in the PAD population.

The overall mean sedentary time across studies that reported on sedentary time in min/day was 544.9 mins/day ranging from 433 to 640 mins/day. Sedentary behaviour among patients with PAD was associated with lower survival rates. Some studies showed a relationship between reduced sedentary behaviour and increased overall walking distance. Additional randomized controlled trials are needed to explore the effects of reducing sedentary time in patients with PAD. These trials should also evaluate the feasibility and acceptability of different intervention approaches.

### **3.11.1 Methods to assess sedentary time**

Numerous subjective tools, such as questionnaires, diaries and logs have been used to assess sedentary time (79). Subjective methods, such as questionnaires, are subject to measurement error and response bias (80). Objective tools, such as accelerometers have been used increasingly in research, providing a more accurate measurement of sedentary time by capturing all types of sedentary behaviour (81). The triaxial accelerometers assess sedentary time better, as it measures movements in the three dimensions of space, while the

uniaxial accelerometer measures only one dimension, so it may lack some movements (82),(83).

In this review, Hernandez et al.,(46) reported a mean sedentary time of 433 min/day which is less than the 480 min/day cut off for high-risk sedentary time (78),(37). There is a possibility they may have underestimated the sedentary time, as they used a uniaxial accelerometer (ActiGraph GT1M) waistband.

The location of accelerometer placement may also influence the accuracy of sedentary time measurement. In a study by Marcotte et al., (84) placed triaxial accelerometers on the right hip and nondominant wrist. Results showed that the wrist underestimated sedentary time. A systematic review noted that placing the device on the hip was associated with higher accuracy compared to the wrist (85). One of the included studies in our review Whipple et al., (31) reported a mean sedentary time of less than 480 min/day in patients with PAD, thus not reaching the cut off of high-risk sedentary time (37, 78). There is a potential that the authors may have underestimated sedentary time measurement, as they used a wrist worn triaxial accelerometer. Thus, triaxial accelerometer placed on hip associated with higher sedentary time assessment accuracy.

### **3.11.2 Exploring the complex relationship between sedentary time and PAD**

The mechanism clarifying the pathogenesis between sedentary time and PAD is still unclear. Many possible explanations have been theorised by existing evidence. Excess sedentary time has independent effects on cardiometabolic biomarkers, such as lipids, glucose metabolism and the vascular system, resulting in atherogenesis (86). Additionally, time spent in sedentary behaviour has been associated with high-sensitive C-reactive protein (hs-CRP), glucose, plasminogen activator inhibitor-1 activity and fibrinogen. Even after adjusting for variables like sex, age, physical activity status, body mass index, and PAD severity, a relationship between sedentary behaviour and markers remained evident (27) . Another probable mechanism is that sedentary time increases reactive oxygen species, which is associated with the increased cytokine production and other inflammatory markers, eventually leading to endothelial dysfunction (87).

Park et al., (57) noted that sedentary behaviour reduces lipoprotein lipase activity, muscle glucose, protein transporter activities, impairs lipid metabolism, and diminishes carbohydrate metabolism. As a result, patients with more sedentary time have a higher prevalence of diabetes mellitus (DM), a higher body mass index, metabolic syndrome, and obesity than patients with less sedentary time (26). Currently, there is no conclusive evidence indicating a direct contribution of sedentary time to PAD. It's possible that the relationship is more indirect, involving PAD risk factors like DM and obesity.

Evidence from the cross-sectional observational studies by Parsons et al., (66); Unkart et al., (24) and Kulinski et al., (32) revealed that sedentary time was associated with higher odds of having PAD which persisted after adjusting for other traditional PAD risk factors as dyslipidemia, hypertension, and diabetes. Additionally, Unkart et al., (24) noted that adjustment for hypertension and diabetes minimally reduced the association between PAD and sedentary time. The authors suggested that blood pressure and glucose regulation did not fully mediate the association. Thus, prolonged sedentary time may have other independent damaging effects on the vascular endothelium (24)

From a different perspective, Intermittent claudication, a primary PAD symptom, diminishes walking capacity. Moreover, PAD decreases exercise capacity, leading to sedentary behaviour even without leg symptoms (88). Hence, A potential bidirectional relationship might exist; sedentary time could induce inflammatory markers, contributing to atherosclerosis, while PAD-related symptoms could promote increased inflammation, influencing sedentary behaviour in turn.

### **3.11.3 Sedentary time discrepancy: PAD patients vs. non-PAD individuals**

Fullwood et al., (89) revealed that older adults with PAD had significantly higher total accumulated time spent in sedentary behaviour than those without PAD (13.1 min per day,  $p < 0.02$ ). The increased sedentary time observed in PAD patients could be attributed to many factors, such as reduced mobility, discomfort linked to mobility, and potential limitations in engaging in physical activities. In addition, prolonged periods of sitting have been linked to impaired blood circulation, which is particularly relevant to PAD patients due to their compromised blood flow to the extremities. This heightened sedentary time might contribute to the exacerbation of PAD-related symptoms and further hinder their overall quality of life.

### **3.11.4 The effect of reducing sedentary time on PAD**

The World Health Organisation (WHO) emphasises the importance of reducing sedentary time (37). There was only one RCT included in our review Laslovich et al., (18). The authors noted that reducing daily sedentary time improved walking distance in the intervention group compared to the control group. In contrast to the above studies, Whipple et al., (31) performed found no significant changes in any of the sedentary time or physical activity variables from baseline. However, there was substantial variability with some persons experiencing 40% less sedentary time at 12 weeks compared to baseline, whereas others experienced an increase in sedentary time of up to 38% more at 12 weeks than at baseline. These results suggest that reducing sedentary behaviour could potentially enhance walking ability and overall physical functioning in patients with PAD. Additionally, focusing on reducing sedentary behaviour might

be more feasible than encouraging individuals with PAD to consistently engage in regular exercise.

### **3.11.5 Sedentary lifestyle and all-cause mortality**

A meta-analysis on sedentary behaviour, all-cause, and CVD mortality, reported that a threshold of 6–8 h/day of total sitting increased the risk for all-cause mortality (90). Furthermore, Stamatakis et al., (78) conducted a large-scale prospective study with 8.9 years of median follow-up for all-cause mortality. The authors revealed that replacing sitting with standing was associated with a small reduction in all-cause mortality risk in low sitters only. Additionally, replacing sitting with walking and vigorous physical activity was associated with a reduction in all-cause mortality risk in high sitters. Therefore, adults should be encouraged to sit less during the day to reduce their daily total sedentary time (91),(78)

In this review, only one study reported on and mortality among patients with PAD (34). During follow up of this observational study 66.6% of patients with PAD died. There was a significantly higher incidence of mortality in the sedentary group (83.3%) compared to the light-intensity group (64.3%) and the moderate to vigorous-intensity group (64.0%). Similar studies among patients with medical conditions other than PAD have been done and revealed similar associations between a sedentary lifestyle and all-cause mortality (92).

### **3.11.6 ABI and walking distance**

The ABI, a reliable prognostic marker for PAD, and walking capacity, a core clinical measure linked to PAD, relate to endothelial function, inflammation, and various clinical indicators (42). Previous studies revealed that in patients with PAD, lower ABI has been associated with lower walking capacity (93, 94). However, Laslovich et al., (18) found no significant associations between ABI and 6MWT distance. One possible explanation could be that the authors incorporated PAD patients who were asymptomatic.

### **3.11.7 Physical activity, exercise and PAD**

Supervised exercise training is vital for PAD patients, improving function and life quality. However, availability restricts their broader public health use. Thus, promoting increased physical activity remains key in clinical practice for patients with PAD (42). Germano-Soares et al., (9) noted that modifying 30 min/week from sedentary behaviour to MVPA was associated with a higher total walking distance in patients with PAD. These quantified relationships provide valuable insights into the potential benefits of increased physical activity and reduced sedentary time in the context of PAD.

### **3.12 Conclusion**

The current systematic review uncovered the association between sedentary behaviour and peripheral arterial disease (PAD). The link between both conditions was mostly independent to physical activity and appears to be bidirectional. Sedentary time might foster inflammation, contributing to atherosclerosis, while PAD symptoms could restrict mobility, inducing sedentary behaviour. Furthermore, sedentary behaviour among patients with PAD was associated with lower survival rates. Some studies revealed a link between less sedentary behaviour and greater total walking distance. The review revealed a lack of robust, PAD-specific data using objective measures of sedentary behaviour, as only one study employed the activPAL accelerometer in participants with asymptomatic PAD, highlighting a gap in understanding the patterns of sitting in this population. Importantly, this systematic review did not provide data on sedentary time in individuals with symptomatic PAD, underscoring the need for further investigation. Addressing this gap provided the rationale for the subsequent cross-sectional studies, which aimed to characterise sedentary behaviour specifically in symptomatic PAD and inform the design of a tailored intervention aimed at reducing sedentary behaviour in patients with PAD.

#### **Authors' contribution**

MS, WT, JJ designed the study. MS, WT, JJ, BG assisted in collecting and screening the data. MS, WT, JJ, BG interpreted the data. MS, WT, JJ drafted the initial manuscript. WT, JJ Conducted a thorough and analytical assessment of the manuscript and made necessary improvements and modifications. The final version of the manuscript was authorised for publication by all the authors.

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#### **Declaration of Competing Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. We sincerely thank the University of Galway for covering the publication fees, which enabled us to share this work more widely

## Chapter 4: Cross sectional study 1

### An accelerometry-based assessment of sitting time in patients with peripheral arterial disease – A cross-sectional study

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#### Abstract

**Aim:** This cross-sectional study aimed to measure sitting time (ST)<sup>c</sup> and moderate to vigorous physical activity (MVPA) using accelerometry in patients with peripheral arterial disease (PAD)

**Methods:** Fifty-six patients with PAD were recruited from the University Hospital Galway outpatient vascular clinic. Hospital records with an interview-based assessment documented current clinical status, including ankle brachial index (ABI). ST and MVPA were assessed with the thigh-worn activPAL accelerometer (PAL Technologies Ltd, Glasgow, UK); worn 24hours/day for seven days. **Results:** Of 56 participants recruited, 43 provided valid activPAL data (eight withdrew and five experienced lost/failed devices). Mean age was 67.8 years (SD:  $\pm 10.4$ ), with 67.4% males and mean ankle brachial index was 0.7 (SD:  $\pm 0.2$ ). Participants spent on average  $9.64 \pm 1.57$  hours/day sitting (65.73% of waking hours) of which  $4.85 \pm 1.63$  hours/day were in prolonged bouts ( $\geq 30$  minutes). The median (IQR) for MVPA was 13.8 (27) minutes/day, which equated to 1452 (3074) steps per day. There was no relationship between PAD severity and sitting time ( $r = 0.055$ ,  $P = 0.730$ ). **Conclusion:** The accelerometry assessment of the studied sample of patients with PAD reveals that they are not meeting key guideline recommendations for MVPA participation and are spending a substantial amount of time sitting, often in prolonged, uninterrupted bouts of sitting. Interventions are warranted along with prompting decision makers to implement strategies aimed at reducing sitting time and promoting MVPA for improved outcomes in this group of patients.

#### Keywords

**Peripheral vascular disease, Intermittent claudication, Sedentary time, activPAL, Triaxial thigh monitor.**

## 4.1 Introduction

Peripheral arterial disease (PAD) stands as the third leading cause of atherosclerotic vascular morbidity following coronary heart disease and stroke (95). Its global impact is significant, affecting over 236 million patients worldwide, and its prevalence is expected to increase due to an aging population (8),(96). As PAD progresses, it significantly affects both the patient's quality of life and functional abilities. Given the shared risk factors for atherosclerotic cardiovascular disease (CVD), it is common for PAD patients to concurrently experience coronary artery disease and cerebrovascular disease, leading to a considerable morbidity and financial burden, along with elevated mortality rates including both all-cause and CVD mortality (97, 98).

The Ankle Brachial index (ABI) serves as a diagnostic tool for identifying PAD, where a value < 0.90 indicates flow-limiting atherosclerotic disease in the lower extremity, potentially resulting in mobility impairment and increased mortality. In individuals with intermittent claudication, a decrease in ABI has been associated with reduced engagement in moderate and vigorous physical activity (16). PAD is largely manageable through intensive control of modifiable risk factors. Well-established approaches are available to address these risk factors, including smoking, hypertension, diabetes, obesity, physical inactivity, and elevated cholesterol levels. Increasing physical activity and reducing sedentary behaviour (e.g., sitting) play crucial roles in improving health outcomes for individuals with established PAD (42, 99). Therefore, it's essential to initiate a comprehensive management plan for PAD early on. This plan should include the promotion of physical activity and the reduction of sitting time, in addition to intensive lifestyle modification, medical and psychological risk factors management. This proactive approach is essential to reduce the severe consequences associated with this condition (100).

Current physical activity recommendations state, according to the 'Make Every Move Count' (MEMC) Guidelines, adults should engage in at least 2 hours and 30 minutes to 5 hours of moderate-intensity aerobic physical activity, or at least 1 hour and 15 minutes to 2 hours and 30 minutes of vigorous-intensity aerobic physical activity per week (101). Being classified as physically active involves meeting recommended physical activity levels, but it does not prevent individuals from spending a substantial part of their day sedentary. Therefore, individuals can be both active and sedentary (102).

Sedentary behaviour, defined as any waking behaviour associated with an energy expenditure of  $\leq 1.5$  metabolic equivalent of tasks (METs), and performed in a sitting, lying, or reclining posture, has been linked to various cardiovascular outcomes (103). High levels of sitting greatly raise the risk of adverse health outcomes. For example, high sedentary time has been

associated with doubling the risk of type 2 diabetes and increasing the incidence and mortality risk for other chronic diseases by 10-20% (104). The risk of death increased with more sedentary time, even after adjusting for various factors as age, sex, body mass index (BMI), socioeconomic status, wear time, and time spent in moderate-to-vigorous physical activity (28). While no specific threshold on sitting time per day currently exists, guidelines now include recommendations aimed at reducing sedentary time and replacing it with light intensity activity (56).

Symptomatic patients with PAD may face challenges in meeting recommended physical activity levels due to factors such as age, comorbidities, and intermittent claudication symptoms, contributing to prolonged sedentary periods (42). Studies indicate that patients with PAD often engage in high levels of sedentary behaviour, comprising more than 50% of their waking hours, with walking activities often combined with intervals of rest (24, 32, 46), (89)

The bidirectional relationship between sedentary behaviour and PAD is underscored by a recent systematic review, suggesting that high sitting time may contribute to PAD development, while PAD-related symptoms may lead to spending more time sedentary (33).

The accurate assessment of sitting time is crucial in establishing its association with various health problems and all-cause mortality (105). In recent years wearable accelerometers that can be worn at various body locations, e.g., the hip, waist, or wrist, are being used to provide a more detailed and objective profile of people's physical behaviours (106),(107). Accelerometers worn on the thigh can not only accurately capture physical activity but also provide a more accurate assessment of sitting time in comparison to other accelerometer wear locations, e.g., waist and wrist (108).

Despite the recognised advantages of accelerometer-based assessment, objective data on sedentary behaviour in individuals with peripheral arterial disease (PAD) remain limited. Although one previous study employed a thigh-worn accelerometer (18), this study was conducted in asymptomatic individuals, and a single study is insufficient to adequately characterise sedentary behaviour in patients with symptomatic PAD, given variability in disease severity and daily activity patterns. In addition, the lack of posture-based measurement restricts understanding of prolonged sitting time, which is clinically relevant in PAD. Therefore, the present study aimed to address this gap by objectively quantifying sitting time and physical activity using a thigh-worn accelerometer in patients with symptomatic PAD.

## **4.2 Methods**

### **4.2.1 Study design.**

This was a cross-sectional observational study focusing on adult patients with established and symptomatic PAD.

### **4.2.2 Inclusion/exclusion criteria**

#### **4.2.2.1 Inclusion criteria**

Participants eligible for inclusion in this study were required to be aged 18 years or older and have had established PAD, diagnosed by meeting at least one of the following criteria: an ankle-brachial index (ABI) of less than 0.90 in at least one lower extremity, Toe pressure index less than 0.6 or evidence of arterial occlusive disease in one lower extremity detected by duplex ultrasonography, computed tomographic angiography, or magnetic resonance angiography. participants' symptoms were verified at recruitment using a study record sheet, which included clinical assessment and self-reported claudication. For one participant, symptom status could not be fully verified; however, their ABI met the diagnostic criterion for PAD, and their data were included in the analysis.

#### **4.2.2.2 Exclusion Criteria**

Exclusion criteria involved several factors: life-threatening diseases, defined by a medical history (e.g. active cancer treatment); known skin allergies or conditions exacerbated by adhesive tape used in accelerometer application; current symptoms indicative of myocardial ischemia; significant mental illness or cognitive impairment; primary factors significantly limiting exercise tolerance beyond claudication, such as severe shortness of breath, arthritis, chest pain, or back pain; severe physical disability resulting in restricted independent movement, such as being wheelchair-bound; breastfeeding or pregnancy; insufficient proficiency in English; and unwillingness or inability to provide informed consent.

### **4.2.3 Study setting**

The participant recruitment centre was the Department of Vascular and Endovascular Surgery at the University Hospital Galway - Ireland (UHG). Ethical approval was obtained (Merlin Park Hospital, Clinical Research Ethics Committee Ref: No: CA2794), ensuring compliance with Good Clinical Practice guidelines. Patients underwent screening for suitability by the vascular team, and potentially eligible participants were provided with an information sheet along with the researchers' contact details. Participants gave written consent after receiving detailed information, covering study aims, methods, benefits, and risks.

In the study's recruitment process (Figure 4.4.1), eligible patients were invited, screened, and consented. They were given an opportunity to ask questions before completing the consent form. Participants were reminded of their right to withdraw. In-person participants utilised hard copy consent forms, while virtual participants received them by post.

#### **4.2.3.1 Face to face interview:**

The baseline interview was conducted face-to-face at UHG in the outpatient vascular clinic. Data collection included age, gender, Rutherford classification, smoking status, diabetes, hypertension, dyslipidemia, cardiac, renal, functional impairment and respiratory conditions following Stoner et al. (109) standards. Body weight, height (for BMI calculation), ankle-brachial index (ABI) and toe-brachial index (TBI) measures were recorded too. Subsequently, participants received information on the activPAL device, including correct fitting and usage procedures. They were provided with activPAL instructions and a diary to record wake and sleep times, as well as any accelerometer removal times. The activPAL was attached using hypoallergenic waterproof dressing (Hypafix) and participants received two dressings for reattachment/removal during the seven-day monitoring. Thus, participants went home with the device fitted, diary/logbook, instructions, and a stamped addressed envelope. After seven days the device was returned using the stamped addressed envelope with the completed diary/logbook.

#### **4.2.3.2 Virtual interview:**

Participants unable to attend in person were offered a virtual consultation. Eligible participants received a package including a patient information leaflet (Appendix 3), consent forms, the activPAL device, diary/logbook (Appendix 4) and application guidance. A video demonstrating accelerometer attachment was shared with participants through communication channels of their preference, such as email, WhatsApp, or messaging. Additionally, a stamped addressed envelope was provided to return documents and device by post.

#### **4.2.3.3 Physical activity and sitting time assessed using the activPAL.**

Participants wore the activPAL3™ (PAL Technologies Ltd, Glasgow, UK), a small thigh-worn accelerometer, 24 hours per day for seven consecutive days (48) (110). After receiving the device back, data from the activPAL were downloaded using PAL Connect and event files (using the VANE algorithm) were exported. These event files were then cleaned, processed, visualised and summarised using Processing PAL version 1.32 (University of Leicester, UK; available at: <https://github.com/UOL-COLS/ProcessingPAL>). A valid day was defined as having  $\geq 10$  hours of valid waking wear time,  $\geq 1000$  steps, and  $\leq 95\%$  of the waking day spent in any one behaviour (sitting, standing, or stepping). A valid file was  $\geq$  three valid days of data. Heatmaps were visually checked for occasions where the automated algorithm, to identify

valid waking wear may have mis-classified wake and sleep times. On these occasions, self-reported diaries were referred to and any mis-classified times were corrected based on data and diary information. Output variables were valid waking wear time, sitting time, prolonged sitting time ( $\geq 30$  minutes), standing time, stepping time, and moderate to vigorous physical activity (MVPA) time based on step cadence ( $\geq 100$  steps per minute = MVPA).

#### **4.2.4 Study outcomes.**

##### **4.2.4.1 Primary outcomes**

- Using the activPAL triaxial accelerometer to assess sitting time (total hours/day) in patients with PAD.
- Assessing prolonged uninterrupted sitting bouts ( $>30$  minutes) in patients with PAD using the activPAL triaxial accelerometer.

##### **4.2.4.2 Secondary outcomes**

- Describe levels of moderate to vigorous physical activity (MVPA) minutes/day among patients with PAD using accelerometry (activPAL).
- Assess the correlation between sitting time, MVPA and ABI.

#### **4.2.5 Sample size**

This pilot cross-sectional study recruited a convenience sample of 56 patients with peripheral arterial disease attending vascular outpatient clinics between March 2022 and October 2022.

#### **4.3 Statistical analysis**

Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS) version 27. Demographic characteristics of the participants were presented descriptively, for continuous variables using mean and SD or median and IQR, for categorical variables were summarised using number and percentage. The distribution of the data was checked using tests for normality based on Shapiro–Wilk tests. Non-normally distributed used non-parametric statistical tests. Bivariate correlation analyses between sitting time and ABI were calculated using either Pearson's or Spearman's rho.

#### **4.4 Results**

In total 56 participants were recruited with 43 providing valid activPAL data (Figure 4.4.1).

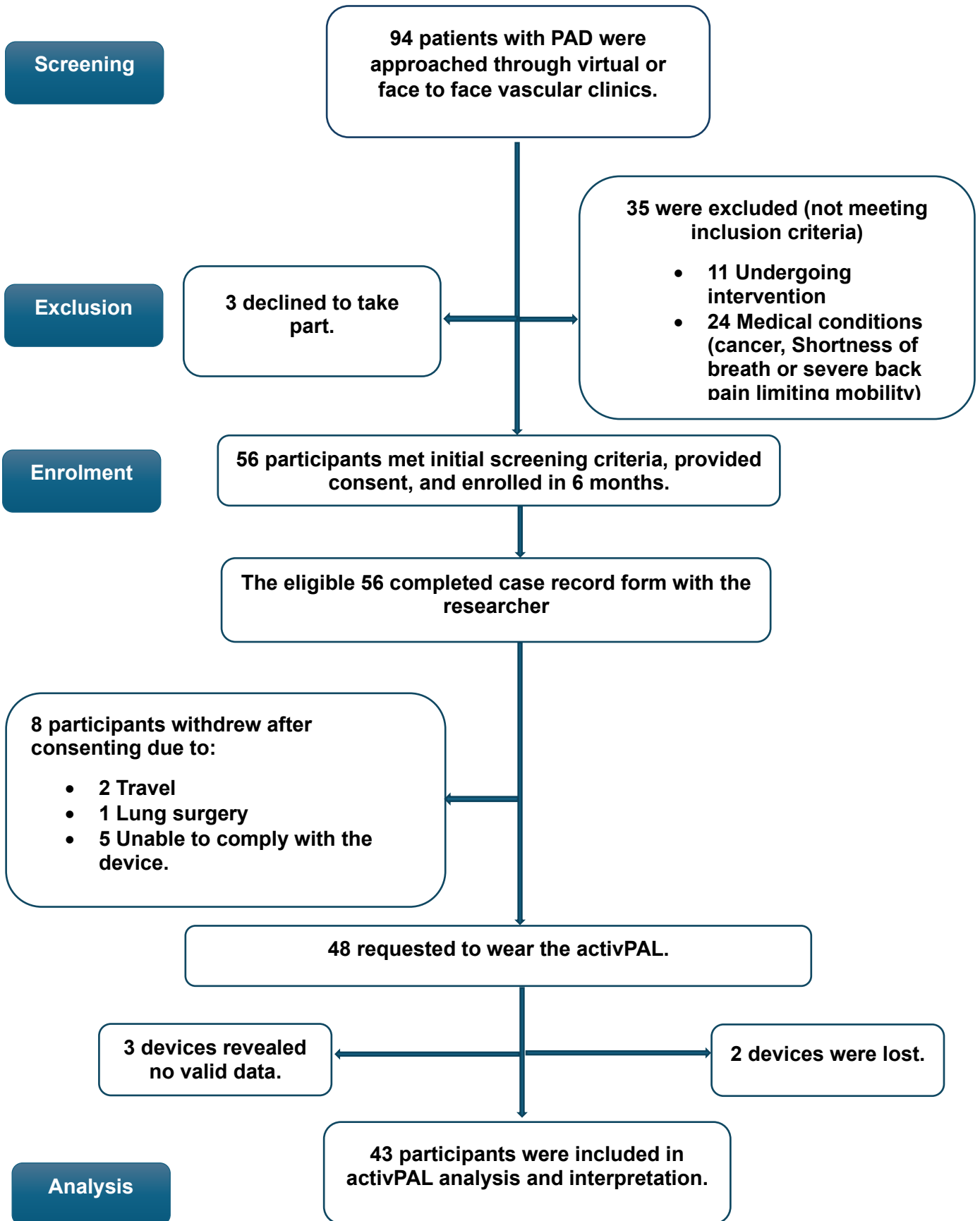


Figure 4.4.1 Flow chart of study enrolment process and analysis

The baseline clinical characteristics of those recruited and providing valid activPAL data are presented in Table 4.4.1. No significant differences were found in age, BMI, ABI, gender, alcohol consumption, smoking, diabetes mellitus, renal condition, cardiac health, hyperlipidaemia, functional status, and antiplatelet therapy between individuals who completed the study and those who did not. However, significant differences ( $P < 0.05$ ) were observed in hypertension (HTN) and Rutherford classification (Table 4.4.1)

**Table 4.4.1 sociodemographic characteristics of the study sample**

<b>Sociodemographic characteristics</b>	<b>All recruited participants=56</b>	<b>Participants had valid activPAL data =43</b>	<b>Significance of differences in the completion status</b>
Age mean (SD) years	68.8 (10.1)	67.8 (10.4)	<i>P</i> = 0.174*
Gender - males N (%)	40 (71.4%)	29 (67.4%)	<i>P</i> = 0.308†
BMI kg/m <sup>2</sup> median (IQR)	7.3 (24.1-30.0)	26.7 (24.3-30.0)	<i>P</i> = 0.778**
Alcohol consumption (yes) N (%)	28 (50%)	22 (51.2%)	<i>P</i> = 0.752‡
Units of alcohol/ week (range)	1-40 units/week	1-40 units/week	
≥10 units/week <10 units/week	4 24	3 19	
Lowest ABI median (IQR)	0.68 (0.60-0.84)	0.67 (0.55-0.84)	<i>P</i> = 0.249**
Lowest TBI mean (SD)	0.4 (0.1)	0.4 (0.1)	
Rutherford 0 = asymptomatic 1 = Mild claudication 2 = moderate claudication 3 = severe claudication	1 (1.8%) 11 (19.6%) 19 (33.9%) 25 (44.6%)	0 11 (25.6%) 12 (27.9%) 20 (46.5%)	<i>P</i> = 0.014§
Diabetes 0 = none 1 = not requiring insulin 2 = controlled by insulin 3 = type 1 or uncontrolled	39 (69.6%) 7 (12.5%) 8 (14.3%) 2 (3.6%)	30 (69.8%) 6 (13.9%) 5 (11.6%) 2 (4.7%)	<i>P</i> = 0.527§
Smoking 0 = none or remote (>10 years) 1 = quit 1-10 years ago 2 = current < 1 pack/year 3 = current > 1 pack/year	25 (44.6%) 12 (21.4%) 8 (14.3%) 11 (19.6%)	19 (44.2%) 10 (23.3%) 6 (13.9%) 8 (18.6%)	<i>P</i> = 0.934§
HTN 0 = none 1 = controlled with 1 drug 2 = controlled with 2 drugs 3 = requiring >2 drugs or uncontrolled	18 (32.1%) 10 (17.9%) 25 (44.6%) 3 (5.4%)	14 (32.6%) 8 (18.6%) 21 (48.8%) 0	<i>P</i> = 0.022§
Renal 0 = normal 1 = Evidence of renal disease, GFR >90 mL/min/1.73 m <sup>2</sup> 2 = GFR 60-89 mL/min/1.73 m <sup>2</sup> 3 = GFR 30-59 mL/min/1.73 m <sup>2</sup> 4 = GFR 15-29 mL/min/1.73 m <sup>2</sup>	12 (21.4%) 19 (33.9%) 14 (25%) 10 (17.9%) 1 (1.8%)	10 (23.3%) 14 (32.6%) 9 (20.9%) 9 (20.9%) 1 (2.3%)	<i>P</i> = 0.521§
Hyperlipidaemia 0 = None 1 = Elevated without drug treatment	16 (28.6%) 0	12 (27.9%) 0	<i>P</i> = 0.225§

2 = Elevated with dietary treatment 3 = Elevated with drug and diet treatment	3 (5.4%) 37 (66.1%)	1 (2.3%) 30 (69.8%)	
Cardiac status 0 = Asymptomatic, with normal electrocardiogram 1 = Asymptomatic but with remote myocardial infarction by history (6 months) or occult myocardial infarction 2 = Any one of the following: stable angina, no angina but significant reversible perfusion defect on dipyridamole thallium scan, significant silent ischemia (1% of time) on Holter monitoring, ejection fraction 25% to 45%, controlled ectopy or asymptomatic arrhythmia, or history of congestive heart failure that is now well compensated	19 (33.9%) 19 (33.9%) 18 (32.1%)	14 (32.6%) 12 (27.9%) 17 (39.5%)	<i>P</i> = 0.048 <sup>§</sup>
Pulmonary 0 = Normal 1 = Asymptomatic or mild dyspnea 2 = Between 1 and 3 3= Vital capacity less than 1.85 liters, FEV1 45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension	28 (50%) 17 (30.4%) 11 (19.6%) 0	22 (51.2%) 12 (27.9%) 9 (20.9%) 0	<i>P</i> = 0.755 <sup>§</sup>
Functional 0 = No impairment 1 = Impaired, but able to carry out ADL without assistance	43 (76.8%) 13 (23.2%)	34 (79.1%) 9 (20.9%)	<i>P</i> = 0.472 <sup>†</sup>
Antiplatelets 0 = none 1 = single agent 3 = dual therapy	5 (8.9%) 38 (67.9%) 13 (23.2%)	5 (11.6%) 28 (65.1%) 10 (23.3%)	<i>P</i> = 0.242 <sup>§</sup>

BMI: body mass index; HTN: hypertension; ABI: ankle brachial index; TBI: toe brachial index

The difference between both groups was calculated using; \* Independent sample t-test, † Fisher's Exact, \*\* Mann-Whitney U test, ‡ Pearson chi square. § Likelihood ratio.

