Developing a person-based intervention to improve treatment adherence in patients with peripheral arterial disease using the perceptions and practicalities approach

Mrs Smaragda Lampridou

ORCID 0000-0002-6700-1687

Imperial College London,

Department of Surgery and Cancer

Faculty of Medicine

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Supervisors

Professor Mary Wells

Professor Alun Davies

Dr Gaby Judah

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Declaration of originality

I declare that the contents of this thesis are my own work. Any parts which are adaptations of other work are appropriately and clearly referenced. Where material is included from my own works published during the PhD programme in peer reviewed journals, this is acknowledged and referenced.

Smaragda Lampridou, Date 6th April 2026

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Abstract

Peripheral arterial disease (PAD) is a condition in which fatty deposits build up inside arteries, affecting 20% of people aged over 60 in the UK. More than 50% of symptomatic patients will experience a major cardiovascular event, or amputation within five years. Although the National Institute for Health and Care Excellence (NICE) guidelines recommend pharmacotherapy (antiplatelet and lipid-lowering agents), smoking cessation and exercise, adherence to these is low, and there are no effective strategies to improve this. This PhD aimed to develop a person-based behavioural intervention to support PAD treatment adherence, using the Person-Based Approach and the Perceptions and Practicalities Approach.

The project was completed in three phases. *Stage 1- Planning:* A scoping review of available adherence-promoting interventions (n=15) to identify current interventions and their components. Semi-structured qualitative interviews with patients with PAD (n=15), their relatives (n=4), and clinicians (n=18) to identify adherence barriers and facilitators. A Freedom of Information Request to explore the availability and structure of PAD services (n=82) in England. *Stage 2- Design:* A data triangulation exercise to identify key adherence influences. 'Guiding principles' were developed to inform the required characteristics of the intervention, and behaviour change techniques that could address the identified influences were selected. A 'logic model' was developed to describe the intervention's mechanism of action. Three rounds of co-design workshops with patients with PAD and their relatives (n=29) were undertaken to develop the intervention prototype, a booklet entitled PAD&Me. *Stage 3 - Optimisation:* Think-aloud interviews with newly diagnosed patients (n=12) were conducted to refine the intervention based on user feedback.

The co-designed PAD&Me booklet intervention aims to address common misconceptions about their disease and treatment, overcome identified barriers, and set goals to support behaviour change. Future research is needed to assess the feasibility and effectiveness of this intervention before its implementation in usual practice.

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Lampridou S, Domun T, Rosenberg J, Lear R, Davies AH, Wells M, Judah G. Multicomponent interventions designed to support adherence to guideline-recommended therapy in patients with peripheral arterial disease: A scoping review. Vasc Med. 2025 Jun;30(3):343-352. doi: 10.1177/1358863X251315071. Epub 2025 Mar 13. PMID: 40079704; PMCID: PMC12171072.

Lampridou S, Saghdaoui LB, Boobier C, Judah G, Wells M, Davies AH. Intermittent claudication services in England: insights from a freedom of information request. BMC Health Serv Res. 2026 Feb 23;26(1):361. doi: 10.1186/s12913-026-14215-9. PMID: 41731504; PMCID: PMC12989127.

Lampridou S, Bolton Saghdaoui L, Judah G, Davies AH, Wells M. Barriers and Facilitators to treatment adherence in patients with peripheral arterial disease: a qualitative study. Patient Preference and Adherence. 2026 May 20;20:588692. doi: 10.2147/PPA.S588692

<u>Conference Presentations</u>

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Intermittent Claudication Services in England: Insights from a Freedom of Information Request. Lampridou S, Bolton Saghdaoui L, Judah G, Wells M, Davies AH. Oral presentation. Vascular Society Annual Meeting, Hull, UK, 27-29th November 2025.

List of Abbreviations

ABPI	Ankle Brachial Pressure Index
AHP	Allied Health Professional
ARC	Applied Research Collaborations
BCT	Behaviour Change Technique
BCTT	Behaviour Change Technique Taxonomy
B-IPQ	Brief Illness Perceptions Questionnaire
BMQ	Belief in Medicines Questionnaire
CLTI	Chronic Limb Threatening Ischaemia
COM-B	Capability Opportunity Motivation of Behaviour Model
COREQ	Consolidated Criteria for Reporting Qualitative Research
CQUIN	Commissioning for Quality and Innovation
CRN	Clinical Research Network
CSM	Common-Sense Model
ESVS	European Society for Vascular Surgery
IC	Intermittent Claudication
ICB	Integrated Care Board
ICHNT	Imperial College Healthcare NHS Trust
IM	Intervention Mapping
IMD	Index of Multiple Deprivation
JBI	Joanna Briggs Institute
JLA	James Lind Alliance
HCP	Healthcare Professional
HRA	Health Research Authority
GP	General Practitioner
GRIPP2	Guidance for Reporting Involvement of Patients and the Public
MARS	Medication Adherence Report Scale
MeSH	Medical Subject Headings
mHealth	Mobile Health
MMAS-8	Morisky Medication Adherence Scale

MoA	Mechanism of Action
MOSAIC	Motivating Structured Walking Activity in People With Intermittent Claudication
MoSCoW	Must have, Should have, Would have
NCF	Necessity-Concerns Framework
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NVR	National Vascular Registry
PAD	Peripheral Arterial Disease
PaPa	Perceptions and Practicalities Approach
PBA	Person Based Approach
PIC	Patient Indentification Centre
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QoL	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SDM	Shared Decision Making
SET	Supervised Exercise Therapy
SPSS	Statistical Package for Social Sciences
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
SVN	Society of Vascular Nurses
TATT	Theory and Techniques Tool
TIDiER	Template for Intervention Description and Replication
TDF	Theoretical Domains Framework
VS	Vascular Society
VSGBI	Vascular Society of Great Britain and Ireland
UK	United Kingdom
WHO	World Health Organization

Chapter 1: Introduction and Study Objectives

1.1 Chapter Summary

This chapter provides an overview of peripheral arterial disease (PAD) and its management. It highlights the problem of PAD treatment adherence as the central theme of this thesis. Theories of adherence and adherence determinants contributing to non-adherence are presented, as well as and current research priorities for PAD. The pilot work from my pre-doctoral fellowship exploring barriers and facilitators to non-adherence is also discussed. The PhD study rationale is presented, along with the study aim and objectives, underpinned by behavioural science theory. Finally, an overview of thesis chapters is provided.

1.2 Overview of Peripheral Arterial Disease

1.2.1 Disease prevalence

Occlusive lower-limb peripheral arterial disease (PAD) is a chronic atherosclerotic condition resulting in reduced blood flow to the legs (1, 2) (see Figure 1). Atherosclerosis develops when fatty deposits and fibrous tissue build up beneath the inner lining of the artery wall, a process driven by factors such as inflammation, abnormal lipid levels, endothelial dysfunction, platelet activity, and changes in the vessel's structure (3). PAD is the most common clinical manifestation of atherosclerosis, following coronary and cerebrovascular artery disease (4). It remains a major health problem and is the leading cause of lower-limb amputations worldwide (1, 2). Its prevalence has increased globally, with over 236 million affected individuals in 2015 (1, 4, 5). In the United Kingdom (UK), 20% of people over 60 suffer from PAD (1, 4, 5). Given the ageing population, the prevalence and burden of PAD are expected to rise (4-6).

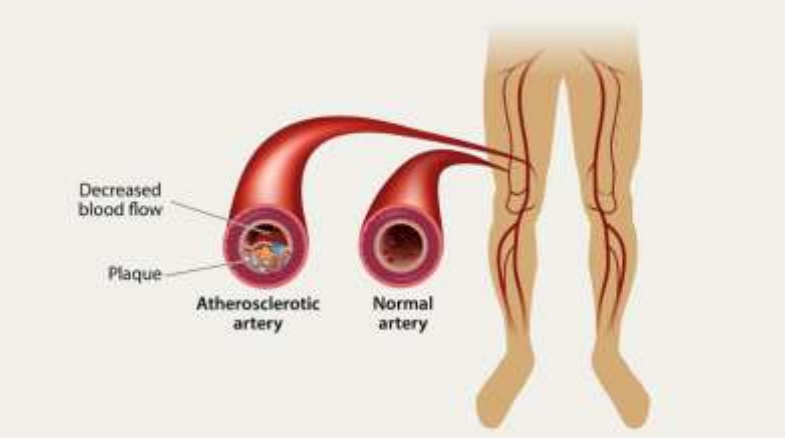


Figure 1 Illustration of Peripheral Arterial Disease. (Adapted from US Centre for Disease Prevention and Control Website)

1.2.2 Diagnosis

Peripheral arterial disease (PAD) is frequently underdiagnosed, and failure to recognise it is a major contributor to preventable amputations (7). Hence, careful attention to diagnostic pathways and the tools used to identify PAD is essential. The NICE guidance recommends the diagnosis of PAD through a structured assessment that begins with identifying people at risk, including those with symptoms such as intermittent claudication (IC) (muscle pain in the calf due to reduced blood flow), diabetes, non-healing leg or foot wounds, unexplained leg pain, or those being considered for lower-limb interventions or compression therapy (8). Evaluation involves taking a thorough medical history on symptom severity and features of IC or chronic limb-threatening ischaemia (CLTI), followed by a physical examination of the legs and feet for signs such as ulceration and palpation of the femoral, popliteal, and pedal pulses (8). A key diagnostic test is the ankle–brachial pressure index (ABPI), measured with the patient resting and supine, using a Doppler probe to record systolic pressures in both arms and in the posterior tibial, dorsalis pedis, and, when possible, peroneal arteries (9, 10) (see Figure 2). The ABPI for each leg is calculated by dividing the highest ankle pressure by the highest arm pressure, providing an objective measure to support the diagnosis (9, 10). An ABPI reading below 0.9 is generally indicative of PAD, with progressively lower values reflecting more severe disease (9, 10).

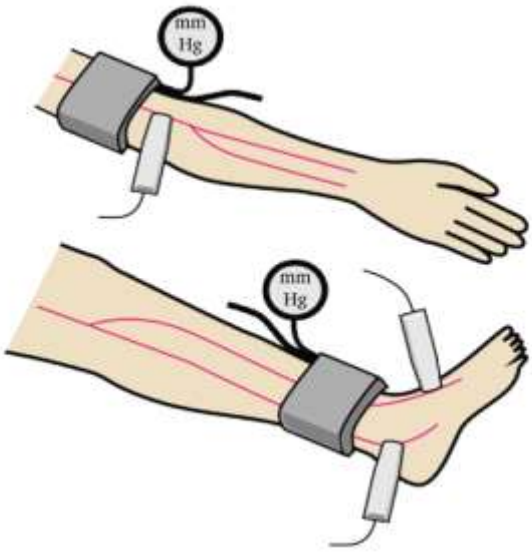


Figure 2 Measurement of ABPI. (Adapted from Nordasting, 2024) (11).

1.2.3 Clinical presentation of PAD

The clinical manifestation of PAD is characterised by reduced blood flow, and its presentation depends on the location and severity of the disease. The Fontaine classification categorises the clinical presentation of PAD in four stages (see Table 1) (12). The classification is primarily based on clinical symptomatology and is widely used in clinical research but not routinely employed in day-to-day practice (12).

Table 1 Fontaine classification of PAD (Adapted from Fontaine,1954) (12).

Grade	**Symptoms**
Stage I	Asymptomatic, incomplete blood vessel obstruction
Stage II	Mild claudication pain in limb
Stage IIA	Claudication at a distance > 200 m
Stage IIB	Claudication at a distance < 200 m
Stage III	Rest pain, mostly in the feet
Stage IV	Necrosis and/or gangrene of the limb

More than half of individuals with PAD are asymptomatic (2), with only a small proportion, about 7-15%, developing symptoms later in life (13). Most individuals with symptomatic PAD experience IC, or in its more advanced form, CLTI (1,5). Claudication is a cramp-like muscle pain in the calf, thigh, or buttock after walking, due to reduced blood flow, for a specific distance (claudication distance), that improves with rest

within minutes. Chronic limb-threatening ischaemia is characterised by rest pain, nocturnal recumbent pain, skin discolouration, and chronic ulceration, which in turn increase the risk of gangrene and amputation (14). Even mild clinical stages of PAD can develop from IC to CLTI in 21% of patients (14, 15), highlighting the progressive and debilitating nature of the disease.

1.2.4 The Burden of PAD

1.2.4.1 Burden on patients and their quality of life (QoL)

Previous research has shown that patients with PAD have poorer QoL than the general population, as they often struggle with anxiety, depression, and stigmatisation (16, 17). The impact of patients' experiences and disease on their QoL varies according to the disease stage. Data from a qualitative systematic review indicate that from the point of diagnosis, patients feel powerless and frustrated, as they usually require multiple medical appointments to get a definitive diagnosis (18). Intermittent claudication not only affects mobility, but it also undermines balance, restricts daily activities, and reduces patients' QoL due to social isolation, increased dependence on others, and loss of control (18). For those who progress to CLTI, the impact is even more significant. In CLTI, QoL declines rapidly due to a number of factors: persistent ischaemic pain restricts mobility; chronic, non-healing wounds and infections requiring frequent hospital visits, disrupting daily life; and the fear of limb loss causes ongoing emotional distress (19). Those with rest pain report a major impact of PAD on their daily life, mainly due to lack of social activities and sleep interruption (18). Patients who have experienced an amputation have an even higher burden (20). Most patients remain wheelchair bound, affecting their overall physical activity, independence and mental health (21). However, even patients who receive a prosthetic limb experience difficulties (21). A systematic review demonstrated that limited mobility in these patients negatively influenced QoL and often led to depression and social isolation (22). Moreover, patients reported that their bodies were never "whole" again and found it difficult to adapt to their new reality (23). Most amputees also experience financial struggles and unemployment following a major amputation, which can further affect their wellbeing (24).

1.2.4.2 Financial burden

Besides the burden on patients' QoL, PAD places a substantial financial burden on the NHS. In the first year after diagnosis, healthcare costs are particularly high, mainly due to outpatient visits and lower limb-related procedures and complications (ulceration, gangrene, rest pain, cardiovascular events, and amputations), with only a small percentage of costs attributed to pharmacotherapy (25-27). A study conducted in Sweden identified that in the first year following a diagnosis of PAD, the average healthcare costs per patient rose by 90% (26). The Economic Modelling for PAD in England and Wales indicated that amputations are associated with significant NHS costs (28). Hence, shifting clinical pathways to reduce the proportion of patients undergoing amputation could save the NHS a large amount of money annually (28). A budget impact analysis using national vascular registry data from 2022, identified that if the NHS could reduce the amputation rate from 10% to 3% by using appropriate limb-salvage management, it could save over £8 million (27).To reduce the burden of PAD on patients and the healthcare system, early identification of patients with PAD and effective management are needed.

1.2.5 Treatment and management of intermittent claudication

Delayed disease progression is crucial for optimal patient outcomes, and it has been identified as a James Lind Alliance (JLA) PAD Research Priority (29). With that in mind, this thesis primarily focuses on IC management rather than CLTI. According to NICE, the management of IC includes cardiovascular risk modification, supervised exercise therapy, and surgical revascularisation interventions (8). These will be discussed in further detail in the relevant sections below.

1.2.5.1 Cardiovascular risk modification

The risk factors for PAD largely mirror those seen in other atherosclerotic conditions. Its development is driven by a combination of modifiable and non-modifiable risk factors, including older age, smoking, hypertension, diabetes, and hypercholesterolaemia (30).

Patients with PAD have up to 15-fold increased mortality risk, mainly due to cardiovascular events (myocardial infarction or stroke), when compared to healthy individuals (31). Within five years of symptom initiation, more than half of patients with PAD are expected to have a major cardiovascular event (myocardial infarction or stroke), or amputation (1, 2). Hence, cardiovascular risk reduction is vital for these patients.

International and national guidelines recommend that to reduce the cardiovascular risk of patients with PAD, and improve their symptoms and prognosis, every patient should: take antiplatelet or antithrombotic medications, lipid-lowering medications, antihypertensives (in the case of hypertension); manage their diabetes (if diabetic); quit smoking; and modify their lifestyle through healthy dietary habits, weight management, and regular physical activity in accordance with national and international physical activity guidelines (8, 11, 32). Antithrombotic and lipid-lowering agents have substantial benefits for patients with PAD, specifically in the reduction of major adverse cardiovascular event and major limb event rates (33-35). The CAPRIE trial, comparing the effectiveness of clopidogrel (an anti-platelet medication) versus aspirin in reducing cardiovascular risk, found that PAD patients on clopidogrel had a 23.8% reduction in risk (36). A Cochrane meta-analysis of 17 lipid-lowering trials reported a 26% reduction in cardiovascular events among patients with PAD treated with statins (35). Additionally, previous randomised trials demonstrated that high-intensity treatment with statins may also improve maximum walking distance (37, 38). As for smoking, patients with PAD who quit had reduced mortality (14% vs 31%) and increased amputation-free survival (81% vs 60%) when compared to smokers (39).

Adherence to this cardiovascular risk modification plan is associated with a 40% reduction in major cardiovascular and limb events and increased life expectancy by six years (15, 40). Hence, it is essential that adherence is optimised to reduce cardiovascular risk factors.

1.2.5.2 Physical activity and Exercise in PAD

Physical activity and exercise are important components of PAD management but are distinct concepts. According to the World Health Organisation (WHO), physical activity refers to any bodily movement produced by skeletal muscles that results in energy expenditure, including activities undertaken during work, transport, household tasks, and leisure time (41). Exercise is a subcategory of physical activity that is planned, structured, repetitive, and purposeful, with the objective of improving or maintaining physical fitness (41).

The 2020 WHO physical activity guidelines recommend that adults, including those living with chronic conditions, should undertake at least 150–300 minutes of moderate-intensity aerobic physical activity, or 75–150 minutes of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity activity, each week (42). Additionally, they should also do muscle-strengthening activities at moderate or greater intensity that involve all major muscle groups on two or more days a week (42).

Specifically for the management of IC, guidelines recommend that all patients with IC should be offered a supervised exercise therapy (SET) programme as part of their management (8, 11, 32). Such programmes typically involve around two hours of supervised exercise each week over three months and encourage patients to exercise to the point of maximal pain (8).

Over the past 30 years, results from systematic reviews and meta-analyses have demonstrated that SET effectively increases both maximum and pain-free walking distance in individuals with IC (43-45). A 2013 Cochrane review on the benefits of SET versus non-supervised exercise therapy for IC found that participation in SET can increase walking distance by up to 180 metres more than non-supervised exercise therapy (43). An updated 2018 Cochrane review found that SET remains more effective at improving walking distance than home-based therapy or walking advice alone (45). There is no clear evidence to support whether home-based therapy or walking is more effective (45). Beyond functional benefits, a systematic review of randomised controlled trials identified that SET can also improve QoL in patients with PAD (46).

Specifically, SET training resulted in small, yet significant improvements in physical functioning and daily activity capacity (46). However, no significant improvements were observed in mental health–related QoL (46). Despite this robust evidence, further research is needed to understand the long-term benefits and effects of SET on everyday physical activity and QoL (45).

Although SET is strongly recommended for IC symptom management, it has a different primary aim from general physical activity. SET is specifically designed to improve walking ability, increase pain-free and maximum walking distance, and reduce IC symptoms (8). On the other hand, the WHO physical activity guidelines aim to improve overall cardiovascular health and physical fitness and muscle strength (42). Hence, both physical activity and exercise should be considered complementary components of PAD management.

1.2.5.3 Revascularisation in terms of angioplasty, stenting and bypass

Angioplasty or stenting may be offered to people with IC only after optimal conservative management has been attempted without sufficient claudication symptom improvement (8). Conservative management includes optimal cardiovascular risk medication and completion of a supervised exercise programme, or adoption of daily exercise (8). Additionally, the suitability of patients for revascularisation interventions should be confirmed through appropriate imaging (8). Bypass surgery should be considered for people with severe, lifestyle-limiting IC only when angioplasty has failed or is not suitable, and imaging confirms that surgical bypass is appropriate (8).

Functional outcomes following revascularisation are influenced by a range of clinical, anatomical, and patient-related factors typically assessed during the pre-operative assessment (11). These include the location and severity of arterial disease, the quality of inflow and outflow vessels, procedural techniques and technologies, use of adjunctive medical and exercise therapies, and the patient's baseline functional status and comorbidities (47, 48). Peri-procedural and post-operative complications can compromise long-term outcomes, and increase rates of hospital readmission after

revascularisation, often due to symptom recurrence or procedure-related complications (49). Given these risks, conservative management remains the first-line treatment for most patients. Evidence from a large prospective cohort demonstrates that the risk of major amputation (above knee) is low (1.1% and 0.2% per five years, respectively) in patients on conservative management (50). On the other hand, early revascularisation may put patients at higher risk of re-interventions and disease progression (50).

Hence, decisions regarding revascularisation should be made on a case-by-case basis and guided by shared decision-making, balancing potential improvements in functional capacity and QoL against procedural risks and long-term outcomes (11). It is also important to note that patients' perceptions of their condition and their willingness to follow their conservative plan should be taken into consideration to optimise the long-term treatment outcomes of revascularisation (11).

1.3 Adherence

1.3.1 Adherence definitions

The definition of adherence has evolved over the past years. Originally, the term *compliance* was used to describe "the extent to which the patient's behaviour matches the prescriber's recommendations" (51). However, this does not take into consideration active patient involvement in decisions about their care. Therefore, this term is not used anymore and has been replaced by *adherence*, which is "the extent to which a patient's behaviour matches recommendations **agreed** with their health professional" (52). This definition takes patient involvement into consideration and supports shared decision making (52).

Adherence is an umbrella term including health behaviour uptake and maintenance of behaviour. Uptake (also referred to as adoption or initiation) describes the decision to commence a recommended health behaviour for the first time (e.g. starting a prescribed medication) and is strongly linked to motivation to adopt a new behaviour

(53). In contrast, maintenance (or persistence) refers to the continued performance of that behaviour over time after it has been initiated (53). While these concepts are closely related, they represent different stages of behaviour change and are influenced by different factors. For example, a patient may initiate a treatment but subsequently struggle to maintain it long term. Throughout this thesis, the term adherence will be used to describe the uptake and maintenance of behaviours, while factors affecting both will be considered.

Specifically for medication adherence, terms “initiation”, “discontinuation”, “implementation” and “persistence” are often used to give more detail into adherence behaviours (see Table 2) (54, 55). In the context of this thesis, all four types of adherence will be considered and the term “adherence” or “non-adherence” will be used to describe them.

Table 2 Definitions of medication adherence (54, 55)

Term	**Definition**
Initiation	Occurs when the patient takes the first dose of a prescribed medication
Discontinuation	Occurs when the patient stops taking the prescribed medication, for whatever reason(s)
Implementation	Is the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen, from initiation until the last dose
Persistence	Is the length of time between initiation and the last dose, which immediately precedes discontinuation

As for adherence to smoking cessation, there is no clear definition or a gold standard as to the level of adherence that is effective (56). Researchers often relate adherence to taking smoking cessation medications (56). The WHO defines adherence as the extent to which a person follows agreed recommendations from a healthcare provider in terms of medication, diet, and lifestyle changes (57). In line with this definition, this thesis characterises adherence in relation to smoking abstinence. Similarly, there is no universal definition for adherence to exercise behaviours. It is usually associated with attendance or participation in exercise programmes (58, 59). Considering the WHO

definition of adherence (57), this thesis defines adherence to exercise as the uptake of physical activity for 150 minutes weekly, in line with the NICE PAD guidance (8).

1.3.2 Measures of adherence

There are multiple measures of adherence, and each of these have strengths and limitations. Methods to measure medication adherence are more widely used, compared to those measuring smoking cessation and exercise uptake. Table 3 presents the various methods, providing examples, strengths and limitations.

Table 3 Measures of adherence

Adherence measurements	**Examples**	**Strength**	**Limitation**
Self-reported	Diaries, logs, questionnaires	Easy and practical	Patients can over-estimate, bias, inaccurate
Objective measures	Pill count, proportion of days covered, pedometer	Objective and easy	Can be inaccurate, costly (e.g. for pedometer), snapshot
Biochemical measures	Blood or urine concentration, exhaled carbon monoxide	Accurate and objective	Costly, invasive, specialised testing, snapshot

Self-reported measures usually involve participants reporting taking their medications, quitting smoking, or performing exercise activities. Although they are easy to use, they are prone to bias and inaccuracy. Patients can often over-estimate their adherence, mainly due to social desirability (60, 61) or poor recall (62, 63). Validated self-reported questionnaires are often the most preferred method of self-reported measures of adherence, but these may also be subject to bias. Objective measures are considered more accurate for measuring adherence than self-reported methods. However, these data may reflect a specific period rather than long-term adherence. Specifically in relation to medication adherence, prescription data from medical records provides evidence of prescription fulfilment or receipt, but does not necessarily mirror the actual medication intake (61, 64). Lastly, biochemical measures, such as exhaled carbon

monoxide to assess smoking, are the most accurate way to measure adherence (65). However, conducting such tests is very costly, invasive, requires hospital visits and specialist training to perform them (66). Hence, these are not often used in regular clinical practice.

1.4 The problem of adherence in PAD

1.4.1 Adherence rates to PAD treatments

Despite the proven benefit of conservative management for PAD, adherence to PAD treatment remains low (59, 67), posing a significant risk of life-threatening complications for patients (15, 68). Although international registry data indicate that adherence to pharmacotherapy is high (up to 85%) (67), a recent rapid review reported antiplatelet adherence between 27.5% and 96.3% and lipid-lowering drugs between 23.5% and 92.0% (69). The review suggested that most available data are based on prescription records and, hence, may not be an accurate representation of adherence (69). Additionally, this wide variation in adherence rates can be explained by increased public awareness of PAD in recent years, as in studies published between 2016-2020, higher adherence rates were reported (69). Of concern, however, over half of patients with PAD discontinue statin use within the first year (70). In my pre-doctoral observational study, it was identified that only about a third of patients have high medication adherence to antiplatelet medications and statins (71). Regarding lifestyle modifications, despite advice to quit smoking, up to 78% of PAD patients continue to smoke; and only a tenth attend a SET class (59, 67).

1.4.2 Current vascular research priorities and gaps related to adherence

Recognising the urgency to improve clinical outcomes, the JLA Vascular Society (VS) Priority Setting Partnership has identified effective PAD management as a research priority (29). Six of the top ten JLA PAD research priorities (2021) emphasise the need for better education for patients and healthcare professionals, easier access to support,

delayed disease progression and reduced cardiovascular risk (29). The relevant priorities are listed below (29):

1. What can be done to improve outcomes in patients with severe circulation problems to their legs?
2. How can we educate other doctors and health care workers so that they gain a better understanding of the consequences of a diagnosis of poor circulation to the legs?
3. How can we help educate better those patients who have poor circulation to their legs?
4. How can we make it easier for patients to get help for this problem (poor circulation to the legs)?
5. How can we slow down any progression of symptoms in those patients with poor circulation to their legs?
6. How can we reduce cardiovascular risk in PAD patients?

Research into adherence to PAD management addresses several of these priorities. However, the 2021 JLA PAD report identified that ways to improve adherence to cardiovascular risk reduction therapies have not yet been fully explored (29). In line with this, the Abbott 2021 Beyond Intervention White Paper highlighted gaps in patients' experience of PAD, including limited awareness, communication issues, and time constraints during clinical appointments (72). The updated 2023 Abbott Beyond Intervention report emphasised the importance of comprehensive care experience and patient engagement, beyond treatment success (73). Additionally, it highlighted the urgency of addressing the unmet need of patient treatment adherence (73). Lastly, the NICE guidelines for the diagnosis and management of PAD identified exploring patients' beliefs as a research priority (8).

Although recent literature has focused on addressing this research priority, current research focuses on either improving surgical techniques (74-76) or SET (77-79), without considering all aspects of PAD treatment. Presently, there is a growing body of evidence examining interventions that support patients with PAD with adherence to their treatment. Section 1.4.4 discusses such interventions and their limitations.

1.4.3 Current research on factors affecting adherence to PAD treatment

Whilst there has been an attempt to understand the reasons for non-adherence in PAD patients, previous literature has been purely quantitative and has focused on sociodemographic and clinical predictors of non-adherence, which are largely non-modifiable (70, 80-86).

Factors associated with non-adherence include older age (84, 86), female sex (84), employment (85), being a new statin user (70, 85), polypharmacy (85), and the presence of comorbidities (84). In two observational studies people who were previously non-adherent were more likely to initiate statins and anti-platelets following a cardiovascular event, such as ischaemic stroke or myocardial infarction (81, 86). Moreover, previously being on high-intensity statins seems to be associated with an increased probability of re-starting statin therapy (86). Being on two different antiplatelet tablets was also seen as an adherence facilitator (83). Although prescription initiation by a general practitioner (GP) can improve adherence to antiplatelet medication, conflicting evidence suggests that it can decrease patients' adherence to statins and antihypertensive medications (82, 86). Factors associated with smoking cessation in patients with PAD are less well researched. A recent study utilising retrospective data from France indicated that previous quit attempts, a high motivation to quit, frequent follow-up visits, and the prescription of nicotine patches were associated with higher quitting rates (87). Few studies have examined factors influencing exercise adherence. Common barriers to exercise and supervised class attendance include adverse weather, limited time, and the distance required to travel to exercise classes (88, 89). Although some literature describes reasons for non-adherence to guideline-recommended therapy in PAD, most studies examine only a single aspect of management, and there is little qualitative or theory-based research on modifiable factors.

Current literature from various chronic disease patient populations, including cardiovascular disease, highlights that patients' perceptions and understanding of their

condition and treatment options can significantly impact behaviour change and treatment adherence (90, 91). When it comes to the association between illness perceptions and adherence to the conservative management of PAD, there is limited research available. A systematic review of 14 studies exploring how patients with PAD perceive and understand their condition identified substantial variation in illness perceptions (92). Many patients demonstrated limited understanding of the chronic nature of PAD, including misconceptions about symptom identity, disease causes, and long-term progression (92). Beliefs about control and treatment also varied widely, with some individuals feeling motivated to engage in physical activity, while others believing that walking could worsen their condition (92). Fear about future deterioration and loss of control was common, reflecting concerns about disease progression (92). An additional theme highlighted the lived experience of PAD as an ongoing process of adaptation, in which patients attempt to regain a sense of control over their condition (92). In summary, patients with PAD shape their own understanding of their condition, and these personal beliefs may influence how they manage their disease and engage with their recommended treatment plan (92).

Specifically for the link between medication adherence and illness perceptions, a recent longitudinal study of 128 patients with PAD conducted in Sweden identified that stronger beliefs about the chronicity of illness, greater perceived personal control, and higher emotional distress were all linked to poorer medication adherence (93). On the other hand, greater confidence in treatment effectiveness and a clearer understanding of the illness were associated with better adherence (93). Overall, the findings suggest that patients' perceptions and emotional responses to their condition play a vital role in their willingness and ability to follow prescribed medication regimens. The study concluded that these factors should be taken into consideration when providing patients with information about their secondary prevention, conservative treatment plan (93).

1.4.4 Existing interventions to support PAD treatment adherence

Effective adherence-promoting interventions can significantly influence patients' health outcomes, surpassing the impact of medical advancements (94). Although there is a plethora of such interventions in other chronic conditions, there is limited research of PAD-related interventions.

One intervention, deemed feasible, aimed to improve medication adherence by promoting appropriate prescribing in primary and secondary care (95). However, it focused on changing clinicians' behaviour without addressing patient involvement (95). Another intervention solely targeting medication adherence was found to be ineffective (96). The study involved telephone counselling for patients with PAD, aortic aneurysm, or high blood pressure, and showed no improvement in adherence at follow-ups (96). The authors indicated that the high number of patients who dropped out of the study and forgetfulness in taking medication could have affected the study results (96).

A pilot study showed the feasibility of a supported self-management intervention, led by psychologists, targeting lifestyle aspects of the conservative treatment plan (e.g., walking, smoking, weight) (97). Still, its implementation within the NHS would pose challenges due to the limited availability of vascular health psychologists.

The Motivating Structured Walking Activity in People With Intermittent Claudication (MOSAIC) behaviour change intervention indicated that home-based motivational interviewing can enhance walking distance in patients with IC at 3-month follow-up, compared with usual care (77). Although the study was effective in improving walking distance, the long-term maintenance of these results is unknown, hence, the authors recommended for further research investigating this prior to implementation (77). Currently, the MOSAIC II trial (NIHR Award ID: NIHR208123) is being undertaken, to explore the use of the MOSAIC intervention within primary care (98). Additionally, a pilot randomised controlled trial found that use of the mobile health intervention TrackPAD was associated with improvements in walking capacity in patients with symptomatic PAD (99). The authors highlighted that although this pilot study was feasible, it was not

adequately powered to detect a significant difference, therefore, further research is required to assess the effectiveness of the intervention (99).

Although these studies are effective in improving walking uptake and capacity, they do not take into consideration all aspects of the conservative treatment plan for PAD. Moreover, discussions with my established PAD patient and public involvement (PPI) group have highlighted hesitance and scepticism around the use of digital interventions. Some patients do not have smartphones/devices or access to the internet, whilst others prefer to have contact with a clinician, rather than a mobile device.

As presented, most of these studies address one component of guideline-recommended therapy only, leaving a gap in knowledge about strategies to enhance adherence to all cardiovascular risk reduction therapies among patients with PAD (29). Having multiple different interventions for different aspects of PAD management may feel confusing and fragmented from a patient's perspective. Given that patients need to adhere to all aspects of PAD treatment to improve their outcomes, targeting and changing multiple behaviours simultaneously could improve the management of patients with chronic conditions (100, 101), like PAD. Addressing multiple behaviours within a single intervention presents unique challenges that differ from those encountered when focusing on just one behaviour. As a result, multi-component interventions are likely to be more broadly applicable and useful in effectively supporting patients with changing multiple behaviours. Despite this, existing interventions do not fully encompass all aspects of PAD management, resulting in a lack of comprehensive strategies to improve adherence to cardiovascular risk-reduction therapies and, consequently, a lack of reliable data demonstrating improved outcomes in patients with PAD (29).

Last but not least, most existing interventions targeting adherence in PAD have not been systematically developed using behavioural theories or frameworks, nor have they consistently addressed specific determinants of adherence. Current literature on behaviour change techniques (BCTs) focuses primarily on physical activity, rather than

adherence more broadly. A 2013 review that identified intervention studies and classified them using the Behaviour Change Technique Taxonomy (BCTTv1) (102) highlighted a lack of high-quality evidence to determine their effectiveness in increasing exercise uptake, making it challenging to draw conclusions (103). However, the most commonly used BCTs were problem-solving, self-monitoring, and feedback (103). The authors highlighted the need for better-designed studies examining the effect of BCTs for exercise (103). In response, a more recent review concluded that interventions that use BCTs are more effective at increasing short-term daily physical activity (104).

1.5 Using health psychology to understand adherence

1.5.1 Importance of a health psychology approach

Understanding why patients adhere or do not adhere to their treatment is critical for promoting meaningful behaviour change. Health psychology offers a pragmatic approach to exploring this by examining how psychological, behavioural, and socio-cultural factors influence physical health and illness (105). Health behaviours, such as medication taking, exercise uptake and smoking cessation, are influenced by personal beliefs, social influences, and cultural context, which make adherence difficult to predict and address (106). Using health psychology supports the identification of factors (health determinants) that facilitate or hinder adherence, and is therefore essential for developing effective interventions to support adherence (106).

1.5.2 Theories of behaviour change applied to adherence

The use of theory provides a comprehensive way of organising and explaining phenomena or behaviours and specific relationships between different factors (107). By applying theory during intervention development, modifiable factors that affect these phenomena or relationships can be more clearly identified (108). This, in turn, will support the development of mechanisms of action and explain how the intervention will work (109, 110).

Choosing an appropriate behaviour change theory can be challenging due to the number of available explanatory theories (111). A previous review identified 82 theories relevant to a variety of behaviours (e.g., increasing physical activity, smoking cessation) (112). Another systematic review identified 100 theories that explained behaviour change through five interlinked mechanisms of action: motives, self-regulation, psychological and physical resources, habits and environmental and social influences (53). Any of these theories may help explain the determinants of change; yet most theories are similar or overlapping, making it challenging to explore key determinants of change (113).

A 2014 Cochrane review of medication adherence interventions for chronic conditions found that only a minority of available interventions have been effective in improving adherence and/or altering patient outcomes (114). An NIHR commissioned review by Horne et al. found that interventions are often ineffective due to: failure to identify and target modifiable determinants of adherence; lack of person-centred approach; lack of systematic, theory-based, intervention development; and suboptimal study design and methodology (52).

As highlighted in this Chapter, in vascular surgery, there are limited studies aimed at identifying determinants of adherence; available interventions are single-component, use a one-size-fits-all approach, are not person-focused, and do not incorporate theory in their development. To strengthen the likelihood of this PhD intervention being successful, relevant behaviour change theories were taken into consideration.

The following models of behaviour change were considered for this project: the Capability Opportunity Motivation of Behaviour (COM-B) Model, the Theoretical Domains Framework (TDF), the Common Sense Model (CSM) and the Perceptions and Practicalities Approach (PaPa). Their strengths and limitations are discussed below.

1.4.2.1 The Capability Opportunity Motivation of Behaviour (COM-B) Model

The COM-B model is a behavioural framework developed by Michie et al., in 2011 (106). It suggests that individuals must have sufficient capability (C), opportunity (O), and motivation (M) to perform a behaviour (B) (113) (see Figure 3). Capability includes an individual's psychological capability (knowledge and skills) and physical capability (strength and stamina) to engage in a behaviour (106). Opportunity consists of external physical opportunity (resources) and social opportunity (cultural norms and social cues) that influence a behaviour (106). Lastly, motivation includes reflective motivation (conscious or analytical decision-making) and automatic motivation (habits or emotions), which influence whether an individual engages with a behaviour (106). These behavioural factors interact to influence behaviour.

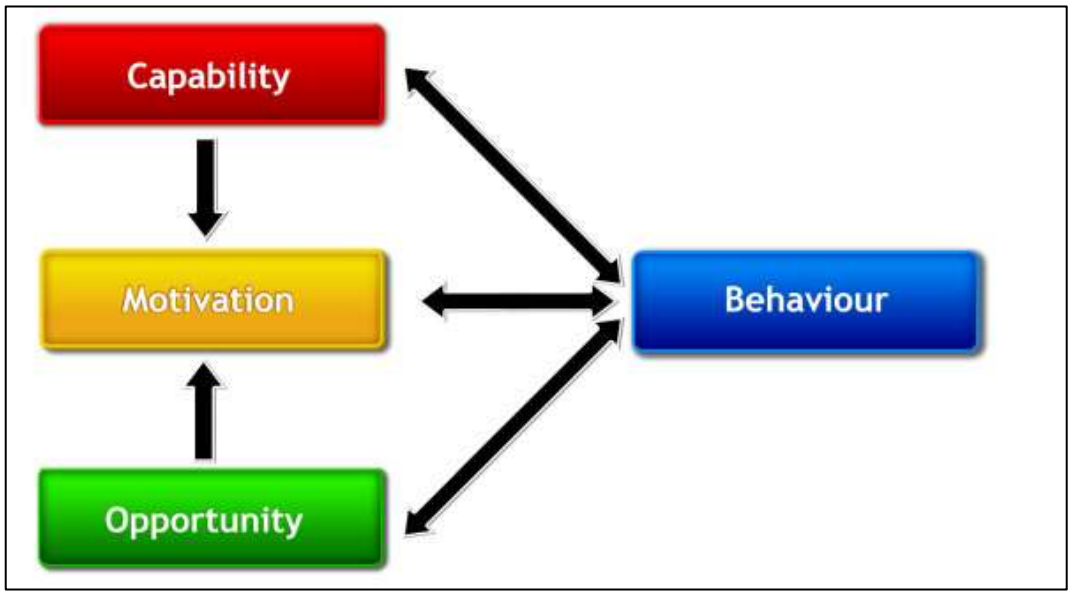


Figure 3 The COM-B Model (Adapted from Michie, 2011) (106)

When desired behaviours are not performed, or unwanted behaviours persist, it is necessary to examine influences on behaviour to identify what needs to be addressed to enable behaviour change. This identification of key influences is an important first step in intervention development (113). The COM-B model provides a useful framework for understanding influences on therapeutic engagement in practice (113). It has been utilised across various clinical areas to inform the development of behaviour change interventions to support patients with a number of chronic diseases, e.g. adherence

and self-management in asthma (115), stroke (116), and heart failure (117). Despite its application in multiple settings, a critical paper by a leading health psychologist has questioned the tendency to use the COM-B as a default framework for behaviour change (118). The authors instead advocate selecting alternative behavioural change theories that are applicable to the study context (118).

1.5.2.2 The Theoretical Domains Framework (TDF)

The TDF was developed in 2005 using expert consensus and systematic reviews of behaviour change theory to integrate and simplify a large and fragmented evidence base (119). Initially, it synthesised 33 behavioural theories and 128 theoretical constructs into 12 domains (108) (see Table 4). Following further validation, the framework was refined in 2012 to include 14 domains to improve clarity and usability (119). The 14 domains of the TDF are Knowledge; Skills; Social/Professional Role and Identity; Beliefs about Capabilities; Optimism, Beliefs about Consequences; Reinforcement; Intentions; Memory, Attention and Decision Processes; Environmental Context and Resources; Social Influences; Emotion; and Behavioural Regulation (119). The TDF was designed to support systematic investigation of factors influencing behaviour and to address the inconsistent and limited application of theory in intervention development (119). It provides a structured and accessible way to identify behavioural determinants and inform intervention design (119). Additionally, the TDF is closely aligned with the COM-B model. Each of the 14 TDF domains maps onto one of the COM-B components, allowing COM-B to offer a high-level behavioural diagnosis, while the TDF provides a more detailed, domain-specific analysis (113).

Table 4 The 14 TDF domains mapped to the COM-B (Adapted from Cane, 2012) (119).

COM-B		**TDF Domain**	**Definition ***
Capability	Physical/ Psychological	Skills	An ability or proficiency acquired through practice
	Psychological	Knowledge	An awareness of the existence something
		Memory, Attention and Decision Processes	The ability to retain information, focus selectively on aspects of the environment

			and choose between two or more alternatives
		Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions
Opportunity	Social	Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours
	Physical	Environmental Context and Resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour
Motivation	Reflective	Beliefs about Capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use
		Beliefs about Consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation
		Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way
		Goals	Mental representations of outcomes or end states that an individual wants to achieve
	Reflective/automatic	Social/Professional Role and Identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting
		Optimism	The confidence that things will happen for the best or that desired goals will be achieved
	Automatic	Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus
		Emotion	A complex reaction pattern involving experiential, behavioural, and physiological

			elements, by which the individual attempts to deal with a personally significant matter or event

*Definitions as per the American Psychological Associations of Psychology (120).

Beyond its use in designing complex behavioural interventions, the TDF has a plethora of applications. It can be used to guide data collection (through questionnaires and interviews); to synthesise systematic reviews; and to evaluate interventions to identify mechanisms of change (121). The TDF has mainly been used to identify factors influencing clinical behaviours in healthcare settings, but it can also be applied to other specialities, such as public health or non-healthcare-related specialities (e.g., environment and transport) (121). Additionally, the TDF has been widely used in cardiovascular disease to identify adherence barriers and facilitators for statins (122), cardiac medications following coronary heart procedures (123), and heart failure (124).

A key limitation of the TDF is that it is not a theory of behaviour, but rather a compilation of potential influences on behaviour (121). As such, it is not specifically designed to explain adherence, and it does not clearly identify the mechanisms that drive behaviour change in the way a formal behavioural theory would (121). Although it was intended to provide a comprehensive overview of factors influencing behaviour, this breadth can also be a disadvantage (121). The inclusion of a wide range of domains means that some may be irrelevant in a given context, and using the framework to structure research may therefore lead to attention being given to unnecessary topics (121). Moreover, it focuses primarily on qualitative research and offers little guidance on its use with other methods, such as surveys or observational data (121). Additionally, the framework has been criticised for being resource-intensive, in terms of staffing, funding and timing (121). Another limitation is that the framework primarily focuses on the identification of barriers, with limited scope to identify enablers, making it difficult to envisage the positive impact they might have (125). Some domains overlap, and other key influences on adherence (e.g. side effects) cannot clearly be categorised to one domain, making the precise categorisation challenging (121).

Although both the TDF and the COM-B have been used in adherence interventions, they have not been specifically designed to address adherence determinants; hence, they were not deemed to be the most appropriate models for this PhD project.

1.5.2.3 Leventhal's Common-Sense Model of Self-Regulation (CSM)

The concept of illness perceptions describes the process by which individuals use their existing knowledge, experiences, emotional responses and background to explain their current symptoms and disease diagnosis (126). The theoretical foundation of illness perceptions is Leventhal's Common-Sense Model of Self-Regulation (CSM), which suggests that patients seek to make sense of their condition logically, including the problem (disease) and the solution (treatment) (126). According to the CSM, individuals process both beliefs about their illness and emotional responses in parallel, and these two systems interact to guide coping behaviours (127) (see Figure 4). Both processing systems involve the individual forming a representation, selecting appropriate coping strategies, and appraising the success of these strategies (127).

At a cognitive representations level, patients hold implicit common-sense beliefs about their illness, that reflect how they perceive, understand and react to threats to health. These guide the selection of coping behaviours which will attempt to resolve the health threat (127). Five key illness perceptions influencing cognitive perceptions were identified by Leventhal et al. (1992): identity, timeline, consequences, causes and cure/control (127) (See Table 5). Alongside cognitive representations, health threats also trigger emotional responses. The same health event can produce very different emotional reactions between individuals, such as fear, worry, anger, or sadness, while others may experience little emotional response (127). These emotions play an essential role in shaping how people cope, influencing the actions they take to manage both the illness itself and the emotional distress it causes (127). Previous research has highlighted that health threats can provoke a wide range of emotional reactions, and these are closely connected to how patients understand and represent their illness (128).

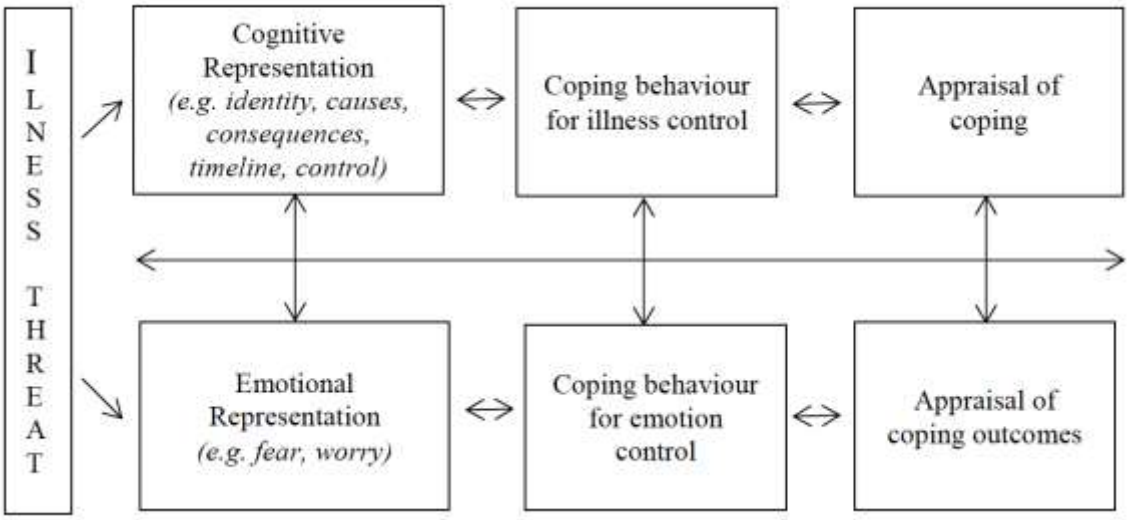


Figure 4 Illness Perceptions (Adapted from Leventhal, 1992) (127).

The Illness Perceptions Questionnaire (IPQ) was developed to assess individuals' cognitive representations of illness, including beliefs about identity, cause, timeline, consequences, and control (129). It has been widely used to examine the relationship between illness perceptions and health outcomes across multiple conditions. The Revised Illness Perceptions Questionnaire (IPQ-R) was later introduced to improve psychometric performance and expand the measure (90) (See Table 5). Revisions included separating cure/control into treatment control and personal control, adding a cyclical timeline dimension, and incorporating emotional representations and illness coherence, which capture emotional responses and overall understanding of the illness (90). It is recommended that the questionnaire should be modified for each clinical context, due to the different characteristics of each condition (90).

Table 5 Illness Perceptions (Adapted from Leventhal, 1992 and Moss-Morris, 2002)

Illness perceptions defined by Leventhal et al. (1992) (127)	
Identity	The label given to the illness or symptom experiences
Causes	Beliefs around what caused the illness
Timeline	Perceived chronicity of illness
Cure/control	The extent to which the patient feels the illness can be cured or controlled
Consequences	Perceived consequences of the illness

Additional illness perceptions identified by Moss-Morris et al. (2002) (90)	
Treatment control	Belief in the treatment or recommended advice
Personal control	Belief in personal control and self-efficacy
Timeline acute/chronic	Perceived chronicity of illness
Timeline cyclical	The extent to which symptoms come and go over time
Emotional representations	Assessment of the emotional responses generated by the illness
Coherence	The extent to which a patient's illness representation provides a coherent understanding of the illness

Current literature from various patient populations and chronic conditions, including cardiovascular disease, suggests that patients' pre-existing beliefs about their illness and treatment are determinants of treatment adherence (129, 130). Although the CSM model is useful for understanding the association between patients' perceptions and their adherence behaviours, it does not take into account practical factors that affect adherence. Hence, it cannot be used in isolation to understand and address adherence issues.

1.5.2.4 The Perceptions and Practicalities Approach (PaPa)

To understand and address non-adherence, the NICE Medicines Adherence Guidelines recommend applying the PaPa, recognising that non-adherence can be both unintentional and intentional (131). The PaPa was developed by Professor Horne in 2001 (132). It suggests that adherence interventions should address both the perceptions (beliefs about treatment and illness) and practicalities (capabilities and resources) that affect each patient's ability and motivation to adhere (132, 133) (see Figure 5). A key recommendation of the PaPA is to take a 'no-blame' approach, encouraging an open discussion about non-adherence between clinicians and patients (52, 132).

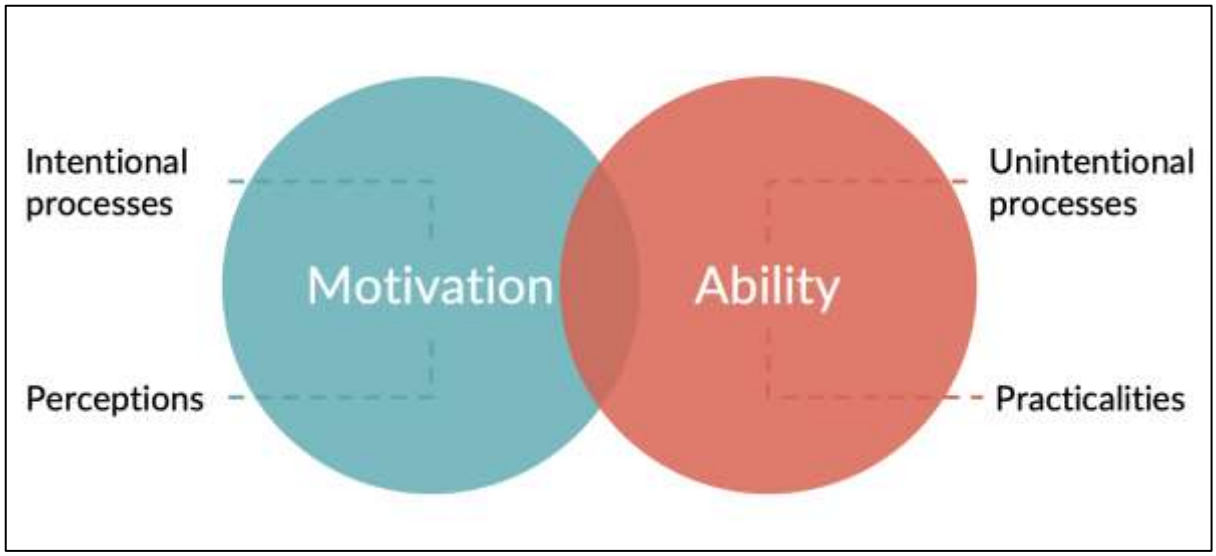


Figure 5 Perceptions and Practicalities Approach (PaPa) (Adapted from Horne, 2001) (132).

At the heart of the perceptual dimension of the PaPa is the Necessity Concerns Framework (NCF), which highlights that adherence depends on how patients balance their perceived need for treatment against their concerns about taking it (133). According to the NCF, patients make a personal, often dynamic, cost–benefit judgement: "Do I need this treatment?" versus "Do the risks or side effects worry me?" (91, 132). Therefore, effective adherence support should strengthen beliefs in the necessity of treatment while reducing concerns. In this way, a logical connection between the illness and its management will be created.

The PaPa extends the NCF by incorporating both intentional and unintentional drivers of non-adherence. Recognising these multiple contributors allows PaPa to provide a more comprehensive framework for designing interventions. Another key feature of the PaPa is recognising that every patient has a unique mix of perceptual and practical barriers to treatment engagement (132, 133). Thus, a person-centred approach should be followed when supporting patients with their treatment (132, 133). Such intervention strategies are more likely to be effective than targeting motivation or ability alone (52).

Although it has primarily been used for medication adherence interventions, it offers a theoretical model for understanding the underlying logic of any health behaviour that depends on motivation and the capability to act (132). Hence, it can also be applied to interventions targeting other health behaviours and treatments. Although the PaPa has

been adopted as a leading theory for adherence-promoting interventions in other diseases, no studies have utilised this approach in vascular surgery. For these reasons, the PaPa has been selected as the theoretical framework for this PhD. A detailed justification for this decision is presented in Chapter 2 (Section 2.3)

1.5.3 Linking intervention techniques to theory

An essential step when designing interventions is to identify the intervention content and implementation options by choosing relevant BCTs and modes of delivery (113). The BCTTv1 was developed to increase recognition of the need for a standardised language and a comprehensive reporting of behaviour change interventions (102). The taxonomy includes 93 distinct BCTs to support researchers in selecting potentially active ingredients for their interventions (102) (see Appendix 1).

The development of the taxonomy has enabled more transparent and precise reporting of behaviour change interventions, thereby improving their reproducibility, translation into clinical practice, and robust evaluation (134). This addresses longstanding problems caused by poor descriptions of interventions (102). The BCTTv1 has been used to identify BCTs across different health behaviours and settings, specifically for physical activity (135), medication adherence (136) and smoking cessation (137). Reviews have also been conducted to identify which BCTs were used in published interventions and to assess their effectiveness (138).

1.6 Pre-Doctoral Project and Rationale for this PhD

Since undertaking my Masters in Preventive Cardiology, at Imperial College London (2016-2017), I have been interested in the role of health determinants in cardiovascular risk prevention and always wanted to do a PhD. During my clinical role as a cardiac rehabilitation nurse (2019-2021), I became aware of some of the challenges patients with PAD face when it comes to treatment adherence. In my clinical practice, I was in charge of the management of patients who had mixed coronary and peripheral arterial disease. These patients faced greater challenges engaging with their treatment and

were often the ones who dropped out of exercise classes. Given my interest in finding the best way to support my patients, I searched the literature to identify relevant studies that could inform my practice. Since I was unable to find any studies exploring barriers and facilitators to conservative PAD management, I decided it was a logical step for me to undertake such a study.

To address gaps in the current literature and explore behavioural factors affecting adherence, I conducted a mixed-methods study during my pre-doctoral fellowship at Imperial College Healthcare NHS Trust (ICHNT) (2021-2023). The first part of my study involved a bespoke survey of 105 PAD patients, using validated adherence and illness perceptions questionnaires to identify sociodemographic, clinical, and illness perceptions factors that affect treatment adherence (71). The survey revealed that only a third of patients were adherent to pharmacotherapy, 25% were smokers (with 14% of smokers attending a smoking cessation programme), and only 20% were offered SET (71). Furthermore, a quarter of patients were unable to identify any causal factors for their disease (71). Results highlighted that treatment adherence among PAD patients is notably low, largely influenced by patients' negative perceptions of their illness (71). Specifically, poor disease understanding, low perceived treatment effectiveness and low personal control were significantly associated with poor medication adherence, lack of motivation to quit smoking and reduced exercise levels (71).

To further explore these findings, during my pre-doctoral fellowships, I conducted semi-structured interviews with 12 patients at ICHNT, using the PaPa to inform the topic guide and data analysis (139). To my knowledge, this is the first qualitative study of PAD patients' perspectives on adherence barriers and facilitators, thereby providing an in-depth exploration of behavioural adherence determinants (139). Seven themes were identified, and these were categorised as either perceptions or practicalities (see Figure 6). The qualitative analysis identified that perceiving treatment to be effective, having a positive mindset and social support, as well as establishing a daily routine were reported as adherence facilitators (139). However, challenges to adherence included insufficient information and personalised care; side effects and claudication pain; adverse weather and a lack of exercise spaces (139).

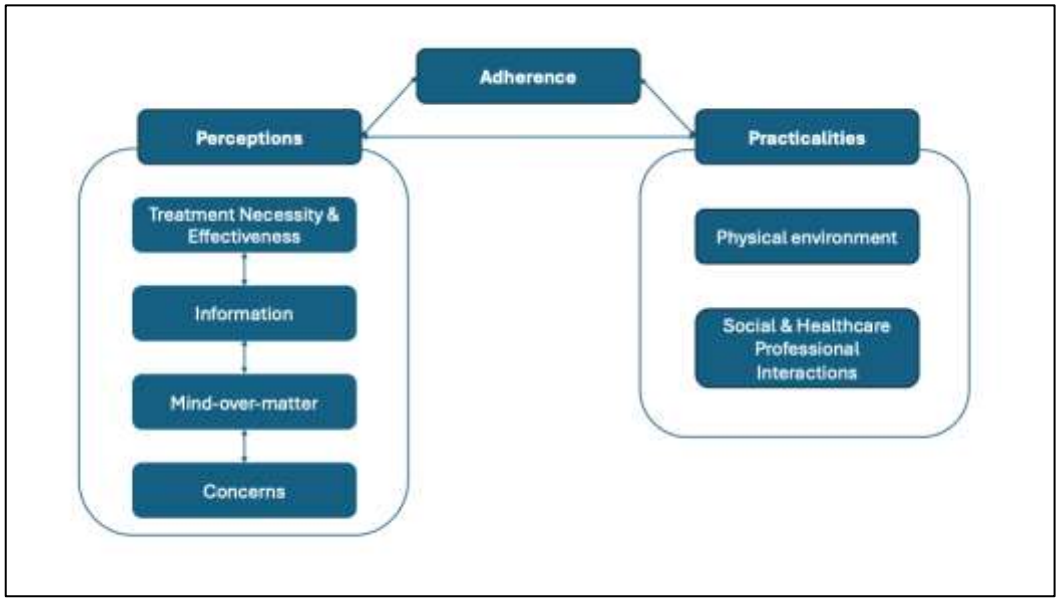


Figure 6 Pre-doctoral qualitative study themes (Adapted from Lampridou, 2025) (139).

Feedback from my PAD patient and public involvement (PPI) group (see section 2.6) indicated that patients rarely received comprehensive information about their conservative treatment plan, and were unaware of its various components. They often remarked on feeling like a "number on someone's list" and "being stuck between clinical appointments" with no one addressing their concerns. Similarly, discussions with vascular clinicians highlighted a need to focus on patients' personal goals and challenges beyond acute, clinical needs. The information received from patients and clinicians indicated the importance of ongoing discussions and personalised care, as patient priorities evolve over time.

Although the existing literature has highlighted several barriers and facilitators to treatment adherence in patients with PAD, this area has not been comprehensively investigated using behavioural theory, so there is a limited understanding of factors influencing adherence. My pre-doctoral project was limited to patients from a single centre in London, and did not investigate perspectives of patients' family members and friends, as well as healthcare professionals. Hence, there is a need for an in-depth exploration of perceived barriers and facilitators to patient adherence from multiple perspectives.

To conclude, evidence-based, theory-driven, person-based intervention strategies are needed to support patients with PAD with their adherence to conservative treatment. This PhD project aims to address this gap and contribute to the JLA PAD research priorities, by developing a person-centred, theory-informed behavioural intervention to support patients with PAD with adherence to their complex treatment plan. The intervention will target potentially modifiable factors associated with non-adherence that I have previously identified through my pre-doctoral project and will continue to explore during this PhD, following a perceptions and practicalities approach. This intervention will be designed so that it can be implemented within the NHS, and will have the potential to alleviate the burden of non-adherence, by empowering PAD patients to manage their care, enhance their treatment adherence, optimise their outcomes, and support their overall well-being.

1.7 Research questions, Aims and Objectives

Aim: To co-design a person-based, theory-informed behavioural intervention to support patients with PAD with their treatment adherence.

Objectives:

1. To explore what multicomponent interventions have been developed to support adherence and uptake of medications (antiplatelet, lipid-lowering and antihypertensive agents), smoking cessation, diet, weight management and/or physical activity in patients with PAD (Assessed in Chapter 3).
2. To explore experiences and views regarding illness, current treatment information and plan; and perceived barriers and facilitators that influence patients' adherence to their treatment plan from the perspective of patients, their relatives and healthcare professionals (Assessed in Chapter 4).
3. To co-design and user-test a theory and evidence-informed intervention that will support patients with PAD to address their perceptual and practical barriers to adherence (Assessed in Chapters 5-7).

Research questions:

1. What multicomponent interventions exist to support adherence to medications (antiplatelet, lipid-lowering, antihypertensive), smoking cessation, weight management, diet, and/or physical activity in patients with PAD? (Assessed in Chapter 3).
2. What are patients' experiences of PAD and of the treatment information and support they receive? How do these experiences influence adherence? (Assessed in Chapter 4).
3. What are the perceptions and practicalities that enable or hinder patients to adhere to their treatment plan? (Assessed in Chapter 4).
4. How can we support patients with PAD to address perceptions and practicalities to adherence? (Assessed in Chapters 5-7).