*P*-value < 0.05 was considered statistically significant.

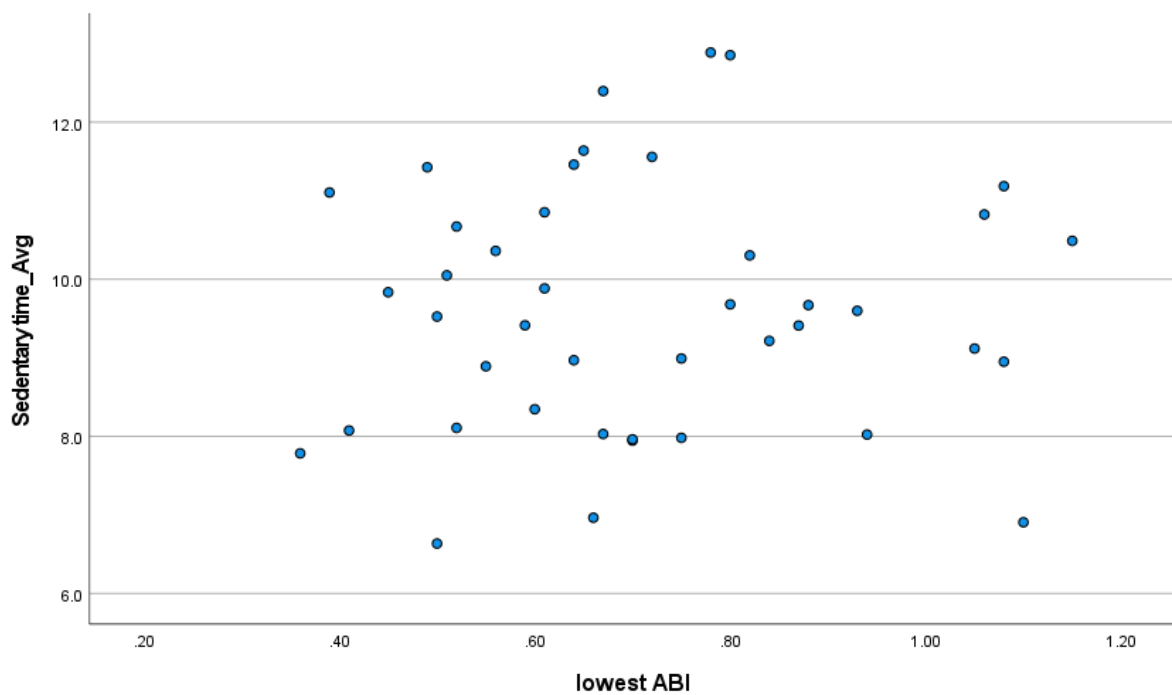
Table 4.4.2 displays the sedentary behaviour and physical activity data from the activPAL. Participants spent (mean  $\pm$  SD) 9.64  $\pm$  1.57 hours/day sitting (65.73%  $\pm$  11.19 of daily awake time) of which 4.85  $\pm$  1.63 hours per day was in prolonged bouts (49.86% (13.51) total sitting time). The mean standing time was 3.79  $\pm$  1.53 hours per day. Median (IQR) total time spent in moderate-to-vigorous physical activity (MVPA) was 13.8 (27) minutes/day representing 20.7% of their total stepping time. When considering purposeful walking at an MVPA intensity (defined as MVPA bouts lasting more than 1 minute) was only 1.2 (7.2) minutes per day on average; representing 1.6% of their total stepping time.

<b>Table 4.4.2 activPAL outcomes from 43 patients.</b>	
<b>Variable</b>	<b>Mean (SD) or Median (IQR)</b>
<b>Average Hours/Day Variables</b>	<b>hours/day</b>
Valid waking wear time	14.87 (1.16) <sup>a</sup>
Sitting time	9.64 (1.57) <sup>a</sup>
Prolonged sitting time (bouts $\geq$ 30minutes)	4.85 (1.63) <sup>a</sup>
Standing time	3.79 (1.53) <sup>a</sup>
Light stepping time	0.57 (0.23) <sup>a</sup>
Total stepping time	1.22 (0.67) <sup>b</sup>
Stepping Time $\geq$ 100 steps/min (MVPA level)	0.23 (0.45) <sup>b</sup>
Stepping Time $\geq$ 100 steps/min in 1 min bouts (MVPA level in 1 min bouts)	0.02 (0.12) <sup>b</sup>
<b>Average Percentage/Day Variables</b>	<b>Percentage/Day</b>
Sitting time (% of waking wear time)	65.73% (11.19) <sup>a</sup>
Prolonged Sitting Time (% of Sitting Time)	49.86% (13.51) <sup>a</sup>
Standing time (% of waking wear time)	25.44% (9.46) <sup>a</sup>
Stepping Time $\geq$ 100 steps/min (MVPA level) (% of stepping time)	20.71 % (29.89) <sup>b</sup>
Stepping Time $\geq$ 100 steps/min in 1 min bouts (MVPA level in 1 min bouts) (% of stepping time)	1.61% (11.6) <sup>b</sup>

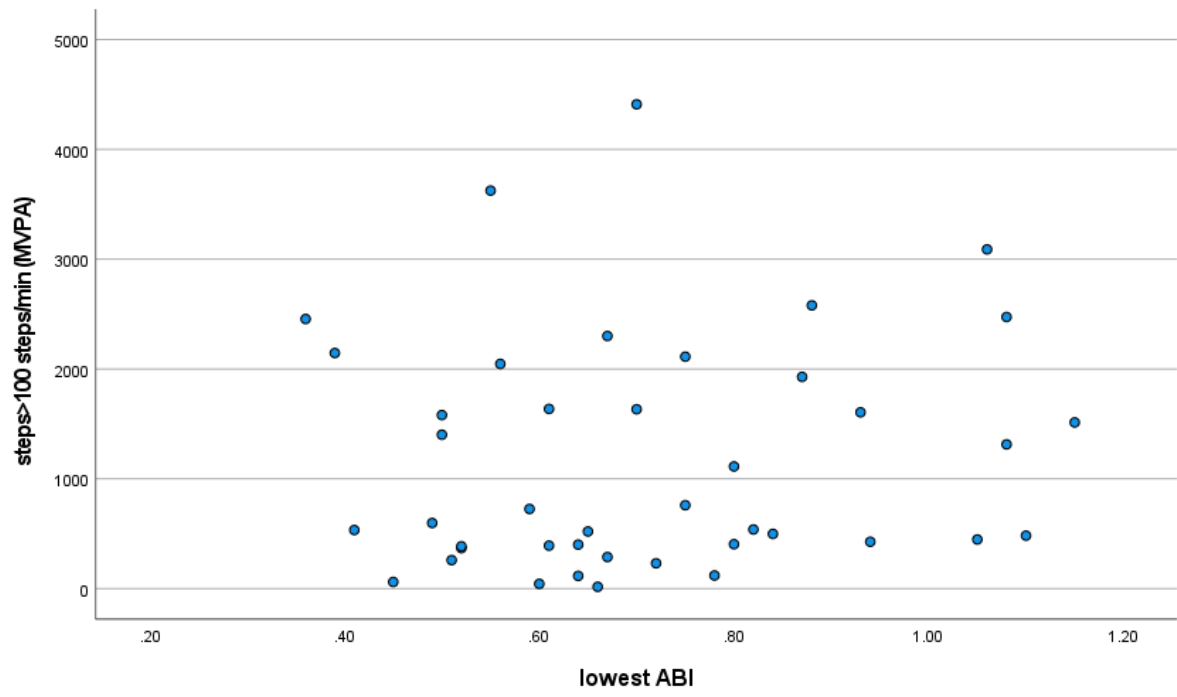
Average Number/Day Variables	Number/Day
Steps	5676 (2936) <sup>b</sup>
Steps $\geq$ 100 steps/min (MVPA level)	1452 (3074) <sup>b</sup>
Wear time days	7.00 (1.00) <sup>b</sup>

<sup>a</sup> Mean (SD), <sup>b</sup> Median (IQR)

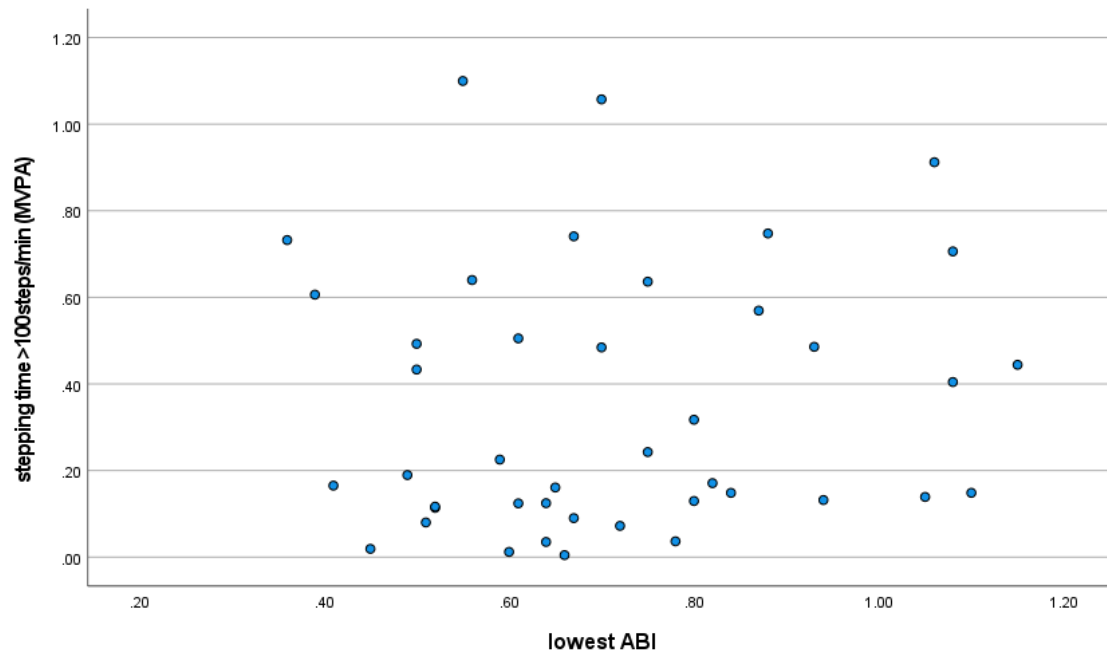
The Pearson correlation coefficients between average sitting time, MVPA time and MVPA steps and lowest ABI were 0.055 ( $P= 0.730$ ), 0.139 ( $P= 0.380$ ), and 0.130 ( $P= 0.411$ ), respectively (Figures 4.4.2 - 4.4.4).



**Figure 4.4.2 Scatter plot illustrating the relationship between participants' lowest Ankle-Brachial Index (ABI) and their average sitting time**



**Figure 4.4.3 Scatter plot illustrating the relationship between participants' lowest Ankle-Brachial Index (ABI) and the MVPA level steps**



**Figure 4.4.4 Scatter plot illustrating the relationship between participants' lowest Ankle-Brachial Index (ABI) and the Stepping time $\geq$ 100steps/min (MVPA level).**

#### 4.5 Discussion

Peripheral artery disease (PAD) is frequently underestimated when compared to cardiovascular disease (CVD). Likewise, the association between PAD and sitting time is not fully understood and little is known about levels of sitting time of patients with PAD (66). Thus, the present cross-sectional study measures sitting time among a cohort of patients with PAD.

The current study demonstrated that patients with PAD accumulated a total of  $9.64 \pm 1.57$  hours/day (mean  $\pm$  SD) sitting down, which was 65.73% of their waking hours. This is consistent with a recent systematic review (33) which revealed an average duration of 9.10 hours per day of sitting time in patients with PAD. Only one of the studies included in this review used a thigh-worn accelerometer with 38 patients (mean aged 68 years) from the USA. The level of sitting time of  $9.58 \pm 0.75$  hours/day was very similar to the present study (18).

The specific pathogenic mechanisms linking sedentary behaviour and PAD remain unclear. Excessive sedentary time independently impacts cardiometabolic biomarkers, contributing to atherogenesis (60). Sedentary behaviour also correlates with markers like high-sensitive C-reactive protein, glucose, plasminogen activator inhibitor-1 activity, and fibrinogen, maintaining significance even after adjusting for various factors. Another potential mechanism involves sedentary time elevating reactive oxygen species, leading to inflammation and endothelial dysfunction (27). Additionally, sedentary behaviour diminishes lipoprotein lipase activity, muscle glucose, and protein transporter activities, contributing to conditions like diabetes

mellitus and obesity. Alternatively, intermittent claudication reduces walking capacity, potentially contributing to increased sedentary behaviour (26, 27). This suggests a bidirectional relationship where sitting time may induce inflammatory markers leading to atherosclerosis, while PAD symptoms may promote inflammation, influencing sedentary behaviour (33).

Extended unbroken sedentary periods, especially beyond 90 minutes, pose the highest risk of all-cause mortality in middle-aged and older adults (111). In the present study participants engaged in a proportion of prolonged sitting bouts, with 49.86% % of total sitting time (4.85 hours per day) being accumulated in bouts lasting over 30 minutes. A possible explanation is that patients with PAD have walking impairment and other comorbid conditions due to the disease characteristics and severity (42). Hernandez et al. (46) justified this by observing that when patients with claudication walked, they showed short bursts of activity followed by two to three minutes of rest. These findings are significant in understanding the impact of PAD on the daily activities of patients with PAD.

Tracking daily steps is vital for patients with PAD as it serve as a fundamental unit of movement and can quantify the intensity of physical activity. Therefore, tracking daily steps, step rate (cadence), and duration of MVPA are meaningful metrics to evaluate activity levels in individuals with claudication (98). Furthermore, regular physical activity is highly beneficial and recommended as adjunct therapy for many chronic diseases. For peripheral artery disease (PAD), supervised exercise like intermittent walking is the first-line therapy to improve functional capacity and quality of life (112). Understanding the biological mechanisms behind exercise's benefits in PAD is crucial for understanding the disease pathophysiology and developing new treatments (113). Exercise positively modulates biological mechanisms related to inflammation and vascular endothelial dysfunction involved in the atherosclerotic process and attenuates myopathy progression in lower extremities. These improvements at the whole-body level translate into better functional status and health-related quality of life (HRQoL) (113)

In the present study, the median duration of total time spent in moderate-to-vigorous physical activity (MVPA), defined as stepping time at a cadence of  $\geq 100$  steps per minute, was 13.8 minutes/day and only 1.2 minutes/day of this was in purposeful stepping (bouts lasting at least one minute). In agreement with the study conducted by Gerage et al. (42) involving 174 claudicating patients with PAD, the findings revealed that participants spent an average of 15 minutes/day engaged in MVPA as measured by the ActiGraph accelerometer worn on the waist. This level falls below the recommendations for health benefits (42).

Gardner et al. (114) determined that patients with PAD and claudication are usually not able to reach a cadence of 100 steps/min and patients with PAD encounter challenges when engaging in MVPA. Potential justification could be due to the potential exacerbation of intermittent claudication symptoms that higher-intensity activities may trigger. As a result, patients with PAD typically select for lower-intensity physical activities to avoid the occurrence of these symptoms (42). The median steps/min recorded in the study was 1452 steps/min ( $\geq 100$  steps/min representing MVPA). While PAD-related vascular impairment affects both large and micro vessels, influencing physical activity behaviours, microvascular reactivity, and arterial stiffness (18), the observed step pattern likely reflects short bouts of movement rather than sustained moderate-to-vigorous activity. This suggests that although participants reach MVPA intensity briefly, overall physical activity remains limited, which may have implications for functional capacity and cardiovascular health

In the present study, the mean  $\pm$  SD standing time was  $3.79 \pm 1.53$  hours per day, while the mean light stepping time was  $0.57 \pm 0.23$  hours/day. The estimated level in the current study shows similarities to what has been observed in a study conducted by Gerage et al. (42). The results revealed that, on average, participants spent  $4.50 \pm 1.60$  hours per day engaging in low-light activities when utilising the ActiGraph accelerometer worn on the waist.

The results revealed no significant correlation between ABI and sitting time possibly due to factors such as age, height, ethnicity, and even the order of measurement. Also, the collateral vessels develop in response to PAD to provide alternate pathways for blood flow. The presence of well-developed collateral vessels can lead to falsely elevated ABI values. Conversely, insufficient collateral circulation may lead to lower ABI values, indicating more severe blockages and reduced blood flow. Considering collateral circulation is important when interpreting ABI results for assessing PAD severity (115). In addition, reliability of the ABI can be affected by several factors as recency of tobacco smoking, caffeine intake and exercise (116).

#### **4.6 Study strengths and limitations.**

The strength of the current study is in its use of the activPAL accelerometer particularly within a patient group where evidence is limited. By offering detailed data on sitting time and physical activity levels, accelerometers shed light on the activity patterns of patients with PAD, enhancing the robustness and reliability of the findings. However, the sample size was small and from one geographical region so findings may not be generalisable to populations with PAD with diverse cultures and lifestyle. The study did not examine the influence of gender, age, or height on the relationship between ABI and sitting time, despite these data being

available. In addition, ethnicity was not collected, precluding assessment of their potential effects. Further research with larger samples is warranted to explore the influence of these factors on ABI and sedentary behaviour in patients with PAD. Despite these limitations, the study emphasises the need for additional research to investigate sedentary behaviour among patients with PAD.

#### **4.7 Conclusion**

This study, using the activPAL accelerometer, demonstrated that patients with PAD engage in extensive sedentary behaviour, with a significant proportion of their day spent sitting, often in long and uninterrupted bouts. Furthermore, this was coupled with concerning low levels of moderate-to-vigorous physical activity (MVPA). Effectively addressing sedentary time is known to translate to numerous positive biological, physiological and long-term survival outcomes. These findings highlight further research is warranted to identify effective approaches that achieve meaningful reductions in overall sedentary time and interrupt prolonged sitting bouts; replacing sitting time with active movement interspersed throughout the day.

#### **Acknowledgement**

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None declared.

#### **Conflict of interest:**

The author(s) declared no conflicts of interest with respect to the research, authorship, and/or publication of this article.

#### **Authors contribution**

M.S. conducted recruitment, performed statistical analysis, interpreted results, and drafted the manuscript. J.J. and W.T. contributed to the study design, statistical analysis, and critically revised the manuscript. C.E. contributed to the processing and interpretation of activPAL data and revised the manuscript. S.S. and M.A. contributed to recruitment from the vascular clinic.

Every author granted final approval and committed to being responsible for all facets of the work.

### **Availability of data and materials**

The final anonymous datasets were shared upon reasonable and approved request. Requests could be made via email to the Principal Investigator and were subject to the trial's ethical approval conditions.

### **Ethics approval and consent to participate.**

Ethical approval was obtained from the Merlin Park Hospital., Clinical Research Ethics Committee Ref: No:CA2794. The procedures ensured investigators followed Good Clinical Practice guidelines by the International Conference on Harmonisation (ICH). The researcher ensured no participant engaged in any activity before giving informed consent. Written consent was provided after participants received detailed information, and the verbal explanation covered all key elements from the written information.

The researcher informed participants about the study's aims, methods, benefits, potential hazards, and any discomfort it may cause. Participants had the opportunity to ask questions before signing and dating the informed consent form. They were also asked for permission to share relevant data with university collaborators or regulatory authorities if needed. Completed consent forms were archived in the researcher's master file.

Participants were informed of their right to withdraw consent at any time without penalty or loss of entitled benefits. Those who refused or withdrew consent were excluded but assured continued medical care.

### **Data protection and availability**

Patient data were securely stored with unique identifiers, encrypted, and only coded information was accessible. Data will be retained for five years after thesis acceptance and can be accessed by participants or the research ethics committee upon request.

## Chapter 5: Cross sectional study 2:

### A comparison of Self-Reported and Accelerometer-Measured Sitting Time in People with Peripheral Arterial Disease: A Cross-Sectional Study

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#### Abstract

**Background** There is compelling evidence supporting physical activity and structured exercise in managing peripheral arterial disease (PAD). Prolonged sitting time is now recognised as a significant health concern and remains underexplored. The International Physical Activity Questionnaire (IPAQ) queries self-reported sitting time, whereas the activPAL, a research-grade thigh-worn accelerometer, robustly measures sitting time.

**Objectives** This study compared IPAQ and activPAL-measured sitting time and MVPA in people with PAD. **Methods** Participants were adults with established PAD attending the vascular outpatient clinics. Agreement between IPAQ and activPAL was assessed using Bland-Altman analysis, equivalence testing, the Mean Absolute Percentage Error-(MAPE) and the Intraclass Correlation Coefficient-(ICC). **Results** Of 56 participants, 41 (73%) completed both IPAQ and activPAL measurements. The median (IQR) sitting times recorded by activPAL and IPAQ were 9.5 (2.7) and 6.0 (2.7) hours/day, respectively. IPAQ underestimated sitting time compared to the activPAL, with wide limits of agreement. Equivalence testing showed significant deviation from  $\pm 5\%$ , ICC indicated poor agreement, and MAPE revealed high variability. IPAQ MET-min/week scores overestimated activity levels compared to activPAL-measured MVPA. **Conclusion** IPAQ underestimated sitting time and overestimated physical activity in PAD compared to thigh worn accelerometry, with a clinically significant 3.5-hour difference in sitting time, emphasising the need for caution when using self-reported tools in PAD research and clinical assessments. Identifying accurate tools for this high-risk population is warranted.

#### Keywords

sitting time, PAD, activPAL, IPAQ, MVPA

## 5.1 Introduction

Peripheral artery disease (PAD) affects over 200 million people globally demonstrating significant health risks (2). PAD is influenced by modifiable risk factors, including smoking, dyslipidemia, diabetes, obesity, and physical inactivity (117). Current physical activity guidelines recommend that adults, including those with PAD, engage in at least 150 minutes of moderate or 75 minutes of vigorous activity per week or a combination of both (56). For people with PAD, structured exercise programmes should involve walking at moderate-to-strong claudication pain for 30 to 45 minutes, three times per week, over a minimum duration of three months (118). Supervised exercise therapy (SET) is endorsed as a Class IA guideline for people with symptomatic PAD (119). However, the exercise therapy consensus statement does not explicitly address the importance of reducing sedentary behaviour, despite evidence suggesting that decreasing sitting time can significantly enhance the effectiveness of exercise therapy in this population (120).

Sedentary behaviour, characterised by low-energy activities ( $\leq 1.5$  METs) such as sitting and reclining (121), has been increasingly studied since 2000 for its adverse health effects. Recent findings link high sedentary behaviour to metabolic dysfunction, cardiovascular disease and increased mortality (57, 122). The combination of insufficient physical activity and high sedentary behaviour can have both independent and interconnected effects on cardiovascular risk. Notably, adults may meet or exceed physical activity recommendations yet still spend most of their waking hours sitting, further impacting their cardiovascular health (123),(124). The risk of all-cause mortality rises significantly beyond 7.5 hours of daily sedentary time, with a 48% higher risk at 10 hours (125).

While physical activity levels among individuals with PAD are well-documented, there is a notable lack of studies focusing specifically on sedentary behaviour. Evidence suggests that people with PAD accumulate an average of nine hours per day of sitting time (33). Despite recommendations, people with PAD often fail to meet recommended levels of moderate-to-vigorous physical activity (MVPA) (126).