1.8 Thesis overview

Chapter 1. Introduction: This chapter describes the clinical context of PAD and the burden of non-adherence for patients with PAD as a central theme for this thesis. The pilot work from my pre-doctoral fellowship exploring barriers and facilitators to non-adherence is also discussed. Finally, the chapter presents the need for a theory-informed behavioural intervention that addresses the multiple components of treatment adherence, given the limited success of existing interventions.

Chapter 2. Methodology: This chapter provides an overview of intervention development approaches. The selection of the Person Based Approach is justified. The chapter also highlights the central role of patient and public involvement in this project.

Chapter 3. Scoping review of multicomponent interventions that support adherence to guideline-recommended therapy in patients with PAD: This chapter discusses the methods used in the scoping review and summarises the content and delivery of multicomponent interventions that have been designed to support adherence in patients with PAD.

Chapter 4. Qualitative study of patients, their relatives and HCPs to identify adherence barriers and facilitators: This chapter presents the detailed methods and findings of semi-structured interviews about experience with PAD treatment and care, and adherence barriers and facilitators, conducted with patients, relatives and HCPs across the UK.

Chapter 5. Understanding the clinic context of intermittent claudication services in England: insights from a freedom of information request (FOIR). This chapter presents the methods and results of a FOIR conducted to better understand the provision of claudication services, in terms of claudication clinics, SET, lifestyle and psychological support services, prior to the co-design workshops.

Chapter 6. Intervention Development Phase 1: Triangulation of theory and evidence to generate outline intervention: This chapter triangulates findings on modifiable influences on PAD treatment adherence from various sources and identifies intervention content and BCTs to address these influences. The guiding principles and the logic model of the intervention are also discussed.

Chapter 7. Intervention Development Phase 2: Co-design and development: This chapter outlines the co-design workshops undertaken, resulting in the design of the PAD&Me booklet intervention.

Chapter 8. Intervention optimisation through think-aloud interviews: This chapter describes the refinement of the intervention through user testing, using think-aloud interviews.

Chapter 9. Discussion: The final chapter provides a summary of the thesis. The implications, limitations, and recommendations for further work are also described, along with the main conclusions drawn from the previous chapters.

Chapter 2. Methodology

2.1 Chapter summary

This chapter provides an overview and a critical examination of methodological approaches used for developing complex interventions for behaviour change. The overall study design was informed by the Person Based Approach (PBA), which was used to guide intervention development. The Perception and Practicalities Approach (PaPa) was used to understand and address the issue of adherence. The selection of the evidence-, theory- and person-based approach for this study is justified. An overview of the methodology used in this PhD is presented, along with my philosophical standpoint. Specific methods for each stage of the study are discussed in the methods section of subsequent chapters. Finally, the chapter describes the central role of patient and public (PPI) in the development of the intervention.

2.2 Complex healthcare intervention development approaches

Healthcare interventions are designed to enhance the health and well-being of patients, caregivers, and/or healthcare professionals (HCPs) (140). Interventions that have multiple components operating either independently or in combination to achieve a goal, are characterised as complex interventions (141). To maximise the effectiveness of such interventions, it is important to employ methodological rigour at each step of intervention development (141). Previous research has identified that up to 85% of healthcare research investment is wasted due to interventions that are not rigorously developed (142). As identified by a review of 51 pragmatic trials funded by the NIHR Health Technology Assessment programme, costly clinical trials are often undertaken on interventions that are inadequately designed, unacceptable to service users and stakeholders, or ultimately ineffective (143).

Additionally, interventions found to be effective in controlled clinical trial settings are often not deemed effective when translated into clinical practice (144); or may not even be replicable into real-world settings (145). Therefore, to ensure that research is robustly developed, replicable and translatable into clinical practice, it is essential to

follow guidance on the development and reporting of healthcare interventions (146, 147).

Three different approaches to developing interventions will be discussed below, including their strengths and limitations: The Medical Research Council (MRC) Framework, Intervention Mapping (IM) and the Person Based Approach (PBA). These approaches were considered when selecting an appropriate framework to develop the PAD adherence intervention. The selection and its justification are presented in Section 2.3.

2.2.1 The MRC Framework

The MRC is the most widely used framework for developing complex healthcare interventions (148). The framework was initially introduced in 2000 (149), revised in 2008 (150), and an updated version was published in 2021, commissioned by the NIHR (141). The original 2000 framework illustrated a phased, linear approach for developing complex interventions, including a theory phase, a modelling phase, a testing phase and an implementation phase (See Figure 7) (149). Although this approach was novel at the time, the complexity of the healthcare system, as well as social, environmental and political factors that could be influencing the intervention development stage, were not taken into consideration (150).

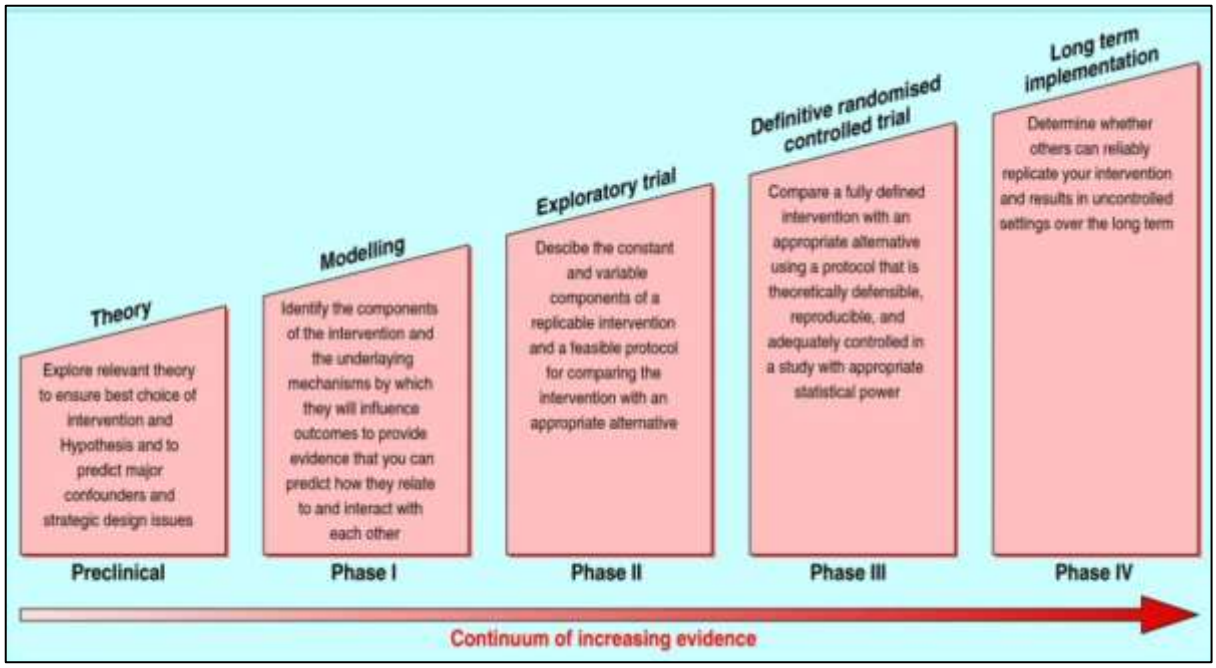


Figure 7 The original MRC Framework (2000) (Adapted from Campbell, 2000) (149).

The updated 2008 framework recommended a more iterative approach across phases of the intervention development cycle, as well as clear guidance on the development and evaluation stages. The revised framework includes four stages (Figure 8): 1) Development, 2) Feasibility/piloting, 3) Evaluation, and 4) Implementation.

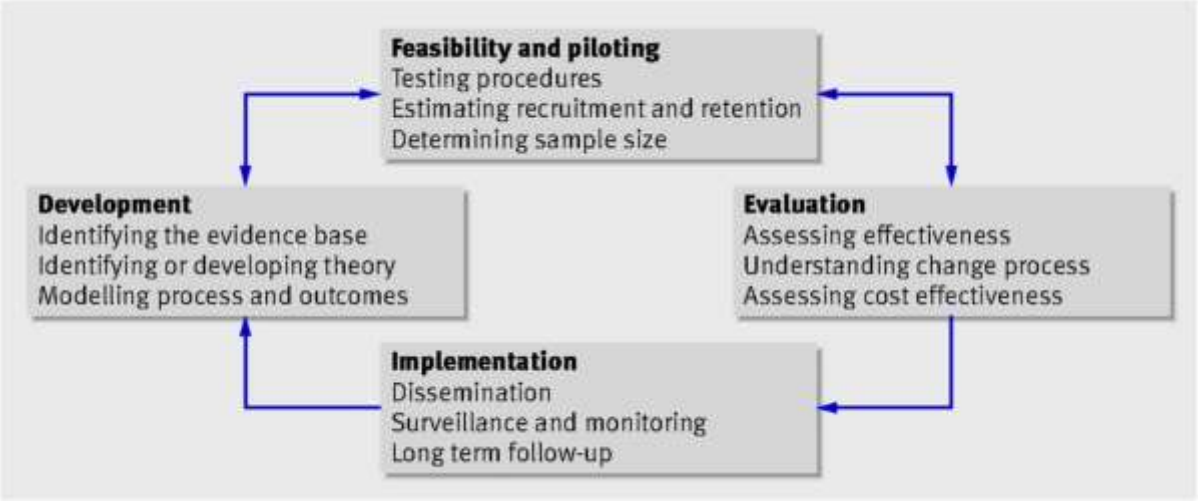


Figure 8 The updated MRC Framework (2008) (Adapted from Craig, 2008) (150).

Despite being more detailed than its original version, this model still has considerable limitations. Although the refined 2008 version provides more guidance for each stage, in the development stage (151), there was a lack of explicit guidance on how to systematically assess and incorporate the context in which an intervention will be delivered (152). This is a major limitation, as understanding real-world settings is essential for effective intervention design and implementation.

To address these shortcomings, a further iteration was undertaken to develop the 2021 MRC version (141). The four stages (development, feasibility/piloting, evaluation, implementation) of the 2008 version are incorporated, as well as core elements that could influence interventions. These core elements include the context, programme theory, stakeholder engagement, key uncertainties, intervention refinement, and economic considerations (141) (see Figure 9).

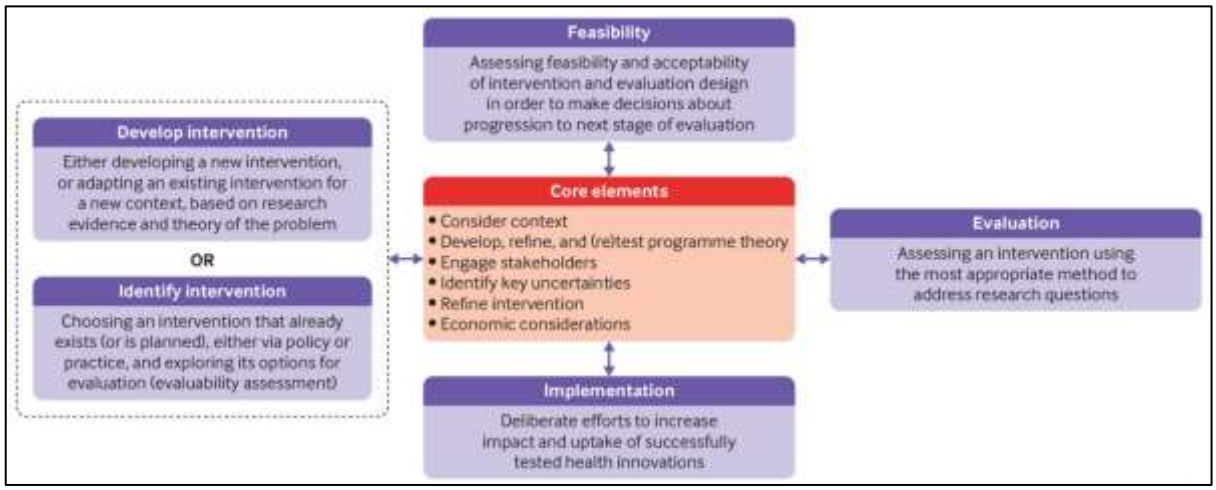


Figure 9 The updated 2021 MRC framework (Adapted from Skivington, 2021) (141).

The updated framework illustrates that intervention effects are highly context-dependent, shaped by dynamic and multidimensional factors such as organisational, social, cultural, and economic considerations (141). Additionally, it highlights the importance of programme theory, which explains how and why an intervention works, for whom, and under what conditions, guiding design, evaluation, and transferability (141). The importance of meaningful involvement of patients, the public and relevant stakeholders is also recommended across all stages to enhance the intervention's relevance, feasibility, and impact (141). Moreover, the framework states that research

must explicitly address key uncertainties using flexible, theory-informed, and mixed-methods approaches (141). Lastly, economic evaluation should be embedded throughout to assess the cost-effectiveness of the intervention (141).

A critique of the updated MRC framework highlights that whilst the revised framework is more detailed and moves beyond a narrow focus on whether interventions work, it offers limited practical guidance on how to utilise it effectively (153). For instance, while including a mixed-methods evaluation of the intervention can be beneficial, the framework does not advise on how to appropriately/effectively combine different methodological approaches which are often based on conflicting philosophical assumptions (153). This in turn can make it difficult for researchers to apply the framework consistently or to explain why interventions succeed or fail in different settings (153).

2.2.2 Intervention Mapping (IM)

The IM approach is a comprehensive and rigorous methodology that is generalisable and evidence-based, enabling the design of an effective intervention across diverse contexts (154). The IM approach addresses environmental and personal factors that may influence the acceptability of the intervention and health behaviour (154). The IM follows a five-step process, in which each step builds on the previous one while allowing for an iterative and flexible planning approach (154) (see Figure 10). The process begins with a needs assessment to define the scope of the problem and identify the behavioural determinants involved (154). Based on this assessment, intervention objectives are then set and key determinants to target are selected (154). The next step involves choosing theory-driven behaviour change methods that align with these determinants, and translating them into practical strategies (154). These strategies are subsequently combined into a structured intervention programme, with decisions made about its format and delivery (154). The final stages focus on implementing and evaluating the intervention (154).

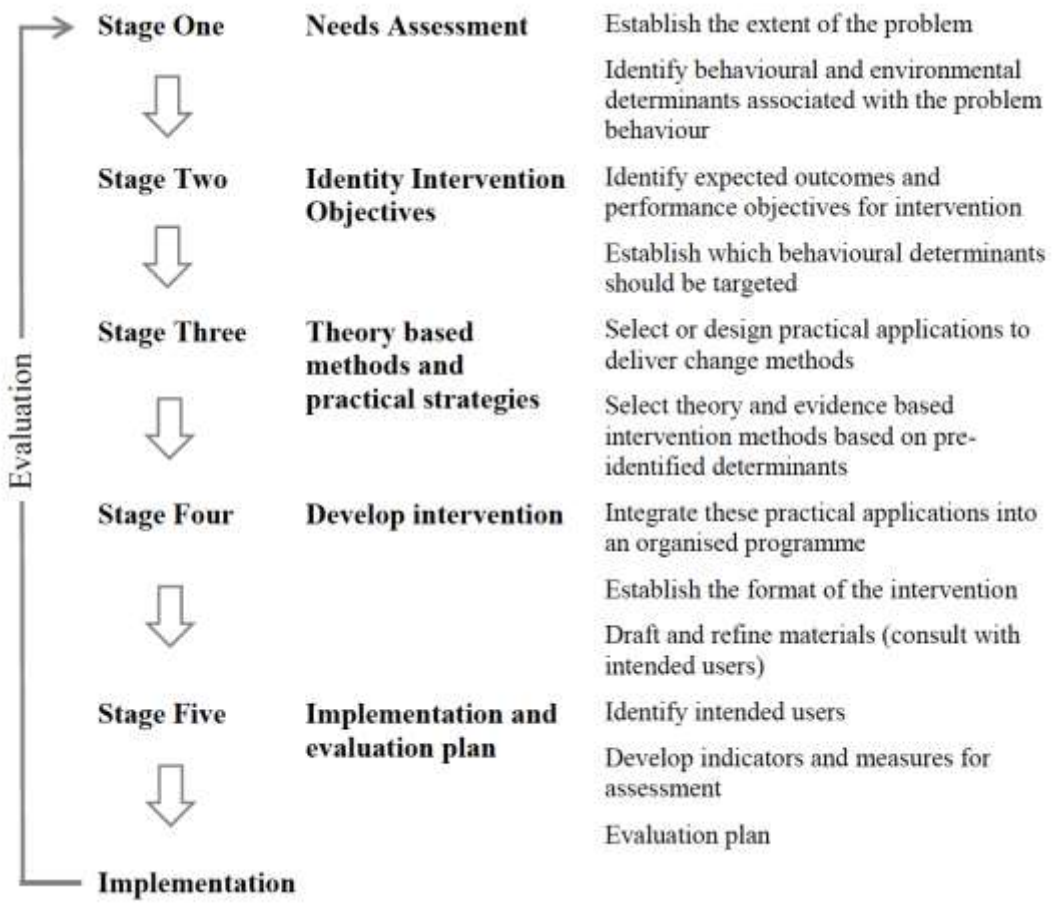


Figure 10 Intervention Mapping Framework (Adapted from Bartholomew et al., 1998) (154).

Although the IM is a systematic approach, it has several limitations. The framework is resource- and time-intensive, requiring substantial investment in funding, expertise, and personnel, which can limit its usability for time-limited projects (e.g. PhD projects) or those requiring rapid development or implementation (155, 156). Additionally, it is methodologically complex, with limited flexibility to adapt to the different needs of service-users (155, 156). Moreover, there is limited guidance on involving service users and stakeholders in a balanced way (155, 156). Lastly, IM has been criticised for overlooking the needs of underserved groups, limiting its ability to be inclusive and patient-focused (157). These limitations highlight the need for careful application, adequate resources, and critical reflection when using IM in research and practice.

2.2.3 The Person Based Approach (PBA)

The PBA is a user-focused framework that utilises qualitative research to ensure behavioural change interventions consider the perspectives, needs and experiences of the individuals who will use them (158) (see Figure 11). In this way, interventions are more likely to be acceptable, engaging, and meaningful to users. Furthermore, the PBA is designed to be used in combination with other theory- and evidence-based approaches (158). It offers a rigorous, systematic approach to developing interventions (158, 159). Yet it is flexible, making it ideal for PhD programmes, where researchers must be adaptable and work within time constraints. A key strength of the PBA is that it has been used successfully to design interventions tested in fully powered trials, which have proven to be both effective and cost-effective (158, 160). However, the PBA has several limitations, including its resource intensity and the requirement for substantial participant engagement (161).

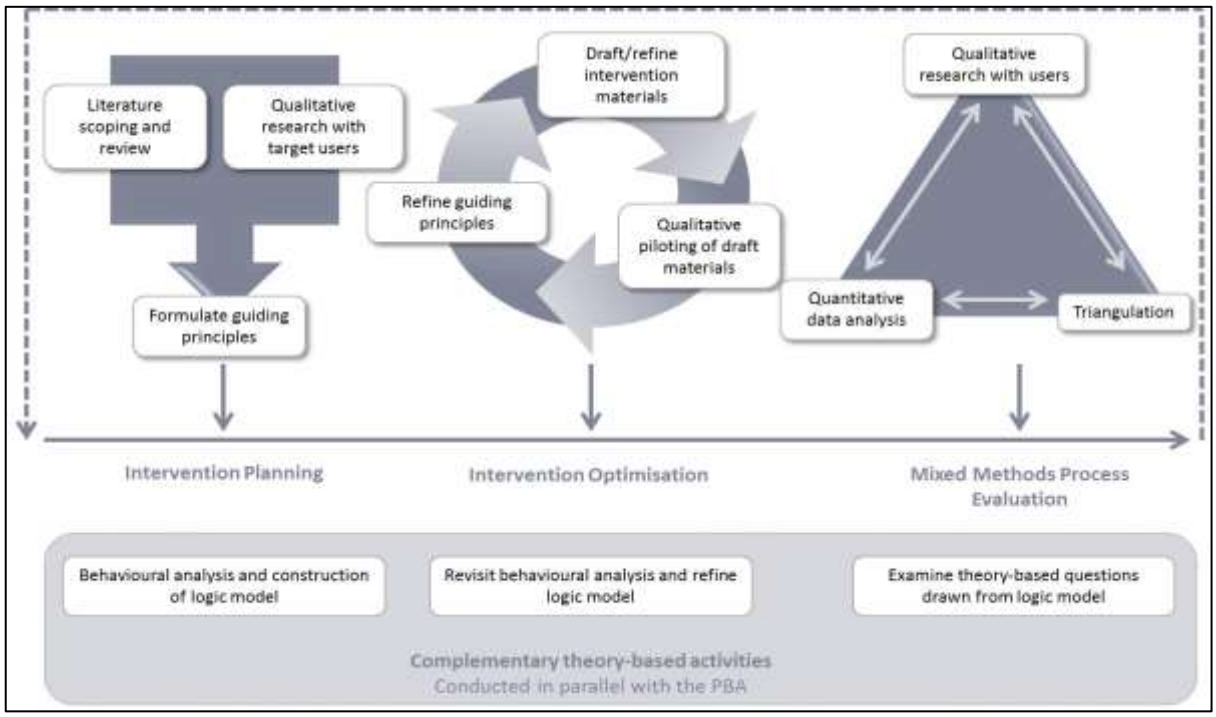


Figure 11 The Person Based Approach (Adapted from Yardley, 2015) (162)

The key features of the PBA are the integration of qualitative and participatory research throughout all stages of intervention development and the creation of guiding principles (159). Guiding principles describe the intervention's design objectives and key features,

to inform decision-making throughout the development process (158, 159). Qualitative research is a core element of the PBA, where it is used to focus on understanding users' experiences and subjective perspectives in depth, providing rich insights that guide the development and refinement of interventions (158, 159). Patients and the public are involved throughout the process, allowing for continuous feedback (158, 159). Additionally, new research participants are involved in the ongoing research process, offering a fresh perspective to the study (158, 159). This continuous engagement supports the exploration of perspectives from a diverse range of individuals, enhancing the relevance of the intervention (162). The PBA framework emphasises adapting interventions so they align with the needs of the target population while remaining practical and engaging (162). To achieve this, interventions should be repeatedly iterated and evaluated across different populations and settings to improve usability, acceptability, and successful implementation (162). The approach also highlights the importance of thoroughly documenting the development process and providing clear guidance on implementation, thereby enhancing transparency and supporting replication (162).

2.3 Selection of an evidence-, theory- and person-based approach

The overall approach used in this PhD study is described as an evidence-, theory- and person-based approach (159). When selecting an intervention development approach, a systematic review providing a taxonomy of approaches for intervention development recommends considering the following six questions (140):

1. *'What is the intention of the intervention?'*

As illustrated in Chapter 1, the intention of the proposed intervention is to support patients with PAD with their adherence to the PAD conservative treatment plan. This intention aligns with approaches that guide the development of person-based behavioural health interventions with an educational and/or behavioural change focus. Taking into consideration the topics discussed above, and that patients with PAD feel

"forgotten" and "under-represented", the PBA was chosen as the most suitable framework for this PhD, as it is patient-centred.

The theory underpinning the study is the PaPa (described in detail in Chapter 1). The PaPa was selected because it is specifically designed to explain and address adherence behaviours. Although it has primarily been used for medication adherence interventions, it offers a theoretical model for understanding the underlying logic of any health behaviour that depends on motivation and the capability to act (132). Hence, it can also be applied to interventions targeting other health behaviours and treatments. Alternative frameworks, such as COM-B and TDF, were not selected despite their prior use in adherence, as they are broader behaviour change frameworks rather than adherence-specific models. Although these frameworks are useful for understanding behavioural determinants, they do not explicitly differentiate between perceptual and practical adherence determinants. Given the specific focus of this intervention on understanding and addressing non-adherence, the PaPa framework was therefore considered the most appropriate and theoretically coherent choice.

2. *'What is the context of the intervention?'*

The intervention was designed to fit within existing clinical pathways. During the PPI sessions I undertook prior to applying for PhD funding, we discussed the delivery of the intervention (e.g. face-to-face, digital, leaflet). This was then further explored during the PhD project. In line with the PBA, it was essential to understand the target-users' varied contexts and ensure their perspectives were prioritised throughout the development process.

3. *'What values inform the intervention development?'*

The intervention was designed to be evidence-based, theory-informed and person-centred intervention. Key values included: 1) incorporating evidence and theory into the development process; 2) placing the target-population at the centre of the development process. As described in Section 2.2.3, the PBA addresses both these values by integrating frameworks and theories, combining qualitative research with PPI,

developing grounding principles based on theory, and supporting true partnership with relevant service-users (162).

4. *'What skills and experience does the team bring?'*

Throughout my academic and clinical training, I have developed skills in leadership, qualitative research, health psychology and intervention development approaches. During my undergraduate nursing degree, I completed a module in Health Psychology, for which I got a distinction. During my MSc in Preventive Cardiology, I was trained in Motivational Interviewing and my research was focused on the influence of spouses in smoking cessation in patients following myocardial infarction (163). During my pre-doctoral fellowship, I undertook training in qualitative research (University College London); and behavioural science and complex intervention development (Oxford University), where I was taught about the PBA. I also gained practical skills in qualitative research and the application of the PaPa model, resulting in a published paper (139). During my PhD, I undertook further training in advanced qualitative methods (Oxford University).

Additionally, it is essential to highlight the strengths of my multi-disciplinary supervisory team. Professor Mary Wells is an experienced qualitative researcher and has supported the development of multiple cancer person-centred interventions, including the Supporting Women with adhErence to hormonE Therapy following breast cancer (SWEET) NIHR- funded adherence interventions using the PaPa model. Professor Alun Davies is a Professor of Vascular Surgery, with extensive experience in clinical services and clinical trials research; he is the Chief Investigator for multiple NIHR funded PAD studies. Dr Gaby Judah is a behavioural scientist and mixed-methods researcher, with expertise in co-designing medication adherence interventions.

It is important to note that, during my Pre-Doctoral and Doctoral Fellowships, Professor Horne (who developed the PaPa) has acted as a collaborator and advisor on this project, enabling me to gain a better understanding of the PaPa framework and its application. Lastly, the PPI and stakeholder groups that contributed throughout the study brought diverse skills and lived experience to strength the intervention.

5. *'Which approaches have resulted in interventions shown to be effective?'*

There is limited evidence of effective interventions in vascular surgery and specifically in PAD research. In line with other chronic conditions, effective interventions incorporate theory and are person-centred.

6. *'What resources are available for the intervention development?'*

The intervention was developed during my three-year NIHR Doctoral Research Fellowship based at Imperial College London. I independently completed all work related to this project, and I had funding available for training, PPI activities, printing materials, and use of clinical spaces. Hence, adopting a resource-intensive approach, such as the PBA, was feasible. However, combining the PBA with another time-consuming approach, such as the TDF would not have been feasible during this PhD. Additionally, I had previously utilised the PaPa for my pre-doctoral project, so it was more feasible to continue using a framework that I was familiar with. This enabled the smooth running of this study.

In summary, the PaPa and the PBA were selected to guide the development of the intervention. These two models complement each other by enabling a clear theoretical understanding of the target behaviours to be combined with a user-centred approach to intervention design. In this study, the PaPa will guide the identification of the most relevant determinants of adherence, while the PBA will ensure that intervention strategies derived from PaPA are developed and refined in ways that are acceptable, engaging, and feasible for the intended users. Together, the PaPA and PBA can create interventions that are both theoretically informed and meaningful, maximising effectiveness and engagement. These two frameworks have been used together in other adherence projects, in multiple clinical contexts, specifically for nicotine replacement therapy (164), breast cancer medications (165) and HIV prophylaxis (166).

2.4 Overview of the methodology for this thesis

Table 6 provides a detailed description of each stage of the PBA and the relevant projects that should be undertaken at each stage. In the intervention planning stage,

the behavioural analysis should be conducted by reviewing the literature and undertaking qualitative exploratory work to understand the barriers and facilitators to the problem in question (162). In the intervention design stage, the findings of the behavioural analysis are utilised to design the guiding principles for the intervention (162). Finally, in the optimisation stage, the intervention should be refined (using think-aloud interviews) and then further evaluated using a mixed-methods approach (162).

This PhD study will cover all PBA stages mentioned above (see Table 6 for an overview). However, the optimisation stage of this PhD will include only intervention refinement, given the limited time available to complete a mixed-methods evaluation during this NIHR Doctoral Fellowship.

Table 6 Use of the PBA in the development of the adherence intervention

Stage of intervention development and evaluation	Specific PBA activities useful at each stage	Activity	Additional activities
1. Intervention planning	• Synthesise previous qualitative studies of user experiences of similar interventions • Carry out qualitative research to elicit user views of the planned behaviour changes and intervention (including relevant previous experience, barriers and facilitators)	• Review of existing multi-component adherence interventions in the field (Chapter 3) • Survey of adherence levels (pre-doc) • Qualitative studies (pre-doc & Chapter 4)	• Freedom of information request for Claudication services in England (Chapter 5)
2. Intervention design	• Use themes arising from the intervention planning stage to identify key issues, needs and challenges the intervention must address • Create guiding principles, comprising (a) key intervention design objectives and (b) key distinctive features of the intervention needed to achieve objectives	• Use themes from qualitative study to identify key issues, needs and challenges that the PAD adherence intervention must address (Chapter 6) • Create guiding principles (Chapter 6)	
3. Intervention optimisation and evaluation of acceptability and feasibility	• Elicit and observe user reactions to every intervention element (e.g. using think-aloud techniques), iteratively modifying intervention to optimise acceptability and feasibility • Carry out detailed longitudinal mixed methods case studies of independent intervention usage	• Create PAD&Me intervention prototype (Chapter 7), conduct think aloud interviews and modify the intervention accordingly (Chapter 8) • Evaluation of the intervention is outside the scope of this PhD	

Figure 12 provides a visual overview of the research plan for this PhD. A detailed description of the projects undertaken for each stage is provided below. The detailed methodology for each project is described in their respective chapters.

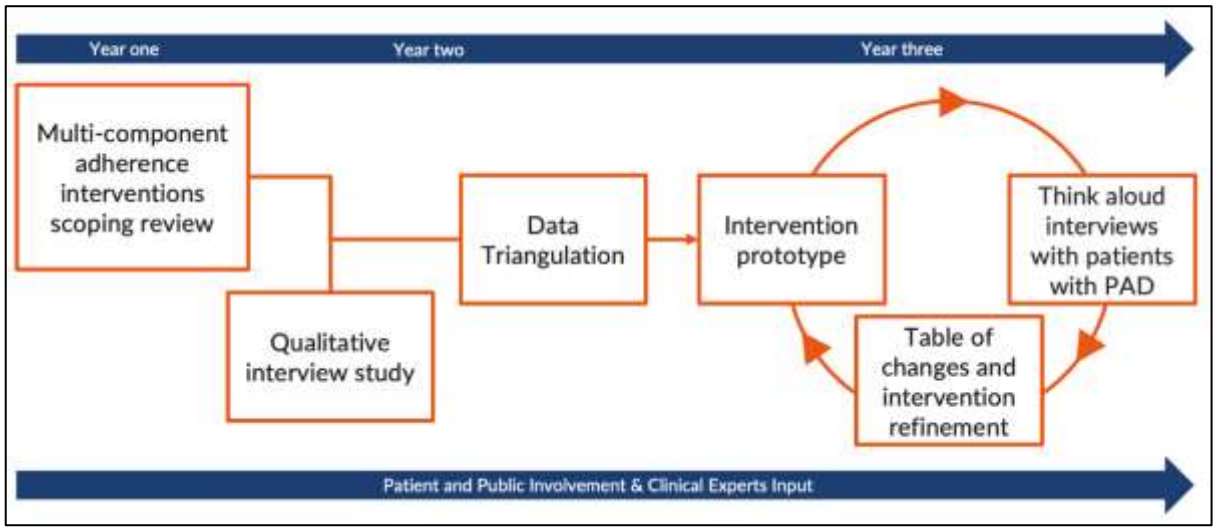


Figure 12 The Research Plan for this PhD study in line with the PBA

2.4.1 Stage 1: Planning

This phase identified key behaviour issues, needs, and challenges the intervention must address, informed by:

Chapter 3: Scoping review of existing multi-component interventions to support patients with PAD with their adherence to guideline-recommended treatment. Using the Joanna Briggs Institute (JBI) methodology for conducting scoping reviews, this review identified existing interventions, their content, delivery, and effectiveness, thereby identifying any gaps that needed to be addressed during this PhD. Additionally, it informed the topic guides for the qualitative data collection phase. The data were presented narratively and in tabular form, in line with the JBI guidance.

Chapter 4: Qualitative semi-structured interviews with patients with PAD, their relatives and healthcare professionals looking after patients with PAD to explore the treatment information and support patients receive and how these influence adherence, as well as the perceptions and practicalities that enable or hinder patients to adhere to their treatment plan. The study was informed by the PaPa framework. The data were

analysed thematically (inductive and deductive analysis) and presented as Perceptions and Practicalities.

Chapter 5: Freedom of information request describing the available services for intermittent claudication (IC) in England. This activity was conducted to better understand the clinical context prior to the development of the intervention. A questionnaire was sent to NHS Trusts in England to gather information on the availability and structure of IC clinics, SET, lifestyle and psychological support services. Descriptive statistics were utilised to analyse the data.

2.4.2 Stage 2: Development and Design

Chapter 6: Data triangulation and development of guiding principles. Findings from my pre-doctoral projects and the PhD qualitative study were triangulated to identify key adherence influences and the Guiding Principles for developing the theory-informed intervention (the PaPa).

Chapter 7: Intervention co-design. Three rounds of co-design workshops with patients and their relatives were undertaken to develop the intervention prototype. Stakeholder meetings were conducted between the patient workshops to ensure the intervention was in line with current NHS practice. The intervention prototype was produced, which was then optimised in Stage 3.

2.4.3 Stage 3: Intervention Optimisation

Chapter 8: Intervention user-testing. Qualitative think-aloud interviews were conducted with newly diagnosed patients with PAD to observe and describe their reactions to each element of the intervention. Content analysis was used to analyse the data. These were presented in a table of changes and were prioritised based on the Must have, Should have, Would have (MoSCoW) criteria. The intervention was then refined based on the patients' feedback.

2.5 Philosophical and theoretical considerations

Ontology describes how we experience the world around us, and the nature of reality, whereas epistemology describes knowledge of the world and how this knowledge is acquired (167). Philosophical assumptions underpin all research and influence how studies are designed and carried out (168). These assumptions are often described as a research paradigm or worldview, reflecting the researcher's fundamental beliefs and values. A paradigm is commonly defined by its position on ontology, which concerns the nature of reality; epistemology, which addresses how knowledge is generated and the relationship between the researcher and the object of study; and methodology, which refers to the approaches and methods used to conduct the research (168). Considering the ontological/epistemological continuum, my problem-solving personality aligns with the Pragmatism paradigm. As a pragmatist, I believe that research should generate practical knowledge that will contribute to changing and challenging existing norms and pathways (169). Pragmatism suggests that the methods for a project are chosen based on what best addresses the research questions; it is therefore often utilised for mixed or multiple methods designs (170, 171). Within pragmatism, problems are defined by those who experience them (for this project patients with PAD), supporting the development of research questions that are relevant and useful in practice. Pragmatism accepts that reality may be understood in different ways, while acknowledging that knowledge is shaped by human experience and context, and there are no absolute truths (170, 171).

In line with this paradigm, my research and methodology focus on engaging with patients, relatives, and stakeholders (described in detail in section 2.6). In that way, I can understand the issue of adherence from their perspectives and interactions. As already described, this PhD study utilises multiple methods of data collection and approaches to data analysis, to ensure a pragmatic, holistic approach to understanding and addressing the issue of treatment adherence in patients with PAD.

2.6 Patient and Public Involvement and Stakeholder Engagement

2.6.1 Overview

Patients with lived experience of PAD were at the core of this project. Patient and public involvement discussions informed every stage of the research, from the early planning of the pre-doctoral project through to the development and implementation of the PhD study.

The PPI was established during my pre-doctoral fellowship to ensure that the project was patient-centred and clinically relevant. The group consisted of six patients with PAD (ages 56-72), including one woman and an individual from an ethnic minority. The group met every three months to discuss the project's progress and provide feedback. All meetings were held virtually as per members' request. Meetings were scheduled according to patients' preferred times, mainly in the late afternoon, and offered both virtually and in person, with most members opting for virtual participation due to time and travel constraints. Individual discussions were also arranged for those unable to attend group meetings.

Before each meeting, participants received written instructions outlining the meeting's expectations. Patients interested in receiving PPI training or becoming PPI ambassadors were given the opportunity to undergo training provided by the Imperial College Patient Experience Research Centre. To report the PPI activities, the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) checklist was used (47) (see Appendix 2). All members were reimbursed for their involvement in line with National Institute for Health Research (NIHR) PPI Guidance, and these expenses were covered by my NIHR Fellowship.

2.6.2 Project Planning

Initial discussions with patients with PAD and their clinicians took place in October 2020, during the planning phase of my pre-doctoral project. The discussions took place at Charing Cross Hospital, Imperial College Healthcare NHS Trust (ICHNT), and

involved 10 patients with PAD, one nurse, two doctors and two physiotherapists. All reported treatment adherence as challenging, mainly due to the complexity of the PAD conservative treatment plan and the lack of clear guidance on how to promote behaviour change.

The pre-doctoral PPI group subsequently informed the development of this PhD project. Before submitting the doctoral funding application, the group met online to review the proposed research plan. All group members emphasised the need for intervention strategies that would support their individual treatment needs and address their concerns. Regarding the content of treatment information and support, the advisory group concluded that each member has different priorities, emphasising the importance of tailoring the behaviours they choose to prioritise, which is what led me to consider designing person-based intervention strategies. Regarding the study context, the patients expressed a preference for the intervention strategies to be implemented in secondary care settings, as they perceived the level of vascular expertise to be higher there than in primary care. This rationale was then further explored through qualitative interviews conducted during the PhD project (see Chapter 4). Regarding intervention delivery, patients preferred receiving booklets or one-to-one sessions with their clinicians.

In relation to the qualitative approach, five out of six members of the patient advisory group expressed discomfort with discussing their adherence challenges in a focus group setting and preferred individual interviews. Relatives of patients with PAD also preferred one-to-one interviews, and some reported they would not want to take part in dyadic interviews as they would feel uncomfortable discussing their challenges and perspectives in front of patients. Two patients from the PPI group and a healthy volunteer from the North West London NIHR Research Support Service reviewed the plain English summary for the doctoral funding application and provided written feedback via email, which greatly benefited the project.

2.6.3 Project Conduct

Throughout the duration of this work, patients remained actively involved in the study design and dissemination of results (see Table 7). During my PhD, I also established a collaboration with the Arterial PPI Registry at Leicester University, which has access to a national pool of patients with PAD and their relatives. In this way, I was able to expand my PPI group further and allow more patients, from both rural and urban centres, to participate in this project. By collaborating with the PPI Registry, I identified four additional patients with PAD, two of whom have experienced CLTI, to further advise on the study. Specifically, three members of the PPI group participated in the ethics submission process by reviewing and providing written feedback via email on the Plain English Summary and the Patient Information Sheet. Three other members of the group provided written and verbal input via telephone for the development of the interview topic guide. Once the initial themes were developed, they were presented to the PPI group to check whether they matched or differed from their experience and whether I needed to consider additional questions for inclusion in the topic guide for subsequent interviews.

Table 7 Summary of PPI group involvement in this research

PPI Group Involvement	
Scoping review	• Discussion of research questions • Discussion of findings in relation to their experiences so these can be further explored during the interviews
Qualitative study	• Discussion of research questions • Discussion of research method • Preference for one-to-one interviews • Provided feedback on plain English summary, patient information sheets, topic guide • Piloted part of the topic guide • Validation of themes
Data Triangulation	• Discussion of identified adherence determinants
Co-design workshops	• Discussion of co-design workshops plan
Think-aloud interview study	• Provided feedback on plain English summary, patient information sheets, topic guide

	• Piloted sections of the topic guide
Overall PhD findings	• Review of findings from overall PhD
Dissemination	• Creating lay summaries of study results

In collaboration with the patient advisory group, a lay summary of the study results is being created to disseminate the results to PAD patients and the general public. Two members of the PPI group have agreed to help with this. The lay summary will be distributed through ICHNT and charities, such as Circulation Foundation and Leg Matters to reach a broader audience.

Chapter 3. Scoping review of multicomponent interventions designed to support adherence to guideline-recommended therapy in patients with peripheral arterial disease

3.1 Introduction

This chapter provides an overview of the content and delivery of multicomponent interventions that have been designed to support adherence in patients with PAD. This complements the broad literature review reported in Chapter 1, which provides background to the overall project. This scoping review was the first part of the intervention planning phase for the PhD. By synthesising the available evidence, this review provided critical insights that shaped the design and focus of the subsequent qualitative study, described in Chapter 4, ensuring it targeted existing research gaps.

As described in Chapter 1, adherence to the guideline-recommended treatment plan for patients with PAD is a complex issue that should be addressed holistically, rather than focusing on individual aspects of the treatment plan. Given the frequent co-occurrence of various health behaviours, focusing on multiple behaviours has the potential to better support the management of patients living with chronic conditions (100, 101). Although a few studies of multi-component interventions to support treatment adherence exist, there is no clear consensus regarding their optimal content, delivery, and context. Hence, there was a need to map out interventions that support treatment adherence in patients with PAD, providing a theoretical foundation to guide my research and inform the development of an enhanced care and clinical pathway. Following a preliminary search of Cochrane, PROSPERO, Embase (Ovid), MEDLINE (Ovid), APA PsycINFO (Ovid) and CINAHL (Ebsco) databases, no current or ongoing scoping or systematic reviews were identified that explore multi-component interventions to support treatment adherence in patients with PAD. Available

systematic reviews have focused on patients' disease experiences (18, 92), smoking cessation interventions (172), or supervised exercise programme dose and attendance (59, 173). Additionally, during the preliminary search (October 2023), a systematic review protocol (PROSPERO, CRD42023416816) was identified for a review of interventions addressing adherence to cardiovascular medications in PAD (174) . This review was subsequently published in November 2025 (175), after this PhD scoping review was completed and published. None of the above reviews focus on the behavioural aspects of interventions to address all treatments, nor systematically describe the components of such interventions.

3.2 Aim and Objectives

Aim: To systematically synthesise evidence on multicomponent adherence interventions for patients with PAD, with a focus on intervention components, theoretical frameworks, outcomes used, and barriers to implementing such interventions within clinical pathways.

Review question: What multicomponent interventions have been developed to support adherence and uptake of medications (antiplatelet, lipid-lowering and antihypertensive agents), smoking cessation, diet, weight management and/or physical activity in patients with PAD?

Objectives:

1. To assess the key characteristics (e.g., mode of delivery, behaviour change techniques) of multicomponent interventions to support treatment adherence in patients with PAD, and which of these characteristics appear to be effective in supporting adherence
2. To assess if any interventions developed using a theoretical framework or designed to address specific determinants of non-adherence
3. To assess if specific determinants of non-adherence were identified, and whether and how these were targeted during the intervention
4. To assess how adherence is defined and/or measured in these interventions

5. To assess what helps or hinders the implementation of these interventions in clinical practice

3.3 Methods

3.3.1 Overview and rationale for study design

Various review methodologies are available (176). Table 8 presents the primary methodologies considered for this review, selected for their comprehensive guidance and structured processes that help minimise bias (176-179).

As this specific review was focused on answering a broader question, a systematic review or a rapid review did not seem appropriate. A scoping review methodology was chosen for the following key reasons. Multi-component interventions are likely to be complex, and their contexts, behavioural underpinnings and active characteristics need to be clearly defined. A scoping review can provide a comprehensive overview of the available literature and the study's focus (179). Typically preceding a systematic review, it lays the groundwork for guiding decision-making, particularly regarding intervention effectiveness (179). Furthermore, the scoping review will provide a detailed perspective on existing strategies, identifying gaps for future research on multicomponent adherence interventions. These findings will inform the co-production of a personalised behavioural multicomponent intervention to support adherence in PAD patients, contributing to the JLA PAD research priorities.

The Arksey and O'Malley Scoping Review Framework (180) and the Joanna Briggs Institute (JBI) Scoping Review Framework (181, 182) are two widely used methodologies for conducting scoping reviews, but they have some key differences. The comparison between the two methodologies is presented in Table 9. Both frameworks are similar and widely used, however the JBI framework was chosen for this review as it adds methodological rigour, focusing on transparency and protocol development. The JBI approach is considered more robust for ensuring systematic documentation and reproducibility, aligning it with systematic review standards.

Table 8 Key review methodologies considered

Review methodology	Aim	Searches	Evidence included	Need for Critical appraisal	Analysis & Synthesis	Time & Resources
Systematic Review (177)	Identify, appraise, and synthesise peer-reviewed evidence to address specific research question(s)	Rigorous, structured, comprehensive process	Peer-reviewed empirical research that meet pre-determined eligibility criteria	Mandatory, rigorously completed by at least two reviewers	Guided by the type of included studies, often including numerical analysis (i.e. meta-analysis)	High
Scoping Review (179)	Determine the scope or coverage of the literature on a particular topic, providing an overview of the available evidence. Usually answers broader research question(s)	Broad and comprehensive search across multiple databases and grey literature	Peer-reviewed empirical research and grey literature that meets pre-determined eligibility criteria	Not mandatory, depending on the research question.	Mapping and summarising the evidence, often using tables, graphs and narrative synthesis	High
Rapid Review (178)	Simplified systematic review methods to address specific research question(s) within a short timeframe	Similar to systematic reviews, but usually limited due to limited time and resources	Peer-reviewed empirical research that meets pre-determined eligibility criteria	Mandatory but not as rigorously completed, e.g. only one reviewer completes it, due to limited time and resources	Similar to scoping reviews	Low

Table 9 Scoping review methodological frameworks considered.

Framework	Purpose/Aim	Protocol	Methodological Rigour	Stakeholder/PPI engagement	Flexibility
Arksey and O'Malley (2005) (180)	Developed to provide a systematic approach for mapping the breadth of existing literature in a given field, particularly when the topic is broad or not well-defined. Its focus is on identifying gaps in knowledge and providing a foundation for future research.	Not required, up to the discretion of the researcher	Flexible and adaptable framework, but it lacks clear guidance on the methodological rigour, especially in terms of study selection and data extraction. There is less emphasis on systematically documenting decisions.	Optional but suggested as a way to ensure that the findings are relevant to stakeholders.	More flexible and less structured, allowing for adaptation based on the needs of the review.
Joanna Briggs Institute (181)	Developed to refine and build upon Arksey and O'Malley's methods, adding more rigour, structure, and clarity. It emphasizes not just mapping the evidence but also ensuring that scoping reviews align closely with best practices for systematic reviews, including a more explicit focus on transparency, reproducibility, and stakeholder involvement.	Required	Associated with a higher methodological rigour with predefined inclusion/exclusion criteria, protocol development, and data extraction forms. It also recommends transparency in reporting and aligning the review to the PRISMA guidelines.	Encouraged throughout, particularly in developing the research question and protocol, ensuring that the scoping review addresses practical and policy needs effectively.	While still flexible, the JBI framework provides more structure, with clear guidance on how to conduct each step, ensuring consistency and replicability.

Abbreviations: JBI: Joanna Briggs Institute; PPI: Patient & Public involvement; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

3.3.2 Search strategy

The search strategy aimed to identify both peer-reviewed and non-peer-reviewed primary studies. The 3-phase search strategy, as recommended by the JBI (181), was adopted for this review. An initial literature search was conducted on MEDLINE (Ovid) to identify articles on the topic. With the support of a senior health sciences librarian, the text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles, were used to develop a full search strategy for MEDLINE (Ovid) (see Table 10). The key search concepts were: PAD, adherence and intervention. The search strategy, including all identified keywords and index terms, was adapted for each included information source. Phase 1 of this scoping review included searching the following databases: Embase (Ovid), MEDLINE (Ovid), Cochrane Library, PsycINFO (Ovid), CINAHL (EBSCOhost), and Web of Science Core Collection.

To minimise publication bias, unpublished grey literature was searched for (phase 2) on ProQuest Dissertations and Theses Global (ProQuest) and Google Academic. The search strategy used the fixed database terms “Peripheral Arterial Disease” and “Patient Compliance”, following consultations with an academic librarian. Although adherence is a more appropriate term than compliance, this option was not available within the controlled vocabulary of these databases. Therefore, the term compliance was used to capture the relevant literature. The intervention term was not included in order to maximise sensitivity and ensure that potentially relevant unpublished studies were not excluded due to inconsistent or poorly indexed reporting of interventions in grey literature sources. Similarly, registries such as clinicaltrials.gov were searched, using key terms “Peripheral Arterial Disease” and “Patient Compliance” to identify registrations of prospective clinical trials or study protocols of multicomponent interventions.

In the third search phase, the reference lists of articles included in the review were screened for additional papers that could meet the eligibility criteria. No language limits were applied, to minimise the risk of missing relevant studies. Given that English is the

predominant language for scientific communication (183), it was anticipated that most of the research would be available in this language. Google Translate would be employed for papers in other languages in instances requiring translation. Additionally, the proficiency of two reviewers, who are native Greek and Spanish speakers, respectively, would be leveraged, if necessary, to facilitate comprehension and interpretation. As the first PAD guidelines were published in 2007 (184) the search was limited from 2007 to the date of the search (15th January 2024). A repeat search was conducted on the 12th of June 2024, before submitting the manuscript to the Vascular Medicine Journal.

Table 10 Medline (Ovid) Search strategy conducted on 15th January 2024

Search	**Query**	**Records retrieved**
#1	Peripheral Arterial Disease/ OR (Peripheral Arter* adj2 Disease*).mp. OR Intermittent Claudication/ OR claudication.mp. OR PAD.mp.	60,859
#2	"treatment adherence and compliance"/ OR Patient Compliance/ OR Treatment Refusal/ or Patient Dropouts/ OR exp Attitude to Health/ OR Patient Satisfaction/ OR medication adherence/ OR patient participation/ OR (Dropout or drop-out or drop out).mp. OR Uptake.mp OR Adhere*.mp.	1,162,793
#3	Educat*.mp. OR (patient-education or "patient education").mp. OR ("patient cent*" or patient-cent*).mp. OR (patient-focus* or "patient focus*").mp. OR (“management plan" or management-plan).mp. OR Behavio?r*.mp. OR Cognitive Behavio?ral Therapy/ or Motivational Interviewing/ OR "behav* intervention*".mp. OR Intervention*.mp. OR Intervention* study or Complex intervention*.mp. OR Health program*.mp. OR Health promotion/ OR "follow-up*".mp. OR “follow-up*” adj3 communit* OR “Follow-up” adj3 care OR Exercise Therapy/ OR "exercise program*".mp. OR Support program*.mp. OR behav* change.mp OR Nurs* led.mp. OR nurs* based.mp. OR telephone based.mp. OR (phone adj2 "follow up").mp. OR Telehealth.mp. OR mHealth.mp. OR community based.mp. OR Multidisciplinary.mp. OR multicomponent.mp. OR multifactorial.mp. OR (rehab* adj2 program*).mp.	5,862,966
#4	#1 AND #2 AND #3	1049
Limit added for papers published between 2007- present		848

3.3.3 Eligibility criteria

The eligibility criteria for scoping reviews are generally structured similarly to those of systematic reviews, based on the review's aims and questions. Traditionally, systematic reviews use the PICO (participants, intervention, comparator, outcomes) framework (177). Given that scoping reviews have broader aims, their eligibility criteria are framed differently using the Participants, Concept, Context framework (181).

3.3.3.1 Participants

This review considered studies describing interventions designed for patients diagnosed with PAD (aged ≥ 18 years), regardless of age, gender, ethnicity or comorbidities. Studies were included where PAD is defined by the ankle-brachial index (ABI) measurement (ABI < 0.9) or diagnostic equivalent, as well as studies in which PAD was not defined using a diagnostic equivalent but report that participants had PAD, asymptomatic PAD, IC or CLTI. Studies involving patients with neurogenic claudication were excluded. Studies were also excluded if they included participants with more than one cardiovascular condition, including PAD, in which PAD data could not be isolated.

3.3.3.2 Concept

Studies describing multicomponent interventions designed to support adherence and uptake of medications (antiplatelet, lipid-lowering and antihypertensive agents), smoking cessation, diet, weight management and/or physical activity in patients with PAD were included. For this review, for an intervention to be considered as a multiple health behaviour change intervention, it would have to target two or more behavioural domains (e.g. medication and smoking), instead of multiple aspects of one behavioural domain (e.g. exercise uptake and calories burned). Interventions describing single-component interventions were excluded. All interventions were considered, regardless of delivery mode, or who delivered the intervention. This could include digital (e.g. mobile Health, remote monitoring) and non-digital interventions, as well as home or

hospital-based interventions. Interventions could be psychosocial, behavioural, educational or pharmacological, as well as group or individual-based.

3.3.3.3 Context

Studies conducted in any geographical location or healthcare setting (e.g. primary or secondary care) were included in this review.

3.3.3.4 Types of sources

This scoping review considered grey literature and peer-reviewed primary studies (quantitative, qualitative, and mixed-methods) describing the development, implementation, or evaluation of interventions that support treatment adherence in patients with PAD, published since 2007. Quantitative studies such as experimental and quasi-experimental studies, including randomised and non-randomised controlled trials, blinded or non-blinded were included. Intervention protocols, as well as studies (qualitative or surveys) evaluating the feasibility, and/or fidelity, and/or acceptability of interventions, were also included if data on interventions could be extracted. Reviews (literature, scoping, rapid or systematic), meta-analyses, case reports, opinion articles and conference abstracts/posters were excluded. However, the reference lists of relevant reviews were screened for potentially eligible studies.

3.3.4 Study selection

Following the search, references from all individual databases were imported into Covidence software (Veritas Health Innovation, Melbourne, Australia), where duplicates were automatically removed. After automatic deduplication, any remaining duplicates were manually removed by the lead researcher (SL). To strengthen the review process, three reviewers with diverse backgrounds, including cardiovascular (SL), psychology (JR), and public health (TD), independently screened records for inclusion. The lead researcher (SL) screened 100% of records at both the title/abstract and full-text stages. At the title and abstract stage, a second independent reviewer also screened 100% of records to determine eligibility. Following this, full texts of potentially

eligible studies were retrieved. During full-text screening, SL screened all papers, while each of the other two reviewers independently screened 50% of the papers to confirm inclusion decisions.

Reviewers were blinded to each other's screening decisions. The interrater reliability using the Cohen's kappa statistic was 0.52 for title and abstract screening, indicating moderate agreement between reviewers (185). As for full-text screening, the interrater reliability was 0.87, indicating almost perfect agreement between reviewers (185). Any disagreements that arose between the reviewers at each stage of the selection process were resolved through discussion or with a fourth reviewer (academic supervisor). The results of the search are presented in the PRISMA flow chart.

3.3.5 Data extraction, Data synthesis and Integration

Data were extracted using a bespoke template in Covidence for each paper, independently by two reviewers and then compared for consensus. The tool was used to extract: study characteristics (title, authors, year of publication, aim, study design, country of origin and setting), participant characteristics (age, gender, ethnicity, comorbidities), and key results. Additionally, the template for intervention description and replication (TIDiER) framework (see Table 11) was adapted to describe the characteristics and details of the interventions (147). Finally, the content of each intervention was mapped onto the Behavioural Change Taxonomy v.1 (102) (see Appendix 1) to detail and categorise the behaviour change techniques (BCTs) used. The BCT Taxonomy v.1 (102) is a validated classification system categorising 93 behaviour change techniques into 16 overarching categories (see Appendix 1). This taxonomy provides definitions and examples of the 'active ingredients' that facilitate behavioural change. This standardised approach aids the classification of interventions and enables the replication of techniques in research and practice, regardless of frameworks or theories employed to develop the interventions (102). For this review, the lead researcher (SL) independently coded every BCT directed at patient behaviour reported in an intervention (note that interventions can include multiple BCTs). A second reviewer (TD) also independently coded BCTs for 100% of these studies, and

these were cross-checked by a third reviewer (JR or GJ). All reviewers had previously undertaken training on the BCT Taxonomy, offered by the BCT Taxonomy website (186). To increase validity, reviewers were blinded to each other's extracted data until the consensus stage. Any conflicts were resolved through discussion and an additional reviewer.

Table 11 The TIDiER Framework (Adapted from Hoffman, 2014) (147)

Item	**Description**
Brief Name	Provide the name or a phrase that describes the intervention.
Why	Describe any rationale, theory, or goal of the elements essential to the intervention.
What	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).
	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.
Who provided	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.
How	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.
Where	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features
When & how much	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.
Tailoring	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.
Modifications	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).
How well	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.
	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

A narrative synthesis was conducted, following the JBI guidance (181), and the characteristics of the included studies were presented in tabular and narrative formats.

The intervention synthesis was guided by the TIDieR framework (147). The full scoping review is reported following the PRISMA scoping review guidance (182).

3.3.6 Quality Assessment

Assessing the quality of the papers was not within the scope of this review (187). Existing methodological frameworks for scoping reviews (180, 187, 188) suggest that a formal quality assessment of included studies is not required. Arksey and O'Malley (180) argued that critical appraisal is not integral to the scoping review process, though they acknowledge this as a limitation of scoping reviews. The JBI methodology (187), which was adopted for this scoping review, does not mention anything in their guidance about undertaking a quality assessment.

The absence of quality appraisal may limit the ability to comment on the robustness of the evidence base and could restrict the translation of findings into policy or practice (189). However, the purpose of this scoping review was to map the breadth of research activity and identify gaps in the literature, rather than evaluate the research. While some researchers recommend conducting a quality assessment in scoping reviews to assess methodological weaknesses (190, 191), given the aim of scoping reviews, all studies should be included regardless of their quality (180, 187, 188). Therefore, while critical appraisal can add value in some contexts, it was not essential for achieving the primary objectives of a scoping review, which was to assess what multi-component interventions currently exist, rather than critique their quality.

3.4 Results

3.4.1 Study selection

The initial search identified 3,557 studies, of which 878 were removed as duplicates (see Figure 13). Of the 2,681 studies reviewed at the title and abstract stage, 35 met the eligibility criteria for full-text review. At the full-text stage, we identified three potentially relevant studies for which only abstracts were available (192-194). Despite contacting

the authors and searching for full texts, we could not obtain them; therefore, these studies were excluded from the synthesis. Finally, 18 papers were identified for data extraction and synthesis. Of these, three studies had more than one relevant publication for inclusion (195-197). Where both the protocol and the study results were published separately, these were merged at the data extraction level. Hence, 15 studies were included in the review (78, 195-208).

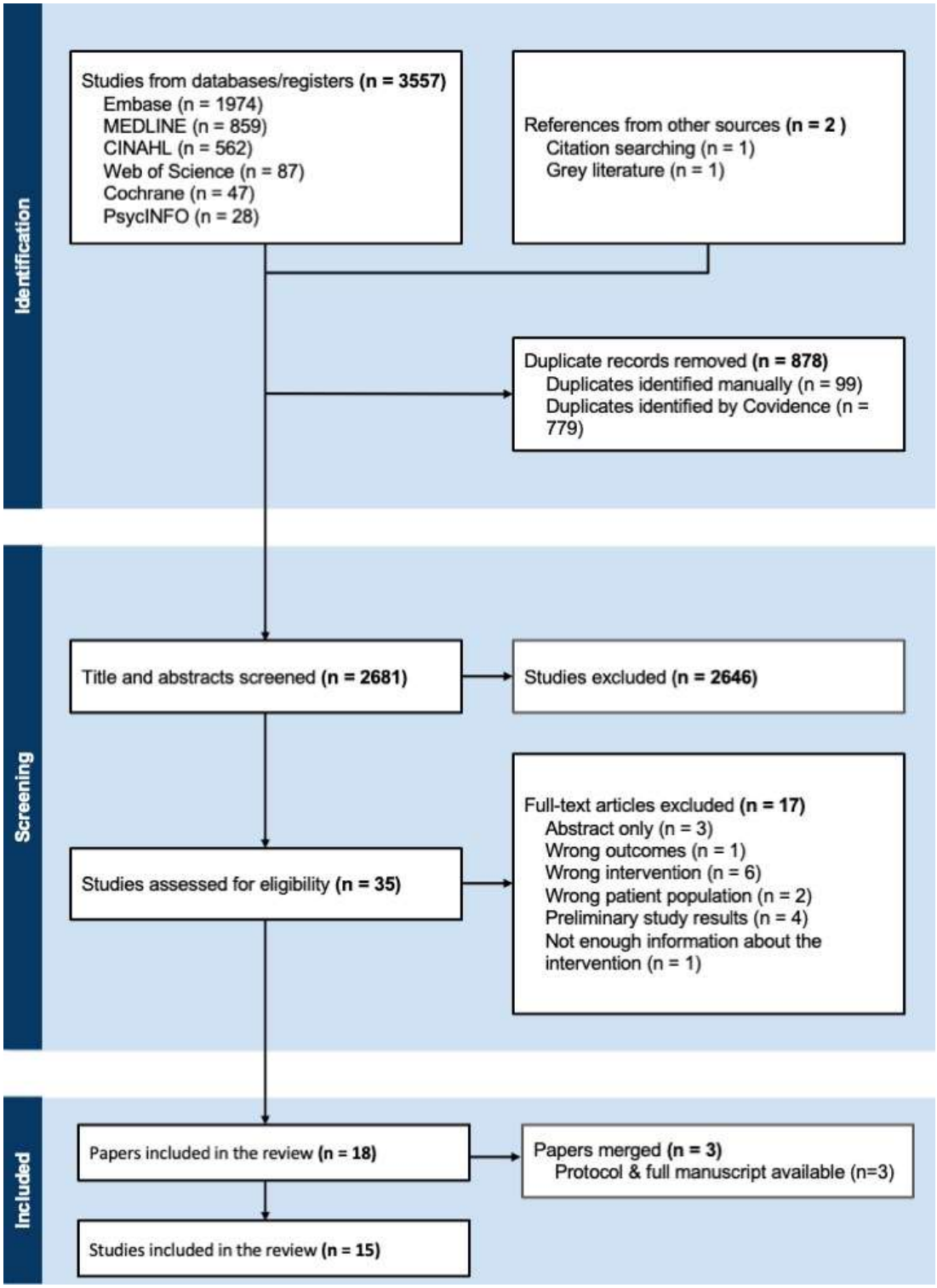


Figure 13 PRISMA Flow Chart

3.4.2 Study Design and Country of Origin

Study designs included two protocols for randomised controlled trials (RCTs) (78, 206), one intervention development (198), one quasi-experimental study (208), five RCTs (195-197, 202, 204), and six observational studies (199-201, 203, 205, 207). Around half of the studies (7/15) were undertaken in Europe (196, 197, 199, 202, 204, 206, 207), three studies in the UK (78, 201, 205), two in the USA (203, 208), two in Canada (195, 200) and one in Latin America (198). A summary of the included studies is presented in Table 12.