Assessing PA and sedentary time is complex, requiring valid and reliable instruments that are also practical (127). Questionnaires, such as the International Physical Activity Questionnaire (IPAQ) (128), are widely used due to their low cost and ease of administration (129). The IPAQ measures sitting time and PA levels consistently across its short and long forms (130) but self-reports tend to overestimate MVPA but underestimate sedentary time by around 1.74 hours per day compared to device-based measures (44)

Accelerometry can estimate both physical activity and sedentary behaviour, but the choice of device depends on its metrics, validity, and reliability. The optimal accelerometer for specific

populations remains unclear. Most accelerometers focus on physical activity rather than sedentary behaviour, though newer models track movement across three planes, improving activity classification, differentiation between sedentary and active behaviours, and energy expenditure estimates (131),(132). Thigh-worn devices like activPAL demonstrate high accuracy in detecting posture and activity (133),(134). Despite their precision, accelerometers and self-reported tools have distinct strengths and limitations. Questionnaires like IPAQ remain practical in clinical settings but show weak correlations with accelerometry, particularly in populations with unique activity patterns, such as people with PAD (135). While wearable devices capture all sporadic MVPA, self-reports provide behavioural context, highlighting the need for both methods to obtain a comprehensive assessment of activity and sedentary behaviour (136).

This study aimed to compare the IPAQ against activPAL in people with PAD, assessing the differences in self-reported measures within this high-risk group. The IPAQ Long Form was used to assess sedentary behaviour and physical activity, as it provides detailed information across multiple domains (work, transport, domestic, and leisure) and separately captures sitting time. In contrast, the IPAQ Short Form includes fewer items and provides only a single estimate of total sitting time (128).

While research has highlighted discrepancies between self-reports and accelerometry in general populations, it remains unclear whether these findings apply to people with PAD, who exhibit distinct sedentary behaviour and PA patterns. The results will contribute to refining sedentary time and PA assessment and informing tailored interventions for PAD management. Thus, the main aim of this cross-sectional study was to evaluate the agreement between sitting time assessed by the International Physical Activity Questionnaire (IPAQ) long form and research-grade accelerometry (activPAL) in people with peripheral artery disease (PAD) attending the vascular outpatient clinic at University Hospital Galway, Ireland. This comparison is clinically relevant because self-reported measures, commonly used in practice, may be inaccurate in patients with PAD due to mobility limitations and intermittent claudication.

## **5.2 Methods**

### **5.2.1 Study design and population**

This was a cross-sectional observational study, focusing on adult people with established PAD. This analysis draws from the same study population as our previous work (137); however, as completion rates differed and the specific aim was distinct, the results are reported separately.

### **5.2.2 Inclusion/exclusion criteria**

### **5.2.2.1 Inclusion criteria**

- Participants aged 18 years or older.
- Confirmation of established PAD through at least one of the following:
  - Ankle-brachial index <0.90 in at least one lower extremity.
  - Evidence of arterial occlusive disease in one lower extremity detected by duplex ultrasonography, computed tomographic angiography, or magnetic resonance angiography.
- Willingness to participate and capacity to provide informed consent.
- Compliance with the activPAL accelerometer.

### **5.2.2.2 Exclusion Criteria**

- History of life-threatening diseases (e.g., active cancer treatment).
- Present symptoms of myocardial ischemia.
- Significant mental illness or cognitive impairment.
- Known skin allergies or conditions aggravated by adhesive tape used for accelerometer application.
- Primary factors severely limiting exercise tolerance aside from claudication (e.g., severe symptoms of dyspnea, arthritis, chest or back pain).
- Patients with severe physical disabilities and limitations in independent movement (e.g., wheelchair-bound individuals).
- Breastfeeding or pregnant individuals.
- Inadequate proficiency in English to comprehend and communicate questionnaire content.

### **5.2.3 Study setting**

The participant recruitment centre was the Department of Vascular and Endovascular Surgery at the University Hospital Galway - Ireland (UHG). Ethical approval was obtained (Merlin Park Hospital, Clinical Research Ethics Committee Ref: No: CA2794), ensuring compliance with Good Clinical Practice guidelines. Individuals underwent screening for suitability by the vascular team from both in-person and virtual clinics, and potentially eligible participants were provided with an information sheet along with the researchers' contact details. Participants gave written consent after receiving detailed information, covering study aims, methods, benefits, and risks.

In the study's recruitment process (Figure 5.2.3.1), eligible individuals were invited, screened, and consented. They were given an opportunity to ask questions before completing the

consent form. Participants were reminded of their right to withdraw. In-person participants utilised hard copy consent forms, while virtual participants received them by post.

#### **5.2.3.1 Face to face interview:**

The baseline interview was conducted face-to-face at UHG in the outpatient vascular clinic. Data collection included age, gender, Rutherford classification, smoking status, diabetes, hypertension, dyslipidemia, cardiac, functional impairment and respiratory conditions following the Society for Vascular Surgery (SVS) reporting standards (109). Body weight, height (for BMI calculation), ankle-brachial index (ABI) and toe-brachial index (TBI) measures were recorded too. Subsequently, participants received information on the activPAL device, including correct fitting and wear procedures, and a diary to record wake and sleep times, as well as any accelerometer removal times. The activPAL3™ micro (PAL Technologies Ltd, Glasgow, UK), a small thigh-worn accelerometer-based monitor, 24-hours per day for seven consecutive days. It was attached using a hypoallergenic waterproof dressing (Hypafix) and participants received two dressings for reattachment/removal during the seven-day monitoring. Participants went home with the device fitted, diary/logbook, instructions, IPAQ, and a stamped addressed envelope. Individuals were instructed to complete the long-form IPAQ after removing the activPAL device, which had been worn for 7 days. After seven days the device was returned using the stamped addressed envelope with the completed diary/logbook and IPAQ.

#### **5.2.3.2 Virtual interview:**

Participants unable to attend in person were offered a virtual consultation. Eligible participants received a package including a patient information leaflet, consent forms, IPAQ, the activPAL device, diary/logbook and application guidance. A video demonstrating accelerometer attachment was shared with participants through communication channels of their preference, such as email, WhatsApp, or messaging. Individuals were instructed to complete the long-form IPAQ after removing the activPAL device worn for seven days. Additionally, a stamped addressed envelope was provided to return documents and device by post.

#### **5.2.3.3 Physical activity and sitting time assessed using the activPAL.**

Physical activity and sitting time were assessed using the activPAL. Participants wore the activPAL3™ for seven days. After collection, data were downloaded via PAL Connect and exported as event files using the VANE algorithm. These files were processed and visualized with Processing PAL version 1.32 (University of Leicester, UK). A valid day required at least 10 hours of valid waking time, a minimum of 1,000 steps, and no more than 95% of the waking day in one activity. A valid file consisted of at least three valid days of data. Heatmaps were reviewed to correct any misclassified wake and sleep times using self-reported diaries as a

guide. Key output variables included valid waking time, sitting time, prolonged sitting ( $\geq 30$  minutes), standing time, stepping time, and moderate to vigorous physical activity (MVPA) based on a cadence of  $\geq 100$  steps per minute.

#### **5.2.3.4 The IPAQ**

The current study employed the self-administered long form of the International Physical Activity Questionnaire (IPAQ) (Appendix 2), which evaluates four main categories of physical activity (vigorous, moderate, light, and sitting time) across five domains over the previous seven days. Missing or incomplete responses were excluded, and activity durations exceeding 180 minutes per session were truncated. Total physical activity was calculated in MET-minutes per week using standard MET values (3.3 for walking, 4.0 for moderate, and 8.0 for vigorous activity). Participants were then classified into three PA levels based on these criteria:

- Low: meets neither moderate nor high criterion.
- Moderate: meets any of the following three criteria: (a) three or more days of vigorous-intensity activity of at least  $20 \text{ min}\cdot\text{d}^{-1}$ , (b) five or more days of moderate-intensity activity and/or walking of at least  $30 \text{ min}\cdot\text{d}^{-1}$ , and (c) five or more days of any combination of walking, moderate-intensity, or vigorous-intensity activities achieving a minimum of at least  $600 \text{ MET}\cdot\text{min}\cdot\text{wk}^{-1}$ .
- High: meets any one of the following two criteria: (a) vigorous-intensity activity on at least 3 d and accumulating at least  $1500 \text{ MET}\cdot\text{min}\cdot\text{wk}^{-1}$  and (b) seven or more days of any combination of walking, moderate-intensity, or vigorous-intensity activities accumulating at least  $3000 \text{ MET}\cdot\text{min}\cdot\text{wk}^{-1}$ .

Participants classified as having moderate or high activity levels were considered sufficiently active based on physical activity guidelines.

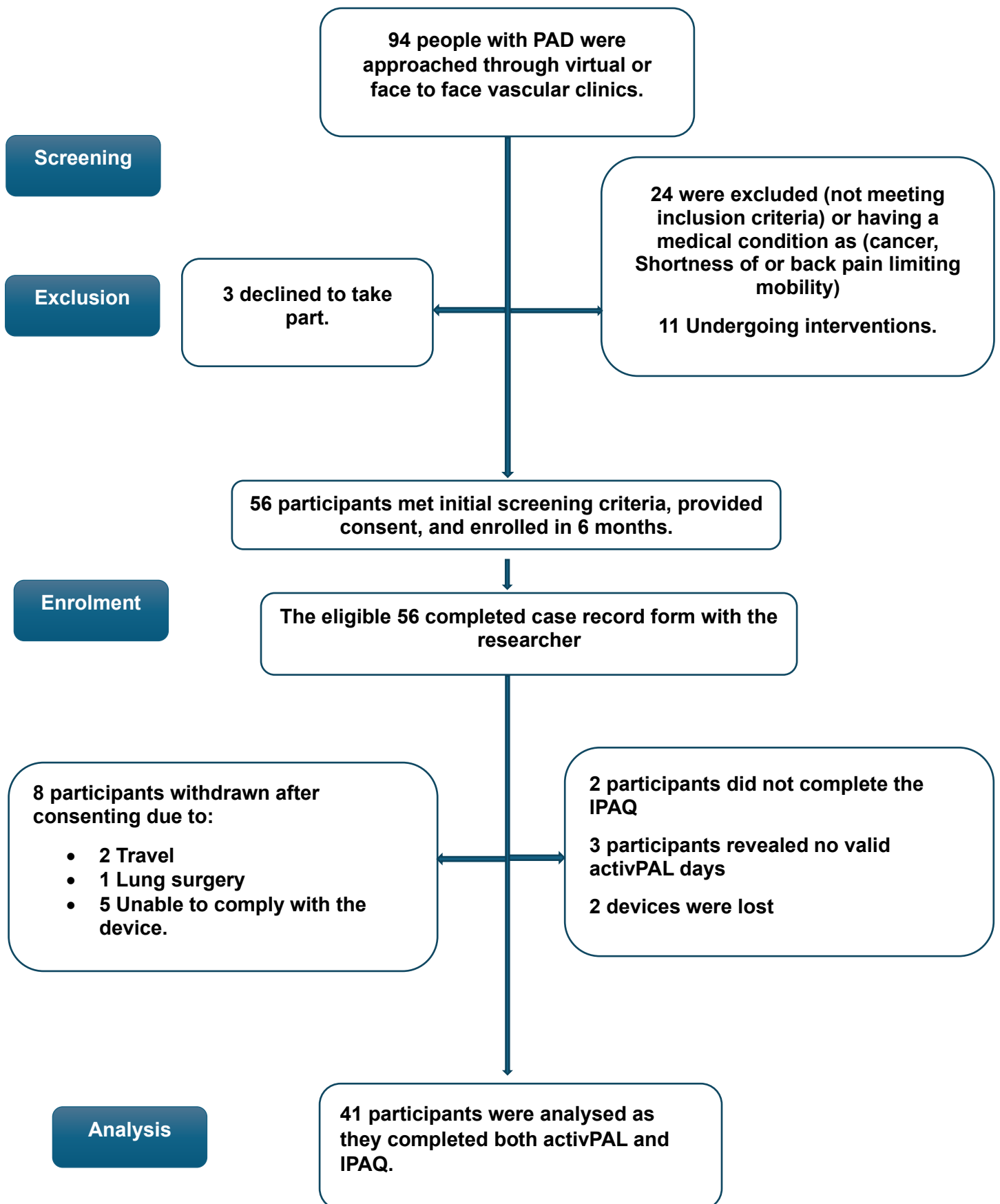


Figure 5.2.3.1 Flow chart of study recruitment process and analysis

## **5.2.4 Study outcomes**

### **5.2.4.1 Primary outcomes**

The study provided an estimation of total sitting time in people with PAD using both the IPAQ long form and the activPAL accelerometer.

### **5.2.4.2 Secondary outcomes**

The study offered data on MVPA levels in people with PAD, obtained through both the IPAQ long form and activPAL. It assessed whether the median MVPA levels estimated by both the IPAQ and activPAL met the physical activity guidelines  $\geq 150$  minutes per week of MVPA).

### **5.2.5 Sample size**

Based on the current available knowledge, no studies have compared sitting time and MVPA using the activPAL accelerometer and the long-form IPAQ in people with PAD. To compare data from the activPAL accelerometer and the long-form IPAQ in people with PAD, a convenience sample of 56 participants was recruited for this pilot cross-sectional study conducted from March to October 2022.

## **5.3 The statistical analysis**

Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS) version 27. Demographic characteristics of the participants were presented descriptively, for continuous variables using mean and SD or median and IQR, for categorical variables were summarised using number and percentage. The distribution of the data was checked using tests for normality based on Shapiro–Wilk tests. Non-normally distributed used non-parametric statistical tests. The study compared self-reported sitting time (IPAQ) with device-assessed sitting time (ActivPAL) using multiple statistical methods (Bland-Altman Plot, Equivalence testing, Mean Absolute Percentage Error (MAPE) and Interclass Correlation Coefficient [ICC]. Statistical significance was established for  $P < .05$ .

## **5.4 Results**

### **Characteristics of the participants**

A total of 56 participants were recruited for the study, with 41 completing it, resulting in a completion rate of 73%. Table 5.4.1 presents the baseline sociodemographic and clinical characteristics of both groups: all participants ( $n=56$ ) and those who completed both activPAL and IPAQ measurements of sitting time ( $n=41$ ) and any differences between these two groups.

The activPAL recorded a median sitting time of 9.5 hours/day (IQR: 2.7), which equated to 64.9% of daily waking time. Median (IQR) time spent in moderate-to-vigorous physical activity (MVPA) was 13.8 (27) minutes/day (Table 5.4.2).

**Table 5.4.1 sociodemographic characteristics of the study sample**

	All participants n=56	Participants completed the study n=41	Significance of differences in the completion status
Age means (SD) years	68.8 (10.1)	67.5(10.5)	$P = 0.10^*$
Gender - males n (%)	40 (71.4%)	28 (68.3%)	$P = 0.307^\dagger$
BMI median (IQR) kg/m <sup>2</sup>	27.3 (24.1-30.0)	26.8 (24.2 – 29.7)	$P = 0.304^{**}$
Alcohol consumption n (%)	28 (50%)	22 (53.7%)	$P = 0.365^\ddagger$
Units of alcohol/ week range	1-40 units/week	1-40 units/week	
≥10 units n (%)	4	3	
<10 units n (%)	24	19	
Lowest ABI median (IQR)	0.68 (0.60-0.84)	0.67 (0.56 – 0.83)	$P = 0.271^{**}$
Lowest TBI mean (SD)	0.44 (0.14)	0.44 (0.14)	
Rutherford n (%)			$P = 0.009^\S$
0 = asymptomatic	1 (1.8%)	0	
1 = Mild claudication	11 (19.6%)	11 (26.8%)	
2 = moderate claudication	19 (33.9%)	11 (26.8%)	
3 = severe claudication	25 (44.6%)	19 (46.3%)	
Diabetes n (%)			$P = 0.423^\S$
0 = none	39 (69.6%)	30 (73.2%)	
1 = not requiring insulin	7 (12.5%)	4 (9.8%)	
2 = controlled by insulin	8 (14.3%)	5 (12.2%)	
	2 (3.6%)	2 (4.9%)	

3 = type 1 or uncontrolled			
Smoking n (%) 0 = none or remote (>10 years) 1 = quit 1-10 years ago 2 = current < 1 pack/year 3 = current > 1 pack/year	25 (44.6%) 12 (21.4%) 8 (14.3%) 11 (19.6%)	19 (46.3%) 9 (22%) 6 (14.6%) 7 (17.1%)	$P = 0.893^{\S}$
HTN 0 = none 1 = controlled with 1 drug 2 = controlled with 2 drugs 3 = requiring >2 drugs or uncontrolled	18 (32.1%) 10 (17.9%) 25 (44.6%) 3 (5.4%)	14 (34.1%) 8 (19.5%) 19 (46.3%) 0	$P = 0.038^{\S}$
Renal n (%) 0 = normal 1 = Evidence of renal disease, GFR >90 mL/min/1.73 m <sup>2</sup> 2 = GFR 60-89 mL/min/1.73 m <sup>2</sup> 3 = GFR 30-59 mL/min/1.73 m <sup>2</sup> 4 = GFR 15-29 mL/min/1.73 m <sup>2</sup>	12 (21.4%) 19 (33.9%) 14 (25%) 10 (17.9%) 1 (1.8%)	10 (24.4%) 14 (34.1%) 8 (19.5%) 8 (19.5%) 1 (2.4%)	$P = 0.518^{\S}$
Hyperlipidemia n (%) 0 = None 1 = Elevated without drug treatment 2 = Elevated with dietary treatment	16 (28.6%) 0 3 (5.4%) 37 (66.1%)	11 (26.8%) 0 1 (2.4%) 29 (70.7%)	$P = 0.252^{\S}$

3 = Elevated with drug and diet treatment			
Cardiac status n (%)			<i>P</i> = 0.376 <sup>§</sup>
0 = Asymptomatic, with normal electrocardiogram	19 (33.9%)	14 (34.1%)	
1 = Asymptomatic but with remote myocardial infarction by history (6 months) or occult myocardial infarction	19 (33.9%)	12 (29.3%)	
2 = Any one of the following: stable angina, no angina but significant reversible perfusion defect on dipyridamole thallium scan, significant silent ischemia (1% of time) on Holter monitoring, ejection fraction 25% to 45%, controlled ectopy or asymptomatic arrhythmia, or history of congestive heart failure that is now well compensated	18 (32.1%)	15 (36.6%)	
Pulmonary n (%)			<i>P</i> = 0.948 <sup>§</sup>
0 = Normal	28 (50%)	21 (51.2%)	
1 = Asymptomatic or mild dyspnea	17 (30.4%)	12 (29.3%)	
2 = Between 1 and 3	11 (19.6%)	8 (19.5%)	
	0	0	

3 = Vital capacity less than 1.85 Liters, FEV1 45 mm Hg, supplemental oxygen uses medically necessary, or pulmonary hypertension			
Functional n (%) 0 = No impairment 1 = Impaired, but able to carry out ADL without assistance 2= Needs some assistance to carry out ADL or ambulatory assistance 3 = Requiring total assistance for ADL or non-ambulatory	43 (76.8%) 13 (23.2%) 0 0	34 (82.9%) 7 (17.1%) 0 0	<i>P</i> = 0.078 <sup>†</sup>
Antiplatelets n (%) 0 = none 1 = single agent 3 = dual therapy	5 (8.9%) 38 (67.9%) 13 (23.2%)	5 (12.2%) 26 (63.4%) 10 (24.4%)	<i>P</i> = 0.162 <sup>§</sup>

BMI: body mass index; HTN: hypertension; ABI: ankle brachial index; TBI: toe brachial index

The difference between both groups was calculated using; \* Independent sample t-test, † Fisher's Exact, \*\* Mann-Whitney U test, ‡ Pearson chi square. § Likelihood ratio.

*P*-value < 0.05 was considered statistically significant.

**Table 5.4.2 activPAL results based on valid data from a study sample of 41 people with PAD.**

<b>Variable</b>	<b>Mean (SD) or Median (IQR)</b>
<b>Average Hours/Day Variables</b>	<b>hours/day</b>
Valid waking wear time	14.8 (1.2) <sup>a</sup>
Sitting time	9.5 (2.7) <sup>b</sup>
MVPA time (Stepping Time $\geq$ 100 steps/min)	0.23 (0.45) <sup>b</sup>
Purposeful MVPA time (Stepping Time $\geq$ 100 steps/min in 1 min or more bouts)	0.02 (0.12) <sup>b</sup>
<b>Average Percentage/Day Variables</b>	<b>Percentage/Day</b>
Sitting time (% of waking wear time)	64.9%
MVPA Time $\geq$ 100 steps/min (% of total stepping time)	19.2%
Purposeful MVPA $\geq$ 100 steps/min in 1 min bout (% of total stepping time)	1.7%

<sup>a</sup> Mean (SD), <sup>b</sup> Median (IQR)

### **IPAQ**

IPAQ results showed that the median sitting time was 6.0 hours per day (IQR: 2.7) and the median total physical activity score was 2058 MET-minutes per week (IQR: 3562) (Table 5.4.3).

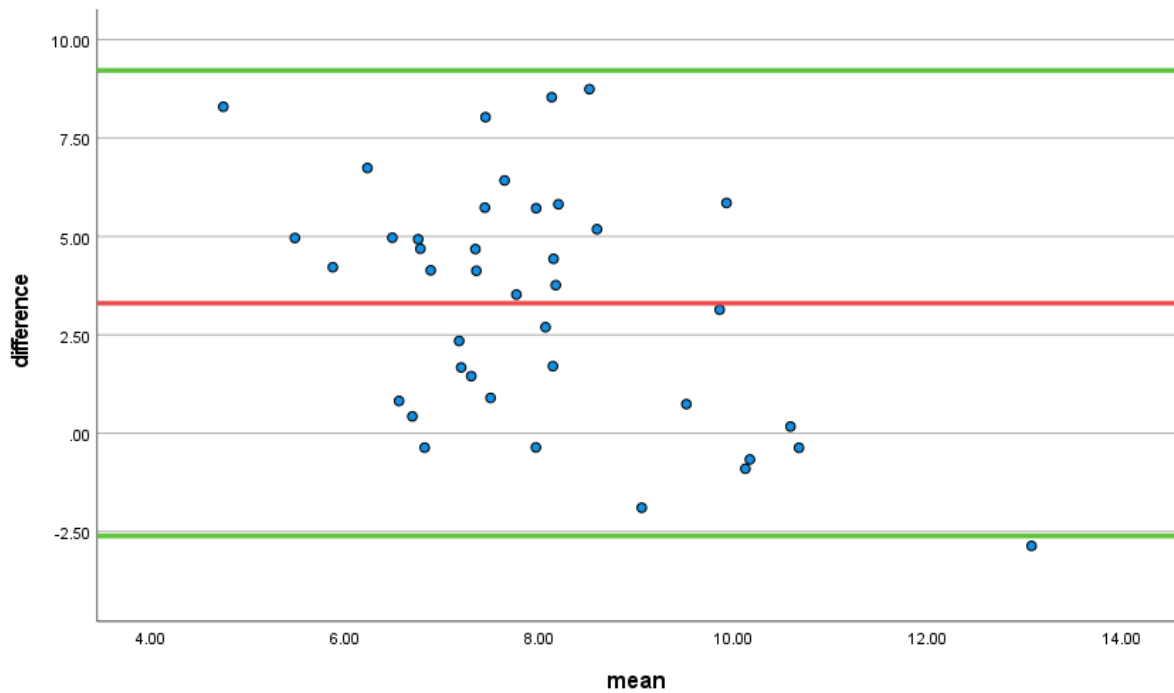
**Table 5.4.3 Analysis of IPAQ results from a study Sample of 41 people with PAD.**

Sitting time hours/day <sup>a</sup>	6.0 (2.7)
Average total physical activity MET-minutes/week score <sup>a</sup>	2058 (3562)
IPAQ physical activity category	
Low	10 (24.4%)
Moderate	5 (12.2%)
High	26 (63.4%)

<sup>a</sup> Median (IQR)

The Bland-Altman plot (figure 5.4.1) revealed a systematic bias, with IPAQ underestimating sitting time in compared to the activPAL, and wide limits of agreement, indicating poor agreement and significant variability between the two methods. Equivalence testing showed that the mean difference between subjective and device measured sedentary time significantly

deviated from the predefined equivalence thresholds ( $\pm 5\%$ ) (138), confirming that the two methods are not statistically equivalent. The Intraclass Correlation Coefficient further supported poor reliability, with single and average measures indicating no meaningful agreement between the methods. Finally, the MAPE suggested moderate to low accuracy of self-reported sitting time compared to activPAL data, with high variability and a wide range of errors. Overall, these results indicate that self-reported sitting time showed significant underestimation and variability as presented in table 5.4.4.



**Figure 5.4.1: Bland-Altman plot showing wide limits of agreement between IPAQ and activPAL. The X-axis represents the mean sitting time, and the Y-axis represents the difference in sitting time, with IPAQ underestimating sitting time compared to activPAL.**

**Table 5.4.4 Comparison of self-reported (IPAQ) and device-assessed (activPAL) sitting time: statistical agreement and accuracy metrics**

<b>Statistical Test</b>	<b>Result</b>	<b>95% Confidence Interval</b>	<b>P-value</b>
<b>Bland-Altman Plot</b>	Mean difference: -2.6 hours/day	Limits of agreement: -2.6 to 9.2 hours	-
<b>Equivalence Testing</b>			
Test against -5% threshold	Mean difference: 1.75	0.75 to 2.74	0.001
Test against +5% threshold	Mean difference: -8.25	-9.25 to -7.26	<0.001
<b>Intraclass Correlation Coefficient [CCI]</b>			
Single measures ICC	-0.009	-0.313 to 0.296	0.523
Average measures ICC	-0.019	-0.910 to 0.457	0.523
<b>Mean Absolute Percentage Error (MAPE)</b>	38.09%		
Standard Deviation (MAPE)	22.69		
Range of Absolute Percentage Errors (APE)	1.61% to 93.31%		

### **Meeting physical activity guidelines**

Self-reported physical activity from the IPAQ Long Form was recorded in minutes per week for each activity domain. For comparison with activPAL data, these minutes were converted to moderate-to-vigorous physical activity (MVPA) time by summing all reported activity at  $\geq 3$  METs, in accordance with IPAQ scoring guidelines. Objective sedentary and MVPA time were simultaneously measured using activPAL, which provides minute-by-minute postural data, allowing direct comparison with IPAQ-derived MVPA estimates.

The median physical activity level reported via the IPAQ was 2058 MET-min/week, indicating that participants met or exceeded the World Health Organisation's recommended guidelines

for moderate to vigorous physical activity (MVPA), which suggest at least 150-300 minutes of moderate-intensity or 75-150 minutes of vigorous-intensity activity per week, or an equivalent combination, corresponding to 500-1000 MET-min/week (56). In contrast, using the activPAL, the median (IQR) time spent in MVPA was 13.8 (27) minutes/day, which does not meet the recommended guidelines.

## 5.5 Discussion

The association between Peripheral Arterial Disease (PAD) and sitting time (ST) is not fully understood and little is known about the pattern of sitting time and physical activity of people with PAD (66). To our knowledge, no attempts have been made to compare the self-reported and device-assessed sedentary behaviour in PAD populations. The present cross-sectional study assessed sitting time (ST) in a cohort of people with PAD using an accelerometer and subjectively using the International Physical Activity Questionnaire (IPAQ) long form tool. The study compares the alignment between these two measurement methods.

The study demonstrated that, on average, sedentary time reported via the IPAQ was underestimated by 3.5 hours per day relative to objectively measured sitting time using the accelerometer in people with PAD, with high variability between the two methods. Equivalence testing demonstrated a clear deviation from the  $\pm 5\%$  threshold, and the ICC indicated poor agreement. MAPE further confirmed discrepancies between measures. The observed poor agreement highlights the need for caution when using IPAQ to quantify sitting time in people with PAD and underscores the importance of recognising the wide variability between self-reported and thigh-worn accelerometry.

In agreement with Blackwood et al., (2022) self-reported measures have consistently been shown to underestimate sedentary time when compared with device-based assessments (134). This underestimation may reflect the structure of multi-domain physical activity questionnaires such as the IPAQ, in which sitting time is assessed as a single item within a broader survey. While standalone sedentary behaviour questionnaires may provide more detailed contextual information on sitting time, the IPAQ was selected in the present study because it is widely used, well-validated across populations, and commonly applied in cardiovascular and clinical research, allowing comparison with existing literature. Evaluating the performance of the IPAQ against device-based measures therefore remains important for understanding its limitations and utility in PAD research (44)

Self-report methods capture the respondent's perception of their behaviour and provide context, like the type of sedentary activity (e.g., TV watching, screen time). In contrast, devices measure continuous bodily movement or specific postures (e.g., sitting/lying) but usually lack

contextual details, except when using tools like wearable cameras or user-monitor devices (44).

Recently, accelerometers have been more widely used to measure sedentary behaviour and activity patterns. These devices provide a more accurate and reliable assessment, overcoming many of the shortcomings of self-reports, and are particularly suitable for use in older adults (139). The activPAL has been validated against direct observation for measuring total sitting time, demonstrating  $\geq 95\%$  agreement in both laboratory settings and real-world environments. The activPAL categorises activities into sitting, standing, and stepping. Its ability to distinguish between sitting and standing is crucial for accurately quantifying sedentary time a feature that has led to its recognition as the “gold standard” for objective measurement of sedentary behaviour. Additionally, it has been validated for measuring sit-to-stand transitions and breaks in sitting time in free-living conditions (80, 134). Although the measurement of sedentary behaviour using accelerometers and inclinometers has become increasingly common, the associated cost-to-utility ratio remains relatively high due to the high costs of devices and resources, as well as the need for proximity to respondents. Consequently, self-reported assessments continue to be the most practical method for monitoring sedentary behaviour in most national surveillance systems (44).

Prior research indicates that self-reported physical activity tends to overestimate time spent in moderate to vigorous physical activity (MVPA) when compared to accelerometer measurements (135). In this study, the median physical activity level reported via the IPAQ was 2058 MET-min/week, indicating that participants met and exceeded the World Health Organisation's recommended guidelines for moderate to vigorous physical activity (56) as the recommended amount of moderate to vigorous physical activity (MVPA) for adults is at least 150–300 minutes of moderate-intensity or 75–150 minutes of vigorous-intensity aerobic physical activity per week, or an equivalent combination, which corresponds to 500–1000 MET-min/week (56) Based on the recommendation, the median physical activity level of 2058 MET-min/week indicates that the guideline recommendations were met and exceeded.

In contrast, using the activPAL accelerometer, median (IQR) MVPA time (stepping time  $\geq 100$  steps/min) was 13.8 (27) minutes/day, indicating that on average participants were not reaching the recommendation. A possible explanation is that self-report questionnaires are subject to limitations such as recall bias. Recall bias is particularly significant, as individuals may have difficulty accurately recalling time spent sitting, especially when sedentary periods are broken up throughout the day (44).

The significant difference observed in this study underscores the need for caution when interpreting single item self-reported sitting time in both research and clinical settings. Self-

report measures vary in accuracy, but multi-item questionnaires better align with accelerometer data and provide contextual insights important for managing sedentary behaviour-related conditions.

Furthermore, the results suggest the importance of integrating measurement tools like accelerometers in large-scale epidemiological studies and public health surveillance systems. While self-report tools are more cost-effective and easier to implement, their validity and reliability issues could compromise the quality of data collected. While device measures improve accuracy, they do not capture the context or domains of sedentary behaviour. When accelerometers are not an option, studies often use multi-item questionnaires to assess specific sedentary activities.

### **5.6 Limitations of the study**

Compliance may be limited, as the activPAL must be worn for seven days, and individuals with PAD may experience discomfort during this period. Participants who completed both activPAL and IPAQ measures may have been more motivated than the broader PAD population. Additionally, factors such as comorbidities (e.g., diabetes or obesity) may influence activity levels and sitting time. Furthermore, some individuals, especially older adults or those with low technological literacy, may be unfamiliar with wearable technology or completing questionnaires. Finally, the IPAQ long form relies on self-report and is subject to recall bias, likely contributing to the underestimation of sitting time observed.

### **5.7 Conclusion**

Accurately measuring sedentary behaviour is crucial due to its negative health impacts. This study identifies significant discrepancies between self-reported sitting time using the long-form IPAQ and accelerometry assessed sitting time using activPAL in people with PAD. The findings suggest that the IPAQ, while practical and feasible, it underestimates sitting time in people with PAD by nearly three hours per day compared to activPAL. This highlights the need for more reliable tools, such as the activPAL accelerometer, in both research and public health settings. Future studies should improve self-report measures and integrate device assessments to enhance sedentary behaviour measurement. This would help at-risk populations, like people with PAD, reduce health risks associated with sedentary behaviour

## **Chapter 6: A Sedentary Behaviour Reduction Programme in Patients with Peripheral Arterial Disease: A Mixed-Method Feasibility Study**

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## Abstract

**Background:** People with peripheral arterial disease (PAD) have high levels of sedentary behaviour (SB), which contributes to declining mobility, poorer quality of life, and increased cardiovascular risk; however, few studies have targeted reducing SB in this population.

**Objective:** To evaluate the feasibility and acceptability of delivering and evaluating a 12-week remotely delivered intervention designed to reduce sedentary time in people with PAD.

**Methods:** This was a single-arm, single-centre feasibility study in participants with PAD. The intervention combined an online education, a wearable physical activity tracker, and weekly coaching calls. At baseline and 12 weeks, sedentary behaviour and physical activity were measured with activPAL, functional capacity was assessed remotely using the Timed Walk app for the 6-Minute Walk Test, and semi-structured interviews were conducted at 12 weeks to evaluate acceptability.

**Results:** Thirty participants provided consent (77% recruitment rate) and took part in the study, with 21 (70%) attending follow up. Valid activPAL data at baseline and follow up was provided by 18 participants (60% of those consented). At baseline participants spent 63% of their waking day sitting (9.58 hours/day), which was slightly lower at 12 weeks (60%). Qualitative analysis identified four themes covering awareness, motivation, engagement, and barriers. Participants valued weekly calls and feedback on physical activity from the wearable.

**Conclusion:** Overall, the intervention was feasible and acceptable, and data suggest it may reduce sedentary time. Methods to enhance retention and compliance to the activPAL would be needed for a larger trial.

### Keywords

**Peripheral arterial disease (PAD); sedentary; sitting; physical activity; feasibility study; digital health; wearable technology; activPAL.**

## 6.1 Introduction

### 6.1.1 background

Peripheral Arterial Disease (PAD) is a common yet often under-recognised condition, affecting more than 200 million people worldwide (2). It is characterised by atherosclerotic narrowing of the lower limb arteries, leading to reduced blood flow and an increased risk of serious cardiovascular events such as stroke and myocardial infarction (140). An ankle-brachial index (ABI) of  $\leq 0.90$  is associated with more than a two-fold increase in the 10-year risk of coronary events, cardiovascular mortality, and all-cause mortality. Within five years, 20% of patients with Intermittent claudication (IC) will experience a myocardial infarction or stroke with a mortality rate of 10–15% (140). Multiple risk factors contribute to PAD and growing evidence highlights the importance of lifestyle factors, particularly regular physical activity and low levels of sedentary behaviour, in its management (33).

Sedentary behaviour is defined as waking time spent in sitting, lying, or reclining positions with low energy expenditure (1.0–1.5 times the basal metabolic rate) (141). The World Health Organisation (WHO) recommends that adults undertake at least 150–300 minutes of moderate-intensity aerobic activity per week (or an equivalent amount of vigorous activity) and acknowledges the importance of limiting sedentary time, although it does not specify absolute limits (37). Evidence with accelerometry-based measurements indicates that accumulating 9.5 hours or more per day of sedentary time is strongly associated with an increased risk of all-cause mortality (28).

High levels of sedentary behaviour have been linked to negative cardiovascular outcomes, exacerbating PAD symptoms and further limiting mobility (28). Conversely, regular physical activity is known to improve blood flow, reduce symptoms of intermittent claudication, and improve quality of life for individuals with PAD (88). Despite this, the impact of reducing sedentary behaviour has not been adequately studied in people with PAD, with most research focusing on increasing moderate to vigorous physical activity rather than addressing sedentary behaviour directly. For patients with PAD, reducing sedentary time may have the potential to mitigate the progression of the disease and improve overall function (33).

Interventions targeting sedentary behaviour are gaining attention in other chronic conditions, with promising results in populations with diabetes, obesity, and cardiovascular disease (142, 143). For people with PAD, interventions that replace sedentary time with light or moderate-to-vigorous activity may be especially beneficial given pain and mobility challenges. Educational support, personalised goals, and tracking tools could help promote active living while limiting sedentary time.

### **6.1.2 Aim**

To evaluate the feasibility and acceptability of delivering and evaluating a 12-week remotely delivered intervention designed to reduce sedentary time in people with PAD.

### **6.1.3 Objectives**

#### **6.1.3.1 Primary Objectives:**

To evaluate key aspects of feasibility, including recruitment, attrition, and data completion rates, to determine the practicality of the intervention. Additionally, to assess the acceptability of the intervention and gather insights into participants' experiences with the intervention used.

#### **6.1.3.2 Secondary Objectives:**

To evaluate potential changes in sedentary behaviour and physical activity levels using research-grade accelerometry-derived data (activPAL). Additionally, to assess potential changes in 6-Minute Walk Test performance using the Timed Walk application (144).

## **6.2 Methods**

### **6.2.1 Study Design**

A mixed-methods single group, pre-post, feasibility study in individuals with PAD. The intervention consisted of a remotely delivered online education programme, supplemented by weekly coaching calls. A consumer physical activity tracker (Huawei Band 6) was used to deliver vibration prompts, reminding participants to break up sitting after 60 minutes of inactivity. Baseline and 12-week measurements were collected to assess recruitment, retention, acceptability, participant experiences, and data completion rates.

### **6.2.2 Study Setting**

Recruitment took place at the vascular outpatient clinic at Galway University Hospitals (GUH), Ireland. The Croí Heart and Stroke Centre was used to meet with some participants for baseline assessment and follow-up visits when this was more feasible for them.

### **6.2.3 Participants and Sample Size**

Symptomatic PAD patients attending routine appointments at the GUH vascular outpatient clinic were screened, and those meeting the inclusion criteria were invited to participate. The study was planned as a pilot feasibility study, with recruitment taking place over a six-month period from the vascular outpatient clinic. Following screening and eligibility assessment, 30 participants were successfully enrolled. This sample size aligns with pilot study

recommendations (24–50 participants) (145) and was considered appropriate given the limited research on reducing sedentary time in patients with PAD.

#### **6.2.4 Inclusion Criteria**

Participants were eligible if they were adults ( $\geq 18$  years) with established PAD, indicated by an ankle-brachial index (ABI) of  $< 0.90$  in at least one lower extremity, a toe-brachial index of  $< 0.60$ , or arterial occlusive disease confirmed by duplex ultrasonography, CT angiography, or MRI.

#### **6.2.4 Exclusion Criteria**

Participants were excluded if they had severe impairments affecting mobility or cognition as documented in their medical records, significant comorbidities that hindered their ability to participate in physical activity, or implantable cardioverter-defibrillators (ICDs) or pacemakers. Additionally, pregnant or lactating women were not eligible to participate in the study. As the intervention included an education session, potential participants with a poor command of the English language were excluded.

#### **6.2.5 Recruitment Process**

Recruitment was conducted at GUH's vascular outpatient clinic. The vascular team screened patients based on the inclusion criteria. Patients expressing interest were given a patient information leaflet (Appendix 5) and the opportunity to ask questions. Those who agreed to participate signed a consent form (Figure 6.2.5.1)

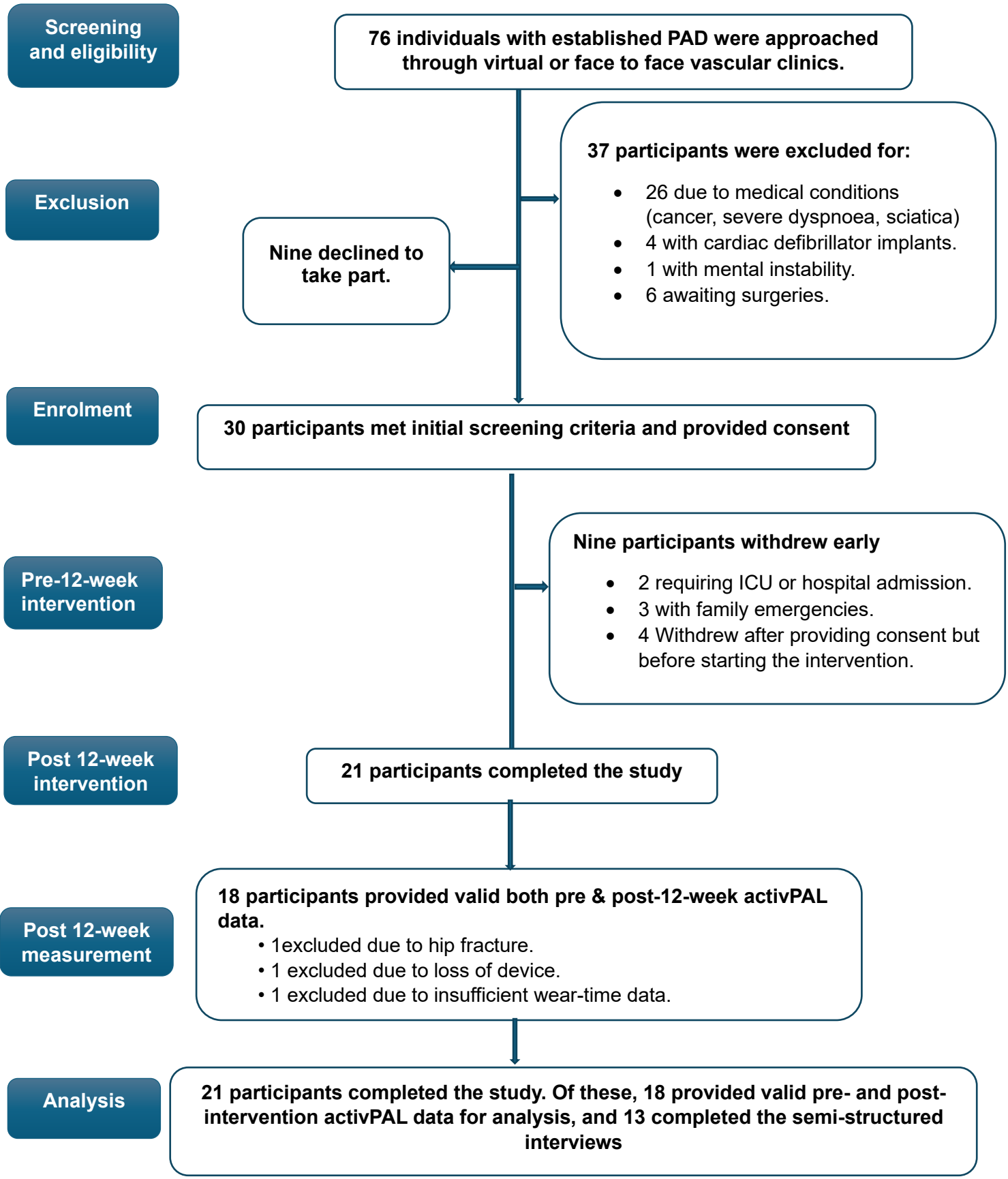


Figure 6.2.5.1 Flow chart of study enrolment process and analysis

### **6.2.7 Procedures**

Participants who provided consent were invited to attend a baseline assessment, either in person at the Croí Heart and Stroke Centre or remotely via telephone or zoom. During the initial assessment, demographic data were recorded using a case record form, which captured baseline characteristics such as date of birth, gender, smoking status (current, former, never), Ankle Brachial Index (ABI), medical history, and health-related conditions, including type 2 diabetes, heart disease, hypertension, dyslipidemia, cardiac, functional impairment and respiratory conditions following the Society for Vascular Surgery (SVS) reporting standards (109)

All participants were provided with an activPAL3™ accelerometer-based device (PAL Technologies, Glasgow, UK), either during their in-person appointment or via a postal pack, along with instructions on how to secure the device to the thigh and wear it continuously 24 hours per day for seven consecutive days. The researcher had follow-up contact with participants to ensure that the device was properly fitted, functioning correctly, and that participants were completing daily diary entries on the provided log sheet.

During the initial assessment, participants completed the six-minute walk test (6-MWT) using the Timed Walk application (Dario Salvi, Malmö University) (144). This remote application has been validated as a reliable and feasible tool for assessing six-minute walk distance (146). Participants underwent all measurements at baseline and 12-weeks from recruitment. Semi-structured interviews were conducted at the 12-week follow-up with 13 participants to capture diverse experiences and gather feedback on the programme's acceptability, suitability, and potential improvements. Interviews were audio-recorded, transcribed using Otter AI, and manually checked for accuracy. Reflexive Thematic Analysis (RTA) was used to iteratively code and develop themes, with two researchers reviewing data collaboratively and documenting analytic decisions in a research diary (147, 148).

### **6.2.8 Patient and Public Involvement (PPI) group**

The Patient and Public Involvement group from Croí, The West of Ireland Cardiac Foundation contributed to the development and review of the programme. The group comprised six members (men and women). Some participants were recruited through the Croí PPI network and had lived experience of chronic cardiovascular disease, while others were patients with symptomatic peripheral arterial disease (PAD) recruited from the vascular clinic, ensuring representation of the target population for the study.

PPI members reviewed key elements of the study as part of the intervention development process, including the study design, procedures, and participant-facing materials. Their

feedback focused on clarity, feasibility, and potential participant burden. This process helped ensure that the intervention and study procedures were acceptable and relevant for individuals with symptomatic PAD. Although no major changes were required, the PPI input confirmed that the study design and materials were appropriate and aligned with the study objective

The PPI group was provided with several key components of the programme for review, including:

- An online education session adapted from the successful SMART Work & Life intervention, which highlighted the adverse effects of sedentary behaviour and introduced strategies to reduce sitting time (149) (150).
- Tools for assessing and self-monitoring daily sedentary time, along with guidance on using various free apps to track activity levels.
- An action plan and goal-setting worksheet designed to encourage participants to reduce sedentary time to less than 50% of waking hours and incorporate movement every 30 minutes.

In addition to these elements, the group was briefed on the planned use of a wrist-worn activity tracker (Huawei Band 6) and weekly phone or video coaching sessions to provide ongoing support and motivation. Their feedback confirmed that these components were well-structured and aligned with the study's aims.

### **6.2.9 Intervention**

Developing effective sedentary behaviour reduction interventions necessitates an understanding of what drives behavioural change and the underlying mechanisms influencing sedentary time. The "Behaviour Change Wheel" framework identifies nine key intervention functions, including education, persuasion, and training, to facilitate behavioural modifications (54, 151).

This study carefully selected behaviour changes techniques (BCTs) to form a multicomponent intervention aimed at reducing sedentary time in patients with PAD. The selection process considered factors such as affordability, practicability, and acceptability to ensure feasibility within the target population. Table 6.2.9.1 outlines the BCTs incorporated into the intervention, which consists of an online education programme, health coaching calls, and a physical activity tracker (54).

**Table 6.2.9.1: Mapping of behaviour change techniques (BCTs) utilised in the intervention-to-intervention components**

<b>BCT</b>	<b>Description</b>	<b>Education programme</b>	<b>Coaching calls</b>	<b>Activity tracker</b>
<b>Goal Setting 1.1</b>	Establishing a specific, measurable target for behaviour change.	✓	✓	-
<b>Problem Solving 1.2</b>	Identifying barriers to behaviour change and developing strategies to overcome them	✓	✓	-
<b>Action Planning 1.4</b>	Creating a detailed plan that specifies when, where, and how to perform the desired behaviour.	✓	✓	-
<b>Review Behaviour Goals 1.5</b>	Regularly assessing progress towards behaviour goals	-	✓	-
<b>Discrepancy Between Current Behaviour and Goal 1.6</b>	Highlighting the difference between current behaviour and the desired goal to motivate change.	✓	✓	-
<b>Commitment 1.9</b>	Encouraging a promise to change behaviour.	-	✓	
<b>Feedback on Behaviour 2.2</b>	Providing information on how well someone is performing the desired behaviour.	-	✓	✓
<b>Self-Monitoring of Behaviour 2.3</b>	Tracking one's own behaviour over time to increase awareness and control.	-	✓	✓
<b>Information About Antecedents 4.2</b>	Providing information on triggers that lead to the behaviour	✓	-	-

<b>Information About Health Consequences 5.1</b>	Explaining the health impacts of the behaviour.	✓	-	-
<b>Prompts/Cues 7.1</b>	Using reminders or signals to encourage the behaviour	-	-	✓
<b>Habit Formation 8.3</b>	Repeating a behaviour in a consistent context to make it habitual	✓	✓	-
<b>Credible Source 9.1</b>	Presenting information from a trustworthy and respected source.	✓	-	-
<b>Pros and Cons 9.2</b>	Discussing the advantages and disadvantages of changing the behaviour.	✓	✓	-

### **6.2.9.1 The Intervention Strategies**

The intervention strategies were implemented following the completion of the baseline assessment, with participants commencing a 12-week programme aimed at reducing sedentary time. The intervention was designed to empower participants to decrease their sitting time through structured support and behavioural strategies.

Participants received an action plan and a goal-setting worksheet to facilitate sedentary time reduction, with the core intervention messages emphasising sitting for less than 50% of waking hours and moving every 30 minutes. In addition to the free self-monitoring and prompt tools introduced during the online education session, participants were provided with a wrist-worn activity tracker (Huawei Band 6) to remind them to break up prolonged sitting throughout the intervention period.

To further support and motivate participants, the researcher conducted weekly phone or video coaching calls. These sessions focused on reviewing progress, setting new goals, addressing challenges, and providing encouragement to reduce sedentary time and incorporate more movement into daily routines. Follow-up assessments were conducted at 12-weeks to evaluate the intervention's impact.

The SMART Work & Life online education programme was used in this intervention. This programme has previously been evaluated in a randomised controlled trial among adults with type 2 diabetes, demonstrating significant reductions in sitting time and improvements in cardiometabolic health markers (149, 152, 153). At the time of this study's design, there were no published sedentary behaviour interventions specifically developed for people with symptomatic PAD; available studies focused on asymptomatic populations (18). While PAD-targeted programmes such as BREAK-UP (154) exist, at the time the current study was designed the BREAK-UP intervention was still ongoing and included structured physical activity alongside strategies to reduce sedentary behaviour. The SMART Work & Life programme was therefore selected based on its established evidence base, behavioural focus, and suitability for adaptation to a cardiometabolic clinical population.

### **6.2.9.2 Online Education Session**

All participants received access to an interactive online education session from the SMART Work and Life programme, which was well received (155) and successfully reduced sitting time in desk-based workers (149). It comprised 19 sections, covering topics such as the risks of excessive sitting, benefits of breaking up sitting time, self-reflection, self-monitoring, use of prompts, goal setting, action planning, and overcoming personal barriers. Participants could complete it at their own pace, typically taking 60–90 minutes. The session emphasised

reducing sitting, aiming for less than 50% of waking hours spent sitting and incorporating movement every 30-minutes.

### **6.2.9.3 Health Coaching Calls**

Following the online education session, participants received ongoing support through weekly phone or video coaching calls delivered via Zoom or Teams. During these sessions, participants' activPAL outputs were reviewed in detail, with colour-coded epoch charts shared to illustrate patterns of sitting, standing, and stepping. These visual summaries were used to identify periods of prolonged sitting, longest sedentary bouts, and opportunities for interruption, which then informed personalised goal setting. Coaching discussions focused on reviewing individual progress, identifying barriers, and collaboratively developing tailored strategies to reduce sedentary time and increase movement within daily routines. The coaching approach was informed by the COM-B model, exploring participants' capability, opportunity, and motivation to reduce sitting time. Participants attended between 9 and 12 coaching sessions, each lasting approximately 15–30 minutes.

The researcher received health coaching training prior to delivering the intervention. Training also covered the use of intervention materials, motivational interviewing techniques, and guidance on goal-setting strategies, incorporating participant feedback from activPAL data. A coaching form was provided for each session to guide content, and all sessions were documented using a session log. This log recorded participant ID, week/date, contact frequency, method, average call length, reasons for missed sessions, topics discussed, and any barriers encountered. Fidelity was monitored through periodic review of these logs and random observation of coaching calls to ensure adherence to the protocol and consistency across participants.

### **6.2.9.4 Self-Monitoring and Prompts**

To support behaviour change, participants were given a wrist-worn physical activity consumer device (Huawei Band 6) to encourage them to reduce sitting time and break up prolonged sedentary time. This device provided real-time feedback on daily activity levels, helping participants monitor their progress. In addition, it delivered a vibration prompt after 60 minutes of inactivity, reminding participants to break up prolonged sitting. To ensure consistency across participants, all wrist bands were set up according to a standardised protocol. Vibration prompts and other settings were identical for all participants. Participants received uniform instructions on interpreting alerts and reminders, and coaching calls reinforced correct device use, ensuring comparable behavioural feedback throughout the participants.

## **6.2.10 Measurements**

### **6.2.10.1 Feasibility and Intervention Acceptability**

The feasibility of the study was evaluated based on recruitment and retention rates, as well as study measurement completion rates. Semi-structured interviews at 12 weeks explored participants' experiences, perceived acceptability, and barriers and facilitators to engagement with the intervention.

### **6.2.10.2 Measurement of Sedentary Behaviour and Physical Activity**

Participants wore the activPAL3 activity monitor on their thigh continuously for 24 hours a day, over seven days to measure time spent sitting, standing, and stepping.