Table 12 Summary of included study characteristics

Author & Year	Setting	Setting & Study design	Study population					
			Number	**Gender n (%) male**	**Age (mean ± SD)**	**Ethnicity**	**PAD stage**	**Comorbidities n (%)**
Coca-Martinez M et al., 2023	Secondary care	Pilot RCT - single-blind, 2-arm, parallel, pilot-RCT	24 Intervention 12 Control 12	Intervention 6 (50) Control 4 (33.3)	Intervention 71.7 ± 7.4 Control 69.5 ± 8.1	Not reported	Pre-vascular intervention /surgery*, moderate to severe claudication. All patients were medically optimised and had stable PAD.	Intervention IHD 5 (41.7), HTN 10 (83.3), T2DM 7 (58.3), COPD 2 (16.7), CKD 2 (16.7), Obesity 4 (33.3) Control IHD 5 (41.7), HTN 11 (91.7), T2DM 4 (33.3), COPD 2 (16.7), CKD 2 (16.7), Obesity 7 (58.3)
Mendez CB et al, 2019	Secondary care	Intervention development	N/A – intervention development	N/A – intervention development	N/A – intervention development	N/A – intervention development	No mention of disease stage	N/A – intervention development
Cucato G et al 2022	Secondary care	Protocol for a pilot RCT	Target recruitment: 60	N/A - protocol	N/A - protocol	N/A - protocol	Non-severe PAD or CLTI	N/A - protocol

Haile ST et al., 2023	Secondary care	Non-blinded RCT	204 Intervention 99 Control 105	110 (54) Intervention 59 (60) Control 51 (49)	Intervention age median (IQR) = 71 (66 to 76) Control age median (IQR)= 72 (69 to 77)	Not reported	Patients with IC post vascular intervention /surgery*	Intervention IHD 34(34), HF 4(4), HTN 83 (84), COPD 17 (17), CVA/TIA 15 (15), CKD 1 (1), T2DM 32 (32), Previous vascular intervention 33 (33) Control IHD 31 (29.5), HF 10 (9.5), HTN 91 (86.7), COPD 19 (18.1), CVA/TIA 16 (15.2), CKD 3 (2.9), T2DM 34 (32.4), Previous vascular intervention 37 (35.2)
Höbaus C et al., 2017	Secondary care	Longitudinal prospective follow-up study	702 Intervention 370 Control 332	Intervention 245 (66) Control 206 (62)	Intervention 69.1 ± 10.6 Control 66.7 ± 12.4	Not reported	Stable PAD patients.	Intervention CAD 117 (32), MI 60 (16), Carotid artery disease 145 (39), HTN 340 (92), Hypercholesterolaemia 359 (97), T2DM 108 (29.2) Control

								HTN 256 (77), Hypercholesterolaemia 276 (83), T2DM 111 (33.4)
Hussain MA et al., 2016	Secondary care	Observational cohort study	791 Intervention 290 Control 501	Intervention 180 (62.1) Control 316 (63.1)	Intervention 67.9 ± 10.4 Control 68.2 ± 11.2	Not reported	Symptomatic PAD, post vascular intervention /surgery*	Intervention HF 21 (7.2), Stroke 16 (5.5), MI 19 (6.6), CAD 58 (20), COPD 11 (3.8), CKD 24 (8.3), Diabetes 55 (19) Control HF 62 (12.4), Stroke 28 (5.6), MI 49 (9.8), CAD 111 (22.2), COPD 18 (3.6) CKD 63 (12.6), Diabetes 123 (24.6)
Matthews S et al., 2016	Primary care	Audit	54	N/A	N/A	Not reported	Symptomatic PAD with no recent intervention.	N/A
Rosenberg Y & Behrendt CA., 2023	Secondary care	Single centre pilot RCT	40 Intervention 20	27 (67.5%) Intervention 12 (60)	72.5 ± 9.0 Intervention 74.2 ± 8.5	Not reported	Symptomatic PAD patients of all stages who have	Intervention IC 9 (45), CLTI 11 (55), Previous revascularisation intervention 18 (90),

			Control: 20	Control 15 (75)	Control 70.9 ± 9.5		undergone vascular intervention /surgery*	Previous minor amputation 1 (5), Any diabetes 4 (20), Diabetes under pharmacological treatment 2 (10), Kidney failure 7 (35), Dialysis 1 (5), CAD 10 (50), MI 6 (30), HF 3 (15), Current cardiac dysrhythmia 3 (15), Current or former cardiac dysrhythmia 5 (25), HTN 18 (90) Control IC 6 (30), CLTI 14 (70), Previous revascularisation intervention 13 (65), Previous minor amputation 3 (15), Any diabetes 7 (35), Diabetes under pharmacological treatment 7 (35), Kidney failure 8 (40), Dialysis 4 (20),

								CAD 6 (30), MI 4 (20), HF 2 (10), Current cardiac dysrhythmia 5 (25), Current or former cardiac dysrhythmia 7 (35), HTN 17 (85)
Siercke M et al., 2021	Combination of primary and secondary care	RCT	118 Intervention 46 Control 47	Intervention 23 Control 21 Female control 26 (44), female intervention 23 (39)	Intervention 70.5 ± 7.0 Control 70.1 ± 7.3	Not reported	Medically managed PAD patients who have not had a previous vascular intervention /surgery*	Intervention Diabetes 11 (19), MI 9 (15), Congestive HF 6 (10), CVA/TIA 7 (12), COPD 8 (14), Psoriasis 2 (3), Prolapsed disc 7 (12), Atrial flutter/fibrillation 5 (8), Spinal stenosis 3 (5), Osteoporosis 3 (5), Back pain, undiagnosed 2 (3), Osteoarthritis 6 (10), HTN 44 (75) Control Diabetes 7 (12), MI 9 (15), Congestive HF 6 (10), CVA/TIA 8 (14), COPD 14 (24), Psoriasis 5 (8)

								Prolapsed disc 7 (12), Atrial flutter/fibrillation 5 (8), Spinal stenosis 4 (7), Osteoporosis 4 (7), Back pain, undiagnosed 1 (2), Osteoarthritis 9 (15), HTN 42 (71)
Sutton M et al., 2018	Primary care (private cardiology practice)	Quality Improvement / prospective observational study	24	10 (41.7)	66.92 ± 8.75	White 18 (75)	PAD patients who required endovascular intervention	HTN 17 (70.8) T2DM 12 (50)
Davins Riu M et al., 2018	Secondary care	Pilot RCT - pragmatic, parallel, randomized controlled trial	150 Intervention 75 Control 75	Intervention 68 (90.7) Control 68 (90.7)	Intervention >70 years old 28 (46.7) <70 years old 47 (52.2) Control: <70 years old 43 (47.8) >70 years old 32 (53.3)	Not reported	PAD patients with IC symptoms	Intervention Diabetes 31 (41.3), HTN 60 (80) Control Diabetes 34 (45.3), HTN 58 (77.3)
Hatfield J et al., 2008	Secondary care	Service evaluation / prospective	78	51 (65.4)	median age, 65 years	Not reported	Patients with newly diagnosed IC	Diabetes with a HbA1c > 7.0%: 6 (11.7) HTN 44 (56.4)

		observational study			(IQR: 56–74 years)			
Elfghi M et al., 2021	Combination of primary and secondary care	Protocol for a randomised, parallel group, active-control trial	Target recruitment: 208 patients (104 per arm)	N/A - protocol	N/A - protocol	N/A - protocol	Symptomatic PAD patients	N/A - protocol
Lovell M et al., 2011	Secondary care	Quasi-experiment (before-after) study	103	63 (61)	58	Not reported	Symptomatic PAD	MI 17 (16.7) Diabetes 35(34)
Fallon et al., 2024	Secondary care	Prospective, observational, single centre study	114	88 (77.2)	median age 66 years (IQR: 59.80-70.00 years)	Not reported	Symptomatic PAD, post-vascular intervention /surgery *	HTN 81 (71.1) T2DM 29 (25.4)

*No further information on the type of vascular surgical intervention was provided by the study

Abbreviations: ABI: ankle-brachial index; CAD: Coronary artery disease; CKD: Chronic kidney disease, CLTI: chronic limb-threatening ischemia; CVA: Cerebrovascular accident,; COPD: Chronic obstructive pulmonary disease; IC: Intermittent Claudication; IHD: Ischaemic heart disease; HF: Heart Failure, HTN: Hypertension; MI: Myocardial infarction; T2DM: Type 2 diabetes; TIA: Transient ischaemic attack; PAD: Peripheral arterial disease; RCT: Randomised controlled trial

3.4.3 Participant characteristics

The included studies encompass a total of 2,462 patients with PAD (60.4% male). Three studies excluded patients who did not speak English or the language of the country where the study was conducted (195, 202, 206), whilst another study excluded those unable to read and write (203). This same study was the only one to report the ethnicity of the participants (203). Most studies included patients with stable claudication, both before (195, 197, 205) or after vascular surgery (200, 202, 207), while some did not report the patients' previous vascular surgery history (78, 198, 204, 206, 208). Patients with severe claudication and CLTI were excluded from five studies (78, 195, 199, 201, 207). The selection criteria for each study are presented below in Table 13. This variability in selection criteria highlights the lack of consistency in defining eligible PAD participants across studies, which may affect the generalisability of findings and the design of future interventions. It also suggests that certain groups are under-represented in PAD research, particularly non-native speakers, those with lower literacy levels and those with advanced disease. Hence, current findings may not be applicable to real-world, diverse patient populations.

Table 13 Selection criteria of included studies.

Author & Year	**Selection criteria**	
	Inclusion	**Exclusion**
Coca-Martinez M et al., 2023	PAD patients (>50 y.o) affected by moderate to severe intermittent claudication as evidenced 1) clinically by functional limitations in walking activity and symptoms consistent with IC; 2) anatomically, by imaging evidence of stenosis below the inguinal ligament; and 3) hemodynamically, by an ABI ≤0.80 of the index leg	1) Ischemic rest pain, ulceration or gangrene in the index leg 2) Significant lesion(s) affecting the common iliac or the external iliac vessels 3) Planned surgical bypass 4) Urgent or emergent open surgery repair 5) Prior interventions on the index leg 6) Unable to speak English or French 7) Premorbid conditions that precluded exercise and fitness assessments

Mendez CB et al, 2019	PAD diagnosis	N/A - intervention development
Cucato G et al 2022	1) Diagnosis of PAD confirmed by ABI <0.90 in one or both limbs 2) Age>=40 3) Able to walk distance >50m, 4) Live in an area deemed in lowest 30% of super output area from Office of National Statistics	1) CLTI 2) Short claudication distance <50m 3) Severe heart disease (Grade III or IV, New York Heart Association) 4) Severe ischemic or haemorrhagic stroke or neurodegenerative diseases 5) Severe HTN (systolic blood pressure of more than 180 mm Hg, and diastolic blood pressure of more than 100 mm Hg) 6) Uncontrolled cardiac disease (presence of complex arrhythmias, unstable angina during the previous month and myocardial infarction during the previous month) 7) A resting heart rate of more than 120 beats per minute 8) Has already undergone angioplasty, bypass or other surgical intervention for PAD 9) Other severe comorbid conditions preventing the ability to engage in physical activity inability or unwillingness to undertake the commitments of the study
Haile ST et al., 2023	1) Age at least 18 years 2) Diagnosed with IC 3) Absence of signs of CLTI 4) Ability to speak and understand the Swedish language	1) Dementia 2) Planned discharge to a nursing home 3) Not being accountable for administrating own medications 4) Survival expectancy of less than 1 year
Höbaus C et al., 2017	1) Stable PAD (ABI <0.9, Fontaine stage I–II, Rutherford stage I–III) 2) Age between 40 and 90 years.	1) Serum creatinine >0.265 mmol/L 2) Connective tissue disease 3) Hormone replacement therapy 4) Critical illness within the last 6 months 5) Type 1 diabetes mellitus 6) Rest pain 7) Ulcers 8) Gangrene 9) Known cancer

Hussain MA et al., 2016	Patients with symptomatic PAD, defined as one of the following: 1) a clinical history of intermittent claudication, ischemic rest pain, or tissue loss in conjunction with an ABI £ 0.9 2) previous peripheral arterial bypass surgery 3) previous percutaneous transluminal angioplasty (PTA) with or without a stent 4) a lower limb amputation for ischemia.	1) Patients seen by vascular surgeons at their institution-affiliated hospitals 2) Patients with atherosclerotic disease who were younger than 40 years
Matthews S et al., 2016	1) Patients with claudication symptoms limiting their everyday activity 2) Patients who have not had recent surgical intervention.	1) Asymptomatic PAD patients 2) Recent vascular surgery intervention 3) Unstable angina 4) Uncontrolled cardiac arrhythmias, 5) CLTI 6) Decompensated HF 7) Severe or symptomatic valvular heart disease
Rosenberg Y & Behrendt CA., 2023	1) Adult patients (≥18 years) 2) Symptomatic stages of PAD, including IC and CLTI 3) Underwent inpatient treatment at the study centre, 4) Undergoing endovascular or surgical procedures as well as amputations and diagnostic angiographies were included, 5) The possession of a phone to be contacted during the pilot study	1) Patients who were not capable of giving consent (e.g. dementia), 2) Patients who were limited in the German language (a total of five patients during our recruitment process) or 3) Patients hospitalised in an intensive care unit
Siercke M et al., 2021	1) Conservatively treated patients with newly diagnosed IC using clinical assessment and ABI 2) Age > 18 years 3) Speaks and understands Danish 4) Able to provide informed written content 5) Citizens of one of eight municipalities of Greater Copenhagen belonging to the local healthcare centre 6) Expected to be able to manage transportation	1) Failure to understand and cooperate according to the trial instructions 2) Comorbidity complicating physical activity and exercise training 3) Lack of informed consent

	7) Perform exercise	
Sutton M et al., 2018	1) Patients with PAD who required endovascular intervention 2) The ability of the subject to read and write	1) Patients with inability to ambulate 2) Unstable angina 3) Decompensated HF 4) Uncontrolled cardiac arrhythmias 5) Severe or symptomatic valvular heart disease 6) Who were unable to read or write.
Davins Riu M et al., 2018	1) Intermittent claudication confirmed by a vascular surgery specialist according to clinical, physical, and hemodynamic criteria 2) Aged 18 years or older 3) Signed informed consent 4) Access to the Internet by the patient or a relative 5) Fluency in the Catalan and/or Spanish language	1) Serious psychiatric disorder or cognitive impairment before consideration for the study 2) Previous patent arterial surgery 3) Severe chronic obstructive pulmonary disease (GOLD stage III/IV) 4) Severe congestive heart failure (NYHA class III/IV) 5) Active malignant disease with expected survival of less than 1 year
Hatfield J et al., 2008	Newly diagnosed PAD patients with IC	No specific exclusion criteria. However they report that 23 patients had coexisting coronary heart disease and were excluded from this analysis.
Elfghi M et al., 2021	1) [3]18 years 2) PAD: diagnosed by at least one of the following a) ABI< 0.90 in at least one lower extremity, b) Toe brachial index of less than 0.60, c) Evidence of arterial occlusive disease in one lower extremity detected by duplex ultrasonography, computed tomographic angiography, or magnetic resonance angiography 3)Symptomatic PAD (Rutherford category 2 and above) 4) Patients should have at least one of the following risk factors: a)Blood pressure > 140/80 mmHg, b)Fasting blood sugar (FBS) > 53 mmol/mol, c)Glycosylated haemoglobin (HbA1c) > 7%, d)Total cholesterol > 5 mmol/L, e)Low-density lipoprotein (LDL) cholesterol > 2.6 mmol/L, f)Triglycerides > 1.7 mmol/L, g)High-density lipoprotein (HDL) < 1.0 mmol/L in men and < 1.2 mmol/L	1) Involvement in another clinical trial in the previous 6 months 2) Legal incapacity 3) Inadequate English language ability to understand the content of the intervention programme 4) Significant cognitive impairment or mental illness 5) Refusal to participate in a certain part of the intervention 6) Patient suffering from a comorbidity that could affect either their physical participation in the intervention arm or influence outcomes (e.g. ischemic heart failure or severe chronic kidney disease with an estimated glomerular filtration rate of less than 30 mL/min) 7) Patient is immobile 8) Contraindication to anticoagulation and antiplatelet medications or any of the risk factors treatment.

	in women, h)Physical activity less 30 min for 5 days per week, i)Body mass index (BMI) > 25 kg/m2, j)Waist circumference > 80 cm in women, and > 94 cm in men, k)Current smoker or exposure to tobacco in any form, l)Unhealthy diet, Mediterranean diet score less than 10 points	
Lovell M et al., 2011	1) PAD diagnosis 2) PAD patients who were not on antiplatelet therapy 3) PAD patients who had suboptimal blood pressure control and elevated lipid profiles	Not reported
Fallon et al., 2024	1) An ABI ≤0.9 in either leg, or previous surgery for PAD 2) Ongoing exertional leg symptoms	CLTI, including pain at rest, non-healing ulceration or gangrene (Fontaine Classification III and IV)

Abbreviations: ABI: ankle brachial index; CLTI: chronic limb threatening ischemia; HF: Heart failure; HTN: Hypertension; IC: Intermittent claudication; PAD: Peripheral arterial disease

3.4.4 Adherence definition and assessment

All included studies described activities related to adherence, however, most studies did not define the term. Adherence was often described as “compliance with the medical plan”, “risk factor management”, “commencing medications” and “exercise class attendance”. Only one study provided a clear definition of medication adherence, as “the proportion of days covered calculated by dividing the number of available dispensed doses (registry data) by the number of days the patient was prescribed the medication (data from medical records)” (196).

The assessment of adherence was also underreported. Most studies (9/15) used self-reported methods (78, 195, 196, 198, 200-202, 204, 206). For medication adherence, one study used a validated questionnaire (Morisky-Green test) (204), while another used prescription records (202). Two studies used carbon monoxide assessment to evaluate smoking cessation (78, 205), and only one used a pedometer to monitor exercise behaviour (78). One study mentioned using standardised measures to track

risk factor management, including smoking cessation; however, these measures were not described (207).

3.4.5 Rationale and Theory for Intervention

Most studies (10/15) did not employ a theory or framework for developing their interventions (195, 199-207). Only two studies utilised validated frameworks: the FASTIC study employed the Medical Research Council (MRC) complex intervention framework (196) , and Mendez et al. (198) used the Contextualized Instructional Design model. The CIPIC rehab intervention (197) was the only study to incorporate a behavioural theory, specifically Bandura's Social Cognitive-Behavioural Theory (209), though this was detailed only in the study protocol (210). Two studies utilised care pathways: Person-Centred Care (211, 212) in the FASTIC study (196) and the Chronic Care Model (213) in Lovell's study (208). Cucato's study uniquely incorporated co-production elements and specific BCTs, while also addressing adherence barriers such as financial limitations and travel distances (78). A more detailed description of the theories/models used for the studies in presented below in Table 14.

Table 14 Description of theories used for interventions

Study	Theory/Model used	Explanation of theory/model
Siercke M et al., 2021(197)	Social Cognitive-Behavioural Theory	A psychological theory that emphasizes how people learn by observing others. It suggests that behaviour is shaped by a dynamic and reciprocal interaction between an individual's personal factors (like beliefs and self-efficacy), their behaviour, and their environment. Key concepts include self-efficacy (the person's confidence in their abilities to perform a behaviour), observational learning, and the idea that individuals have agency and can self-regulate their actions.
Haile ST et al., 2023 (196)	Person-Centred Care	Care model developed at the University of Gothenburg, which includes: i) creating a partnership between patients and HCPs;

		ii) patient narratives; and iii) establishing a self-care plan with goals, self-care tasks, and future follow-up
Lovell M et al., 2011(208)	Chronic Care Model	Care model for patients with chronic diseases and is based on the hypothesis that improving care for chronic diseases requires an approach that includes patient-, HCP-, and system-level interventions

3.4.6 Intervention characteristics

All interventions focused on patients with PAD, as opposed to family, caregivers or healthcare providers. Their characteristics are described below.

3.4.6.1 Targeted behaviours

Interventions focused on different targeted behaviours required for guideline-recommended therapy, including exercise and exercise class attendance (12/15), adoption of optimal nutrition habits (8/12), medication adherence (12/15), smoking cessation (14/15), alcohol reduction (2/15) and weight management (1/15) (See Tables 15 and 16). In this review, exercise and exercise class attendance were presented as a single target behaviour to facilitate more comprehensive coding. Additionally, weight management was presented as a target behaviour in the included studies. Weight reduction, often used as the measured outcome, is more accurately considered an outcome of behaviour change, typically a result of either dietary and/or physical activity modifications. For this review, diet and exercise have been examined as target behaviours and weight management as an outcome of target behaviour. Only two of the 15 interventions covered all recommended treatment aspects (206, 207) (See Tables 15 and 16). Two further interventions only targeted two different aspects of the treatment plan, with Hussain's study addressing medication adherence and smoking cessation (200); and Mendez focusing on medication adherence and exercise (198).

Table 15 Intervention characteristics as per TiDIER Framework

Author & Year	Name	Theory & Rationale	Description	Materials	Provider	Mode of delivery & Location	Duration/ time-points	Tailoring	Intervention modification
Coca-Martinez M et al., 2023	N/A	No theory/ framework	Multimodal multidisciplinary prehabilitation programme delivered prior to vascular surgical intervention using the following components: i) weekly supervised exercise session; ii) home-based exercise prescription; iii) nutritional counselling and supplementation; iv) smoking cessation	1) Treadmill, 2) Elastic bands, 3)BP monitor, 4) Exercise logbook, 5) Patient Generated Subjective Global Assessment, 6) 3-day food diary, 7) Fagerstrom Test for Nicotine Dependence, 8) Relaxation audio, 9) SET	MDT & elements of patient self-management	F2F, hospital-based and home-based. SET was group-based and delivered in hospital.	12 weeks. -SET 1h/once per week. -Home based advised to walk for at least 30–40 min at moderate intensity 3 times/week & muscle training 3 times/week. Assessments: Baseline, 3,6 and 12	Yes- for exercise, diet and psychological intervention	Not reported

			therapy; and v) psychosocial support.				months follow up.		
Mendez CB et al, 2019	N/A	No theory used. Framework: Contextualized Instructional Design (CID) model.	Educational, app-based intervention that also allows the exchange of messages between the patient & HCP.	1)Access to an IOS or Android smartphone and WIFI/Cellular data, 2)App that was developed for the ANDROID and IOS platforms.	Self-managed by the patients. A HCP is available for questions that can be requested by the patients through the app.	App/ Virtual. Home-based	N/A	Not reported	N/A – intervention development
Cucato G et al 2022	Textpad	No theory/ Framework. Specific barriers to SET they are trying to target are financial limitations and travel distances.	A home-based, virtual exercise and an individual educational lifestyle programme.	1) Smart phone/device, 2) Internet connection, 3)Zoom app, 4) Educational materials and videos	Elements of patient self-management, plus delivery by health trainers	Remote & Home-based	12 weeks intervention. Exercise programme twice/week, lifestyle programme once/week	Yes- Elements of tailored plan and shared decision making	N/A – protocol

Haile ST et al., 2023	FASTIC	No theory used. Framework: MRC. Model of care pathway used: the Gothenburg person-centred care (PPC) model.	Nurse-led, person-centred, health-promoting programme, including establishment of a partnership between the HCP and the patient; patient narratives; and a documented self-care plan with goals, self-care activities, and a plan for future follow-up and revision.	1)Training nurses in motivational interviewing and PPC 2) Mediums for information i.e. movies, 3) Printed information sheets, 4) Referrals to support groups	Vascular nurse specialists trained in PCC and in motivational interviewing	Remote phone calls and F2F appointments. Hospital and home-based	1 year after surgical treatment. Three visits at the outpatient clinic and two telephone calls.	Yes – self-care plan	Not reported. When hand searched the protocol and the RCT paper, no modification were identified.
Höbaus C et al., 2017	N/A	No theory/ framework	A secondary care, vascular medicine centre based medical management intervention.	1)Letters with the updated medication regime, 2) Letters to relay information to participants, 3) Self-monitoring blood	Vascular surgeon and vascular specialist technicians.	F2F. Hospital-based	Patients were followed up for a 5 year period and had an appointment every 6 or 12 months.	N/A	Not reported

				pressure machine, 4) Monetary resources for non-generic drugs.					
Hussain MA et al., 2016	N/A	No theory /framework	A programme that focuses on guideline-recommended cardiovascular risk-reduction therapies, including: antiplatelet agents, statins, angiotensin-converting enzyme inhibitors, blood pressure control, lipid control, diabetic glycemic control, smoking cessation, and target body mass index	1)Educational material and leaflets about clinical practice guidelines on PAD risk management for HCPs 2) Informational letters for patients about risk factors, and management strategies.	Vascular nurse specialist and vascular surgeon	F2F. Hospital-based	Not reported - data collected from July 1, 2004, to April 30, 2007	N/A	Not reported

Matthews S et al., 2016	N/A	No theory/ framework	A community-based podiatry-led lower limb arterial assessment service and a cardiac rehabilitation supervised exercise programme.	An established cardiac rehabilitation team.	Cardiac rehabilitation staff and vascular triage team	F2F. Hospital-based	12 weeks cardiac rehabilitation.	Yes-exercise plan	Not reported
Rosenberg Y & Behrendt CA., 2023	N/A	No theory/ framework	An educational structured risk factor management intervention and supervised exercise.	1)Questionnaires, 2)Education, 3) A copy of the brochure and a list of contact data for SET in Hamburg, Germany, 4) SET centres, 5) Trained staff to administer educational	Trained final year medical student about best medical therapy for symptomatic patients with PAD. A supervisor was also present if necessary.	Combination of F2F (for the assessment) and home-based (for those doing home-based exercise)	10 weeks. The intervention was given twice during hospitalisation following vascular intervention. Post-hospitalisation: One planned telephone	Not reported	Not reported

				sessions, telephones.			contact per week.		
Siercke M et al., 2021	The CIPIC Rehab	No framework. Theory: Social Cognitive-Behavioral Theory.	A cross sector (community/hospital) exercise and lifestyle intervention, cardiac rehabilitation programme in a community based setting for patients with IC.	1)Pedometer, 2) Logbook, 3) Circuit training and strength training equipment	Multidisciplinary approach including cardiac physiotherapists, nurses and dietitians.	F2F and remote (text-messages). Community rehab based and home-based	12 weeks. 2 weekly exercise sessions. Study follow-up: 6 and 12 months.	Yes-personalised follow-up texts	Not reported. When hand searched the protocol and the RCT paper, no modification were identified.
Sutton M et al., 2018	N/A	No theory/ framework	A nurse- and doctor-led clinical follow-up risk factor management programme	1)Handouts for risk factor modification care plan, 2) Cleveland Clinic ‘‘PAD Walking Program’’	Cardiologist and nurse practitioner	F2F. Clinic/ practice based.	90 days. 4 visits in total.	Yes-customised risk modification plan	Not reported
Davins Riu M et al., 2018	Control Telehealth Claudication Intermittent	No theory/ framework	A virtual educational and self-management intervention	1)Internet access, 2) Computer or device (smart phone or tablet), 3) Intervention app	Self-managed by the patient via the app, with stand-by healthcare professional input	Combination of F2F, hospital-based (for initial assessment and any follow ups	12 months study follow up. 3 months follow ups	Yes-Personalised advice depending on how they answer	Not reported

	(CONTECI)					needed) and remote (app)		the questions	
Hatfield J et al., 2008	N/A	No theory/ framework	Nurse-led risk management programme	Exercise regimen provided to patients.	Vascular nurses and patient self-management. Referral to specialist nurses (e.g. diabetes) when required.	F2F. Hospital based	3 months. Patients had a single nurse assessment at baseline and 3 months	N/A	Not reported
Elfghi M et al., 2021	N/A	No theory/ framework	A nurse-led, community-based, lifestyle and risk factor modification and exercise intervention	1) Food diary, 2) Pedometer, 3) Exercise class and educational workshops, 4) Basic equipment for measures (BP, BMI, glucose, lipid)	Multidisciplinary approach including nurses, dieticians, and exercise specialists	Combination of F2F, hospital based (for assessments) and F2F community, group-based, (for intervention)	12 weeks intervention. Visit: baseline, 12 weeks and 1 year. Weekly classes.	Yes-individualised assessment with goal planning	N/A – protocol. They will report in the main paper any modifications occurred.
Lovell M et al., 2011	N/A	No theory/ framework. Model of care pathway	A multi-disciplinary team approach for cardiovascular risk factor	1)Equipment for clinic and dedicated clinic space; 2)Educational	Multidisciplinary approach including vascular nurse trained	F2F. Hospital based	Average follow-up time was 528 days. Patients	Yes – personalised based on	Not reported

		used: Chronic Care Model (CCM)	management and modification using elements of the CCM.	materials, 3)Graphs depicting their cholesterol levels, BP, HbA1C levels and overall risk-assessment score, 4) Education materials from vascular societies, 5) Vascular risk management database containing patient and clinical information, 6) Electronic patient charts with previous hospital visits and diagnostic tests,	in using elements of the CCM, dieticians, vascular surgeons and family physicians		were assessed initially and at regular follow-up periods (3 – 6 months)	patient's needs and clinical factors (e.g cholesterol adapted graphs)	

				7) Follow up letters sent to the referring vascular surgeon and family physicians.					
Fallon et al., 2024	N/A	No theory/ framework.	A standalone PAD rehabilitation programme, involving two individualised exercise sessions, a group education session and other individual interventions to control risk factors per week.	1) Outpatient gymnasium 2) Exercise equipment including treadmill, bikes, rowers, stairs and cross trainers, and weights, 3) Basic equipment for measures (not specified), 4) BP monitor	Multidisciplinary approach including nurses, dietitians, physiotherapists	F2F, hospital based. Group based for education session.	10 weeks intervention delivered twice a week.	Yes- personalised risk factor and medication adherence management, as well as individualised exercise sessions.	Not reported

Abbreviations: HCP: Healthcare Professional; F2F: Face to face; MDT: Multidisciplinary team; MRC: Medical Research Council; PAD: Peripheral arterial disease; RCT: Randomised control trial; SET: Supervised exercise therapy

Table 16 Targeted behaviours, Behaviour Change Techniques and intervention effectiveness

Author & Year	Study design	Number of participants	Target behaviour	Behaviour Change Techniques	Intervention effect on adherence	Intervention effect on clinical outcomes
Coca-Martinez M et al., 2023	Pilot RCT - single-blind, 2-arm, parallel, pilot-RCT	24 Intervention 12 Control 12	Smoking cessation, Exercise, Diet	1) Instructions on how to perform the behaviour (through education), 2) information about health consequences, 3) Social support (emotional) (psych component), 4) Social support (unspecified) (from HCPs), 4) Biofeedback (using logbooks, CO test for smoking), 5) Self monitoring of behaviour (patients record in diary), 6) Demonstration of the behaviour	2 patients (40% of the active smokers) successfully stopped smoking [a] Adherence to each prehabilitation component was 83% for in hospital supervised exercise, 90% for home-based exercise and 69% for nutrition [a]	Change in functional and walking capacity between intervention vs. control at 12 weeks results, mean (SD): <u>6 Min Walk Test distance:</u> 60 (74) vs. -11 (40) meters, **p<0.05** Claudication Onset distance: 48 (79) vs. −26 (65), p=0.64 Walking Impairment Questionnaire: 15.6 (13.0) vs −1.7 (21.7), **p<0.05**

Mendez CB et al, 2019	Intervention development	N/A – intervention development	Medication adherence, Exercise	1) Instructions on how to perform the behaviour (through education), 2) Self monitoring of behaviour, 3) Prompts and cues (reminders to enter info), 4) Conserving mental resources (food recipes)	N/A – intervention development paper	N/A – intervention development paper
Cucato G et al 2022	Protocol for a pilot RCT	Target recruitment: 60	Smoking cessation, Exercise, Diet & alcohol	Potential BCTs: 1) Instructions on how to perform a behaviour 2) Goal setting (behaviour), 3) Problem solving, 4) Self-monitoring of behaviour, 5) Social support (unspecified), 6) Social support (practical), 7) Information about health consequences,	N/A – protocol	N/A – protocol

				8) Comparative imagining of future outcomes 9) Demonstration of the behaviour		
Haile ST et al., 2023	Non-blinded RCT	204 Intervention 99 Control 105	Medication adherence, Smoking cessation, Exercise	1) Goal setting (behaviour), 2) Social support (emotional), 3) Information about health consequences, 4) Instruction on how to perform a behaviour, 5) Comparative imagining of future outcomes, 6) Verbal persuasion about capability, 7) Self-monitoring of behaviour, 8) Feedback on behaviour, 9) Review of behavioural goals	Intervention vs. control at 1 year: <u>Statin adherence:</u> 79% vs. 82%, p=0.464, Antiplatelet adherence: 92% vs. 91%; p=0.700 <u>Ex-smokers:</u> 78 (80%) vs. 79 (77.5%), p=0.734 <u>Current smokers:</u> 12 (12%) vs. 15 (14.7%), p=0.544	12 months results Intervention vs Control, n(%): LDL Patients within treatment goal (≤ 1.8 mmol/l): 36 (41) vs. 39 (43), p= 0.880 Deteriorated from treatment goal (n = 44|47): 20(46) vs. 12 (28), p=0.086 Total cholesterol Patients within treatment goal (≤ 5 mmol/l): 70(78) vs. 81(87), p=0.186 Deteriorated from treatment goal (n =75|79): 12(16) vs. 4(5), **p=0.034** HbA1c

						Patients within treatment goal (≤ 52 mmol/mol with diabetes, ≤ 46 mmol/mol without diabetes) (n =81|84): 57(70) vs. 71(85), **p=0.040** Reached treatment goal (n = 26|14): 6(23) vs. 5(36), p=0.469 Systolic blood pressure (n = 93|98) Patients within treatment goal (< 140 mmHg): 39(42) vs. 32(33), p=0.231 Reached treatment goal (n = 55|69): 19(35) vs. 16(23), p=0.228 Diastolic blood pressure (n = 93|98) Patients within treatment goal (< 90 mmHg): 87(94) vs. 89(91), p=0.594 Reached treatment goal (n = 9|7): 8(89) vs. 3(43), p=0.106

						Pain-free walking distance Patients with unlimited pain-free walking distance at 1 year after surgery (n = 93|95): 61(66) vs. 56(59), p=0.370 Deteriorated pain-free walking distance at 1 year after surgery (n = 55|71): 12(22) vs. 21(30), p=0.415 ABPI Change (1 year – baseline), median (i.q.r.): 0.30 (0.14 to 0.42) vs. 0.27 (0.13 to 0.43), p=0.146 BMI Change (1 year – baseline), median (i.q.r.): −0.29 (−0.73 to 0.34) vs. 0.00 (−0.35 to 0.91), p=0.869 Waist circumference (cm) Change (1 year – baseline), median (i.q.r.): −2 (−6 to 1) vs. −1 (−6 to 2), p=0.471

Höbaus C et al., 2017	Longitudinal prospective follow-up study	702 Intervention 370 Control 332	Medication adherence, Smoking cessation, Exercise	1) Review of behavioural goals, 2) Feedback on behaviour, 3) Biofeedback 4) Information about health consequences	Statins use increased from 48.8% (baseline) to 89% (6 months). [a] Antiplatelet medication use increased from 88.7% (baseline) to 90.9% (6 months). [a] ACE inhibitors/ARB use ranged from 74.3% (baseline) to 86.1% (6 months). [a] Active smoking declined from 34.7% (baseline) to 24.4% (6 months) [a]	At the end of follow up, survival in the intervention group was 90.8% vs 66% in the control group (absolute CI: 18.96–30.73%; 37.6% relative) [a] Mortality was reduced from 82 to 21 events per 1000 patient-years resulting in a rate ratio is 0.26 for intervention group. In the control group, all-cause mortality was increased by a HR of 3.7 (95% CI: 2.51–5.46, **p<0.001**). The intervention group led to the identification of Intensified screening by combination of 48% (n = 176) patients with T2DM, **p<0.001**.
Hussain MA et al., 2016	Observational cohort study	791 Intervention 290 Control 501	Medication adherence, Smoking cessation	1) Instructions on how to perform the behaviour, 2) Feedback on behaviour, 3) Information about health consequences	Baseline vs end of follow up [+] Antiplatelet use (67% vs 80%; **p= 0.03**), Statin use (67% vs 88%; **p< 0.001**),	Patients in the intervention group experienced lower mortality (adjusted HR, 0.60; 95% CI, 0.48-0.75, **p<0.001**) than control patients. Patients in the intervention group were also less likely to

					ACE inhibitor or angiotensin receptor blocker use: 58% vs 72%, **p=0.02**, Smoking cessation: 75% vs 88%, **p<0.001**	undergo major amputation (adjusted HR, 0.47; 95% CI, 0.29-0.77, **p=0.002**), minor amputation (adjusted HR, 0.26; 95% CI, 0.13-0.54, **p<0.001**), or arterial bypass surgery (adjusted HR, 0.47; 95% CI, 0.30-0.73, **p<0.001**). Patients in the intervention group were less likely to be hospitalized due to heart failure: adjusted HR, 0.73; 95% CI, 0.53-1.00, p=0.048 Blood pressure control: baseline 35% vs end-of-follow-up 52%, **p=0.02**, LDL cholesterol control: baseline 63% vs end-of-follow-up 86%, **p=0.002**, Glycaemic control: baseline 44% vs end-of-follow-up 52%, p=0.53, Target BMI: baseline 27% vs end-of-follow-up 38%; **p=0.049**

Matthews S et al., 2016	Audit	54	Medication adherence, Smoking cessation, Exercise advice, Healthy diet & weight management	1) Monitoring of behaviour by others without feedback, 2) Instruction on how to perform the behaviour, 3) Social support (emotional)	45 patients (84%) were on best medical therapy of anti-platelet and lipid-regulating drugs at the completion of the programme, [a] 7 patients (13%) quit smoking, [a] 10 patients (18.5%) had reduced the number of cigarettes they smoke [a] 7 patients (13%) joined a gym, [a] 4 patients (7%) reported a weight reduction [a]	Of the 54 patients who completed the programme, 39 (72%) reported an improvement in their intermittent claudication symptoms, 13 (24%) reported no change and 2 (4%) felt their symptoms had deteriorated. [a]
Rosenberg Y & Behrendt CA., 2023	Single centre pilot RCT	40 Intervention 20	Medication adherence, Smoking cessation,	1) Instructions on how to perform the behaviour,	End of follow up data intervention vs. control: Medication adherence:	End of follow up data intervention vs. control: Reached a normal weight BMI:

		Control: 20	Exercise, Diet	2) Social support (unspecified), 3) Monitoring of outcome(s) of behaviour by others without feedback, 4) Demonstration of the behaviour	100% in both groups [a] Smoking cessation: 0% vs. 13.3% [a] Reduction in smoking consumption: 6.3% vs. 13.3% [a] SET attendance: 0% in both groups [a] Home-based exercise: 62.5% vs. 40% [a] Achieved exercise goals: 31.3% vs. 20% [a]	0% vs. 6.7% [a] Weight reduction but still overweight or obese (BMI >25 kg/m2): 25% vs 33.3% [a] Major adverse limb event: 25% vs. 6.7% [a] Major adverse cardiovascular event: 0% for both groups [a]
Siercke M et al., 2021	RCT	118 Intervention 46 Control 47	Smoking cessation, Exercise, Diet	1) Instructions on how to perform the behaviour, 2) Social support (emotional), 3) Self-monitoring of behaviour, 4) Feedback on behaviour, 5) Biofeedback,	Baseline vs. 6-months follow up, n(%) <u>Healthy diet:</u> Intervention 1(2)/ Control 0(0) vs. Intervention 5(11)/ Control 0(0) [a]	Baseline vs. 6-months follow up, mean (SD): <u>MWD:</u> Intervention 248 (309.9) / Control 188 (300.7) vs. Intervention 350.5 (447.6) / Control 253 (325.4), 95% CI 1.10 – 1.70; **p=0.005**

				6) Information about health consequences, 7) Verbal persuasion about capability, 8) Goal setting (behaviour), 9) Comparative imaging of future outcomes, 10) Demonstration of the behaviour	Physical activity: Intervention 18(31)/ Control 21(36) vs. Intervention 24(52) / Control 15(32), 95% CI 1.66–18.82, **p=0.002** Smoking cessation at 1 year: 7 patients quit smoking in the intervention group compared to baseline, whilst no patients in the control group quit smoking (p=0.58).	Pain free walking distance: Intervention 115 (151.5) / Control 96.5 (157.9) vs. Intervention 133.5 (207.9) / Control 96 (165.8), 95% CI 0.99–1.65, p=0.060
Sutton M et al., 2018	Quality Improvement	24	Medication adherence, Smoking cessation, Exercise	1) Instructions on how to perform the behaviour, 2) Feedback on behaviour, 3) Self-monitoring of behaviour, 4) Goal setting (behaviour), 6) Review behaviour goal(s),	100% statin prescription [a] 2 participants (8.3%) walked for 31-40 times during the 90day intervention, and only 3 participants (12.5%) walked for >40 times during the 90day intervention. [a]	Baseline vs. end of follow-up data, mean (SD): Total cholesterol: 180.17 (40.41) vs. 172.67 (40.52), p=0.066 LDL: 98.29 (32.74) vs. 84.79 (33.64), **p=0.007** Blood pressure control goal as per guidelines: 14 (58.3%)

				7) Information about health consequences	4 (57.1%) reported a reduction in their <u>tobacco</u> use [a]	patients vs. 21 (87.5%) patients [a] <u>Six-minute walk (meters):</u> 178.84 (116.08) vs. 232.44 (98.64), **p=0.030**
Davins Riu M et al., 2018	Pilot RCT - pragmatic, parallel, randomized controlled trial	150 Intervention 75 Control: 75	Medication adherence, Smoking cessation, Exercise	1) Instructions on how to perform the behaviour, 2) Self monitoring of behaviour, 3) Feedback on behaviour, 4) Information about health consequences	Intervention vs. control results, n(%): Medication adherence at 6 months: 57(83.8) vs. 49 (69.0), **p=0.031** Medication adherence at 12 months: 55 (75.3) vs. 50 (70.4), p=0.317 <u>Smoking abstinence at 12 months:</u> 19 (27.5) vs. 14 (20.3), p=0.892 <u>Exercised more at 12 months:</u> 15 (21.4) vs. 10 (14.7), p= 0.125	Intervention vs. control results at 12 months, n(%): Claudication distance: Less 5 (7.1) vs. 11 (15.9) Same 45 (64.3) vs. 38 (55.1) More 20 (28.6) vs. 20 (29) p= 0.243 MWD (meters): <150: 2 (2.9) vs. 8 (11.6) 151-500: 12 (17.4) vs. 13 (18.8) 500-1,000: 15 (21.7) vs. 8 (11.6) >1,000: 40 (58.0) vs. 40 (58.0) p= 0.123 Requiring surgery: 1 (1.4) vs. 4 (5.6), p=0.182

Hatfield J et al., 2008	Service evaluation / prospective study	78	Medication adherence, Smoking cessation	1) Instructions on how to perform the behaviour, 2) Biofeedback, 3) Social support (unspecified)	Baseline vs. 3 months follow-up results, n(%) <u>Antiplatelet adherence:</u> 68 (88.5) vs. 78 (100) [a] <u>Statin adherence</u>: 52 (66.6) vs. 78 (100) [a] <u>Current smokers:</u> 52 (66.6) vs. 43 (55.5) [a]	Baseline vs. 3 months follow-up results, n(%) Diabetics with a HbA1c > 7.0%: 6 (50.0) vs. 5 (41.6) [a] Hypertension (reading > 140/90 mm Hg): 44 (56.4) vs. 38 (48.7) [a] <u>Total cholesterol (mmol/L):</u> 5.2 (4.5–6.1) vs. 4.5 (4.0–4.9), **p<0.001** <u>LDL (mmol/L):</u> 3.1 (2.5–3.7) vs. 2.5 (2.1–2.9), **p<0.001** <u>Triglycerides (mmol/L):</u> 1.7 (1.2–2.5) vs. 1.4 (1.0–2.3), **p=0.001**
Elfghi M et al., 2021	Protocol for a randomised, parallel group, active-control trial	Target recruitment: 208 patients (104 per arm)	Medication adherence, Smoking cessation, Exercise, Diet	1) Instructions on how to perform the behaviour, 2) Goal setting (outcome),	N/A – protocol	N/A – protocol

				3) Review outcome goal(s) (e.g lipid improvement), 4) Problem solving (Identifying barriers to exercise), 5) Self-monitoring of behaviour (pedometer and food diary), 6) Social support (unspecified), 7) Demonstration of the behaviour		
Lovell et al., 2011	Quasi-experiment (before-after) study	103	Medication adherence, Smoking cessation, Diet	1)Verbal persuasion about capability (for disease in general) 2) Goal setting (behaviour), 3) Goal setting (outcome), 4) Problem solving, 5) Instructions on how to perform behaviour, 6) Information about antecedents,	Medication adherence rates were not reported 9 of the 58 patients (16%) who smoked at baseline successfully quit [a]	Baseline vs. end of follow up results, mean (SD): BMI (kg/m^2): 27.6 (5.1) vs. 27.9 (5.6), p=0.09 Systolic blood pressure (mmHg): 143.3 (19.9) vs. 137.3 (16.1), **p<0.001**, Diastolic blood pressure (mmHg): 79.7 (10.9) vs. 75.8 (10.3), **p<0.001**,

				7) Monitoring outcomes of behaviour without feedback, 8) Biofeedback, 9) Feedback on outcomes of behaviour, 10) Social support (unspecified), 11) Prompts and cues, 12) Information about health consequences		LDL (mmol/L): 2.89 (1.05) vs. 2.15 (0.67), **p<0.001**, HDL (mmol/L): 1.15 (0.35) vs. 1.10 (0.35), **p=0.0057,** Total cholesterol (mmol/L): 4.9 (1.1) vs. 4.0 (0.8), **p<0.001**, Blood glucose mmol/L: 6.26 (1.84) vs. 6.13 (1.13), p=0.44
Fallon et al., 2024	Prospective, observational, single centre study	114	Medication adherence, Smoking cessation, Exercise, Diet & alcohol	1)Instructions on how to perform a behaviour, 2) Social support (practical), 3) Demonstration of the behaviour	Medication adherence rates were not reported Non-smokers pre-programme 55 (62%) vs. post-programme 60 (68%), p=0.302	Baseline vs. end-of-programme results, median (Q1, Q3): Systolic blood pressure (mmHg): 137 (122, 147) vs. 134 (124, 143), p= **0.037** Diastolic blood pressure (mmHg): 76 (70, 86) vs. 73 (67, 81), **p=0.003**

						Total cholesterol (mmol/L): 4.30 (3.73, 5.00) vs. 3.90 (3.40, 4.28), **p<0.001** LDL (mmol/L): 2.30 (1.90, 2.98) vs. 1.95 (1.70, 2.30), **p<0.001** HDL (mmol/L): 1.26 (0.99, 1.59) vs. 1.25 (1.03, 1.50), p=0.591 Triglycerides (mmol/L): 1.53 (1.00, 2.11) vs. 1.34 (0.96, 1.85), p=0.076 Glucose levels (mmol/L): 5.30 (4.90, 6.60) vs. 5.50 (5.20, 6.40), p=0.326 HbA1c levels (mmol/mol): 6.05 (5.60, 7.35) vs. 6.15 (5.63, 6.50), p=0.627 Weight (kg): 81.4 (71.3, 88.8) vs. 81.6 (70.8, 87.9), p=0.961 Waist circumference (cm): 95.8 (84.9, 101.9) vs. 99.5 (95.3, 108.8), p=0.073

						BMI (kg/m^2): 28 (25.2-32.0) vs. 28 (25.0-31.0), p=0.493 Maximum claudication distance (metres): 250 (178, 373) vs. 700 (483, 840), **p<0.001** Maximum claudication time (seconds): 298 (215, 432) vs. 795 (553, 960), **p<0.001**

[a] p-value not reported

[+] no specific follow-up time was provided; the median follow-up for the cohort was 5.3 years (interquartile range, 1.8-6.9 years).

Abbreviations: BMI: Body mass index ; LDL: Low-density lipoprotein; MWD: Maximum walking distance; T2DM: Type 2 Diabetes Melitus, RCT: Randomised control trial

3.4.6.2 Behaviour Change Techniques

The application of the BCT Taxonomy v.1 (102) to classify intervention content, identified 21 BCTs used across all the interventions. The number of BCTs coded in each study ranged from three BCTs (200, 201, 205, 207) up to 12 BCTs (208). The mean number of BCTs coded in each study was six. The most used BCT was "instructions on how to perform a behaviour" (13 studies); followed by "self-monitoring of behaviour" (7 studies), and "goal setting (behaviour)" (5 studies). The least frequently used were "conserving mental resources" (1 study), "monitoring of behaviour by others without feedback" (1 study), "review of outcome goals" (1 study) and "feedback on outcomes of behaviour" (1 study). Based on the available studies, we cannot report the proportion of effective BCTs due to the limited statistical power in the included studies, and the fact that only studies evaluated the impact of interventions. Only the study by Cucato et al (78) reported using specific BCTs, hence the accurate extraction of BCTs was feasible. It was challenging to accurately extract BCTs for the rest of the studies due to insufficient reporting of the interventions' ingredients.

Considering the total BCTs used for each target behaviour, most BCTs were used to support physical activity/ exercise uptake (18 BCTs), followed by medication adherence (14 BCTs), diet (12 BCTs) and smoking cessation (11 BCTs) (See Table 17). It is important to note that in one protocol study (42), it was particularly challenging to map some of the BCTs for each target behaviour, given the lack of information.

Table 17 Behaviour Change Techniques used for each target behaviour

BCTs	Intervention target behaviours			
	Medication adherence	**Smoking cessation**	**Exercise**	**Diet**
Goal setting (behaviour)	2*	4	5	4
Problem solving	0	0	1	0
Goal setting (outcome)	2	0	1	0
Review behaviour goals	2	3	3	1
Review outcome goals	1	0	0	0
Monitoring of behaviour by others without feedback	0	0	2	0
Feedback on behaviour	2	4	5	2
Self-monitoring of behaviour	5	3	8	4
Monitoring of outcome(s) of behaviour without feedback	0	0	1	1
Biofeedback	3	1	3	0
Social support (unspecified)	2	2	3	1
Social support (practical)	0	0	1	0
Social support (emotional)	1	1	2	1
Instructions on how to perform the behaviour	10	10	14	7
Information about health consequences	4	4	4	3
Demonstration of behaviour	0	0	6	0
Prompts & cues	1	0	1	0
Comparative imagining of future outcomes	1	2	1	1
Conserving mental resources (cook book)	0	0	0	1
Verbal persuasion about capacity	1	1	2	1

*The numbers represent the number of studies that have used the specific BCTs

Colours 0,1-3 , 4-7, 8-12 ->darker colour means more frequently used.

3.4.6.3 Provider of the intervention

Interventions were delivered by various healthcare professionals (see Table 18), including vascular nurse specialists, vascular surgeons, technicians, physicians, rehabilitation staff, trainers, dieticians, psychologists, kinesiologists, smoking cessation specialists, podiatrists, triage teams, and medical students. Most interventions (9/15) adopted a multidisciplinary approach, with specialists handling specific components, such as dieticians for nutrition, physiotherapists for exercise and vascular specialists (nurses or surgeons) for medical management. Nurses and physiotherapists were most frequently involved. Four studies reported referral to specialist professionals for specific needs, such as diabetes specialist nurses or smoking cessation specialists (196, 200, 205, 207). Specialised training for providers was reported in four studies, covering areas like motivational interviewing (78, 195, 196), person-centred care (196) and best medical therapy (202). Besides healthcare professional input to support adherence, four studies also incorporated elements of patient self-management, including exercise and risk factor modification (78, 195, 196, 205).

Table 18 Intervention providers

	Study														
Provider	Coca-Martinez M et al., 2023	Mendez CB et al, 2019	Cucato G et al 2022	Haile ST et al., 2023	Höbaus C et al., 2017	Hussain MA et al., 2016	Matthews S et al., 2016	Rosenberg Y & Behrendt CA., [illegible]	Siercke M et al., 2021	Sutton M et al., 2018	Davins Riu M et al., 2018	Hatfield J et al., 2008	Elfghi M et al., 2021	Lovell M et al., 2011	Fallon et al., 2024
Multi-disciplinary team	√				√	√	√		√	√			√	√	√
Vascular Surgeon					√	√								√	
Cardiologist										√					
General Practitioner / Family Physician	√													√	
Medical Student								√							
Cardiac/ Vascular Nurse				√		√	√		√			√	√	√	√
Practice Nurse										√					
Vascular specialist technician					√										
Physiotherapist									√						√
Physiologist															
Exercise specialist							√						√		
Kinesiologist	√														
Dietician	√						√		√				√	√	√
Psychologist	√														
Smoking cessation specialist	√														
Podiatrist							√								
Health trainers			√												
Total providers per study	5	0	1	1	2	2	4	1	3	2	0	1	3	4	3

3.4.6.4 Mode of delivery, materials and location

Seven interventions were exclusively face-to-face (F2F) and mainly hospital-based (199, 200, 205, 207, 208) or delivered in community settings (201, 203). Two studies were delivered in both primary and secondary care settings (197, 206). Specifically, exercise classes were group-based in a community setting, whilst clinical vascular follow-ups were undertaken in secondary care. The F2F exercise interventions incorporated exercise equipment like treadmills and elastic bands, alongside supervised exercise sessions (195, 202, 203) and access to cardiac rehabilitation teams and centres (201, 206, 207).

Four studies (78, 195, 196, 202) incorporated both hospital F2F elements and home-based remote monitoring, including remote exercise classes (78, 195, 202) or remote follow-up calls (196). Two interventions were app-based (198, 204), with one of them delivered entirely virtually via an app (198), while another included both virtual and F2F clinic appointments, depending on clinical need (204). In Davin's study, patients could request additional visits via email, with visits typically scheduled within 72 working hours of the request (204). Digital interventions required access to smartphones, tablets, or computers with internet access (78, 198, 204). Cucato's study provided patients with internet access and digital devices as required to facilitate participation in the study (78). The other two studies (198, 204) did not report whether they provided participants with internet access or digital devices.

3.4.6.5 Duration and Time-points

The duration, intensity, and dose of the interventions varied. Intensive programmes included 12-week exercise and education sessions held multiple times weekly (78, 195, 197, 201, 205, 206). Less intensive approaches featured nurse-led cardiovascular risk management with follow-ups and telephone support ranging from weekly (202) to biannual contacts (196). Hobau's study featured the longest follow-up period, with clinical appointments every six or 12 months for up to five years (199). In Davin's e-

health intervention, patients had standard follow-up appointments every three months for 12 months, with the option for more frequent clinician support as needed (204).

Interventions were delivered at different time points in the patient's disease journey, with most targeting post-surgery patients. Only one study intervention was specifically targeted to newly diagnosed patients (205). In two studies, patients were recruited before having revascularisation, but the intervention was delivered post-revascularisation (196, 203).

3.4.6.6 Tailoring of the interventions

Around half of the interventions (8/15) included elements of personalised care, however, the level of tailoring was underreported and varied. Studies typically reported offering a personalised assessment and risk factor management plan, dependent on patient interactions with the intervention (197, 204) or risk stratification (196, 203, 207, 208). Additionally, three studies offered a personalised exercise plan based on the patient's exercise performance (baseline functional capacity results) (195, 201, 207). A study also reported tailoring the intervention for diet, based on the dietary status and conditions of the patient, and psychological support, based on the patients' psychological status (195). Details on the level of personalisation were insufficiently reported in the included studies.

3.4.6.7 Evaluation of Interventions

Of the included studies, all 12 primary studies evaluated the impact of the interventions on the target behaviours (see Table 16). Only Hussain's observational study indicated a statistically significant improvement in both medication adherence and smoking cessation behaviours (200). The CIPIC rehab intervention was only effective in increasing physical activity, whilst it did not significantly improve smoking or diet behaviours (197).

Although eight studies reported an improvement in adherence, confidence intervals and p-values were not reported in six studies (195, 199, 201-203, 205), and the results

were not statistically significant in two studies (196, 204). Although two studies (207, 208) targeted more than one behaviour, they only reported results for one behaviour. In the paragraphs below, a description for the effect of interventions for each target behaviour is presented.

Seven studies (one pilot RCT, one non-blinded RCT, three observational studies, one audit, one quality improvement) examined the effect of interventions on medication adherence (196, 199-202, 204, 205). Six studies showed improvement in medication adherence rates (199, 200, 202, 204, 205), with two reporting 100% adherence at the end of follow-up (202, 205), however, most studies (5/6) did not report whether these results were statistically significant. Of the six studies showing a positive trend, only Hussain's study (200) showed a statistically significant improvement in both antiplatelet use (67% baseline vs 80% end of study; p= 0.03) and statin use (67% baseline vs 88% end of study; p< 0.001), One study noted short-term improvement in medication adherence in the intervention group compared to the control at six months (83.8% vs. 69.0%, p=0.031), but this was not maintained at 12 months (p=0.317) (204). One study was unsuccessful in improving adherence to secondary preventive medication (79% vs. 82% adherence to lipid-modifying agents, p=0.464) (196). Another study reported all patients were prescribed statins by the end of the programme, but adherence rates were not provided (203). Although a further three studies incorporated elements to support medication adherence, they did not report outcomes (197, 207, 208).

Seven reported smoking cessation (195, 200-202, 205, 207, 208), with quit rates ranging from 6% (207) to 40% (195). Only one observational study noted a statistically significant effect of the intervention on smoking cessation (200). Four studies noted a slight reduction in cigarettes smoked (199, 201-203), but none of these studies provided a p-value. Additionally, three studies (196, 197, 204) found that more patients quit in the intervention arm compared to the control, but the results were not statistically significant, indicating no effect of the intervention on smoking cessation, despite all three studies being adequately powered RCTs.

Six studies examined the impact of the interventions on exercise/physical activity uptake (196, 197, 202-204, 207). Only two interventions were found to be effective in increasing walking capacity and exercise uptake, but the statistical significance of the results was not reported (197, 207). Although another intervention was also effective, the impact was not maintained (196). Initially, significantly more patients in the control group compared to the intervention group had unlimited pain-free walking distance (75 of 88 vs. 58 of 97; p=0.001), but this difference disappeared after one year (56 of 95 vs. 61 of 93; p=0.370) (196). In the CONTECI study, although more patients exercised in the intervention group (21.4%) than those in the control group (14.7%), the results were not statistically significant (p=0.125) (204). Moreover, two studies found that fewer than 25% of the patients met the exercise guideline-recommended goal (202, 203).

Lastly, of eight studies incorporating both an exercise and healthy eating component, seven examined the intervention's impact on weight reduction. Of those, only one study was effective in supporting patients to achieve a healthy diet at six months follow-up (197); and one in achieving optimal BMI (200). In three other interventions, the absolute levels indicated a trend towards a positive impact in weight reduction (195, 201, 202), but the results were not statistically significant. Lastly, two studies indicated no significant change in weight management (207, 208).

3.4.6.8 Acceptability of Interventions

Only three studies (78, 196, 197) reported assessing acceptability from either patient or staff perspectives. In the FASTIC study (196), 17 patients who completed the intervention participated in qualitative interviews, describing their views of the intervention's perceived value (214). The CIPIC rehab study also reported conducting a qualitative evaluation of interventions, but the publication detailing these findings is pending (210). Cucato et al.'s study protocol outlined intentions to assess intervention acceptability through semi-structured patient interviews (78). In total 18 patients were interviewed as part of the acceptability study, indicating that the intervention was acceptable from the patients' perspective, but only if technological support (equipment and training on how to use the equipment) was provided (215). Besides the three

studies reporting intervention acceptability (78, 196, 197), the remaining studies did not report feasibility data or practical considerations for implementing interventions in current clinical settings.

An additional study included an economic evaluation to assess the intervention's cost-effectiveness (204). Specifically, CONTECI e-health intervention showed a reduction in healthcare costs, mainly due to a 95.95% reduction in the number of scheduled F2F outpatient visits ($p<0.000$) and mean number of emergency department visits (intervention 0.19 vs. control 0.017; $p=0.017$) (204).

3.5. Discussion

3.5.1 Main findings

This scoping review examined multicomponent interventions designed to support treatment adherence in patients with PAD. The synthesis focuses on two key areas for discussion: a) the nature and design of the interventions themselves, and b) how these interventions were evaluated and assessed in the included studies.

Overall, the review revealed that effective multicomponent personalised interventions for this population are lacking. A key finding was the underutilisation of behavioural science approaches, which are essential to systematically identify and address adherence barriers. This lack of theoretical underpinning likely contributed to the limited effectiveness of interventions, as many were not designed with a clear understanding of the behavioural mechanisms influencing adherence, nor with the use of frameworks or theories guiding their development. Although the included studies did not explicitly refer to BCTs or apply behavioural theory, we extrapolated the likely BCTs based on the descriptions of the intervention components. The most commonly identified BCTs were instructions on how to perform a behaviour, self-monitoring, and goal setting. However, the variability in how these techniques were applied made it impossible to assess which BCTs were most effective.

Additionally, the review found that while personalised care elements were present in several interventions, the level of individual tailoring was inadequately reported. Hence, it was difficult to assess whether the intervention's effectiveness was linked to the personalised components. The variability in the delivery of these interventions, particularly in relation to the training of intervention providers, further complicated the analysis. Most studies utilised multidisciplinary teams, with nurse specialists and physiotherapists frequently mentioned, yet the exact roles, qualifications, and training of those delivering the interventions were often unclear and underreported. Most interventions were delivered in hospital settings to stable patients, with only one study targeting newly diagnosed individuals.