The activPAL was initialised using the manufacturer's default settings, and data were downloaded using the manufacturer's software. Events.csv files were generated via PAL Batch and processed using Processing PAL (version 1.31, University of Leicester, UK). Processed data were visually inspected through heatmaps. In cases where the sleep-wake classification appeared inaccurate (e.g., early wake and sleep times, late wake and sleep times), the self-reported log was reviewed, and corrections were applied within Processing PAL if required. Posture-based outcomes, including total sitting/lying time, prolonged sitting accumulated in bouts of  $\geq 30$  minutes, and total standing and stepping time were calculated. Daily stepping time was categorised as light intensity (stepping at a cadence of  $< 100$  steps/min), moderate-to-vigorous intensity (stepping at a cadence of  $> 100$  steps/min), and purposeful stepping at a moderate-to-vigorous intensity (stepping at a cadence of  $> 100$  steps/min in bouts lasting  $\geq 1$  minute). Additionally, participants maintained a daily diary to log their capturing sleep and wake times and record any instances of device removal.

### **6.2.10.3 6MWT**

Functional capacity was assessed remotely at baseline and 12 weeks using the Timed Walk app to conduct the 6-Minute Walk Test (6MWT) (144). The app delivered standardised instructions, timed the test, and recorded the distance covered, enabling measurement of walking capacity at both time points without requiring in-person assessment. The timed walk application was temporarily removed from the Google Play Store and unavailable for some Android users due to a software issue. As a result, baseline 6MWT data could not be captured for a subset of participants, reducing the completeness of the dataset for this outcome measure.

#### **6.2.10.4 12-week follow-Up Assessments**

At the 12-week follow-up assessment, participants repeated the activPAL measurements. In addition, semi-structured interviews were conducted at the 12-week follow-up to explore participants' experiences of the intervention, its acceptability, and perceived barriers, facilitators, and potential improvements for reducing sedentary behaviour, in line with recommendations for feasibility and acceptability studies(156) (157). The interview topic guide was informed by the study objectives, existing literature on sedentary behaviour interventions in clinical populations (158, 159). Key domains included participants' understanding of sedentary behaviour, experiences using the intervention components, perceived impact on behaviour, and suggestions for improvement. The topic guide (Annex 7) was piloted to ensure clarity and relevance, with minor refinements made to wording and flow. Interviews were conducted flexibly, allowing participants to elaborate on issues of importance to them while ensuring consistency across interviews.

#### **6.2.11 Outcomes**

##### **6.2.11.1 Primary Outcomes**

The study evaluated several key aspects, including recruitment rates of participants with PAD, attrition rates throughout the study, and data completion rates for all collected measures. Additionally, participant feedback was gathered to assess their experiences with the intervention and their satisfaction with the intervention components.

##### **6.2.11.2 Secondary Outcomes**

The study explored the potential of the intervention for changing sedentary time and physical activity levels and functional capacity. However, it was not powered to detect significant changes.

#### **6.3 Statistical analysis**

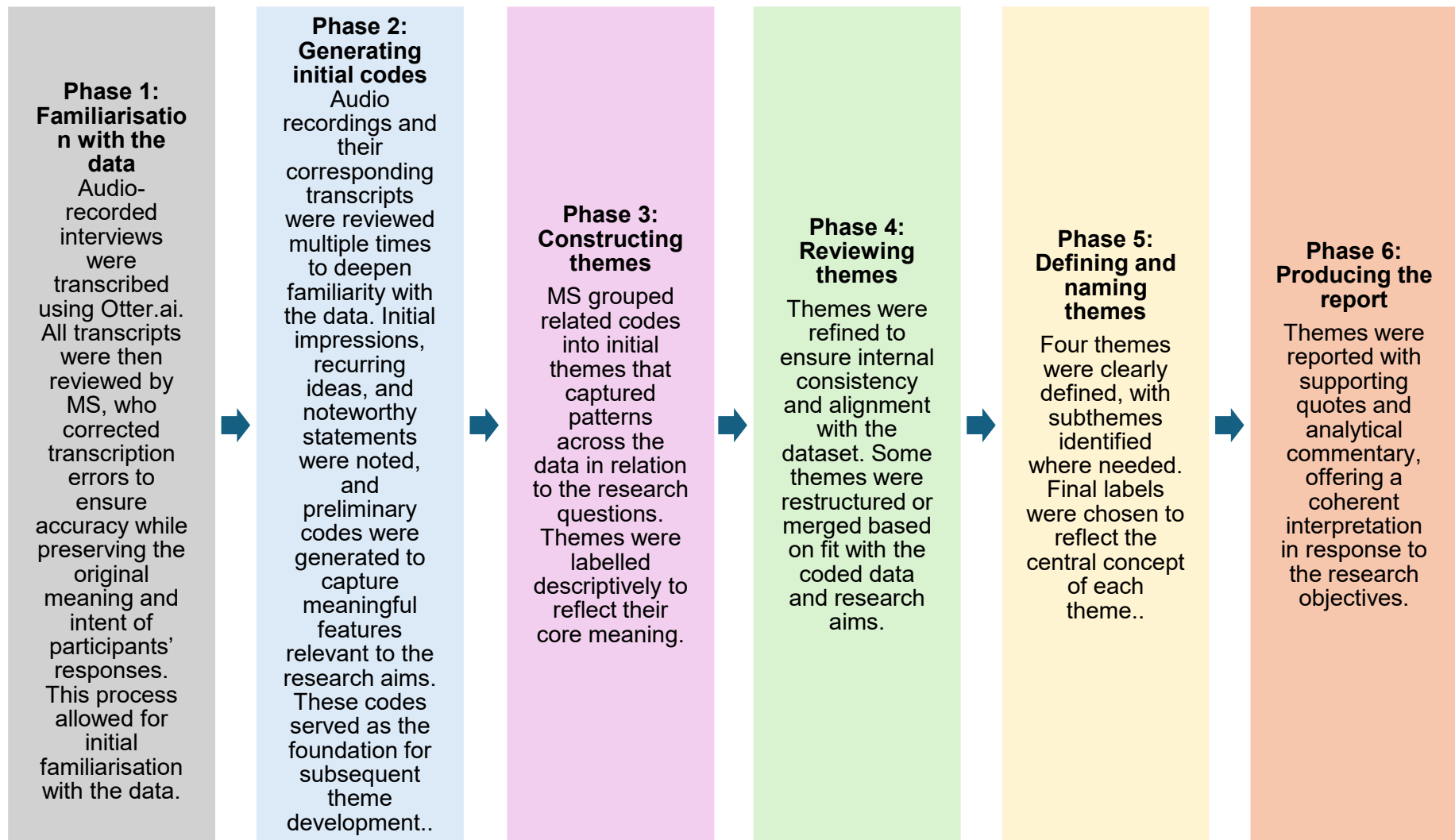
Data analysis was conducted using IBM SPSS Statistics for Windows, Version 29.0 (IBM Corp., Armonk, NY, USA). Recruitment and retention rates were calculated as the proportion of eligible participants who enrolled in the study and the proportion of enrolled participants who completed follow-up assessments, respectively. Completion rates for outcome measures were determined by dividing the number of complete datasets by the total number of enrolled participants and multiplying by 100. Follow-up completion at 12 weeks was similarly calculated as the percentage of participants who completed assessments at that time point out of those

expected. Descriptive statistics were used to summarise participant characteristics: continuous variables were reported as mean and standard deviation (or median and interquartile range, where appropriate), and categorical variables as frequency and percentage. Data distribution was assessed using normality tests.

Baseline and 12-week follow-up values were reported for all key outcomes, including sedentary behaviour, physical activity and functional capacity along with the corresponding observed changes over the intervention period. The potential of the intervention for reducing daily sitting and increasing physical activity was explored using descriptive statistics (mean  $\pm$  SD, frequency, counts and percentages). In line with good practice recommendations for pilot and feasibility studies (160).

Qualitative semi structured interviews were conducted by MS, audio recorded using a digital voice recorder, and transcribed using Otter AI (Otter.ai, Inc., Mountain View, CA, USA). Of the 21 participants who completed the study, thirteen participants were purposively selected for interview to ensure diversity in age, sex, BMI, ABI, and Rutherford classification (Table 6.4.2.1). This sample size was considered sufficient to reach data saturation, defined as the point at which no new themes or insights emerged. All transcripts were independently reviewed by two authors (MS & MC) and manually verified for accuracy before analysis. Reflexive thematic analysis (RTA) was used to interpret the data, following the approach described by Braun and Clarke (2006, 2019) (147, 148).. Reflexive Thematic Analysis (RTA) was chosen over framework approaches because it allows flexibility to capture participants' nuanced experiences while embedding reflexivity throughout the analysis, rather than constraining data into a pre-determined framework (148)

Analysis proceeded iteratively, moving from Phase 2 (initial coding) to Phase 3 (theme development) through repeated reading of transcripts, discussion between researchers, and continuous reflection on potential biases. Reflexive work was documented in a research diary, capturing analytic decisions, emerging interpretations, and adjustments to coding. Two authors (MS and MC) collaboratively reviewed codes and themes, discussing discrepancies until consensus was reached. Figure 6.3.1 illustrates the framework used for qualitative data interpretation.



## **Figure 6.3.1 Framework for qualitative data interpretation**

### **Ethical approval**

Ethical approval was obtained from the Galway University Hospitals, Clinical Research Ethics Committee (approval number: C.A. 2970). The investigator bore the responsibility of ensuring that no patient underwent any trial-related examination or activity until they had provided informed consent. The patient had to provide written consent after receiving comprehensive information. The verbal explanation encompassed all aspects outlined in the written material provided to the patient. The investigator apprised the patient of the study's objectives, methodologies, potential advantages, and possible risks, which might have included any discomfort.

Patients were given sufficient opportunity to seek clarification on any matters they found unclear and, if necessary, request further information. Informed consent forms needed to be signed and dated by participants. Additionally, participants were asked for authorization to share pertinent data with individuals associated with the participating universities or regulatory authorities, where applicable. It was essential to underscore that patients had the freedom to withdraw their consent to participate at any point without facing any penalties or losing benefits to which they would otherwise have been entitled.

## **6.4 Results**

### **6.4.1 Feasibility and acceptability**

Between September 2024 and February 2025, a total of 76 individuals were approached; 39 were eligible, of whom 30 consented to participate, giving a recruitment rate of 76.9% ( $\approx 77\%$ ). Follow-up assessments at 12 weeks were conducted between December 2024 and May 2025. The overall study completion rate was 70.0% (21/30), corresponding to an attrition rate of 30.0%. Attrition reflected participants who withdrew consent or discontinued the study. Of those recruited, 21 (70%) participants provided valid activPAL data at baseline and 18 (60%) provided valid activPAL data at 12-week follow-up, with validity defined as  $\geq 3$  days of wear. We planned 12 weekly calls per participant, and the number completed ranged from 9 to 12. If a participant was unavailable, we attempted to schedule the call on another day. No serious adverse events directly attributable to the intervention or study devices were reported.

Table 6.4.1.1 presents the sociodemographic characteristics of all 30 participants, including the 21 who completed the study and the 18 who provided both pre- and post-activPAL measurements.

**Table 6.4.1.1 sociodemographic characteristics of the study sample**

<b>Sociodemographic characteristics</b>	<b>All participants n=30</b>	<b>Participants completed the study n=21</b>	<b>Participants who provided valid activPAL data n=18</b>
<b>Age means (SD) years</b>	69.4 (8.0)	71.3 (7.1)	70.7 (7.4)
<b>Males n (%)</b>	21 (70%)	13 (61.9%)	11 (61.1%)
<b>BMI median (IQR) kg/m<sup>2</sup></b>	26.5 (25.6-31.1)	27.5 (25.6-32.3)	27.9 (24.1-32.0)
<b>Alcohol average consumption (units/week) n (%)</b>	13 (43.3%)	8 (38.1%)	8 (44.4%)
<b>Lowest ABI mean (SD)</b>	0.75 (0.20)	0.71 (0.20)	0.71 (0.20)
<b>Lowest TBI mean (SD)</b>	0.49 (0.15)	0.47 (0.16)	0.47 (0.17)
<b>Rutherford n (%)</b>			
<b>0 = asymptomatic</b>	0	0	0
<b>1 = Mild claudication</b>	5 (16.7%)	2 (9.5%)	2 (11.1%)
<b>2 = moderate claudication</b>	13 (43.3%)	8 (38.1%)	6 (33.3%)
<b>3 = severe claudication</b>	12 (40.0%)	11 (52.4%)	10 (55.6%)
<b>Diabetes n (%)</b>			
<b>0 = none</b>	23 (76.7%)	17 (81%)	15 (83.30%)
<b>1 = not requiring insulin</b>	4 (13.3%)	2 (9.5%)	2 (11.1%)
<b>2 = controlled by insulin</b>	2 (6.7%)		1 (5.6%)
<b>3 = type 1 or uncontrolled</b>	1 (3.3%)	2 (9.5%)	0
<b>Smoking n (%)</b>			
<b>0 = none or remote (&gt;10 years)</b>	14 (46.7%)	12 (57.1%)	10 (55.6%)
<b>1 = quit 1-10 years ago</b>	6 (20.0%)	4 (19.0%)	3 (16.7%)
<b>2 = current /within last year</b>	10 (33.3%)	5 (23.8%)	5 (27.8%)
<b>HTN</b>			
<b>0 = none</b>	8 (26.7%)	7 (33.3%)	6 (33.3%)
<b>1 = controlled with 1 drug</b>	4 (13.3%)	1 (4.8%)	1 (5.6%)
<b>2 = controlled with 2 drugs</b>	17 (56.7%)	13 (61.9%)	11 (61.1%)
<b>3 =requiring &gt;2 drugs or uncontrolled</b>	1 (3.3%)	0	0
<b>Hyperlipidemia n (%)</b>			
<b>0 = None</b>	5 (16.7%)	4 (19%)	3 (16.7%)
<b>1 = Elevated without drug treatment</b>	0	0	0

<b>2 = Elevated with dietary treatment</b>	2 (6.7%)	2 (9.5%)	2 (11.1%)
<b>3 = Elevated with drug and diet treatment</b>	23 (76.6%)	15 (71.4%)	13 (72.2%)
<b>Cardiac status n (%)</b>			
<b>0 = Asymptomatic, with normal electrocardiogram</b>	9 (30%)	5 (23.8%)	4 (22.2%)
<b>1 = Asymptomatic but with remote myocardial infarction by history (6 months) or occult myocardial infarction</b>	11 (36.7%)	8 (38.1%)	6 (33.3%)
<b>2 = Any one of the following: stable angina, no angina but significant reversible perfusion defect on dipyridamole thallium scan, significant silent ischemia (1% of time) on Holter monitoring, ejection fraction 25% to 45%, controlled ectopy or asymptomatic arrhythmia, or history of congestive heart failure that is now well compensated</b>	10 (33.3%)	8 (38.1%)	8 (44.4%)
<b>Pulmonary n (%)</b>			
<b>0 = Normal</b>	17 (56.7%)	11 (52.4%)	8 (44.4%)
<b>1 = Asymptomatic or mild dyspnea</b>	12 (40.0%)	9 (42.9%)	9 (50.0%)
<b>2 = Between 1 and 3</b>	1 (3.3%)	1 (4.8%)	1 (5.6%)
<b>3 = Vital capacity less than 1.85 liters, FEV1 45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension</b>	0	0	0
<b>Functional n (%)</b>			
<b>0 = No impairment</b>	29 (96.7%)	20 (95.2%)	17 (94.4%)
<b>1 = Impaired, but able to carry out ADL without assistance</b>	1 (3.3%)	1 (4.8%)	1 (5.6%)

<b>Antiplatelets n (%)</b>			
<b>0 = none</b>	1 (3.3%)	1 (4.8%)	0
<b>1 = single agent</b>	21 (70.0%)	14 (66.7%)	12 (66.7%)
<b>3 = dual therapy</b>	8 (26.7%)	6 (26.8%)	6 (33.3%)

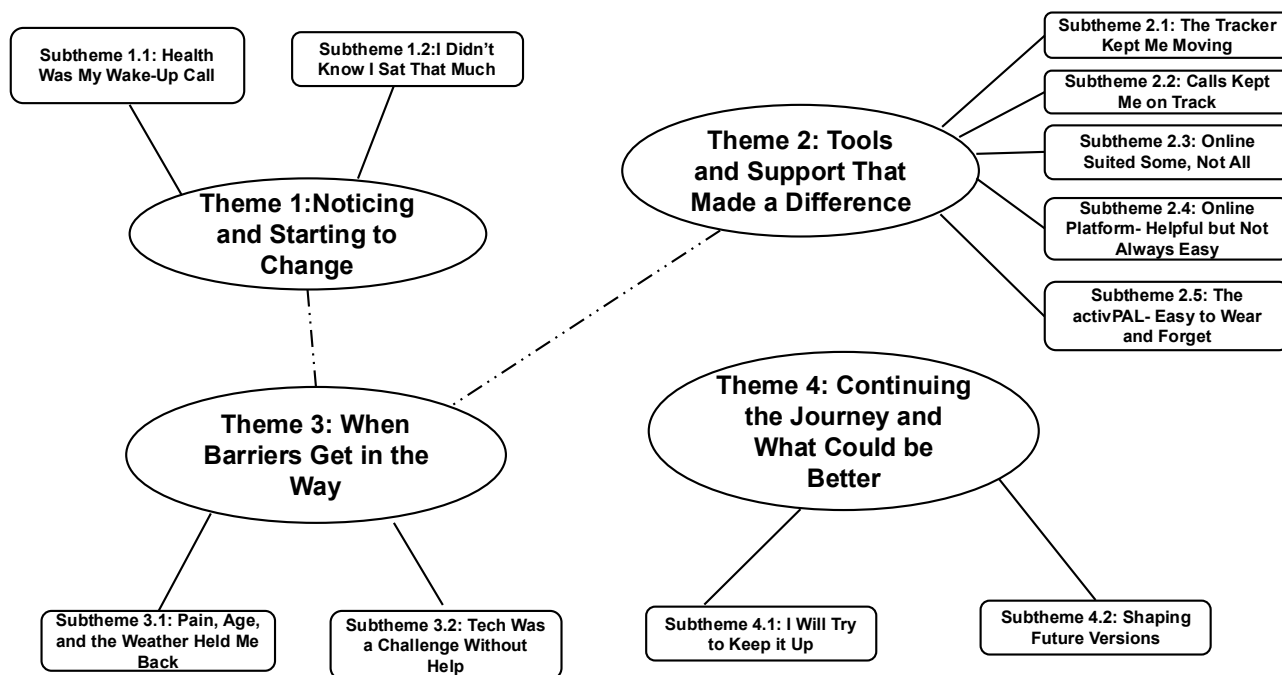
**BMI: body mass index; HTN: hypertension; ABI: ankle brachial index; TBI: toe brachial index.**

#### **6.4.2 Qualitative findings**

A group of 13 participants were interviewed (characteristics are shown in table 6.4.2.1). The duration of the interviews ranged from 19 to 41 minutes. The average duration was 26 minutes. A total of four themes were developed. A thematic map of the themes and subthemes of the qualitative analysis is shown in figure 6.4.2.1. Four overarching themes and eleven sub-themes were developed through reflexive thematic analysis. These themes reflect participants' evolving awareness and motivation, their engagement with various components of the programme, and the barriers and facilitators influencing behaviour change Table 6.4.2.2.

**Table 6.4.2.1 Characteristics of the 13 participants interviewed**

<b>Participant ID</b>	<b>Gender</b>	<b>Age</b>	<b>Rutherford classification</b>	<b>BMI</b>	<b>Lowest ABI</b>
1	F	69	2 Moderate	32.3	0.88
2	M	67	3 severe	33	0.28
3	M	62	3 severe	26.5	0.65
4	F	74	3 severe	26.17	0.58
5	M	74	3 severe	27.5	0.55
6	F	69	2 Moderate	23.5	0.8
10	M	72	2 Moderate	30.6	1.2
11	M	69	3 severe	29	0.87
13	F	92	3 severe	22.3	0.42
15	M	71	3 severe	21.9	0.57
18	F	59	1 mild	38.7	0.63
20	F	80	3 severe	31.1	0.7
21	M	62	3 severe	28.4	0.75



**Figure 6.4.2.1 Thematic map illustrating relationships between themes and subthemes**

### **Theme 1: Theme 1: Noticing and Starting to Change**

This theme explores participants' initial motivations for taking part in the programme, their emerging awareness of sedentary behaviour, and early attempts at change. Participants' desire to improve health, curiosity, and engagement with the programme led to increased recognition of sitting time and early shifts in behaviour. Two sub-themes were developed through reflexive thematic analysis. First, 'Health was my wake-up call' reflects participants' motivation to improve health and manage pain. Second, 'I didn't know I sat that much' captures new awareness of sedentary habits and their health impact.

#### **Subtheme 1.1: Health Was My Wake-Up Call**

Participants reported joining the programme to manage pain, improve activity, and enhance wellbeing

Participants' motivations for taking part in the programme were largely centred around a desire to improve their physical health and daily routines, particularly in relation to pain and inactivity. Many participants expected the intervention might help alleviate physical discomfort, especially leg pain. Others expressed interest in using the programme to support lifestyle changes, become more active, or break up sedentary patterns in their daily routines. For some, the decision to take part was also linked to curiosity about whether the intervention could positively influence their general wellbeing. One participant shared, *"I wanted to see if it would help me be more active in my daily routine and to change my lifestyle affected by depression and back pain"* (Participant 1, female, 69

years). Another reflected, *“I thought it might have an impact on the pain I feel”* (Participant 2, male, 67 years).

### **Subtheme 1.2: I Didn't Know I Sat That Much**

Many described a new awareness of how much they sit and its health implications, prompting greater reflection and attention to their routines.

Participants consistently reported that taking part in the programme increased their awareness of sedentary behaviour. Several described the experience as positive and eye-opening, noting that it made them think more critically about how much time they spent sitting each day. Some participants reflected that the programme prompted them to pay more attention to their daily sitting habits, while others highlighted that the intervention helped them understand what constitutes sitting time and encouraged them to make changes. A few participants commented on how the information was new to them and increased their awareness of the potential health risks associated with prolonged sitting. *“The information about sitting time was new to me. I hadn't realised how much it could affect my health”* (Participant 4, female, 74 years). Others described becoming more conscious of their daily routines: *“It made me think more about my sitting time”* (Participant 5, male, 74 years), and *“This experience made me think more about how much I sit”* (Participant 10, male, 72 years).

## **Theme 2: Tools and Support That Made a Difference**

This theme focuses on participants' experiences with the programme components, including coaching support, digital tools, and the online education. It reflects on perceived usefulness, and the acceptability of remote delivery. Five sub-themes were developed through reflexive thematic analysis. The tracker kept me moving captures how vibration prompts raised awareness and encouraged movement.

Calls kept me on track reflects how weekly calls motivated and supported behaviour change. Online suited some, not all describes how the online education was convenient for some but challenging for others. Feedback on the online education was mixed: participants generally found it helpful, but some reported difficulties with usability. In contrast, the activPAL device was described as comfortable and easy to wear.

### **Subtheme 2.1: The Tracker Kept Me Moving**

The activity tracker (Huawei Band 6), particularly its vibration reminders, was widely described as a helpful and practical tool for increasing awareness of movement and sitting time. Participants valued how it encouraged them to break up long periods of inactivity by prompting them to move after 60 minutes of sitting.

One participant described the watch as “comfortable, easy to charge, and lasted long,” noting that “the vibrations reminded me to move and helped keep me aware of my activity”. Another participant shared that the tracker “helped a lot” by drawing attention to both prolonged sitting and step count.

A participant explained, *“The tracker kept me aware of my sitting time. Although it sometimes failed to connect to my mobile, it was very useful, especially when it vibrated to remind me to move”* (male, 69 years). Similarly, another participant remarked, *“It was effective, as the tracker reminded me to move”* (participant 13, female, 92 years).

Others echoed these experiences. Some participants stated that the tracker helped them stay mindful of their movement throughout the day, particularly through step counts and vibration reminders. One participant said it “made a big difference” to their activity, while participant 10, male appreciated its simplicity and daily use, stating it *“encouraged me to sit less.”*

### **Subtheme 2.2: Calls Kept Me on Track**

Participants consistently described the weekly coaching calls as a valuable and supportive component of the intervention. The calls served as regular reminders and a source of motivation, helping participants stay aware of their sitting habits and offering practical advice on how to break up prolonged sedentary periods. Several participants highlighted that the sessions effectively reinforced key messages, especially the importance of reducing and interrupting extended sitting time. Others emphasised the motivational benefit of the calls, describing them as helpful in maintaining focus and encouraging positive behavioural changes.

Overall, the coaching calls were viewed as an engaging, reassuring check-in that supported both awareness and action towards reducing sedentary behaviour. As one participant put it: *“The calls were really helpful focusing on sitting time and that was good”* (participant 6, female, 69 years). Another added: *“The calls were a good check-in. The sessions motivated me to break up my sitting time and make changes”* (participant 10, male, 72 years).

### **Subtheme 2.3: Online Suited Some, Not All**

Participants generally found the online education convenient and well-suited to their needs, especially those living in remote areas, who appreciated not having to travel long distances. Many described it as easier or preferable to attending in person, with some stating it enabled them to complete the programme fully. As participant 15 noted, *“It was easier to access from home”* (male, 71 years). While the convenience of online access was widely acknowledged, a few participants reported difficulties due to limited digital literacy or lack of technical support, particularly when using links or navigating the online education sessions (participants 6, 10, 18, 20). One participant shared, *“It was handy, but I struggled a bit because I’m not very good with technology”* (participant 18, female, 59 years).

### **Subtheme 2.4: Online Education- Helpful but Not Always Easy**

Participants’ experiences with the online component of the intervention were mixed, reflecting varying levels of digital literacy and comfort with technology. Some participants found the platform clear, informative, and easy to navigate. For instance, one participant found the “top tips and

animation helpful and easy to follow” (participant 3, male, 62 years) while another participant noted that the online sessions *“provided useful tips to reduce sitting time” and were “easy to understand.”* (participant 11, male, 69 years). A third participant acknowledged initial hesitation but eventually *“got used to it” and found the information “new and helpful.”* (participant 4, female, 74 years).

However, several participants encountered challenges related to technology use. Some expressed a lack of confidence or familiarity with online tools, which made it difficult to engage with the digital components independently. For example, participant 10 stated, *“I can’t use a computer,”* while one participant noted that although they liked the graphics, they relied on their daughter for help support that *“wasn’t always available.”* Two other participants, described the system as *“hard to use” and “difficult for someone not used to online tools.”* Despite these barriers, a number of participants still valued the programme content. Participant 21 (male, 62 years) reflected, *“It was difficult... but the information was helpful.”* Similarly, participant 1 (female, 69 years) shared, *“Not easy to use or follow, but good overall. Learned more about my daily sitting,”* while participant 2 (male, 67 years) added, *“Thought it might be tricky at first, but I got through it just fine.”*

### **Subtheme 2.5: The activPAL- Easy to Wear and Forget**

Overall, participants found the activPAL device acceptable and easy to use, with straightforward instructions supporting independent use even among older adults. Several noted they *“barely noticed it after a while”* or that *“it was fine to use”*. The device caused minimal disruption to daily routines, with only occasional removal required for activities like swimming. *I barely noticed it after a while* (participant 5, male 74 years). *“It didn’t really change anything, and I didn’t have any problems with it”* (participant 6, female, 69 years).

Clear instructions, including helpful photos (participant 10) and hospital-based fitting (participants 11 and 15), supported correct placement and boosted user confidence. Importantly, no significant problems were reported. Minor issues, such as accidental water exposure, were managed appropriately thanks to prior guidance.

### **Theme 3: When Barriers Get in the Way**

This theme captures key barriers that affected participants’ full engagement with the programme such as physical limitations, low motivation, weather, and technology-related issues while also highlighting aspects influencing its overall feasibility, including the practicality of using digital tools and completing programme tasks in everyday life. Two sub-themes were developed through reflexive thematic analysis. Barriers to Engagement: Pain, age, weather, and limited digital skills affected some participants’ ability to engage fully.

#### **Subtheme 3.1: Pain, Age, and the Weather Held Me Back**

Pain, fatigue, weather, and ageing affected participants’ ability to stay active and fully engage with the programme, raising important considerations for feasibility. Participants identified several

personal and contextual barriers. As one participant (participant 1, female, 69 years) explained, *“My back pain and depression sometimes made it harder to stay active.”* Similarly, another participant (participant 4, female, 74 years) shared, *“Sometimes moving around was difficult because of my pain,”* while participants 3 and 20 described how *“The wintertime also worsened my leg pain. The weather made it difficult to stay active.”*

Age and motivation also influenced engagement. One participant (participant 15, male, 71 years) reflected, *“From my point of view, I think age is a barrier and I lack urgency since I’ve too much time on hand.”* Another added, *“I sometimes struggled with dizziness, tiredness, and lack of motivation”* (participant 18, female, 59 years).

### **Subtheme 3.2: Tech Was a Challenge Without Help**

Some participants experienced difficulty navigating the online platform or using devices, often requiring support from family members or encountering usability issues. Several participants expressed a need for additional help when engaging with the online education component. One participant (participant 10, male, 72 years) mentioned, *“I can’t use a computer, so the online part was difficult for me to complete.”*

While some participants found the content helpful and the programme generally clear, others encountered challenges due to limited familiarity with digital tools. Many relied on family members for assistance: *“The online part was hard for me to use so I asked my daughter for help”* (participant 13, female, 92 years). Some suggested that more guidance would benefit those less confident with technology, while others simply found the online education difficult to use.

A few participants also reported technical issues with the activity tracker, such as problems connecting it to their mobile phones. Nevertheless, they still found the device helpful. As one participant (participant 11, male, 69 years) remarked, *“I had some trouble connecting the tracker to my mobile. But it did vibrate when I sat for a long time.”*

## **Theme 4: Continuing the Journey and What Could be Better**

This theme captures participants’ reflections on the impact of the programme, including their intentions to continue the strategies, perceived benefits, and suggestions for improvement. It reflects the perceived acceptability and potential for promoting sustained behavioural change. Two sub-themes were developed through reflexive thematic analysis. Participants expressed motivation to continue the behavioural changes and offered suggestions to enhance future versions, particularly around digital accessibility and device usability.

### **Subtheme 4.1: I Will Try to Keep it Up**

Participants generally expressed a strong intention to continue using the behavioural strategies introduced during the programme. Many found them helpful in staying active and more aware of

their sitting time. Some participants noted that they had already started integrating these strategies into their daily routines and had shared the information with others. While a few acknowledged that their routines hadn't changed significantly yet, they still expressed a willingness to persist with the strategies moving forward. Others highlighted plans to walk more regularly and remain focused on reducing sedentary time, reflecting a sustained motivation to apply what they had learned. *"I'll include the programme into my daily routine. Also, I've told my friends about it"* (participant 2, male, 67 years)" and *"I plan to keep using them because they help me stay aware of my sitting time"* (participant 3, male, 62 years)"

#### **Subtheme 4.2: Shaping Future Versions**

Participants offered a few suggestions to improve the programme, primarily focusing on technology-related aspects. Some recommended making the online platform more accessible for individuals with limited digital skills, noting that simpler navigation and clearer instructions could enhance engagement. Improving the reliability of the activity tracker's connection to mobile phones was also suggested. Additionally, one participant recommended offering alternative strap materials for the activity tracker, such as leather or metal, to reduce skin irritation. *"It would be great to make sure to connect the watch to the phone"* (participant 11, male, 69 years). *"It would be good to make the online programme a bit easier for people who are not good with technology"* (participant 18, female, 59 years).

**Table 6.4.2.2 Themes and illustrative quotes for the qualitative analysis**

Theme and subtheme	Illustrative quotes
<b>Theme 1: Noticing and Starting to Change</b>	
<b>Subtheme 1.1: Health Was My Wake-Up Call</b>	<ul style="list-style-type: none"> <li>• I wanted to see if it would help me be more active in my daily routine and to change my lifestyle affected by depression and backpain (participant 1)</li> <li>• I thought it might have an impact on the pain I feel (participant 2).</li> <li>• I wanted to know if it would help with my leg pain (participant 3).</li> <li>• I was curious to see if it would help with the pain I feel (participant 4).</li> <li>• I wanted to see if it could improve my daily routine (participant 5)</li> <li>• I was looking to see if it'd make me feel any better (participant 6)</li> <li>• I just wanted to see if it could help me switch up my daily routine and be a bit more active (participant 10).</li> <li>• Hoping it might help with the pain in my leg (participant 11)</li> <li>• I thought it might help with the pain (participant 13)</li> <li>• To find ways to be more active (Participant 15)</li> <li>• I was looking to move more and cut down on sitting during work (participant 18)</li> </ul>
<b>Subtheme 1.2: I Didn't Know I Sat That Much</b>	<ul style="list-style-type: none"> <li>• It made me think more about how much time I spend sitting (participant 1)</li> <li>• It made me aware of the time I spend sitting and what counts as sitting time (participant 2)</li> <li>• The information about sitting time was new to me. I hadn't realised how much it could affect my health (participant 4)</li> <li>• It made me think more about my sitting time (participant 5)</li> </ul>

	<ul style="list-style-type: none"> <li>• This experience made me think more about how much I sit (participant 10)</li> <li>• This programme made me more conscious of my sitting time and encouraged me to change it (participant 11)</li> <li>• Taking part made me think more about how much time I spend sitting (participant 13)</li> <li>• Taking part was useful in making me more aware of my sitting time and the importance of moving more (participant 15).</li> <li>• This programme made me more aware of how much time I spend sitting and how it affects my health (participant 20).</li> <li>• Taking part helped me become more aware of the problems caused by sitting too much (participant 21)</li> </ul>
<b>Theme 2: Tools and Support That Made a Difference</b>	
<b>Subtheme 2.1: The Tracker Kept Me Moving</b>	<ul style="list-style-type: none"> <li>• Watch was comfortable, easy to charge, and lasted long. Vibrations reminded me to move. Tracker kept me aware of activity (participant 1)</li> <li>• The tracker helped a lot. It vibrated when I sat too long and helped me notice how many steps I was taking (participant 2)</li> <li>• The tracker reminded me to move more (participant 3)</li> <li>• It vibrated when I had been sitting too long, which helped me stay aware of my movement (participant 4)</li> <li>• The tracker kept me aware of my activity (participant 5)</li> <li>• the watch made a big difference in my activity (participant 6)</li> <li>• The tracker was simple and encouraged me to sit less. I used it every day and it was very useful (participant 10)</li> <li>• The tracker kept me aware of my sitting time. Although it sometimes failed to connect to my mobile, it was very useful, especially when it vibrated to remind me to move (participant 11)</li> <li>• It was effective, as the tracker reminded me to move (participant 13)</li> <li>• The tracker was useful as a reminder, and the weekly calls helped reinforce the importance of moving more. The tracker didn't always connect to my phone, which was frustrating (participant 15)</li> <li>• The tracker was a helpful reminder to keep moving (participant 21)</li> </ul>
<b>Subtheme 2.2: Calls Kept Me on Track</b>	<ul style="list-style-type: none"> <li>• It reminded me about sitting, how to reduce my sitting time and other helpful tips (participant 2)</li> <li>• The calls were great reminders which helped me stay aware of my movement (participant 4)</li> <li>• They focused on important things like how to sit less (participant 5).</li> <li>• The calls were really helpful focusing on sitting time and that was good (participant 6)</li> <li>• The calls were a good check-in. The sessions motivated me to break up my sitting time and make changes (participant 10)</li> <li>• They focused on useful things like how to decrease sitting (participant 11)</li> <li>• I think it was effective as the calls kept me on track, and they covered important things like reducing and breaking up sitting time (participant 13)</li> <li>• The weekly calls helped support the importance of moving more (participant 15)</li> <li>• The weekly sessions helped keep me motivated and focused on ways to reduce sitting time, which I found helpful (participant 18)</li> <li>• Useful as they focused on reducing sitting time and finding ways to reduce it (participant 20)</li> </ul>
<b>Subtheme 2.3: Online Suited Some, Not All</b>	<ul style="list-style-type: none"> <li>• It was easier for me because I live in Donegal. I don't think I would have joined if it was all in the hospital because the travel would have taken too long. I'd recommend it to other patients (participant 2)</li> <li>• Online worked fine for me more than in person (participant 3)</li> <li>• The online option was perfect for me (participant 4)</li> </ul>

	<ul style="list-style-type: none"> <li>• I would have liked more help with using it (participant 6)</li> <li>• Online worked fine for me but I found it difficult to use the link because I don't use a computers (participant 10)</li> <li>• Online was better than face to face for me and I completed all of it (participant 11)</li> <li>• It was easier to access from home (participant 15)</li> <li>• It was handy, but I struggled a bit because I'm not very good with technology (participant 18)</li> <li>• Being online was helpful, but I found the online education part difficult to use (participant 20)</li> <li>• The online access worked well for me (participant 21)</li> </ul>
<p><b>Subtheme 2.4:</b> <b>Online Platform-Helpful but Not Always Easy</b></p>	<ul style="list-style-type: none"> <li>• Not easy to use or follow, but good overall. Learned more about my daily sitting (participant 1).</li> <li>• Thought it might be tricky at first, but I got through it just fine (participant 2).</li> <li>• Top tips and animation were helpful and explained things well. I found it easy to follow and understand (participant 3)</li> <li>• At first, I wasn't sure how it would go, but I got used to it. The info about sitting was new to me and helpful. It was easy to follow (participant 4)</li> <li>• It wasn't easy to use, so I waited for my daughter to help. I was surprised to learn what counts as sitting. It was clear and easy to understand once I got help (participant 5)</li> <li>• It was difficult because no one was there to help me (participant 6)</li> <li>• I can't use a computer, so the online part was difficult for me to complete (participant 10).</li> <li>• I completed all the online sessions. The link provided useful tips to reduce sitting time, and the information was easy to understand (participant 11)</li> <li>• It was not easy for me because I'm not used to using devices, so I needed my daughter's help. She wasn't always available, but I liked the graphics (participant 13)</li> <li>• It was useful. I did all the online part. The animations helped explain things. I didn't fill the worksheet—some bits felt the same. Maybe make the messages clearer. It was easy to use. Some parts could explain better how to move more at home (participant 15)</li> <li>• It was useful, but I found it hard to use because I'm not good with technology (participant 18)</li> <li>• I found the online part hard to use and difficult for someone like me who's not used to online tools (participant 20).</li> <li>• It was difficult for me to use, but the information was helpful (participant 21)</li> </ul>
<p><b>Subtheme 2.5: The activPAL- Easy to Wear and Forget</b></p>	<ul style="list-style-type: none"> <li>• It didn't affect my routine much; I just took it off for swimming and used the extra patch after (participant 2)</li> <li>• It was fine to use, and I had no issues with it (participant 3)</li> <li>• It didn't change anything, and I didn't face any problems (participant 4)</li> <li>• I followed the instructions, and it was fine. I barely noticed it after a while (participant 5)</li> <li>• It didn't really change anything, and I didn't have any problems with it (participant 6)</li> <li>• It was fine to use, and I had no problems with its use as I'd the instructions with a photo (participant 10)</li> <li>• It was fine to use as I got it on at the hospital by the doctor (participant 11)</li> <li>• "I followed the instructions, and it was fine. One day, water spilled on it, but I remembered it was safe to wear in the shower, just not in the bath (participant 13)</li> <li>• The device was fitted at the hospital, and everything was fine (participant 15)</li> </ul>
<p><b>Theme 3: When Barriers Get in the Way</b></p>	

<b>Subtheme 3.1: Pain, Age, and the Weather Held Me Back</b>	<ul style="list-style-type: none"> <li>• My back pain and depression sometimes made it harder to stay active (participant 1).</li> <li>• The wintertime also my leg pain (participant 3). the weather made it difficult to stay active (participant 20)</li> <li>• Sometimes moving around was difficult because of my pain but I still managed to complete everything (participant 4)</li> <li>• I can't use a computer, so the online part was difficult for me to complete (participant 10).</li> <li>• I had some trouble connecting the tracker to my mobile. But it was vibrating if I sit for long time (participant 11).</li> <li>• The online part was hard for me to use so I asked my daughter for help (participant 13).</li> <li>• From my point of view, I think age is a barrier and lack of urgency as I've too much time in hand (participant 15).</li> <li>• I sometimes struggled with dizziness, tiredness, and lack of motivation (participant 18).</li> </ul>
<b>Subtheme 3.2: Tech Was a Challenge Without Help</b>	<ul style="list-style-type: none"> <li>• The online education was not easy to use so I waited for my daughter to help me (participant 5)</li> <li>• The online education was helpful, but I found some parts hard to use on my own and I think more guidance is needed for people who find online tools hard to use (participant 6).</li> <li>• To be honest I found the online education part was hard (participant 10)</li> <li>• The online part was hard for me to use so I asked my daughter for help (participant 13)</li> <li>• I liked the content, but I struggled a little with the online format. (participant 18).</li> <li>• I found the online part difficult to use (participant 20)</li> <li>• The programme was clear and easy to follow (participant 21)</li> </ul>
<b>Theme 4: Continuing the Journey and What Could be Better</b>	
<b>Subtheme 4.1: I Will Try to Keep it Up</b>	<ul style="list-style-type: none"> <li>• I'll keep using them because they help me stay active (participant 1)</li> <li>• I'll include the programme into my daily routine. Also, I've told my friends about it (participant 2)</li> <li>• I plan to keep using them because they help me stay aware of my sitting time (participant 3)</li> <li>• I plan to keep using them, and I've also shared what I learned with other people (participant 4)</li> <li>• I'll definitely keep using them (participant 5)</li> <li>• I will try to keep using them, but my routine hasn't changed much yet (participant 15)</li> <li>• Sure, I will continue trying to be more active and reduce my sitting time (participant 18).</li> <li>• I plan to continue making changes and walking more regularly (participant 20)</li> <li>• Yes, I plan to continue using these strategies to reduce my sitting time (participant 21)</li> </ul>
<b>Subtheme 4.2: Shaping Future Versions</b>	<ul style="list-style-type: none"> <li>• It would be great to make sure to connect the watch to the phone (participant 11)</li> <li>• It would be good to make the online programme a bit easier for people who are not good with technology (participant 18)</li> <li>• Making the online platform easier to use would be helpful (participant 20)</li> <li>• It would be good if the activity tracker had a leather or metal strap to avoid skin reactions (participant 21)</li> </ul>

### 6.4.3 Sedentary time and physical activity

Eighteen of the 21 participants provided valid pre- and post measurements. Figures 6.4.3.1 and 6.4.3.2 show the percentage of waking hours spent in sedentary and active behaviours at baseline and at 12 weeks post-intervention for participants with complete pre- and post-intervention activPAL data (n = 18).

The descriptive statistics for the activPAL variables (n=18) are shown in table 6.4.3.1 and figures 6.4.3.1 and 6.4.3.2 show the percentage of waking hours spent in sedentary and active behaviours at baseline (pre-intervention) and at 12 weeks (post-intervention), respectively. At baseline participants spent 63% of their waking day sitting (9.58 hours/day), which was slightly lower at 12 weeks (60%). Data suggest that prolonged sitting time reduced and stepping time remained similar across time points.

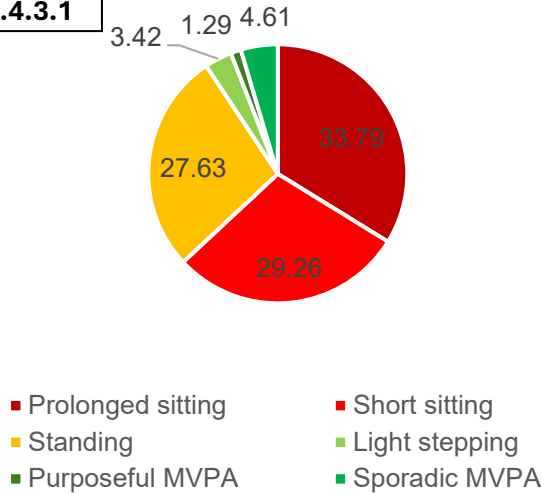
**Table 6.4.3.1 Descriptive statistics for the activPAL variables(n=18)**

<b>Average hours/day variables</b>	<b>Baseline</b>	<b>12 weeks</b>	<b>Absolute change</b>	<b>% change</b>
<b>Valid waking wear time <sup>a</sup></b>	15.20 (±1.53)	14.66 (±1.51)	-0.54 hrs	-3.55%
<b>Total sitting time <sup>a</sup></b>	9.58 (±1.88)	8.88 (±2.87)	-0.70 hrs	-7.31%
<b>Total short sitting bout time <sup>a</sup></b>	4.45 (±1.50)	3.96 (±1.41)	-0.49 hrs	-11.01%
<b>Total prolonged sitting time bouts <sup>a</sup></b>	5.13 (±2.02)	4.91 (±2.32)	-0.22 hrs	-4.29%
<b>Total light stepping time (step cadence &lt;100steps/min) <sup>b</sup></b>	0.48 (0.32- 0.65)	0.49 (0.32- 0.74)	+0.01 hrs	+2.08%
<b>Total MVPA stepping time <sup>b</sup> (step cadence &gt;100steps/min)</b>	0.61 (0.41- 1.15)	0.58 (0.40- 1.11)	-0.03 hrs	-4.92%
<b>Purposeful MVPA time <sup>b</sup> (MVPA lasting ≥ 1 min)</b>	0.06 (0.016-0.297)	0.02 (0.002- 0.213)	-0.04 hrs	-66.70%
<b>Proportions meeting recommendations</b>				
<b>Achieving ≥150 minutes/week MVPA (%)</b>	88.88%	83.33%	-5.55%	-6.27%
<b>Achieving &lt; 9.5 hours total sitting/day (%)</b>	44.44%	66.67%	+22.23%	+50.06%

<sup>a</sup> Mean (±SD)    <sup>b</sup> Median (IQR)

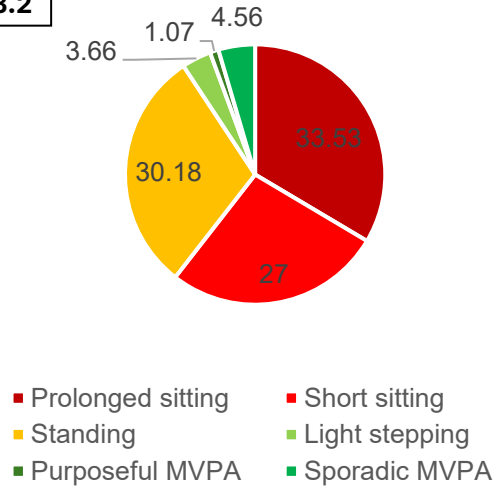
**Figure 6.4.3.1**

%of waking wear time



**Figure 6.4.3.2**

%of waking wear time



**Figure 6.4.3.1 Baseline percentage of waking hours spent in sedentary and active behaviours (mean %)**

**Figure 6.4.3.2 post-intervention (12 Weeks) percentage of waking hours spent in sedentary and active behaviours (mean %)**

#### 6.4.4 Six-Minute Walk Test (6MWT) results

Walking capacity was assessed using the Six-Minute Walk Test (6MWT) via the Timed Walk application at baseline and again after the 12-week intervention. Due to the temporary unavailability of the 6MWT app on Android devices, some participants were unable to complete this outcome measure. Consequently, complete 6MWT data were available for 14 participants. The mean 6MWT distance at baseline was 334.21 metres (SD = 112.41), while the mean post-intervention distance was 329.39 metres (SD = 95.21). This represented a mean reduction of 4.82 metres over 12 weeks, corresponding to a 1.44% decrease in walking distance. Overall, the change in 6MWT distance was small and likely reflects normal individual variability rather than a clinically meaningful decline.

#### 6.5 Discussion

The findings of this study demonstrate the feasibility of delivering a remotely delivered intervention to reduce and break up sedentary time in people with PAD. Of the 76 individuals approached, 30 consented to take part, and 21 (70%) completed the study. 18 participants completed both baseline and 12-week follow-up activPAL measurements. Recruitment of patients with PAD into clinical trials is often difficult due to comorbidities, low engagement, and logistical barriers associated with their

health condition (161),(162). Only around half of clinical studies in this field achieve their target sample size, and just as many do so within the intended timeframe (163)

Recruitment and retention rates, though reflecting known challenges in PAD populations, were sufficient to support feasibility testing. Participants found the intervention acceptable, valuing wearable prompts, online education, and supportive coaching calls. Remote delivery likely aided retention by reducing travel and time burdens for people with claudication, consistent with findings from Brierley et al. (153)

Engagement with the intervention components shows that people with PAD can participate in remotely delivered behaviour change strategies. Most participants completed 9–12 of the 12 scheduled coaching calls, with missed calls successfully rescheduled, demonstrating the value of a flexible approach. Consistent use of online education modules and wearable prompts suggests that technology-based components can be integrated into daily routines. Occasional support from family members was needed to navigate digital tools, highlighting the importance of addressing digital literacy and providing guidance for those less familiar with technology. In line with evidence from other clinical groups, blended interventions combining technology-based self-monitoring with human support seem more effective for sustaining behaviour change than technology alone (153, 154).

In the present study, the attrition rate from consent was 30%, which is relatively high for a short follow-up period and highlights the need for improved retention strategies in future research. Despite this, recruitment, data completion, and the qualitative findings were consistent with the study's feasibility objectives, indicating that the overall approach is suitable for refinement and evaluation in a larger randomised controlled trial (RCT). Retention appeared higher among participants with severe claudication, although this may reflect the distribution of disease severity within the sample. The greater representation of participants with severe claudication at follow-up may indicate that individuals with higher symptom burden perceived the intervention as more relevant or beneficial. However, larger studies are required to determine whether disease severity independently influences retention and engagement.

### **Feasibility and acceptability of the Intervention**

Adherence to the intervention was generally good, with most participants actively using the activity tracker and engaging in weekly coaching calls. Digital health interventions offer promise for improving care in older adults but can present usability challenges, particularly for individuals unfamiliar with technology (164). Issues such as poor design, small fonts, and complex navigation may limit engagement (165). In this study, assistance from family members was needed a few times, but overall engagement indicated that the intervention was both feasible and acceptable.

This aligns with findings by Mercer et al. (166), who reported that older adults with chronic illness generally find wearable physical activity devices useful and acceptable, though some may require support with setup and data interpretation.

The current study adopted the same online education session from the SMART Work & Life study (155) to deliver key sedentary behaviour messages. Consistent with SMART, participants found the session informative and acceptable. Perceived accountability clearly played a role in participants' engagement and behaviour change. The weekly coaching calls served not only as a source of motivation and support, but also as a consistent point of contact that helped participants remain focused and engaged. Participants reported that the calls functioned as a regular check-in, increasing their awareness of sitting habits and encouraging behavioural change. The coaching sessions were perceived as helpful in maintaining focus on reducing sedentary time and supporting sustained behaviour change. This is consistent with findings from the RESIT study, in which health coach support was identified as one of the most valued components of the intervention. Overall, the regular coaching sessions were viewed as acceptable and supportive, contributing to ongoing motivation and adherence (159).

This suggests that knowing someone would follow up and discuss their progress created a sense of responsibility, which likely enhanced adherence to the programme and reinforced key behaviour change messages. McFeeley et al. (167) similarly reported that coaching delivered through digital health programmes supports the adoption and maintenance of healthy lifestyle behaviours.

### **Sedentary Behaviour and Physical Activity**

People with PAD are typically highly sedentary and engage in lower levels of physical activity compared with the general population (33). In the current study, results align with previous reports indicating 433–640 minutes/day of sitting (24, 32, 66), which is higher than observed in older adults without PAD (89), reflecting the mobility limitations and discomfort associated with the disease.

The findings of this study suggest that the intervention has potential to reduce sitting time, although observed differences at follow-up were modest (~3% of waking time). These changes were primarily due to reductions in prolonged sitting, accompanied by increases in standing time. Notably, the proportion of participants achieving <9.5 hours per day of sitting (28) increased from 44.4% pre-intervention to 66.7% post-intervention, representing a 22.2% absolute and 50% relative improvement. Similarly, Perks et al. (30) reported reductions in sitting time of 0.9 hours/day following an 8-week personalised activity plan for people with intermittent claudication, supporting the potential of targeted interventions in this population (154) (18).

These findings align with previous interventions in older adults, which generally reduced total sedentary time, particularly when multiple strategies such as education, self-monitoring, and goal setting were included (168) (158). Evidence from PAD-specific interventions remains limited. A

systematic review (33) highlighted few studies in this population. Among them, Laslovich et al. (18) reported significant reductions in sedentary time using a 12-week home-based intervention with self-monitoring, goal setting, and personalised feedback, whereas Whipple et al. (31), using supervised exercise therapy, found no overall reduction and considerable individual variability, including increases in sedentary behaviour. These findings suggest that exercise alone may be insufficient to reduce sitting time in PAD. Interventions that explicitly target sedentary behaviour using behavioural strategies, as employed in the current study, may be necessary to achieve meaningful changes in sedentary time.

### **Functional Outcomes and the 6-Minute Walk Test**

Functional walking ability, assessed via the remote 6-Minute Walk Test (6MWT) (146), showed a small decline of 4.82 m (-1.44%) over the 12-week study period. This change is below the established minimal clinically important difference for people with PAD, which ranges from 8 to 20 m (169). Although participants reduced sedentary time during the intervention, the accompanying increase in light-intensity activity was insufficient to produce measurable improvements in functional capacity. Previous meta-analyses of home-based exercise programmes in PAD have reported clear benefits for both pain-free and maximal walking distance, with improvements of moderate effect size compared with controls (170). These findings suggest that interventions designed specifically to increase walking or structured exercise may be necessary to enhance functional outcomes, whereas strategies that primarily target sedentary behaviour may be effective in maintaining current walking capacity but not in producing significant gains. Moving forward, combining sedentary behaviour reduction with targeted walking or exercise prescriptions could optimise both health and functional benefits for people with PAD.

### **6.6 Implication of findings**

The findings suggest that while a sedentary behaviour intervention for people with PAD is feasible and acceptable, several refinements are required before progression to a fully powered randomised controlled trial. Future studies should incorporate structured walking or exercise components alongside sedentary time reduction to better support improvements in functional walking capacity. Digital delivery increased accessibility, particularly for participants in rural areas; however, variable digital literacy and temporary loss of app access indicate the need for improved technical infrastructure. Future interventions should include technical support and provide alternative data collection methods where needed. Overall, these findings support an intervention optimisation and feasibility refinement phase, rather than immediate progression to a definitive RCT, to strengthen intervention content, delivery, and data completeness.