The review also highlighted limitations in how these interventions were evaluated. There was a lack of consensus on how adherence was defined and measured, which made comparisons across studies challenging. Moreover, only one observational study (200) demonstrated effectiveness in improving adherence to all targeted behaviours addressed in the intervention: medication adherence and smoking cessation. The intervention was a hospital-based programme that focused on cardiovascular risk management for patients with PAD but did not include behavioural science approaches or address specific adherence barriers in its design (200). It is important to note that the intervention measured self-reported medication use and self-reported smoking cessation measures and did not include any validated measured of adherence in its assessment (200). Additionally, given that this was an observational study, without randomisation or power calculation, caution should be applied when evaluating these results.

Only two studies included patient acceptability interviews, and one study included a cost-effectiveness analysis, limiting insights into how acceptable or feasible the interventions were from the participants' perspective. Finally, the lack of guidance on how to implement these interventions in routine clinical practice, poses further questions about their usability within current clinical settings.

3.5.2 Interpretation of findings in relation to other studies

The challenges identified in this review align with previous research on treatment adherence in vascular surgery and other specialities, where consensus on defining and measuring adherence remains inconclusive (216). Specifically for cardiovascular populations, 24-hour recall diaries and refill history are inaccurate measures of medication adherence when compared with pill counts, in both clinical trials and routine clinical practice (216). While prescription data extracted from medical records can confirm whether medications were dispensed or collected, this does not necessarily reflect the actual medication intake; hence, validated self-reported measures are considered more reliable indicators of medication-taking behaviour (217, 218). However, even validated medication adherence questionnaires have some limitations, including the tendency for patients to overestimate their level of adherence and recall bias (60). Similarly, for exercise, there is no gold standard for measuring patient adherence to supervised or home-based exercise programmes (219). A review of PAD exercise therapy (59) also noted the reliance on self-reported adherence measures, such as exercise diaries, which are prone to overestimation and bias, as participants often report better adherence than they actually exhibit in practice (220, 221). Consequently, self-reporting may not accurately detect poor adherence (220), making it a less reliable measure of adherence. A combination of objective measures, such as step trackers or activity monitors, patient self-reports (e.g. diaries) and clinician evaluations is recommended (222).

Current literature suggests that simply providing information is not enough to change behaviour, which is in line with current literature (223). Evidence from chronic disease management suggests that self-regulatory techniques, like self-monitoring and goal setting, are effective in improving adherence (224, 225), and these BCTs were identified in seven and five studies (respectively) included in this review. However, the influence of patient beliefs about their condition and treatment cannot be overlooked, as these beliefs significantly shape their treatment decisions and adherence behaviour (92). Illness perceptions in patients with cardiac disease have been found to affect decisions

patients make about engagement in rehabilitation (226, 227), treatment control (228) and quality of life (229). However, none of the included studies in the scoping review address illness perceptions. In the context of PAD, my pre-doctoral research has identified a strong correlation between illness perceptions and treatment adherence (71, 139). Specifically, negative perceptions of treatment effectiveness and control were associated with lower medication adherence; lower levels of personal control were associated with a positive smoking history; and lower perceived illness consequences on daily life were associated with higher exercise uptake (71, 139). Therefore, it is important that illness perceptions are assessed within current practice and that treatment information is tailored to align with evidence-based recommendations, while addressing patients' beliefs (133). Studies in other chronic conditions have shown that tailored interventions are more effective in changing behaviour (52), and can lead to better health outcomes by empowering patients and improving self-management (230). In this review, the level of personalisation was under-reported and mainly focused on risk factor modification. This finding supports the need for further research to assess the impact of personalised approaches on treatment adherence in PAD.

Additionally, the review examined studies targeting multiple behaviours simultaneously, such as medication adherence and lifestyle risk factor management. This multi-component approach has been examined by other studies, with a recent meta-analysis identifying that focusing on multiple behaviours simultaneously is effective in chronic disease (diabetes, cancer, cardiovascular, and hypertension) management (231). The meta-analysis found that interventions can increase physical activity, improve dietary habits (increased fruit and vegetable intake, decreased fat intake), reduce alcohol consumption, and enhance medication adherence; but do not influence smoking cessation (231). Positive effects were observed immediately post-intervention and during follow-ups, therefore, the authors urged the need to further explore the science behind multiple behaviour change and the interactions between behaviours (231).It is, however, important to note that most patient populations in the studies examined in this review were stable, raising questions about the transferability of the results of this review to more acute or unstable patient populations.

Moreover, this review highlighted the variability in intervention delivery, with limited information on the training and expertise of the involved healthcare professionals. This gap is particularly significant for interventions where the provider's level of expertise may influence the effectiveness of the intervention (147). Without clear reporting on provider qualifications, roles and training received to deliver the intervention, it is challenging to assess the quality, replicability, and generalisability of these interventions. Inconsistent reporting also hinders the ability to identify which intervention components are essential in achieving successful outcomes, limiting the value of the evidence for future studies. These findings are consistent with other scoping reviews of interventions for patients with multimorbidity, where details on provider qualifications and roles were often insufficiently reported (232). Similar issues have also been identified in scoping reviews examining interventions in patients with chronic diseases, such as stroke and venous ulceration (233-235).

In our review, although a few interventions adopted a self-management approach, these were not effective and there was limited information about the level and structure of self-management techniques. In chronic disease care literature, self-management has been shown to improve clinical outcomes and quality of life, as well as reduce hospital admissions (236, 237). A recent randomised trial identified that a nurse-led self-management intervention was particularly effective in improving medication adherence and health outcomes in older patients with multiple comorbidities (238). However, it is important to note that self-management might not be the best approach for each patient and is dependent on the patients' ability and confidence to self-manage (235). Clinicians should assess patients' autonomy and illness perceptions prior to developing effective self-management strategies (239).

Lastly, most interventions in this scoping review were delivered to patients with stable PAD, primarily in secondary care settings. Only one intervention in this review was delivered to newly diagnosed patients with PAD (205). This is surprising, given the results of my previous study highlighting that newly diagnosed patients perceive their disease to be less chronic and threatening and, hence, are less adherent (71). The

observed lack of focus on newly diagnosed patients highlights a critical missed opportunity for early intervention that could significantly contribute to shaping patients' understanding and perceptions of their disease, encouraging adherence and potentially improving long-term outcomes. The absence of early-stage interventions is therefore concerning, as it suggests that current approaches may be failing to engage patients at a time when behaviour change could be most impactful. These findings highlight the need for further evidence and debate between clinicians, patients and researchers to determine the optimal time in the patients' journey to deliver such interventions.

3.5.3 Strengths and Limitations

This review was the first to synthesise available evidence on multi-component interventions to support treatment adherence in patients with PAD. A rigorous process was followed using the JBI scoping review and PRISMA scoping review guidelines to report the appropriate information. Additionally, using the TIDieR (147) and the BCT Taxonomy (102) strengthens the methodological rigour of this review by improving transparency, reporting and the ability to draw meaningful conclusions about intervention components. Database selection and search terms were meticulously planned and guided by consultations with an independent senior healthcare librarian, identifying papers from journals and grey literature to ensure comprehensive coverage.

Although this review was conducted systematically, several limitations exist. Despite efforts to ensure a robust search strategy, some relevant studies may have been missed. A component network meta-analysis, which estimates the effects of individual components within multicomponent interventions (240) was not feasible due to the scoping nature of this review and the heterogeneity of included studies in terms of study design and reported outcomes. Therefore, we could not assess the effectiveness of individual intervention components or their synergistic or antagonistic interactions (241). Similarly, a detailed analysis of study outcomes and risk of bias was not conducted.

The main limitation of this review is the heterogeneity of included studies and intervention components, making it challenging to answer the research questions fully. Moreover, insufficient information in the included studies hindered detailed BCT analysis, which in turn affects the validity of results. In most studies, it was very difficult to assess which BCTs specifically targeted each behaviour. Although reviewers had undergone BCT training and their coding "matched", given the lack of sufficient information in the publications, BCTs may have been underreported. Lastly, most of the included studies were not statistically powered to improve adherence. This limitation makes it challenging to draw definitive conclusions on the effectiveness and implementation of these interventions in clinical practice.

3.5.4 Implications for future research

The findings from this review highlight several key directions for both future research design, and the development of effective interventions for patients with PAD.

To improve methodological rigour and real-world applicability, there is a need for large-scale, theory-driven studies that employ structured frameworks, like the MRC Framework for Complex Interventions (153). Given the complex nature of interventions to address multiple behaviours, these frameworks support transparent development, evaluation and implementation processes, and the design of interventions that are more likely to be effective and acceptable to patients (242, 243).

There is a need for adequately powered trials with larger and more diverse populations to improve generalisability and detect meaningful effects. Pilot studies in single-centre settings can be used to assess the feasibility of interventions before rolling them out in larger, multicentre trials. These initial studies can help refine intervention strategies and assess their potential to be scaled up. Additionally, the effectiveness of these interventions should be tested against standard care, using validated adherence measures to evaluate their impact on clinical outcomes such as quality of life, cardiovascular risk reduction, and medication adherence. Extended follow-up periods are critical to assess how adherence behaviours can be sustained over time, a

dimension often overlooked but essential for achieving long-term health benefits. Literature suggests that initiating behaviour change requires adequate motivation and support; however, maintaining these changes over time is difficult without continued support and should be monitored(53). Given the underpowered studies in the current review, future research should ensure appropriate sample sizes and study power to detect meaningful differences. Furthermore, studies should involve patients with diverse demographic characteristics (age, gender, ethnicity, and comorbidities) to improve the generalizability of findings.

Future interventions should incorporate multiple BCTs, particularly those that have been demonstrated to work in similar contexts, such as self-monitoring and goal setting. It is also essential to report on the feasibility, fidelity, and effectiveness of these interventions, to guide future intervention designs. Importantly, intervention duration should be sufficient to support behaviour change. A minimum of 12 weeks is recommended by prior evidence as a typical threshold for sustained behaviour and habit formation (244, 245). Interventions should also be co-designed with service users to ensure acceptability and relevance, especially for diverse patient groups.

Lastly, adopting a multidisciplinary approach is also recommended, given the multifaceted nature of adherence challenges in patients with PAD. Teams that include nurses, physiotherapists, psychologists, and pharmacists can offer tailored expertise in patient education, behavioural support, and medication management, which is associated with improved outcomes in other chronic disease populations. The inclusion of clearly defined roles and training for intervention providers would also improve implementation fidelity and replicability. Evidence from studies on heart failure and diabetic foot management suggests that multidisciplinary involvement is associated with a more comprehensive clinical assessment and management, better healthcare resource utilisation and reduced hospitalisation rates (246, 247). However, an updated Cochrane review on interprofessional collaboration highlighted that definitive conclusions regarding its impact on patient outcomes cannot be drawn due to the low methodological quality of existing studies (248).

3.5.5 Implications for this work

The findings from this review have several implications for my ongoing PhD project. While Chapter 1 discussed broader challenges for treatment adherence in PAD, this review also highlights some targeted areas that require further exploration during this PhD.

A key issue that needs to be addressed is the definition and measurement of treatment adherence. As highlighted by this review, most studies defined adherence based on broad measures like risk factor management or exercise attendance. During this PhD, I will explore these terminological discrepancies and attempt to suggest a common terminology that both patients and HCPs use that accurately reflects adherence to the full spectrum of guideline-recommended treatments. This will be achieved through PPI, stakeholder engagement and co-design workshop activities, where I will ask participants to collaboratively define what adherence means in the context of PAD treatment.

The underuse of behavioural science in previous interventions for patients with PAD also presents an opportunity for this PhD. Given the positive results seen when behavioural change theory is used in intervention design (as described in Chapter 1), this PhD will utilise frameworks such as the PBA Approach (162) and the PaPa Framework (133) to inform intervention development. Additionally, the PhD will address the gaps identified in the literature regarding the use of BCTs: i) only a few studies have explicitly used BCTs in the design and description of interventions, and ii) only a limited set of BCTs was identified in existing studies. Although shaping knowledge through information about the disease and treatment is important, it is unlikely to be enough to change behaviour. Techniques such as verbal persuasion about capacity and self-efficacy will be explored in more depth, building on insights gained from my pre-doctoral project, which highlighted that empowering patients to be in charge of their care is vital to ensure adherence (71, 139). Barriers and facilitators to adherence will be further explored during the qualitative interviews. Additionally, a broader set of BCTs

will be considered in the design of my intervention, based on findings from the qualitative work.

Based on the results of this review, a multi-disciplinary approach that includes the referral of patients to relevant specialists for the management of other cardiovascular-related conditions, such as diabetes, could be adopted as part of routine clinical practice. However, this may not always be possible, and this will be explored during the HCP qualitative interviews. Discussions with my stakeholder group revealed a lack of awareness of relevant teams that could support the management of patients with PAD. For example, some HCPs reported that they are not aware of whether there is a cardiac rehabilitation team in their setting that would accept referrals of PAD patients. During the PhD, through qualitative interviews with HCPs, I will explore the level and nature of MDT involvement, identifying barriers and opportunities for collaborative care in PAD management.

For this PhD, it is important to consider the best "location" or care pathway to treat these patients, as most studies included in the review reflected interventions delivered in secondary care. So far, my pilot work, PPI and clinician discussions have unanimously suggested that the care of PAD patients should be delivered by a specialist vascular clinician. Despite travel and access barriers, patients have expressed an overwhelming preference towards being reviewed in secondary care as opposed to in a GP setting, as they have more trust in the vascular specialists. It is important to note that this opposes a key shift in the new 10-year NHS plan, which recommends that chronic disease care should move into the community (249). To further explore this point of view and the role of primary care services in the management of patients with PAD, primary care HCPs will also be interviewed during the qualitative interviews.

Lastly, during this PhD, it is important to explore the optimal time in the patients' journey to deliver an adherence intervention. The results of my pre-doctoral study suggested that newly diagnosed patients perceive their disease to be less chronic and threatening and are less adherent (20). PPI discussions have also highlighted the need

for more comprehensive support at the beginning of the disease pathway, so that patients have sufficient time to modify their lifestyle and adhere to the treatment plan, to delay the disease progression. It is surprising that only one intervention in the scoping review was delivered to newly diagnosed patients with PAD (67). The preferred timing for intervention delivery will be further explored during the qualitative interviews and co-design workshops.

3.6 Conclusion

This review highlights that only a few multi-component interventions target all behaviours, limiting holistic support for patients with PAD. None of the included studies effectively improved adherence to all aspects of the guideline-recommended plan and few studies measured the intervention's impact on adherence. As a result, it remains unclear which intervention characteristics are effective, making it difficult to draw firm conclusions or offer evidence-based recommendations on effective intervention characteristics. Hence, further research is needed to assess their impact accurately. Most studies lacked robust theoretical frameworks or behavioural change methods. As education alone is insufficient to change behaviour, future research should focus on other behavioural change techniques, including promoting self-management, goal-setting, and problem-solving. The lack of detailed information on how interventions were implemented hinders the ability to understand how such interventions may be adapted or personalised to meet individual patient needs. To effectively support patients with PAD in managing their complex treatment plan, robust, evidence-based, behavioural science-informed, and personalised multi-component intervention strategies are needed.

Chapter 4. Barriers and Facilitators to treatment adherence: a qualitative interview study

4.1 Chapter Summary

This chapter presents a qualitative interview study exploring experiences of PAD treatment and care, and adherence barriers and facilitators, among patients with PAD, their relatives and healthcare professionals (HCPs) looking after patients with PAD in England. This is the first qualitative study including the perspectives of patients, relatives and HCPs. The study builds upon the qualitative interview study of patients that I conducted during my pre-doctoral fellowship (see Chapter 1) (139), to address identified gaps: i) the perspectives of relatives and HCPs, ii) participants across England. This PhD study utilised the PaPa framework to inform the topic guides and the data analysis. The findings are presented as perceptual and practical adherence barriers and facilitators.

4.2 Aim and Objectives

Aim: To explore the views, experiences, and perceived barriers and facilitators to adherence to guideline-recommended therapy from the perspectives of patients with PAD, families/friends and HCPs.

Study objectives:

1. Explore experiences and views of PAD patients regarding their illness, current treatment information and plan.
2. Explore the barriers and facilitators that influence patients' adherence to their treatment plan from the perspectives of patients, family members and healthcare professionals.

4.3 Methods

4.3.1 Study Design

This qualitative study explored factors associated with non-adherence from the patients', relatives' and HCPs' perspectives, using semi-structured interviews and informed by the PaPa Framework.

Qualitative research is often used to study participants' lived experiences (250). It provides a rich understanding of the studied phenomenon through participants' perspectives (251). Qualitative research is particularly useful to answer research questions of 'how', 'why', and 'what', rather than quantification alone. A qualitative methodology was appropriate for this project, given the lack of comprehensive and theory-informed research in this area. First, as described in Chapter 1, adherence is a complex and often poorly understood behaviour, with existing research focusing on sociodemographic factors rather than behavioural determinants. Hence, an exploratory approach was required to capture how individuals understand and practice adherence in their daily lives. Additionally, adherence barriers and facilitators are deeply embedded in personal beliefs, motivations, routines, social contexts, and practical issues, and cannot be meaningfully explored without a deep understanding of participants' viewpoints. Adherence is a complex issue that continuously changes over time, and it is experienced in a different way by patients, their relatives and HCPs. Although my pre-doctoral survey (71) identified an association between illness perceptions and adherence, the exact relationship could not be fully explored without qualitative research. Moreover, conversations around adherence may involve sensitive topics such as disease burden, fear of side effects, or negative experiences accessing care, making a qualitative, patient-centred approach particularly suited to eliciting nuanced accounts. These considerations support the use of qualitative research as an appropriate and rigorous methodology for this study.

4.3.2 Ethics

The study received Health Research Authority (HRA) Ethical approval (REC reference 24/WA/0075) and local Imperial College Healthcare NHS Trust (ICHNT) Sponsorship (Research Governance and Integrity Team Reference number 24CX8710) on the 9th of April 2024. The study was adopted onto the NIHR Clinical Research Network (CRN) Portfolio. A substantial amendment was approved on the 3rd of September 2024 to include the identification of eligible participants (patients with PAD) via Primary Care Text Messaging databases and to include Mid Yorkshire NHS Trust as a Patient Identification Centre (PIC).

4.3.3 Participants

4.3.3.1 Inclusion criteria:

Patients: Adults (≥18 years of age), with a confirmed diagnosis of PAD documented in medical notes, at any stage of disease (asymptomatic, intermittent claudication, pre/post-surgical intervention, post-amputation).

Family members and friends: Adults (≥18 years of age) who are family members or friends of a diagnosed patient with PAD and are currently supporting the patient with their treatment adherence.

HCPs: Registered HCPs (nurses, doctors, physiotherapists, vascular scientists), with experience of caring for patients with PAD within the last six months.

4.3.3.2 Exclusion criteria:

Patients, and family members and friends: Participants lacking the physical or mental capacity to participate in an interview.

HCP: Not a registered HCP or not caring for patients with PAD.

4.3.4 Sample size

Given the lack of standardised guidelines for evaluation of sample size in qualitative research, achieving data saturation is often used as the “gold-standard”. Following

grounded theory guidance, the concept of data saturation is the point at which further data collection does not provide any new information (252). However, additional qualitative data arguably always provides some new insights (253). Current research indicates that qualitative researchers often lack transparency when reporting sample sizes and the rationale behind them (254, 255). Authors frequently state that saturation was reached, without clarifying how they determined that saturation had been achieved. Correspondingly, Braun and Clarke (253) argue that data saturation is not a valid concept for all qualitative studies, particularly those that are highly interpretative. When data saturation is referred to, Braun and Clarke (253) recommend clarifying how it is conceptualised.

The concept of "information power" has been recently gaining popularity in qualitative research as an alternative method for determining sample size. This approach is based on the idea that the more relevant information a sample provides in relation to the study's objectives, the fewer participants are needed. According to Malterud et al. (256), information power is influenced by factors such as the scope of the research aim, the specificity of the sample in relation to the aim, the theoretical foundation of the study, the quality of interactions between researcher and participants, and the analytical approach used. While information power offers flexibility (253), it has faced criticism for overlooking aspects like the nature of the research aim and suggesting that data are simply extracted from participants, rather than being constructed through the researcher's interpretive process (257). Additionally, Malterud et al. (256) developed this concept for individual interviews, noting that sample determination for other methods, like focus groups, is more uncertain.

For the purpose of this qualitative study, I have utilised elements of information power and saturation to ensure rigour in my sampling. For this study data saturation was confirmed in three ways: 1) during the interviews themselves, where I started to hear repeated themes with no new information arising; 2) confirmation of this repetition at the level of initial coding; 3) ensuring that efforts had been made to achieve sampling saturation according to the purposive sampling criteria.

In my pre-doctoral study, saturation was achieved after interviewing 12 patients. Given that this was a larger study, including participants across the UK, as well as relatives and HCPs, I anticipated interviewing 12-16 participants from each participant group (patients, relatives, HCPs), giving an estimated total of 36-48 participants. These targets were closely reviewed throughout the study to ensure sufficiently relevant participants were recruited to address the aims of the study. This range was chosen to capture both breadth and depth, ensuring sufficient diversity and richness in the collected data.

4.3.5 Sampling

To ensure the collection of the most relevant data, a purposive sampling approach was employed (258). Purposive sampling is commonly used in qualitative descriptive studies, where participants are deliberately selected to provide the most valuable insights into the phenomenon of interest (258, 259). Additionally, purposive sampling can improve transferability of the findings by including populations with various characteristics (258). Purposive sampling techniques vary based on the specific context and objectives of the study (258, 260). In the context of using the Person Based Approach (PBA) for intervention planning, having a diverse sample is crucial to ensure the intervention addresses the needs of a broad range of intended users (158). This approach aligns with maximum variation purposive sampling, which involves selecting participants with differing key characteristics (261).

To ensure the intervention developed would be applicable in different contexts, recruitment took place in four leading vascular secondary care providers, including ICHNT, Hull University Teaching Hospitals NHS Trust, Mid Yorkshire Teaching Hospital NHS Trust and University Hospitals of Leicester NHS Trust; and primary care centres in North West London. This approach ensured the inclusion of patients from varied ethnic and sociodemographic backgrounds across different parts of England. Leicester, with more than 50% of its population identifying as Asian (43.4%) and Black (7.8%) (262); Mid Yorkshire and Hull, the third most deprived areas nationally, were chosen to ensure

a diverse sample. Primary care networks were chosen to specifically target patients who do not attend their secondary care appointments.

Patients interested in taking part in the study completed a screening questionnaire (paper or online), with the assistance of the researcher (SL), which supported the selection of a diverse sample across sociodemographic characteristics (age, gender, ethnicity, socio-economic deprivation), stages of PAD (e.g., newly diagnosed or diagnosed for several years, pre- or post-surgical intervention/amputation), levels of adherence and factors affecting adherence (e.g., sociodemographic characteristics, disease severity including claudication pain, environmental factors such as weather or access to facilities). Patients who completed the questionnaire were also asked if they were happy to share their contact details with the researcher (SL). They were informed that they might not be selected for the interview study, but that there would be an opportunity to participate in another component of this PhD project (e.g., PPI or co-design). Verbal consent was obtained to record their contact details.

Patients were categorised as adherent or non-adherent based on information from the screening questionnaire, and explicit questions about their medication taking behaviour, smoking status and exercise levels. Their adherence level was confirmed at the interview stage. Adherence was assessed against NICE guideline recommendations for intermittent claudication (8). Patients were considered adherent if they reported behaviours broadly consistent with recommended PAD management: i) taking all or nearly all of their medications; ii) not smoking; and iii) completing a minimum of 150 minutes of weekly, unsupervised physical activity (e.g. walking). However, adherence was not always clear-cut. Some participants met all of these recommendations, while others adhered to some aspects of treatment but not others. For this reason, participants were considered as non-adherent in a particular domain if they reported behaviours such as: i) regularly skipping or halving medications, taking treatment breaks, discontinuing their medications; ii) smoking; and iii) not meeting the guideline-recommended exercise requirements. Patients who were adherent to some behaviours but not others were not excluded; this allowed for variation in adherence levels to be explored within the analysis.

Regarding relatives, participants were included from various sociodemographic backgrounds (age, gender, ethnicity, socio-economic deprivation), differing in the type of relationship with the patient (e.g. blood relative, spouse, friend), supporting patients who were at different stages of their diagnosis (e.g., newly diagnosed or diagnosed for several years); who had different levels of adherence and factors influencing adherence (e.g., sociodemographic characteristics).

Lastly, HCPs with different personal characteristics (gender, ethnicity), professional backgrounds and role titles (e.g., nurses, doctors, physiotherapists, pharmacists, etc), levels of seniority or experience (junior, experienced, specialists) and working within different settings (primary care, secondary care, specialist vascular clinics) were selected.

4.3.6 Recruitment

4.3.6.1 Patients and Relatives

The identification of potential patients with PAD involved screening of both electronic and paper notes to confirm a diagnosis of PAD. At ICHNT, I undertook all recruitment activities and approached patients directly at vascular outpatient clinics, and vascular inpatient wards. For the duration of this study, Hull University Teaching Hospitals NHS Trust, Mid Yorkshire Teaching Hospital NHS Trust and University Hospitals of Leicester NHS Trust acted as PICs. In the PICs, the leading vascular clinicians, during usual clinic appointments, provided the participant information sheet (PIS) and a brief overview of the study to eligible participants. Potential participants who were willing to take part in the study were asked to either contact me directly or give permission to share their contact details with me, after which I would contact them to discuss the study, complete the screening and consent and any study activities.

Additionally, NIHR CRN Primary Care centres in North West London participated as PICs. In the primary care centres a database was created to identify potential eligible participants using the term “Peripheral Arterial/Artery Disease”. A text message was

then sent from the primary care centres to patients in the PAD database. Participants were asked to contact me directly (by phone or email) to discuss the study.

Patients interested in participating were asked if they had a family member or friend who would also be willing to participate in the study. If a family member or friend was interested, their preferred method of contact was shared with me. I then contacted them directly to discuss the study and sent them the PIS by their preferred method of contact (email or post).

4.3.6.2 Healthcare professionals

Recruitment took place at the associated ICHNT sites, and the PICs, as well as through professional networks and social media platforms. The study PIS and leaflet were shared with the Royal College of Nurses forum, the Practice Nurse UK forum, the Society of Vascular Nurses forum, the Society for Vascular Technology forum, the British Association of Chartered Physiotherapists in Limb Absence Rehabilitation, the Vascular Society, Lower Limb Clinicians 2gether Facebook group, the PAD Specialist Interest Group and on X (previously Twitter). Interested HCPs were asked to contact me directly to receive more information about the study.

4.3.7 Data Collection

4.3.7.1 Patient Sociodemographics

Patients were asked to consent to their sociodemographic and clinical information being collected. Following recruitment to the study, sociodemographic characteristics, clinical and medication prescription information were extracted from electronic medical records and cross-checked with patient participants. These included gender, age, postcode, previous medical history, years of PAD diagnosis and a list of prescribed medication specific to PAD. Data about previous vascular interventions and the presence of CLTI were also collected. I also asked patients about their smoking status (never, ex or current smoker) and physical activity level. The latter was assessed by asking patients if they were physically active (yes/no) for more than 30 minutes per day and how many times per week they exercised. The patients' postcode was used to

calculate the deprivation status using the 2019 Index of Multiple Deprivation (IMD) quintile (https://imd-by-postcode.opendatacommunities.org/imd/2019). Quintiles were calculated based on the decile data, with Quintile One representing the most deprived and Quintile Five representing the least deprived.

4.3.7.2 Qualitative Data

In qualitative descriptive studies, interviews are the most frequently used method for collecting qualitative data, with semi-structured interviews being the most prevalent format (263). Semi-structured interviews can be conducted either individually or in groups, and usually last from 30 to 60 minutes (263). During semi-structured in-depth interviews, the researcher/interviewer typically follows a set of pre-planned open-ended questions, whilst maintaining flexibility to include additional questions that may arise naturally from the conversation between the researcher/interviewer and the participant(s) (263). This approach contrasts with structured interviews, where the response options are fixed by the researcher (264).

A key advantage of individual semi-structured interviews is their ability to collect detailed, personal insights from participants, allowing them to share their experiences openly without the influence or pressure of others being present (263, 265). Given the diverse perceptions and behaviours being examined and the involvement of various participants in this study, the flexibility of semi-structured interviews allows the deep exploration of certain topics while still covering a wide range of potential influences in each interview, which may not have been achievable with methods like surveys.

Group interviews, in the form of focus groups were also considered for this study, specifically for families and HCPs to facilitate the exploration of individual experiences in a collaborative setting and to understand a range of views through discussion. Focus groups can be useful for observing participants' different perspectives on the discussed topics, allowing the focus group moderator to explore in depth any similarities or differences in real time (266).

The decision to use individual semi-structured interviews was chosen following feedback from the established PAD patient and public involvement (PPI) group, in which many patients and relatives expressed they would feel uncomfortable speaking in a group. Healthcare professionals also reported that one-to-one interviews would be more feasible given time restrictions and availability. During the recruitment process, although an opportunity was made available to participate in focus groups if any participants (patients, relatives of HCPs) would prefer this, none of the eligible participants opted for a focus group.

In this study, in-depth semi-structured interviews lasting approximately one hour were conducted virtually (telephone/video) or in person at the collaborating NHS sites, based on the participant's and researcher's availability. Before conducting the interviews, I checked verbal consent with participants. At the start of each interview, the aim of the study was explained. Participants were also reminded that there were no right or wrong answers and that they should offer their honest opinions. Time was given for any questions to help create an open, friendly environment.

The interviews were audio-recorded and transcribed by a third-party organisation. For interviews completed virtually by video conference, only voice recordings were kept. Recordings were pseudonymised and stored on an ICHNT computer that is password-protected. The transcripts were verified, pseudo-anonymised using a number coding system, and stored securely in password-protected files. Participants received a £20 voucher as thanks for their participation at the end of the interview. The researcher made field notes during and/or shortly after each interview.

4.3.8 Topic guides

The topic guides were based on previous literature, the pre-doctoral project and the theoretical framework for this study, the PaPa. Topic guides are used for data collection in qualitative research, built around the objectives and questions the researcher wants to explore (267, 268). Topic guides ensure that meaningful and sufficient data is collected (267, 268).

Open-ended questions were used to encourage participants to give detailed answers and to allow for prompts if they had difficulty answering or understanding the main questions. The initial topic guides for interviews were developed based on the results of my pre-doctoral study; the scoping review findings; existing literature and the PaPa framework. The topic guides were discussed with the supervisory team to ensure the questions were appropriately phrased. Each topic guide was then reviewed by the PPI group and relevant healthcare professionals to ensure usability.

A different topic guide was used for each group of participants (see Appendix 3). The patient topic guides covered the understanding of PAD and its management; information and support for guideline-recommended treatment adherence; experiences at each stage of the patient journey related to treatment adherence; the current pathway of treatment for PAD; and perceptual (e.g. beliefs) and practical (e.g. organisational issues) barriers and facilitators to adherence. The relatives' interviews were focused on the perceived patient experiences of management for PAD and the role of social support. The HCP interviews focused on perceived patient experiences of conservative management for PAD, current available guidelines, current service delivery, and systems-level barriers and enablers in the diagnostic and treatment pathway. Participants were also asked to offer solutions and strategies to address or prevent the barriers reported.