### **Implications for Future Trials: Integration of Quantitative and Qualitative Findings**

Triangulation of quantitative and qualitative findings provides a comprehensive understanding of intervention feasibility and informs strategies for refinement. Qualitative interviews revealed that

participants valued coaching calls and wearable devices, but practical barriers such as acute illness, physical limitations, environmental factors, and challenges with digital literacy affected engagement and device wear. Integrating these data allows identification of the behavioural and contextual factors influencing feasibility and highlights where improvements are needed.

Based on this integrated insight, future trials could incorporate targeted strategies to enhance adherence and data completeness. These may include automated reminders, active monitoring of device wear, personalised feedback, simplified and more accessible digital materials, enhanced technical support, and motivational approaches such as appropriate incentives. These measures are likely to improve retention, device compliance, and overall study feasibility in a future randomised controlled trial.

## **6.7 Conclusion**

This study demonstrated that a 12-week, remotely delivered intervention for people with peripheral arterial disease (PAD), incorporating activity trackers, online education, and coaching calls, was both feasible and acceptable. Participants reported the intervention as informative and viewed it positively. Recruitment targets were met, though strategies to improve retention and activPAL compliance would be needed for a larger trial. The intervention showed potential to reduce sitting time. Overall, these findings offer valuable insights into recruitment, retention, and measurement procedures, and will help inform the design of a future adequately powered randomised controlled trial to evaluate effectiveness.

## **6.8 limitations**

Several limitations would be considered when interpreting the findings of this study. First, the sample size was small and drawn from a single geographical region, which may limit generalisability to the wider PAD population with more diverse cultural and lifestyle backgrounds. Second, ethnicity data were not collected, and therefore the potential influence of ethnic differences on sedentary behaviour and intervention response could not be evaluated. Although sedentary behaviour was objectively assessed using activPAL, compliance with wearing the device continuously for seven days may have affected data completeness, particularly among participants who had lower levels of technological literacy.

The intervention primarily targeted reductions in sedentary behaviour and did not include a structured walking or exercise component, which likely limited its potential to improve functional walking capacity. In addition, the timed walk application used to assess the 6-minute walk test was temporarily unavailable for Android users and restricted to iOS users during part of the study period, resulting in incomplete baseline walking data. Digital literacy also posed a challenge, as access to the online education platform and the Huawei Band application differed between operating systems, with Android users required to download the application via a website rather than an app store.

Together, these limitations highlight the need for larger, multi-site studies that collect more comprehensive data from all participants, including reasons for dropout or non-completion, to better inform intervention design. Future studies should also improve digital accessibility and consider combining sedentary behaviour reduction with structured exercise components to more accurately assess effectiveness and generalisability.

## **Chapter 7: Discussion**

This discussion synthesises findings across the components of the thesis, the systematic review, the cross-sectional observational studies, and the mixed-methods feasibility intervention, to develop a coherent understanding of sedentary behaviour in people with peripheral arterial disease, its measurement, and the feasibility of reducing sedentary time in this population. The discussion integrates quantitative and qualitative evidence. The subheadings within this discussion were therefore developed through an iterative process that considered convergence and divergence across all three study components. Key themes such as the burden of sedentary behaviour in PAD, challenges in measurement, the role of awareness and feedback, and the importance of tailored support emerged consistently across the review, observational, and intervention phases.

The World Health Organisation highlights the importance of reducing sedentary time yet, it does not set absolute limits (37). Prolonged sedentary time is associated with adverse cardiovascular outcomes, worsening PAD symptoms and mobility restrictions (28). Despite this, most PAD research has prioritised physical activity promotion over sedentary behaviour reduction, leaving the latter underexplored. Sedentary behaviour itself is now recognised as an independent risk factor for poor health outcomes, including cardiovascular disease, and appears more common in PAD than in healthy populations (89). Accurate measurement remains a challenge: questionnaires mainly assess screen time with moderate reliability but low validity, while most accelerometers measure movement but inadequately capture posture (81). Posture-specific devices such as the thigh-worn activPAL provide valid and reliable distinction between sitting/lying and standing, with over 50 studies supporting their use (48). Accelerometry-based data suggest that sitting for  $\geq 9.5$  hours daily significantly increase all-cause mortality risk (28).

This thesis investigated sedentary behaviour (SB) in PAD through a systematic review, two cross-sectional studies, and a feasibility trial. The findings highlight that people with PAD spend long periods sitting, often in uninterrupted bouts, with little MVPA. Self-reported measurement underestimated sitting and overestimated activity, while behaviour-change strategies reduced sedentary time but did not produce immediate functional gains. Together, these studies provide an integrated understanding of sedentary behaviour in PAD, its consequences, measurement, and the feasibility of intervention.

### **Sedentary behaviour in PAD**

Findings from the systematic review and the two cross-sectional studies converged to confirm that patients with PAD spent a substantial proportion of their waking hours sedentary. The systematic review identified mean sedentary times between 7.2-10.7 hours per day across accelerometer-based studies (18),(31),(46), which aligned with the first cross-sectional findings using activPAL, where sitting time averaged 9.6-9.7 hours per day. Importantly, almost half of this sedentary time

occurred in prolonged, uninterrupted bouts (>30 minutes), a pattern known to exacerbate cardiometabolic risk (121).

The second cross-sectional study further highlighted the discrepancies between self-reported and device-based estimates. While activPAL recorded 9.5 hours per day of sedentary time, IPAQ reports underestimated sitting by an average of 3.5 hours per day. Similarly, IPAQ suggested that participants exceeded WHO physical activity guidelines (37), yet device data showed a median of 13.8 minutes per day of MVPA, below recommended levels. These findings not only confirmed the high prevalence of sedentary behaviour in people with PAD but also demonstrated that reliance on self-report masked the exact time spent in each activity. This echoed broader evidence that self-reported measures systematically underestimated SB (44).

Objective measurement remains crucial. Triaxial accelerometers capture movement in three dimensions, whereas uniaxial devices may underestimate sedentary time. Device placement further affects estimates, with hip-worn devices generally reporting higher sedentary time than wrist-worn devices. For example, studies using uniaxial or wrist-worn accelerometers(31, 46) reported mean sedentary times below the 8 hours/day threshold for high-risk behaviour, suggesting potential underestimation. These observations underscore the value of posture-sensitive, validated devices for accurately assessing sedentary behaviour in PAD and contextualising the high sedentary times and long bout durations observed in this thesis

### **Mechanistic possibility linking SB to PAD outcomes**

Several pathways connect sedentary behaviour to worse outcomes in PAD. Prolonged sitting reduces lower-limb shear stress, limiting nitric oxide bioavailability and flow-mediated dilation; repeated exposure fosters arterial stiffness and microvascular dysfunction (35). Metabolically, uninterrupted sitting impairs glucose and lipid handling, fuelling insulin resistance and inflammation that accelerate atherosclerosis progression and impair collateralisation. Musculoskeletal consequences are also relevant: calf muscle atrophy and mitochondrial decline reduce walking ability and exercise tolerance (28, 121). Experimental studies further support these mechanisms, showing that extended sitting worsens postprandial glycaemia, elevates blood pressure, and impairs endothelial function, while breaking up sitting can reverse some of these effects (171).

The systematic review linked higher sedentary time with worse clinical status, including lower ABI (24),(32),(66), shorter six-minute walk distance, and higher mortality (31),(34). Although causality cannot be inferred from observational studies, the direction of association is physiologically plausible: reduced calf muscle pump activity during prolonged sitting impairs venous return and arterial inflow, contributing to systemic insulin resistance and inflammation that further compromise vascular function (28). Importantly, reallocating time analyses suggested that replacing sedentary time with MVPA was associated with greater walking distance (9), consistent with experimental

evidence that interrupting sitting with light-to-moderate activity improves vascular and metabolic function (121).

Supervised exercise therapy (SET), particularly structured walking programmes, remains one of the most effective treatments for PAD, yet access is poor, and implementation is limited (172). This raises the question of why sedentary behaviour reduction strategies should be prioritised. Both approaches may be complementary. Emerging guidelines support home-based and digitally supported alternatives where SET is unavailable, and behaviour-change strategies are essential to support long-term adherence. Within this context, our feasibility trial showed that sitting time could be reduced through behaviourally informed interventions (173). These findings highlight the need for innovative, non-invasive approaches that integrate sedentary time reduction, behaviour change, and accessible exercise programmes to improve outcomes in PAD.

### **Sedentary behaviour and ABI relationship**

In cross-sectional study 1, no significant correlations were found between sitting time, MVPA, and ABI. This contrasts with findings from the systematic review and is likely explained by methodological limitations. First, the ABI values showed little variation, as most participants clustered within the PAD range, leaving few very low or borderline values to provide contrast. This restricted range reduced the likelihood of detecting associations. Second, the relatively small sample size limited statistical power to identify modest effect sizes. Third, measurement approaches differed. The activPAL provided accurate classification of posture (sitting, standing, stepping) but does not directly measure intensity. MVPA was therefore estimated from cadence or step thresholds, which may underestimate intensity in PAD due to slower gait and frequent rest periods.

Confounding and mediation also warrant consideration. ABI primarily reflects macrovascular stenosis, whereas sitting behaviour is influenced by multiple factors, including symptoms, pain, depression and weather. For instance, if pain reduced both activity and ABI, but unmeasured factors such as analgesic use, mood, winter months, or exposure to supervised exercise therapy also affected behaviour, residual confounding could have biased the observed associations. Importantly, the clinically relevant signal may lie in the pattern of sitting rather than total sedentary time. ActivPAL data indicated that nearly half of sedentary time occurred in long, uninterrupted bouts. Experimental studies have shown that breaking up sitting can provide vascular benefits even when total sedentary time remains unchanged (121). Therefore, if ABI was more closely linked to sitting bout structure than to total sedentary minutes, the lack of association with total sitting time was not unexpected.

### **Variation between subjective and device measures**

Cross-sectional Study 2 highlighted differences between self-reported and device-measured behaviours. The IPAQ underestimated sitting time (6 h/day) compared with activPAL (9.5 h/day) and overestimated activity to levels that appeared to meet WHO guidelines, whereas devices recorded a median of 13.8 minutes/day of MVPA. Bland–Altman showed wide limits of agreement, non-equivalence, and low ICCs indicated that the two methods were not interchangeable. This was anticipated: self-reported measures tended to compress habitual and fragmented behaviours like sitting, were susceptible to recall bias and social desirability, and often missed incidental movement. In contrast, devices provided objective, discrete measurements of posture and cadence (44)

In PAD, these biases were even more pronounced. Participants often mixed being upright with being physically active, leading to self-reports of exercise that rarely met objective MVPA thresholds. Qualitative data confirmed this mismatch. Reliance on questionnaires alone risks underestimating sedentary exposure, obscuring real progress, and misguiding intervention.

### **Intervention outcomes**

The 12-week programme achieved its immediate behavioural targets. Among completers (n=21), total sitting time and prolonged sitting bouts (>30 min) decreased, indicating participants had learned to interrupt and reduce sedentary time. From 8,087 records, 51 studies were included, and meta-analysis of 34 intervention studies showed sedentary time was reduced by 0.37 h/day. Lifestyle programmes reduced sedentary time by 0.40 h/day and sedentary-specific interventions by 0.70 h/day, while no effect was observed for physical activity–only or combined interventions (174).

The feasibility intervention was well tolerated, and qualitative feedback indicated acceptability, particularly for the vibration prompts and coaching support, with participants noting that *'the tracker reminded me to move'* and *'the calls kept me on track.'* These components supported behaviour-change processes including self-monitoring, feedback, prompts, problem-solving, and social support (54). However, MVPA stepping time decreased. This finding suggests that while participants may have replaced prolonged sitting with light-intensity activity, the intervention did not sufficiently encourage or support engagement in higher-intensity movement. This highlights an important consideration for future studies, namely the need to explicitly incorporate strategies that promote MVPA, such as structured walking goals or graduated exercise prescriptions, alongside sedentary behaviour reduction to avoid unintended reductions in higher-intensity activity.

Several factors limited the translation of reduced sitting into meaningful increases in physical activity. Reducing sitting did not automatically lead to more moderate-to-vigorous physical activity (MVPA); participants often substituted sitting with brief standing or light ambulation. Frequent sit-to-stand breaks may have been offset by reduced overall upright time, masking improvements in sedentary patterns. Clinically significant gains in six-minute walk distance (6MWT) in PAD typically require structured, progressive walking interventions over  $\geq 3$ –6 months, whereas this programme

focused on reducing sedentary time without supervised exercise, explaining the lack of functional improvement. Contextual barriers, including winter recruitment and limited digital literacy, further restricted overall engagement with the study. Moreover, app-based 6MWT measurements likely introduced variability, with the observed mean change ( $-4.8$  m) falling below minimal important difference thresholds, suggesting stability within measurement error rather than true decline.

The BREAKUP study intervention for patients with intermittent claudication (IC) comprised an 8-week personalised activity plan designed to break up prolonged sitting with short bouts of physical activity. This resulted in a significant reduction in mean daily sitting time by 0.90 hours and a decrease in prolonged sitting ( $\geq 60$  min) by 0.59 hours/day (154). In comparison, our study also demonstrated a reduction in sedentary time over 12 weeks, with total sitting time decreasing by 0.70 hours per day. However, the reduction in prolonged sitting bouts was smaller  $-0.22$  hours than that observed in the BREAKUP intervention. Furthermore, stepping time in our study remained largely unchanged. Overall, although both studies reported reductions in sedentary time, the magnitude of change and associated increases in upright activity were more pronounced in the BREAKUP study compared with the modest behavioural shifts observed in our cohort. This difference may be explained by the structured design of the BREAKUP intervention, which specifically incorporated short, frequent bouts of physical activity to interrupt prolonged sitting. A recent individual participant data meta-analysis of prospective cohort studies found that reducing sedentary time by 30 minutes per day could prevent 3–7% of all deaths, depending on whether a high-risk or population-based approach is considered, highlighting that even modest reductions in sitting time can meaningfully lower mortality risk (175).

Similarly, Laslovich et al. (18) conducted a 12-week RCT of a home-based online sedentary reduction programme that significantly reduced daily sitting/lying time by 0.80 hours. In contrast, Whipple et al. (31) implemented a 12-week pre/post study of supervised exercise therapy (2–3 sessions/week), which led to a 2.8% increase in average daily sedentary time, though individual responses ranged widely ( $-40\%$  to  $+38\%$ ). These studies involved exercise-based interventions with the primary aim of increasing physical activity, with reductions in sedentary time occurring as a secondary effect.

### **Contribution of the Research**

Despite growing recognition of sedentary behaviour as an independent cardiovascular risk factor, its role in peripheral arterial disease (PAD) remains underexplored, with most research to date centred on physical activity rather than sedentary time reduction. This thesis contributes to addressing this gap by systematically reviewing the existing literature, conducting two cross-sectional studies, and implementing a feasibility and acceptability trial of a sedentary behaviour intervention in patients with PAD. Guided by frameworks for complex intervention development, the

research provides an integrated assessment of sedentary behaviour in this population, highlighting its high prevalence, the limitations of self-reported measures, and the value of device-based, posture-sensitive monitoring such as activPAL.

The feasibility study demonstrated that sedentary behaviour reduction strategies can be introduced in people with PAD; however, it also highlighted important challenges, including high attrition, variable acceptability, and barriers related to digital literacy. These findings suggest that progression to a definitive trial requires careful refinement. Given the attrition observed, enhanced retention strategies are essential, including simplified technology interfaces, blended delivery options (digital plus in-person) and proactive follow-up of participants who disengage. A future RCT should therefore be adequately powered, multi-centre, and include clearly defined inclusion criteria that reflect the heterogeneity of PAD severity. The intervention should incorporate structured support to interrupt prolonged sitting (e.g., scheduled prompts and brief, individualised activity breaks).

Importantly, objective measurement of sedentary time and physical activity (e.g., activPAL) should be retained to ensure precise quantification of behavioural change. Outcomes should extend beyond sedentary metrics to include clinically meaningful endpoints such as walking distance, pain-free walking time, health-related quality of life, and cardiovascular risk markers. A longer follow-up period (e.g., 6–12 months) would be necessary to evaluate the sustainability of behavioural change and explore potential downstream vascular and functional benefits. Such a design would allow refinement of intervention components, adherence strategies, and outcome selection prior to testing effectiveness in a future definitive RCT.

Several questions remain unanswered before a full trial: which subgroups (e.g., those with milder versus more advanced PAD) derive greatest benefit; whether sedentary reduction alone is sufficient or must be combined with exercise training; and how digital literacy and symptom burden influence engagement. Embedding a formal process evaluation, including qualitative interviews with both completers and dropouts, will be critical to understand mechanisms of adherence and disengagement. Patient and Public Involvement (PPI) should move beyond consultation to genuine co-design, ensuring that intervention components, delivery format, and outcome priorities reflect patient realities. Only through this iterative refinement can a definitive RCT adequately test both effectiveness and real-world application.

Overall, this thesis positions sedentary behaviour reduction as a promising but still underdeveloped therapeutic target in PAD. The findings directly inform the design of future RCTs by identifying both the potential benefits and the key implementation challenges that need to be addressed to optimise efficacy, adherence, and sustainability.

### **Practical implications for clinical practice**

Using objective monitoring rather than self-reported tools could minimise misleading clinical decisions. Where feasible, thigh-worn devices are preferable for posture and bout analytics. Target prolonged sedentary bouts as a therapeutic goal, aiming to avoid sitting for more than 30 minutes without a brief stand or short walk. Integrate sedentary behaviour goals into a stepped care pathway that progresses to symptom-guided walking when pain allows, translating reduced sedentary time into functional gains.

## Chapter 8: Conclusion

This thesis synthesised evidence from a systematic review, two cross-sectional studies, and one feasibility study to examine sedentary behaviour patterns in people with peripheral arterial disease (PAD). Across all components of the thesis, it is evident that individuals with PAD spend a substantial portion of their day sedentary, often in prolonged bouts, which may contribute to functional decline and increased cardiovascular risk. The systematic review highlighted consistent findings across existing literature, showing high sedentary time and limited engagement in moderate-to-vigorous physical activity (MVPA). The cross-sectional studies conducted as part of this thesis confirmed these patterns within PAD populations. The feasibility study further explored the potential to reduce sedentary behaviour, demonstrating that such interventions are achievable and acceptable to participants, though functional improvements were limited.

Behavioural changes observed in the feasibility study were limited by PAD-related symptoms, particularly pain, which limited progression from light activity to sustained walking. Participants primarily replaced sitting with brief standing or light activity. Additional contextual factors including winter recruitment, rural living, and limited digital literacy further restricted engagement with the intervention. Functional outcomes, particularly six-minute walk test (6MWT) performance, showed little change across the feasibility study. This aligns with evidence from PAD rehabilitation research, which indicates that clinically meaningful improvements in walking capacity require structured, progressive walking programmes delivered over several months. The absence of a supervised exercise component in the feasibility intervention, which focused primarily on reducing sedentary time, explains the lack of measurable functional improvement.

These findings carry important clinical implications. Sedentary behaviour represents a modifiable risk factor in PAD and should be addressed alongside conventional exercise prescriptions. Even modest reductions in sitting time may confer health benefits, including improvements in endothelial function, metabolic markers, and overall cardiovascular risk. However, for functional gains, reductions in sedentary behaviour must be complemented by structured exercise interventions tailored to overcome PAD related symptoms. Contextual barriers, including seasonality, geography, and digital literacy, must also be considered in intervention design to enhance engagement and adherence.

The thesis also identifies gaps and directions for future research. The current evidence base is limited by small sample sizes, and short-term follow-up. Larger, well-designed prospective studies are needed to quantify the independent effects of sedentary behaviour reduction on vascular outcomes, functional capacity, and quality of life in PAD populations. Future interventions should combine sedentary behaviour reduction with strategies to overcome individual barriers, supported by objective and clinically validated outcome measures.

Finally, this thesis demonstrates that sedentary behaviour is highly prevalent in people with PAD and that interventions targeting its reduction are feasible and generally acceptable. However, reducing sitting time alone appears insufficient to produce clinically meaningful functional improvements, highlighting the need for more comprehensive approaches. Multifaceted, tailored interventions that address PAD-specific barriers, incorporate structured strategies to interrupt prolonged sitting, and use reliable objective measurement methods are likely required to optimise outcomes. While targeting sedentary behaviour represents a promising strategy to improve vascular health, reduce cardiovascular risk, and enhance quality of life, high attrition and variable acceptability indicate that further refinement is needed before progression to a definitive trial. Future multi-centre RCTs should include longer follow-up to assess sustainability, clinically meaningful outcomes such as walking distance and quality of life, and embedded process evaluation with strong patient involvement to address remaining uncertainties regarding intervention design, subgroup responsiveness, and integration with exercise therapy.

### **Key Messages**

- People with PAD are highly sedentary, often accumulating prolonged sitting bouts, which may contribute to functional decline and increased cardiovascular risk.
- Behavioural interventions targeting sedentary time are feasible and acceptable but typically increase light activity or standing rather than moderate-to-vigorous physical activity.
- PAD-related symptoms, especially pain, restrict progression to sustained walking and thereby limit functional improvement.
- Contextual factors, including season, rural living, and digital literacy, influence engagement and adherence to interventions.
- Future interventions for sedentary behaviour reduction should address individual barriers, and use reliable, validated outcome measures.
- Larger, long-term studies are required to determine whether reducing sedentary behaviour can translate into sustained improvements in vascular health, functional capacity, and quality of life in PAD populations.

### **Limitations**

The thesis has several limitations. The systematic review included few studies with heterogeneous designs, outcomes, and follow-up periods, limiting comparability and preventing meta-analysis. Most studies were observational, restricting causal inference. The cross-sectional studies were limited by small, region-specific samples and single time-point measurements, reducing generalisability and causal insight. The feasibility intervention trial was short-term, had a small

sample with some attrition, and lacked a structured exercise component, while PAD-related pain, seasonal factors and digital literacy affected adherence.

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## Appendices

### Appendix 1

#### Search strategy

1. Peripheral Arterial Disease\*
2. Peripheral Artery Disease\*
3. PAD
4. Peripheral vascular disease\*
5. PVD
6. Intermittent Claudication
7. Claudi\*
8. Ankle brachial index
9. ABI
10. Ankle brachial pressure index
11. ABPI
12. Critical limb ischemia
13. Critical limb ischaemia
14. CLI
15. Rest pain
16. Ulcer\*
17. 1 OR 2OR 3 OR 4 OR 5 OR 6 OR 7 OR8 OR9 OR10 OR11 OR12 OR13 OR14 OR15 OR16
18. Sedentary
19. Sitting
20. Reclin\*
21. Lying
22. Inactiv\*
23. Activ\*
24. Behavior\*
25. Behaviour\*
26. Tim\*
27. Intervention\*
28. Prolonged
29. Uninterrupted

- 30. Un-interrupted
- 31. Physical\*
- 32. 18 AND 24
- 33. 18 AND 25
- 34. 18 AND 26
- 35. 18 AND 27
- 36. 19 AND 24
- 37. 19 AND 25
- 38. 19 AND 26
- 39. 28 AND 19
- 40. 29 AND 19
- 41. 30 AND 19
- 42. 31 AND 22
- 43. 31 AND 23
- 44. 28 AND 20
- 45. 29 AND 20
- 46. 30 AND 20
- 47. 28 AND 21
- 48. 29 AND 21
- 49. 30 AND 21
- 50. 28 AND 22
- 51. 29 AND 22
- 52. 30 AND 22
- 53. 18 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40 OR 41 OR 42 OR 43  
OR 44 OR 45 OR 46 OR 47 OR 48 OR 49 OR 50 OR 51 OR 52
- 54. 17 AND 53

## Appendix 2 The International Physical Activity Questionnaires (IPAQ) for cross sectional study 2

### INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

(October 2002)

#### LONG LAST 7 DAYS SELF-ADMINISTERED FORMAT

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health-related physical activity.

#### **Background on IPAQ**

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

#### *Using IPAQ*

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

#### *Translation from English and Cultural Adaptation*

Translation from English is encouraged to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at [www.ipaq.ki.se](http://www.ipaq.ki.se). If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

#### **Further Developments of IPAQ**

International collaboration on IPAQ is on-going and an **International Physical Activity Prevalence Study** is in progress. For further information see the IPAQ website.

#### *More Information*

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at [www.ipaq.ki.se](http://www.ipaq.ki.se) and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 71 (77): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

## INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

### PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

No



**Skip to PART 2: TRANSPORTATION**

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

\_\_\_\_\_ **days per week**

No vigorous job-related physical activity



**Skip to question 4**

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

\_\_\_\_\_ **days per week**

No moderate job-related physical activity



**Skip to question 6**

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

\_\_\_\_\_ **days per week**

No job-related walking



**Skip to PART 2: TRANSPORTATION**

7. How much time did you usually spend on one of those days **walking** as part of your work?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

#### *PART 2: TRANSPORTATION PHYSICAL ACTIVITY*

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

\_\_\_\_\_ **days per week**

No traveling in a motor vehicle



**Skip to question 10**

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

\_\_\_\_\_ **hours per day**

\_\_\_\_\_ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

\_\_\_\_\_ **days per week**

No bicycling from place to place →

***Skip to question 12***

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

\_\_\_\_\_ **days per week**

No walking from place to place →

***Skip to PART 3: HOUSEWORK,  
HOUSE MAINTENANCE, AND  
CARING FOR FAMILY***

13. ***How much time did you usually spend on one of those days walking from place to place?***

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

***PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY***

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

\_\_\_\_\_ **days per week**

No vigorous activity in garden or yard



***Skip to question 16***

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

\_\_\_\_\_ **days per week**

No moderate activity in garden or yard



***Skip to question 18***

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

\_\_\_\_\_ **days per week**

No moderate activity inside home



***Skip to PART 4: RECREATION,  
SPORT AND LEISURE-TIME  
PHYSICAL ACTIVITY***

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

**PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY**

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

\_\_\_\_\_ **days per week**

No walking in leisure time



**Skip to question 22**

21. How much time did you usually spend on one of those days **walking** in your leisure time?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

\_\_\_\_\_ **days per week**

No vigorous activity in leisure time



**Skip to question 24**

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

\_\_\_\_\_ **days per week**

No moderate activity in leisure time



**Skip to PART 5: TIME SPENT SITTING**

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

**PART 5: TIME SPENT SITTING**

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

**This is the end of the questionnaire, thank you for participating.**

## **Appendix 3 Patient Information Leaflet for cross sectional studies.**

### **Patient Information Leaflet**

#### **Study Title:**

#### **Assessment of sedentary behaviour among patients with peripheral arterial disease.**

Invitation to take part in a study:

You are being invited to take part in a research study being conducted by the department of vascular and endovascular surgery at the University College Hospital, Galway. Before you decide, it is important for you to understand why the research is being done and what it will involve. This patient information sheet will tell you about the purpose, risks, and benefits of this research study. If you agree to take part, we will ask you to sign a consent form. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read it. You should only consent to participate in this research study when you feel that you understand what is being asked of you, and you have had enough time to think about your decision.

What is the purpose of this study?

Peripheral arterial disease (PAD) is characterised by a disruption in arterial flow. Many risk factors have been identified for PAD as smoking, increased age, high blood pressure, diabetes, obesity, physical inactivity, and high cholesterol levels. Recently, sedentary behaviour has emerged as an important risk factor for many health problems as cardiovascular disease (CVD) including PAD. So, it is essential to assess sedentary time (ST). Available methods include questionnaires and accelerometers like activPAL. The activPAL™ measures sedentary time and physical activities second by second, in terms of the time spent lying, sitting, standing, stepping. The current study will use both methods.

Why have I been asked to participate?

Our study is looking at assessment of sedentary behaviour among patients with peripheral arterial disease using both tools (questionnaire and activPAL). You have been asked to take part because you have peripheral arterial disease so, we ask to assess your sedentary time.

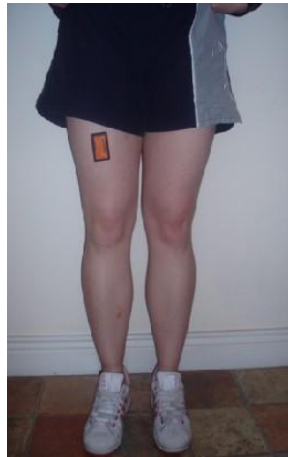
Do I have to take part?

It is up to you to decide whether to take part or not. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your rights in any way.

What will happen to me if I take part?

If you decide to participate in the study, you will be asked to sign a consent form. (You will be given a copy of the consent form to keep). We will need to ask you a few questions regarding your medical history. You will then undergo a screening process. The researcher will fix the activPAL at your thigh with adhesive tape as in this video:

<https://www.youtube.com/watch?v=CHCCX2GW3DM> and give you the tool information sheet and logbook.



**ActivPAL fixed at the right thigh.**

The activPAL will be in place as shown in the above photo for 7 consecutive days. You should remove it when bathing or swimming. Then the researcher will ask you to do a test to assess your walking ability named the 6-minute walk test. After 7 days you will be asked to fill in a questionnaire that assesses your physical activity and sitting time. Then you will be asked to post the activPAL and the filled questionnaire using the registered envelope distributed by the researcher. Throughout the study period, we will need you to repeatedly check the activPAL and record wake up and sleep times in the logbook.

How long will my part in the study last?

You will continue to have the activPAL in place for 7 consecutive days. After the 7 days end, you will have to post the instrument with the filled questionnaire. The researcher will contact you for the feedback as soon as the data analysed.

What do I have to do?

You have to maintain the activPAL in place. You should behave as normal while wearing the device. A logbook will be given to record device wear time and sleep time.

What are the possible benefits in taking part?

Proper management plan for your peripheral arterial disease including risk factor modifications should be started early to prevent any complications. Managing modifiable risk factors as reducing sedentary behaviour and increasing physical activity are both important to promote

health and are recommended to improve outcomes of PAD interventions. Feedback on your results can be very informative and help provide information to change your lifestyle and reduce/interrupt prolonged sedentary time.

What are the possible risks of taking part?

Despite using non-allergenic adhesive tape, possible local allergic reaction can occur at the site of the activPAL. So, if you have known skin allergies or skin conditions that could be worsened by adhesive tape used to apply the accelerometer, please let us know.

What if something goes wrong?

Immediately contact your research doctor. Your research doctor will ensure that this situation is managed appropriately, according to the hospital clinical guidelines.

What happens at the end of the study?

At the end of the study, all data gathered from all participants will be collected and analysed, in view of publishing the results. Only collective data will be published, and you will not be identified in any report or publication. If you wish to obtain a copy of the published data, you can ask your research doctor at the end of the study.

What happens if I change my mind during the study?

It is your choice to participate in this study, and you are free to change your mind and withdraw from the study at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will NOT affect your rights or your medical care and further management and treatment at the vascular department.

What if I have a complaint during my participation in the study?

Highly trained doctors will be involved in every aspect of your care throughout your participation in the study. They will work to make sure you receive the highest standard of care. However, if you do develop an adverse event, they will make sure it is addressed immediately according to your clinical condition. Any adverse events arising within the study will be notified to the regulatory authorities.

Whom do I contact if I have further concerns?

If you have any concerns about this study and wish to contact someone in confidence, you may contact the Dr. Marwa Said at the contact details listed at the end of this information leaflet.

Do researchers need information from my medical records?

Yes. The researchers from the hospital will need access to any information collected throughout the course of the study. However, all information that is collected about you during the research will be kept strictly confidential and will not be shared with anyone else. The information collected in this research study will be stored in a way that protects your identity. Results from the study will be reported as group data and will not identify you in any way.

What if I still have further questions I would like to ask?

In addition to this brochure, all details of the study will be verbally explained to you by your research doctor. Please feel free to ask the doctor to clarify any points that remain unclear. This brochure is yours to keep. If you decide to participate in this study, you will have to sign a consent form and you will keep a copy of that form as well.

**Thank you for taking the time to read this leaflet. Please remember, it is your choice whether to participate or not. You are free to change your mind at any time. Whatever your decision, this will not affect your medical care**

## Appendix 4:

### Thigh monitor instructions (ActivPAL)

Thank you for taking part in this health initiative. We hope you find it useful and worthwhile.

If you have any questions at all please contact:.....

The device will be recording your sitting and activity behaviour. It's really important that when you wear it you behave as you normally would. If you could wear the device and then return it in the stamped address envelope provided. We will then fully analyse your data and will talk you through your results and set some goals as well as signpost to possible tools that might be worth exploring. Your very own personalised approach so hopefully useful to improve claudication pain.

#### How do I fit the Thigh Monitor?

- The Thigh Monitor is attached directly onto the skin and positioned on the front of the thigh, roughly 1/3 of the way between hip and knee with the stick man standing up (see picture).
- Do not take the protective waterproof covering off the Thigh Monitor.
- Rest the monitor on your chosen thigh (facing upwards as shown)
- Take one sheet of the sticky patch and carefully peel off the paper layer.
- Stick this over the Thigh Monitor and push down gently to stick loosely to the skin around the monitor. See [fixomull transparent product video - YouTube](#)
- Peel off the outer layer of protective plastic from the sticky patch.
- Starting from around the Thigh Monitor, press the sticky patch which is now very thin onto the skin and work outwards removing wrinkles.



#### Notes on the Thigh Monitor

- When the monitor arrives Marwa can help you with if needed. We would like you to put the monitor on and then wear it this day and then **every day for the next 7 consecutive days**.
- Please wear the Thigh Monitor continuously (24 hours/day).
- The Thigh Monitor **can be** worn during sleep and is water resistant (to 1m) so you can wear it whilst showering but please **do not wear it** in the bath or for swimming.
- The sticky patch that sticks the Thigh Monitor to your skin may last up to 8 days but to avoid skin irritation to may want to change the patch every couple of days.

*Note: The Thigh Monitor will emit a green flash every 6 seconds. This is an indication that it is working and recording data.*

#### How do I change the sticky patch?

- Remove the Thigh Monitor from your thigh and peel the sticky patch off the Thigh Monitor. The monitor is covered in a waterproof sleeve and wrapped in one sticky patch—please make sure that these remain on the monitor when you do this (they make the monitor waterproof).
- Position the Thigh Monitor in the same spot as before (or on the other thigh if you have had a slight irritation), ensuring that the stick man on the front of the Thigh Monitor is standing up (head facing upwards).
- Peel the covering off a new sticky patch (provided in your pack) and place it over the Thigh Monitor. Press the patch onto your skin, starting from the middle out towards the edges peel back the top layer of the patch and smooth out the air bubbles and wrinkles as much as possible to ensure that the Thigh Monitor is firmly secured to your thigh.
- If you require assistance re-attaching your Thigh Monitor, or if you experience any skin irritation whilst wearing it, please contact Marwa.

### What else do I need to do?

- It is important that you fill in the Daily Log on the following pages every day for the 8 days while you are wearing the monitor.
- This helps us to look specifically at the data from when you were awake.

### How to fill in the daily activity monitor log

- The log is divided into the first day you put on the device and then the next 7 days. Please complete each question for all of the days. Please try and be as accurate as possible, record the exact times if you can, or at least to the nearest 5 minutes of your estimated times.
- Start by writing the **date** in the top row.
- Then record the time that you **woke up** and the time that you got **out of bed** (these times may be the same for some days). We ask for these two times because people sometimes spend time in bed before going to sleep or getting up.
- Please write **AM or PM** next time.
- If you remove the monitor for longer than 10 minutes during the day please note down the **time that you removed the device**, the **time that the device is removed** and the **reason why you removed the device**.
- Then record what time you **got into bed** and the time that you went **to sleep**. (i.e., the estimated time that you fell asleep, not the time that you got into bed).
- Being as accurate and thorough as possible when completing this log enables us to look at your data more accurately.

### Following your data collection phase

- We then ask you to record in the log the exact time you remove the device to return it. This way we know when exactly our analysis should end.
- If you could then return the device and the log you have been keeping in the stamp addressed envelope provided.
- As soon as your device is received, we will run a detailed analysis and produce a summary report.
- If you would then be interested in setting some weekly goals, we would be very happy to repeat the procedure in a few weeks' time and compare!

**Please note that this device is not a GPS tracking device so, it cannot track your location.**

Name & Device ID Number:

On the day that your device arrives please can you note the date and time that you put it on.

Day 0	Times during the day when I took my thigh monitor off and why	Got into bed	Went to sleep
Date and time the device is put on			
<i>e.g. Saturday 18<sup>th</sup> July at 10:30</i>	<i>18:00 for 30 minutes to have a bath</i>	<i>23:00pm</i>	<i>23:30pm</i>
Date and Time Device is Put On (i.e. recording start point)			

Then over the next 7 days please use this sheet daily to record:

- the time you woke up
- the time you got out of bed
- any times that you took off the activPAL monitor (thigh monitor) and why
- the time you got into bed

Day and date	Wake up	Got out of bed	Times during the day when I took my thigh monitor off and why	Got into bed	Went to sleep
<b>Day 1</b> Date:					
<b>Day 2</b> Date:					
<b>Day 3</b> Date:					
<b>Day 4</b> Date:					

<b>Day 5</b> Date:					
<b>Day 6</b> Date:					
<b>Day 7</b> Date					

Finally, when you wake up on Day 8 remove the device and complete the final log, noting the date and time the device was removed.

<b>Day 8</b>  <b>Date and time the device removed. We need this to know when to register the end point.</b>	<b>End of recording: date and time:</b>  
---	---

Now you are ready to return your device and log in the stamped address envelope provided  
Thank you!

## Appendix 5

### Patient Information Leaflet (feasibility study)

#### Study Title:

Feasibility and acceptability of a sedentary time reduction programme in reducing sedentary behaviour in patients with peripheral arterial disease: A mixed methods study.

Invitation to take part in a study:

You are being invited to take part in a research study being conducted by the department of vascular and endovascular surgery at the University Hospital Galway. Before you decide, it is important for you to understand why the research is being done and what it will involve. This patient information sheet will tell you about the purpose, risks, and benefits of this research study. If you agree to take part, we will ask you to sign a consent form. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read it. You should only consent to participate in this research study when you feel that you understand what is being asked of you, and you have had enough time to think about your decision.

What is the purpose of this study?

Peripheral arterial disease (PAD) is characterised by a disruption in arterial flow. Many risk factors have been identified for PAD as smoking, increased age, high blood pressure, diabetes, obesity, and high cholesterol levels. Recently, sedentary behaviour (prolonged sitting/lying) has emerged as an important risk factor for many health problems as cardiovascular disease (CVD) including PAD. Adults tend to spend a significant part of their awake time in sedentary behaviour, and it is suggested to reduce and interrupt sedentary time for better cardiovascular health. The current study will use the activPAL device to assess your sedentary time. You will be asked to use an application (timed walk) to evaluate the distance covered in a 6-minute duration. The study will then implement a 12-week programme designed to reduce/interrupt your sedentary time. A smart band will be given to you to serve as a reminder to reduce/interrupt your sitting time throughout the day. Afterwards, participants' sedentary time will be reassessed using the activPAL device and the timed walked app for 6-minute walk test. A final reassessment will take place after a period of 3 months.

Why have I been asked to participate?

Our study is looking at assessment and reduction of sedentary behaviour among patients with peripheral arterial disease. You have been asked to take part because you have peripheral arterial disease so, we ask to measure your sedentary time and as well assess the feasibility and the effect of the programme designed to reduce your sedentary time.

Do I have to take part?

Your participation is entirely voluntary. If you do decide to take part, you will be asked to sign a consent form. If you plan to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your rights in any way.

What will happen to me if I take part?

If you decide to participate in the study, you will be asked to sign a consent form. (You will be given a copy of the consent form to keep). We will need to ask you a few questions regarding your medical history. You will then undergo a screening process. The researcher will fix the activPAL at your thigh (as in photo) with adhesive tape as in this video:

<https://www.youtube.com/watch?v=CHCCX2GW3DM> and give you the tool information sheet and logbook to fill in.

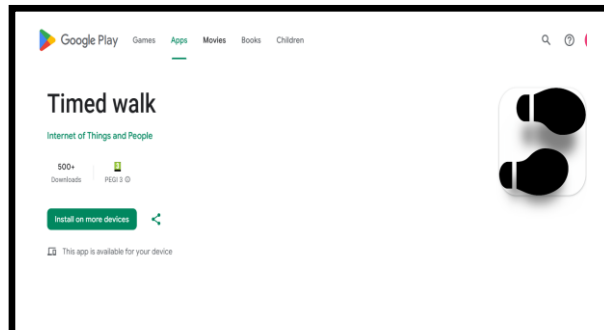
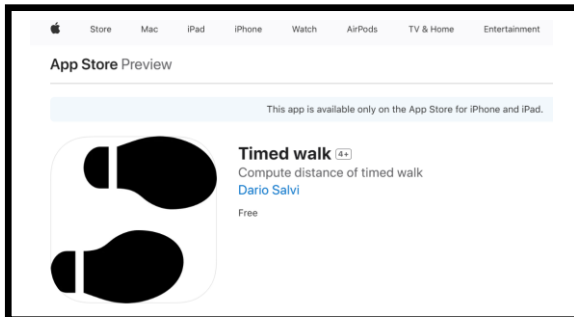
The activPAL will be in place as shown in the above photo for 7 consecutive days. You should remove it when bathing or swimming. Throughout the study period, we will need you to repeatedly check the activPAL and record wake up and sleep times in the logbook. After 7 days you will be asked to post the activPAL and the logbook using the registered envelope distributed by the researcher. The researcher will analyse your data and discuss the results with you. Then you will be involved in a 12-week program to reduce sedentary periods. During the first 4 week, you will access a website that provides information on the impact of sedentary behaviour and benefits of reducing in addition to different materials to help reducing sedentary time. The programme will also involve one weekly call via phone, zoom or in-person for 10-15 minutes to discuss barriers and encourage sedentary reduction. A smart activity monitor band (Huawei band 6) will be used to remind you to interrupt sedentary time. Finally, we will reassess your sedentary time with the activPAL after 12 weeks and 6 months from the programme.



**ActivPAL fixed at the right thigh.**

## Timed walk application

You will need to install the Timed Walk app for iOS and Android, which is available for free. You'll be asked to use it in the first week, at the end of the 12-week program, and again after 6 months to measure the distance you walk in 6 minutes (6MWT).



How long will my part in the study last?

You will continue to have the activPAL in place for 7 consecutive days. After the 7 days end, you will have to post the instrument. The researcher will contact you for the feedback as soon as the data analysed and start the 12-week intervention. The activPAL device will immediately be used following the 12-week programme again after 6 months. The activPAL will be used for 7 consecutive days.

What do I have to do?

Keep the activPAL in place. Continue with your normal activities while wearing it and make sure to complete the wake up and sleep time in the given logbook. Use the smart band to break up periods of sedentary behaviour and utilise the activity cards for ideas on how to reduce your sedentary time.

What are the possible benefits in taking part?

Proper management plan for your peripheral arterial disease including risk factor modifications should be started early to prevent any complications. Managing modifiable risk factors as reducing sedentary behaviour and increasing physical activity are both important to promote health and are recommended to improve outcomes of PAD interventions. Feedback on your results can be very informative and help provide information to change your lifestyle and reduce/interrupt prolonged sedentary time. As, according to current research, even a short reduction in daily sedentary time (lying or sitting) could have several cardiometabolic health benefits. The beneficial effects could be seen in blood lipids, blood glucose, and body weight.

What are the possible risks of taking part?

Despite using non-allergenic adhesive tape, possible local allergic reaction can occur at the site of the activPAL. So, if you have known skin allergies or skin conditions that could be worsened by adhesive tape used to apply the accelerometer, please let us know.

What if something goes wrong?

Immediately contact your research doctor. Your research doctor will ensure that this situation is managed appropriately, according to the hospital clinical guidelines.

What happens at the end of the study?

At the end of the study, all data gathered from all participants will be collected and analysed, in view of publishing the results. Only collective data will be published, and you will not be identified in any report or publication. If you wish to obtain a copy of the published data, you can ask your research doctor at the end of the study.

What happens if I change my mind during the study?

It is your choice to participate in this study and you are free to change your mind and withdraw from the study at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will NOT affect your rights or your medical care and further management and treatment at the vascular department.

What if I have a complaint during my participation in the study?

Highly trained doctors will be involved in every aspect of your care throughout your participation in the study. They will work to make sure you receive the highest standard of care. However, if you do develop an adverse event, they will make sure it is addressed immediately according to your clinical condition. Any adverse events arising within the study will be notified to the regulatory authorities.

Whom do I contact if I have further concerns?

If you have any concerns about this study and wish to contact someone in confidence, you may contact the Dr. Marwa Said at the contact details listed at the end of this information leaflet.

Do researchers need information from my medical records?

Yes. The researchers from the hospital will need access to any information collected throughout the course of the study. However, all information that is collected about you during the research will be kept strictly confidential and will not be shared with anyone else. The information collected in this research study will be stored in a way that protects your identity. Results from the study will be reported as group data and will not identify you in any way.

What if I still have further questions I would like to ask?

In addition to this brochure, all details of the study will be verbally explained to you by your research doctor. Please feel free to ask the doctor to clarify any points that remain unclear. This brochure is yours to keep. If you decide to participate in this study, you will have to sign a consent form and you will keep a copy of that form as well.

**Thank you for taking the time to read this leaflet.**

#### **References**

- Harrington, D.M., Dowd, K.P., Bourke, A.K. *et al.* Cross-Sectional analysis of levels and patterns of objectively measured sedentary time in adolescent females. *Int J Behav Nutr Phys Act* **8**, 120 (2011). <https://doi.org/10.1186/1479-5868-8-120>.

## Appendix 6

### Thigh monitor instructions activPAL (feasibility study)

Thank you for taking part in this health initiative. We hope you find it useful and worthwhile.

The **activPAL** device will be recording your sitting and activity behaviour. It's important that when you wear it you behave as you normally would. If you could wear the device and then return it in the stamped address envelope provided. We will then fully analyse your data and guide you through your results to set some goals to possible tools that might be worth exploring.

#### How do I fit the Thigh Monitor?

- The Thigh Monitor is covered in a waterproof sleeve and wrapped in one sticky patch—**please make sure that these remain on the monitor**. The monitor is attached directly onto the skin and positioned on the front of the thigh, roughly 1/3 of the way between hip and knee with the stick man standing up (see picture).
- Do not take the protective waterproof covering off the Thigh Monitor.
- Rest the monitor on your chosen thigh (facing upwards as shown)
- Take one sheet of the sticky patch and carefully peel off the paper layer.
- Stick this over the Thigh Monitor and push down gently to stick loosely to the skin around the monitor. See <https://www.youtube.com/watch?v=am2J2Vx-itQ>
- Peel off the outer layer of protective plastic from the sticky patch.
- Starting from around the Thigh Monitor, press the sticky patch which is now very thin onto the skin and work outwards removing wrinkles.



#### Notes on the Thigh Monitor

- When the monitor arrives Dr.Marwa Said can help you with if needed. We would like you to put the monitor on and then wear it this day and then **every day for the next 7 consecutive days**.
- Please wear the Thigh Monitor continuously (24 hours/day).
- The Thigh Monitor **can be** worn during sleep and is water resistant (to 1m) so you can wear it whilst showering but please **do not wear it** in the **bath** or for **swimming**.
- The sticky patch that sticks the Thigh Monitor to your skin may last up to 8 days but to avoid skin irritation to may want to change the patch every couple of days.

*Note: The Thigh Monitor will emit a green flash every 6 seconds. This is an indication that it is working and recording data.*

### **How do I change the sticky patch?**

- Remove the Thigh Monitor from your thigh and peel the sticky patch off the Thigh Monitor. The monitor is covered in a waterproof sleeve and wrapped in one sticky patch—**please make sure that these remain on the monitor** when you do this (they make the monitor waterproof).
- Position the Thigh Monitor in the same spot as before (or on the other thigh if you have had a slight irritation), ensuring that the stick man on the front of the Thigh Monitor is standing up (head facing upwards).
- Peel the covering off a new sticky patch (provided in your pack) and place it over the Thigh Monitor. Press the patch onto your skin, starting from the middle out towards the edges peel back the top layer of the patch and smooth out the air bubbles and wrinkles as much as possible to ensure that the Thigh Monitor is firmly secured to your thigh.
- If you require assistance re-attaching your Thigh Monitor, or if you experience any skin irritation whilst wearing it, please contact Dr. Marwa Said.

### **What else do I need to do?**

- It is important that you fill in the Daily Log on the following pages every day for the 8 days while you are wearing the monitor.
- This helps us to look specifically at the data from when you were awake.

### **How to fill in the daily activity monitor log**

- The log is divided into the first day you put on the device and then the next 7 days. Please complete each question for all the days. Please try and be as accurate as possible, record the exact times if you can, or at least to the nearest 5 minutes of your estimated times.
- Start by writing the **date** in the top row.
- Then record the time that you **woke up** and the time that you got **out of bed** (these times may be the same for some days). We ask for these two times because people sometimes spend time in bed before going to sleep or getting up.
- Please write **AM or PM** next time.
- If you remove the monitor for longer than 10 minutes during the day please note down the **time that you removed the device**, the **time that the device is removed** and the **reason why you removed the device**.
- Then record what time you **got into bed** and the time that you went **to sleep**. (i.e., the estimated time that you fell asleep, not the time that you got into bed).
- Being as accurate and thorough as possible when completing this log enables us to look at your data more accurately.

**Following your data collection phase**

- We then ask you to record in the log the exact time you remove the device to return it. This way we know when exactly our analysis should end.
- If you could then return the device and the log you have been keeping in the stamp addressed envelope provided.
- As soon as your device is received, we will run a detailed analysis and produce you a summary report.
- Then we will be setting some weekly goals and repeating the procedure in 12 weeks-time and compare!

**Please note that this device is not a GPS tracking device so, it can not track your location.**

**On the day that your device arrives please can you note the date and time that you put it on.**

Day 0  Date and time the device is put on	Times during the day when I took my thigh monitor off and why	Got into bed	Went to sleep
<i>e.g. Saturday 18<sup>th</sup> July at 10:30</i>	<i>18:00 for 30 minutes to have a bath</i>	<i>23:00pm</i>	<i>23:30pm</i>
Date and Time Device is Put On (i.e. recording start point)			

**Then over the next 7 days please use this sheet daily to record:**

- The time you woke up
- The time you got out of bed
- Any times that you took off the activPAL monitor (thigh monitor) and why
- The time you got into bed
- The time you fell asleep (fill this in the following morning)

Day and date	Wake up	Got out of bed	Times during the day when I took my thigh monitor off and why	Got into bed	Went to sleep
<i>e.g. Sun 19<sup>th</sup> July</i>	<i>07:00am</i>	<i>07:15am</i>	<i>16:00 for 45 minutes to go swimming</i>	<i>23:00pm</i>	<i>23:30pm</i>
<b>Day 1</b> Date:					
<b>Day 2</b> Date:					
<b>Day 3</b> Date:					
<b>Day 4</b> Date:					
<b>Day 5</b> Date:					
<b>Day 6</b> Date:					
<b>Day 7</b> Date:					

Finally, when you wake up on Day 8 remove the device and complete the final log, noting the date and time the device was removed.

<b>Day 8</b>  Date and time the device removed. We need this to know when to register the end point.	<b>End of recording: date and time:</b>
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## Annex 7

### Topic Guide for a qualitative interview

**Study title: The Feasibility, acceptability, and outcome evaluation of a sedentary behaviour reduction programme in patients with peripheral arterial disease: A mixed methods feasibility study.**

#### Introduction:

Confirm purpose of the interview

- To discuss their experiences of the RESPONSE-2-PAD programme.

Reiterate **confidentiality** and lack of impact on their **health** care.

Confirm the interview will be recorded solely for the purpose of data capture and analysis.

All data will be kept in strict confidence. No personal data will be transcribed. Confidence may be broken only in situations where information pertains to any significant harm.

They can **decline** to answer any questions and withdraw from the study at any time.

Confirm rough time (1 hour) and consent (check all submitted consent)

Any questions before we begin.

#### Participation in the study:

- **Can you tell me about your experience of taking part in this study?**

Prompts:

- What **motivated** you to take part?
- Were there any **barriers** affecting involvement in the study?
- Did you have any **concerns** about the study?

#### Experience of using the RESPONSE-2-PAD online education programme:

- **Generally, how did you find the experience of using the online educational tool?**

Prompts:

- What did you find most **useful** in the online educational tool content (and why)?
- Were there any parts of the online education tool that you found **less** useful (and why)?
- Was there anything **missing** that you would have liked to have seen included (and why)?
- Describe your views on the overall quality of the programme and how easy it was to use and **navigate**?
- What did you think of the overall design and delivery of the programme?
- In your view, are there any areas where the information or resources provided through the RESPONSE link could be improved?

#### Experience of using the activPAL device:

- **What was that like for you to use the activPAL device for seven days?**

**Prompts:**

- How was it like to complete the diary and worksheet?
- How did the device affect your daily routine or activity habits?
- Were there any limitations or challenges using the device?
- In your view, how did you find the data collected by the device to inform your daily activity levels?

**Experience of the weekly coaching sessions and use of the fitness tracker:**

- **How would you describe your overall experience with the weekly sessions and the fitness tracker?**
- **Prompts:**
  - How were the **discussion** topics selected during the weekly sessions?
  - How did you find the option of online programmes compared to face-to-face?
  - How did you feel about the materials and resources that were provided to you?
  - How did you feel about the activities and strategies suggested by the programme?
  - How was it like to have a reminder (Huawei band 6) to interrupt your sedentary time?
  - Could you share with me any personal challenges you faced when implementing the programme?
  - Can you tell me about any changes you made to your own lifestyle as a result of the programme?
  - What are your thoughts on incorporating the strategies acquired from the programme into your daily routine going forward?
  - Could you provide suggestions or feedback on what could be improved for future implementation of this programme?

**General:**

Is there anything about the experience of this programme, its tools and approaches that we have not discussed that you would like to share?