4.3.9 Data analysis

All interview audio-recordings were transcribed verbatim by a professional transcription company. Transcripts were managed on Qualitative Data Analysis Software (QSR N-VIVO, Version 14). The interviews were analysed using thematic analysis, as described by Braun and Clarke (269). The process of thematic analysis follows a clear structure: familiarisation with data, generation of initial codes, searching for themes, reviewing themes, defining and naming themes and producing the final report. Additionally, deductive thematic analysis was then conducted, mapping the themes into the PaPa.

Step 1- Familiarisation with the data

The first step of the analysis was to familiarise myself with the data. After I received the transcripts, I listened to the relevant audio-recording and compared the transcripts with the audio recordings to check accuracy, make corrections where necessary and increase my familiarity with the data. Following this, I read the manuscripts at least once, noting down initial thoughts to start critically engaging with the data. These notes were used as part of the reflective journal.

Step 2- Coding

The next step included data analysis with line-by-line open coding to identify segments of data that might be of interest or relevance to the research questions. Coding labels were developed iteratively for each phrase or idea of interest that captured meaning. At least two rounds of coding were undertaken to ensure a fresh perspective on the dataset. Once the coding tree was developed, it was discussed with the supervisory team (MW & GJ), to ensure it was reflective of the data. An example of coding is presented below in Table 19. The coding and analysis framework is presented in Appendix 4.

Table 19 Coding for sub-theme "Systematic nature of disease and treatment benefit"

Theme	**Sub-theme**	**Codes**
Knowledge & Understanding about disease & treatment	Systematic nature of disease and treatment benefit	Lack of understanding of systemic nature of disease; Chronic Vs acute; Unusual concept that exercise and lifestyle changes is the treatment; Patients with better disease understanding engage better with their treatment; Benefit of walking; CVD systemic nature; Why take statins; Link of smoking and PAD; Understanding disease process & aetiology

Step 3- Generating initial themes

Clusters of codes that share the same meaning were then grouped together to describe a potential theme for further exploration. Each theme captured a pattern of shared

meaning across the dataset. I ensured that the themes/subthemes did not simply provide synopses of all participants' comments on specific topics. Interview data from patients, relatives and HCPs were analysed together for several key reasons. The primary aim of the qualitative study was to identify barriers and facilitators to treatment adherence. As similar questions were used across groups to achieve this aim, it was anticipated that similar topics would be discussed during the interviews. Analysing these data sets together facilitated a comprehensive comparison, both within adherence groups (e.g. between adherent and non-adherent patients) and across participant groups (patients, relatives and HCPs), highlighting shared and contrasting perceptions. This combined analysis provided a more comprehensive overview of the explored topic (treatment adherence) from different perspectives.

Step 4- Developing and reviewing themes

To consider the overall "story of the analysis", I then drew a visual thematic map (see Figure 14). The thematic map presented the interconnections between different recurrent features of the data, specifically how they related to each other and how they differed, to support the identification of potential themes and subthemes. I also critically reviewed the potential themes/subthemes to check that they were sufficiently supported with data, clearly defined and coherent, and that all codes were correctly grouped and aligned with each theme. This led to redevelopment of all the themes/subthemes and collapsing of some themes/subthemes. The potential themes were discussed with the supervision team and the PPI group to reach a consensus on the identified themes (see Figure 15). To facilitate the reporting, barriers and facilitators within each subtheme were grouped together. Other considerations related to a theme/subtheme were also grouped together where appropriate.

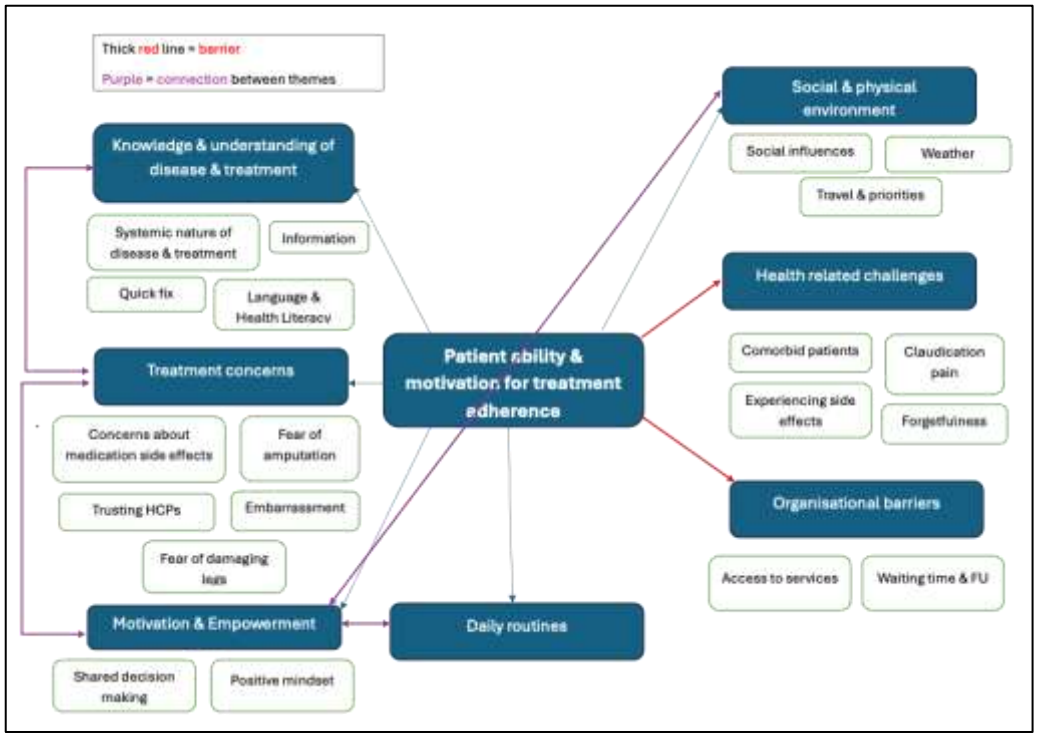


Figure 14 Initial theme generation (January 2025)

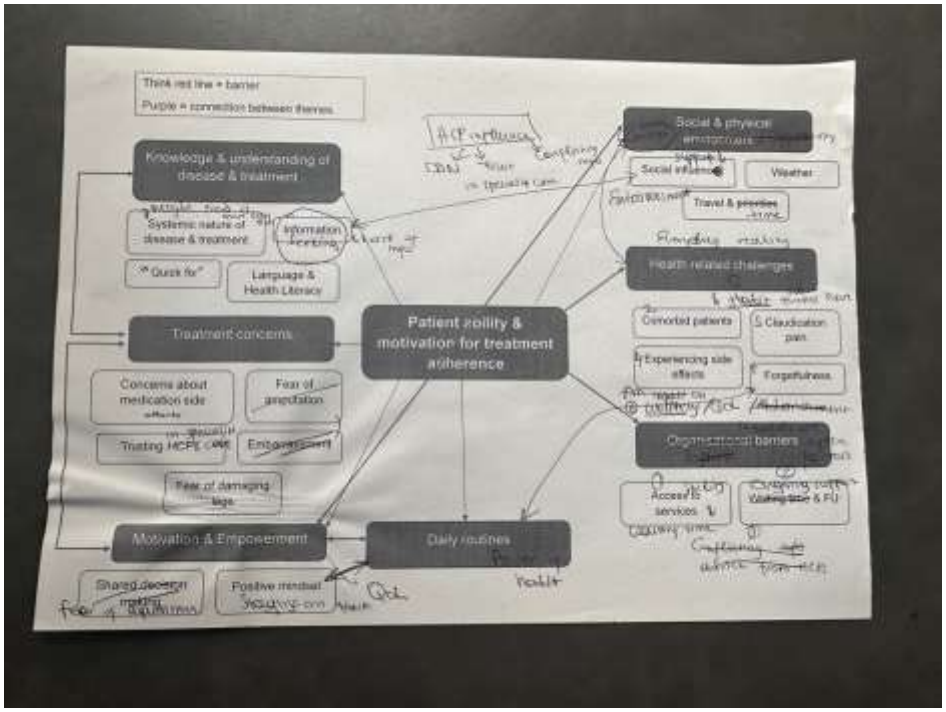


Figure 15 Refinement of themes following feedback from my supervisors (January 2025)

Step 5- Refining, defining and naming themes

In this step, I reviewed the themes/subthemes, writing a brief definition of each theme/subtheme and allocating them informative names (see Figure 16). Refinements to the specifics of themes and thematic patterns continued until a meaningful analysis was achieved; and the thematic map was approved by the supervisory team (see Figure 17).

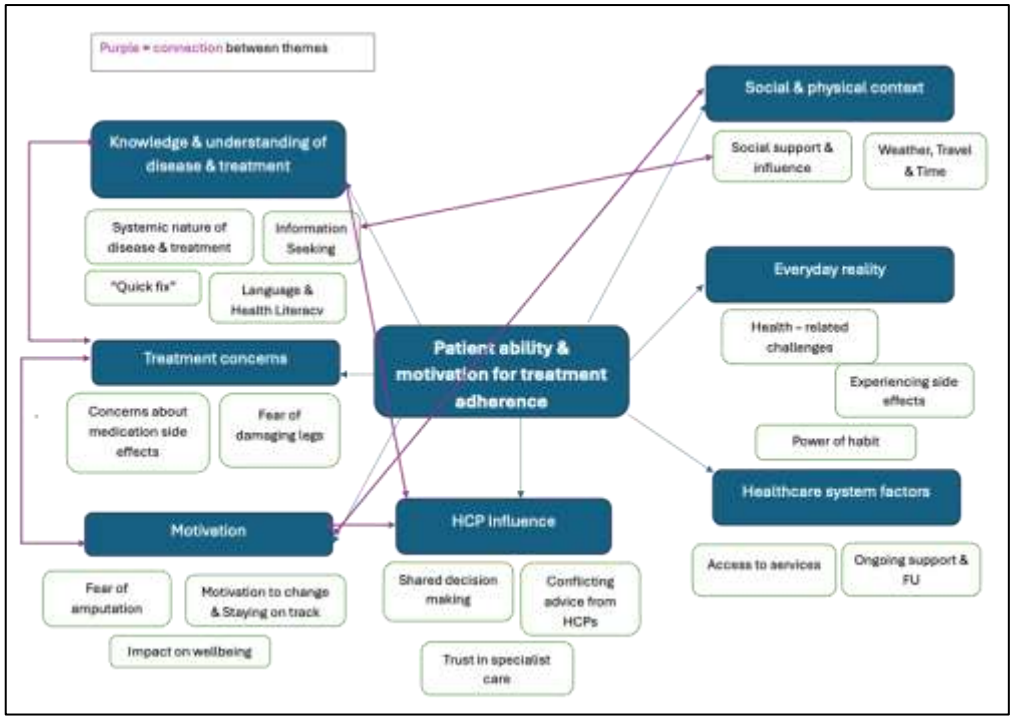


Figure 16 Updated theme refinement (February 2025)

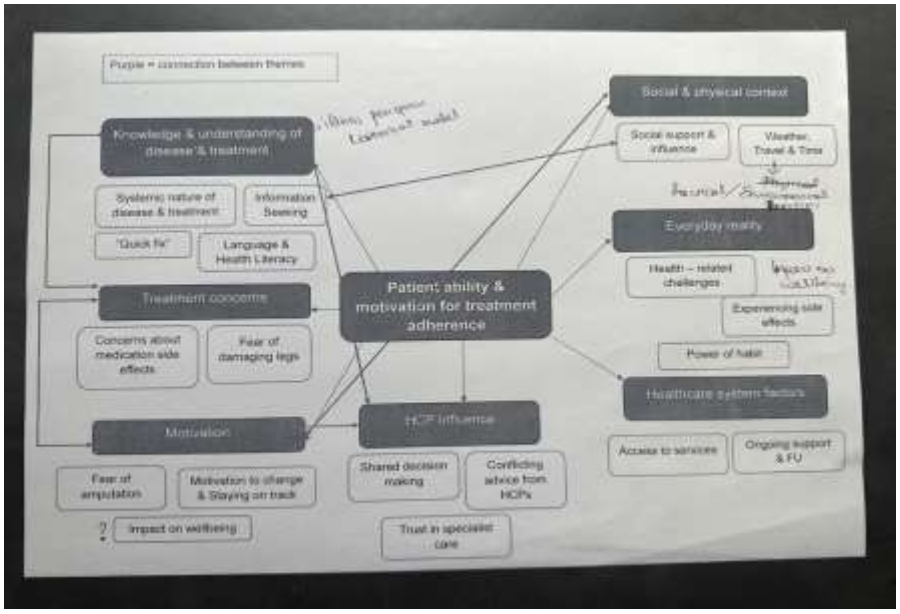


Figure 17 Updated theme refinement following feedback from my supervisors (February 2025)

Step 6- Writing

Both inductive and deductive approaches were used in the qualitative analysis, combining the inductive element, ensuring the analysis closely reflected the data, with the deductive use of the PaPa framework providing additional structure and theoretical grounding. This combined approach is often used for behaviour change intervention development purposes (270-272). Most concepts were drawn directly from the raw data through inductive analysis (270). Deductive thematic analysis was used when exploring adherence barriers and facilitators, using the PaPa.

Initially, inductive thematic analysis was completed at the respondent level to identify overall themes identified by participants from their lived experience, as part of a phenomenological methodology (273). Once I had developed the themes and subthemes, following inductive analysis, I then mapped the identified themes/sub-themes to the PaPa deductively. This allowed the findings to be organised systematically, into perception and practicalities influencing adherence. It is important to note that some themes did not map directly to the PaPa, nevertheless, these are still reported. Through the data analysis, I liaised with the established PPI group to discuss the credibility and meaningfulness of themes. The final themes were discussed with the supervisory team (GJ & MW) and the PPI group until a consensus was achieved.

4.3.10 Reflexivity

I conducted this qualitative study during my full-time NIHR Doctoral Research Fellowship. I recognise that my clinical background, perceptions, experience and biases may influence the data collection, the interactions with the participants, the analysis process and interpretation, therefore reflexivity is crucial (274, 275). Reflexivity involves ongoing, collaborative, and multi-dimensional practices where the researcher critically examines, assesses, and evaluates how their subjectivity and context affect the research process (274, 275). Walsh identified four interconnected and overlapping dimensions of reflexive processes: personal, interpersonal, methodological, and contextual (276).

Personal reflexivity: I am a female cardiovascular nurse with eight years of post-registration clinical experience. I became invested in the field of adherence and PAD during my clinical role as a cardiac rehabilitation nurse specialist in 2019. In my role, I noticed that most patients with PAD were less engaged and less adherent to their treatment plan compared to patients with myocardial infarction. As a clinician, based on discussions with my colleagues, and my experience of looking after patients with PAD, I have developed perceptions and beliefs about factors that might affect patients' treatment adherence. Since then, I have completed training in qualitative research to enable me to conduct patient interviews during my pre-doctoral fellowship. That was my first experience of qualitative research. During my PhD, before undertaking this qualitative study, I completed further training on advanced qualitative methods. To continuously challenge my personal reflexivity, I recorded my biases and perceptions in a reflexive journal, which was then discussed with the study team.

Interpersonal reflexivity: To ensure transparency and rigour, there were no pre-existing relationships between myself and any of the study participants. Before consenting, I informed all study participants of my professional background and my research role during this project, which was to listen to their perspectives, not to offer clinical advice. Regarding patients, I was not directly involved in their care and have never provided care for them in a clinical setting. The patients were told that the

interviews were an opportunity for them to share their experiences of living with PAD, regardless of their adherence, without judgement or any implications for their care. Considering my active presence in the clinical vascular speciality, many of the HCPs interested in taking part in my study may have previously met me in a professional environment, e.g. conference. I aimed to include HCPs with whom I did not closely collaborate or work together, to minimise socially desirable bias in their responses.

Methodological reflexivity: During the interviews, I kept field notes and completed a reflexive journal afterwards. This allowed me to reflect on my interactions with participants, the flow of the topic guide, my initial thoughts, and any necessary adjustments for smooth interviews, as well as my own bias and how this could influence the research. During the data analysis, I continued to complete a reflexive journal to document my analysis decisions. The reflexive journal was reviewed with the study team during data analysis to discuss potential areas of bias. I also liaised with my PPI group to ensure that my assumptions were continually challenged. I conducted all interviews myself to reduce differences in the way questions were asked.

Contextual reflexivity: Being contextually reflexive means understanding and critically reflecting on the unique research setting (276), in this case vascular outpatient settings in university hospitals, and how this shapes the research and findings. Reflecting on the context's impact on the research and vice versa and based on discussions with the PPI and clinician experts, patient interviews were not held on the same day as a clinic appointment, as their experience of the clinic on that day could influence or change answers to the questions asked. Where possible, interviews were conducted separately with patients and family members/friends, so that participants felt able to discuss opinions freely without influence. However, where patients expressed a specific preference to be interviewed with a family member or friend, this was facilitated.

It was also important to reflect on the impact of the interview mode. Whilst video and phone interviews offer flexibility and convenience, they may limit observations of non-verbal cues, whereas in-person interviews may allow for richer rapport and interaction.

Most patient interviews took place in person, in a quiet room near the vascular clinic, but on a different day from their appointment. This familiar setting may have helped patients feel comfortable and contextually connected to their care experiences. However, it may also have influenced their responses, as the hospital environment could evoke emotions related to their recent clinical appointment or treatment. Two interviews were conducted on the same day as the patients' clinic appointment, following their request. In these cases, responses were notably shaped by their immediate experiences.

Regarding HCP interviews, the issues of clinical and professional hierarchies were considered. As most clinicians were more senior than me, conducting interviews in a hospital setting risked reinforcing hierarchical dynamics and affecting conversational flow. Therefore, online interviews were prioritised, as they provided a more neutral space that encouraged openness and reflection beyond the clinical environment. Below I have entered examples from my reflexive journal (See Table 20).

Table 20 Reflexive journal entries

Example 1. Following my visit to Glenfield Hospital in Leicester after interviewing two patients who experienced minor and major amputation
"Deprivation remains a major issue. Many patients I met have lost their jobs, rely on benefits, and struggle to cover basic living expenses. These financial and social pressures influence their health and engagement with care. Their QoL is also affected, mainly due to the amputation, the lack of financial security and limited access to resources. What does QoL mean for different patients? Important to empower patients to achieve their individual goals, whether it's gardening or returning to work or looking after the grandkids, etc. Patients reported that their first point of contact when their symptoms started was their GP. They stayed under GP or district nurse care for 6–8 weeks with little or no progress, and often without a clear explanation of what was happening. One received an incorrect diagnosis, resulting in him developing CLTI and losing his leg. This patient described his GP as rubbish and he became very emotional speaking about his experience. The other patient said that she would prefer to be looked after in the community, but only by the vascular people. Both patients also spoke about the importance of accurate diagnosis and support at the start of their disease journey. They emphasised the need for education, setting clear expectations, and being offered choices. When asked about using technology-based interventions, neither was keen to do so, as they don't have a smartphone and aren't tech-savvy.

What does that mean for my PhD? Are GPs adequately trained or equipped to manage PAD? Generalist Vs Specialist. Need to interview some GPs to understand their perspectives. If I focus on newly diagnosed patients, what does that mean about maintenance? And how about CLTI? It's important to offer something to newly diagnosed patients. It's the best opportunity to make changes. Then maybe we can also talk about habit formation? Like the book I read 'Atomic Habits'. I feel like CLTI is a whole category on its own, and my main focus was always on claudication, rather than CLTI. If we can manage claudication better, then we can prevent CLTI."
Example 2. Following a negative interview with a clinician
"I found this interview difficult as I felt that this doctor was not in touch with the current reality of NHS waiting lists and increasing numbers of CLTI cases. They were blaming primary care for all issues that we experience in vascular surgery, and did not take any accountability for the management of the patients. From their body language and tone, I felt like I was being undermined because of my professional background and institution. I found it very difficult to put my emotions aside during the interview and remain neutral. During the coding of the interview, I need to ensure that I focus on the interpretation of the data and put aside my personal views."
Example 3. Following the completion of interviews and the familiarisation with the data
"I've been reflecting on how many adherence barriers patients face, including lack of understanding, unrealistic expectations, seeking quick results, multimorbidity, and poor access to care. Adherence can't be fixed overnight. It needs to target both patients and clinicians. With this PhD, I am mainly focusing on patient behaviour. Disseminating my results could potentially change clinician behaviour, as they will be more aware of the issues patients experience and how to address them. But how can I fix the issue of access to services? I need to remember I cannot fix everything during my PhD. But other specialities have done this. What is the issue with vascular? The key difference in vascular compared to cardiac rehab is the lack of a uniformed, commissioned care pathway. Why is cardiac rehab commissioned but not SET? Manchester seems to have a good system, but it hasn't been replicated elsewhere. The ICB commissions this, but why is this not the case elsewhere? How can we collaborate with the ICB? I need to start making links with them and think about post-PhD next steps."

4.4 Findings

4.4.1 Participants

Overall, 39 participants were recruited and 37 completed the study: fifteen patients, four relatives and eighteen healthcare professionals. Figures 18 and 19 present the recruitment process and flow of individuals through the study for the patients with PAD

and for HCPs. Despite all patients being asked to nominate a relative to participate in the interviews, only five did so. A patient and a relative who consented to participate in the study withdrew from the study due to medical emergency reasons.

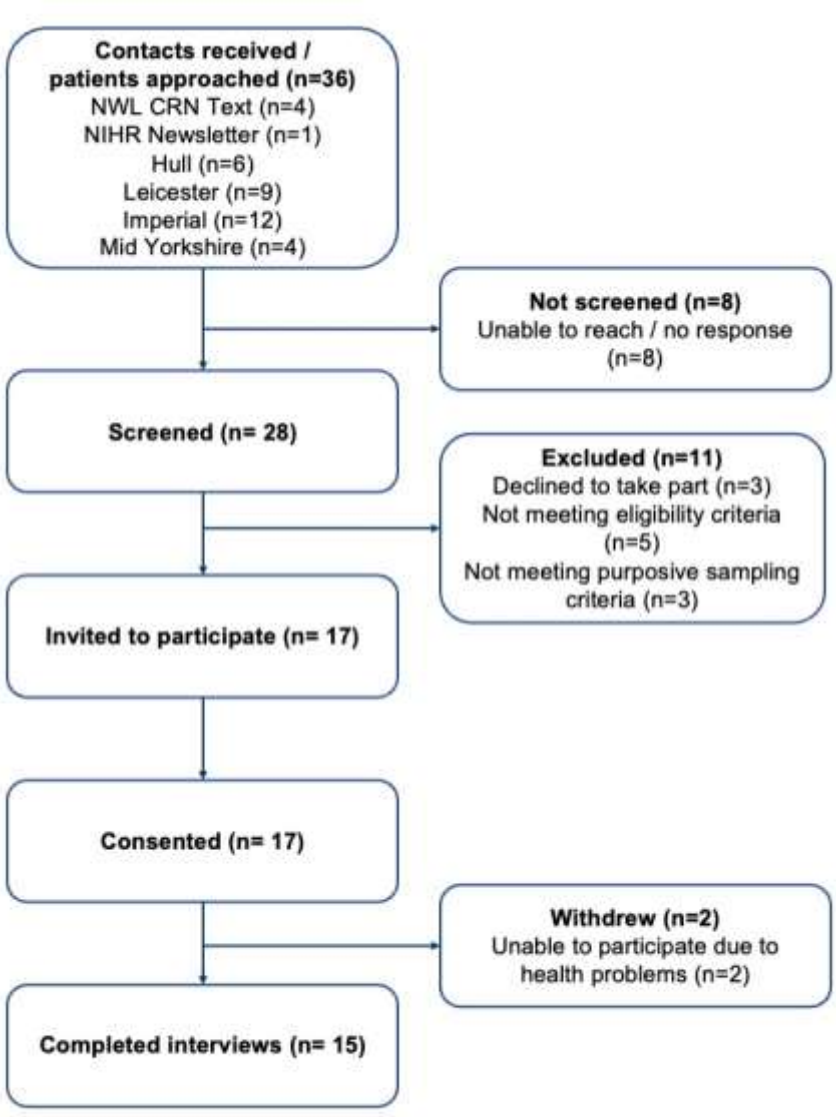


Figure 18 Patients recruitment flow chart

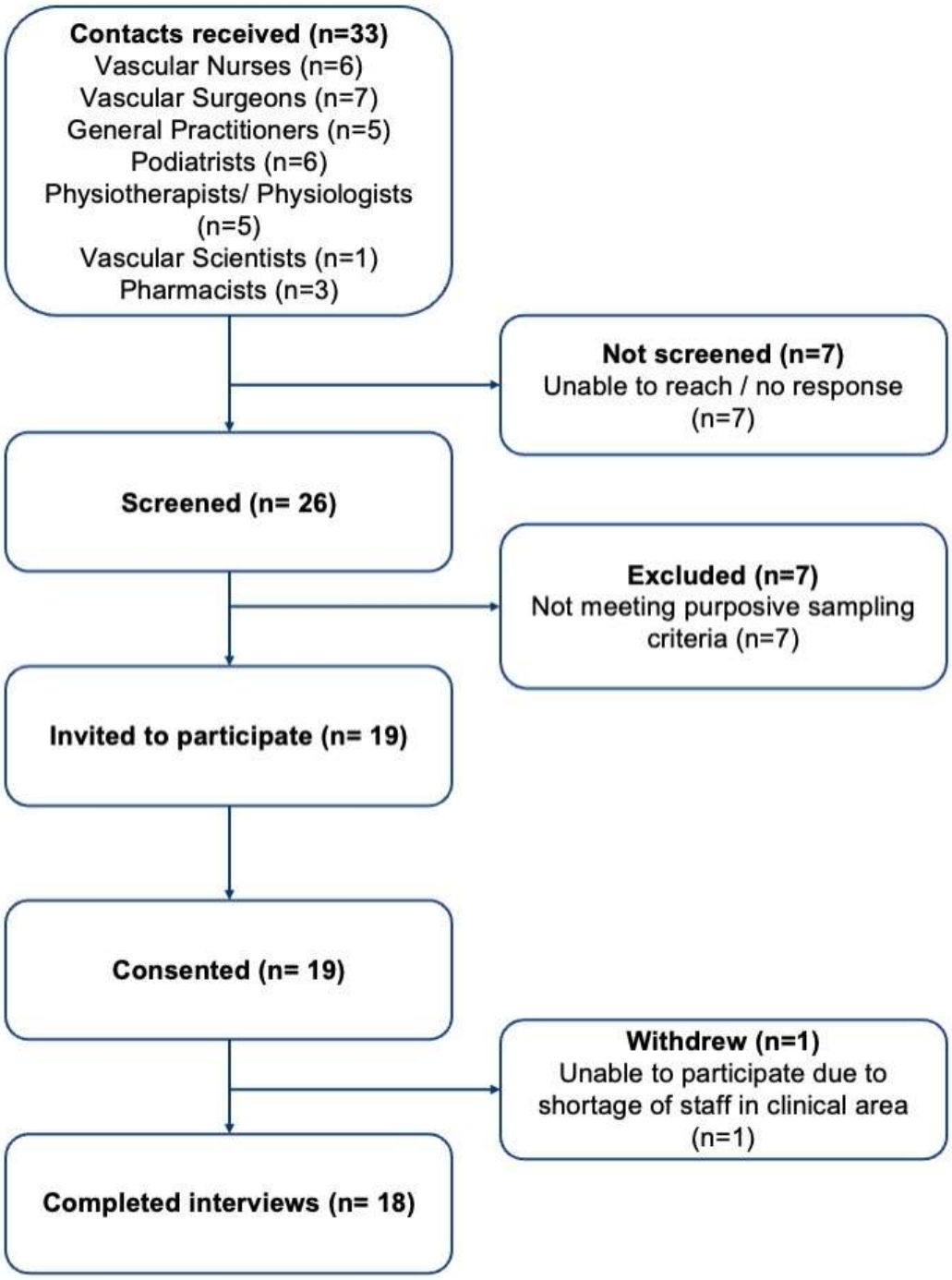


Figure 19 Healthcare professionals recruitment flow chart

Tables 21 and 22 present the characteristics of the included study participants. Patients were recruited from different Trusts in England: five from ICHNT, four from Glenfield Hospital NHS Trust as part of University Hospitals of Leicester NHS Trust,

three from Mid Yorkshire Teaching Hospital NHS Trust and three from Hull University Teaching Hospitals NHS Trust.

Of the 15 patients who took part in the study, eight were men and seven were women, and their ages ranged from 48 to 82. More than half the patients (eight out of 15) were White British, and only one patient did not speak English. This patient participated in a dyadic interview with their relative, who translated on their behalf. Six patients lived in the most deprived areas in the UK (IMD Quintile rank 1), while two patients lived in the least deprived areas (IMD Quintile rank 5). Eight patients had been diagnosed with PAD for less than 6 months at the time of recruitment, with four of them presenting with CLTI at the time of diagnosis. Lastly, most patients (nine out of 15) had previously undergone surgical revascularisation for PAD. Only three patients (P3, P8, P11) were characterised as adherent across all treatment domains; and one patient (P14) was non-adherent across all treatment domains. Three patients (P4, P13, P14) reported not taking any medications, despite these being prescribed by their HCPs. Two patients (P1, P15) reported not taking any statins due to previously experiencing side effects. Although five patients reported taking their statins most of the time, they were non-optimised, as they declined to be on the optimal statin dose following recommendations by their HCPs. Three patients were current smokers (P4, P14, P15), whilst two patients were recent (less than six months) ex-smokers (P5, P13). Lastly, half (eight out of 15), met the daily exercise recommended goal.

Table 21 Patient characteristics based on purposive sampling criteria

Participant	Gender	Age	Ethnic group	Deprivation Index Quintile	Years diagnosed with PAD	Previous vascular intervention	Previous CLTI	Medication adherence	Smoking status	Meeting the exercise goal
P1	Female	72	White British	3	Newly diagnosed - CLTI	Yes	Yes	Not on statins, adherent with aspirin	Ex smoker	Yes
P2	Male	74	Black or Black - African	2	16 years	Yes	No	Yes – high but only on atorvastatin 40mg	Ex	No
P3	Male	67	White British	4	15 years	Yes	No	Yes – high	Ex smoker	Yes
P4	Male	53	Other – Persian	1	Newly diagnosed - CLTI	Yes	Yes	Not taking meds	Smoker	Yes
P5	Male	85	White British	3	Newly diagnosed - CLTI	Yes	Yes	Yes - high	Recent ex-smoker	Currently bedbound - amputee
P6	Female	58	Black or Black - African	4	Newly diagnosed - CLTI	Yes	Yes	Yes with Clopidogrel. On artovastatin –	Never	No

								forgets to take sometimes.		
P7	Male	59	Asian - Any other Asian Background	1	9 years	Yes	No	Yes – high but only on atorvastatin 40mg	Ex	No
P8	Female	66	White British	1	19 years	No	No	Yes - high	Ex	Yes
P9	Female	61	Black or Black - Caribbean	1	8 years	Yes	No	Yes - high	Ex	No
P10	Female	82	White British	5	5 years	Yes	No	Yes – high but only on atorvastatin 40mg	Ex	Yes
P11	Male	70	White British	4	13 years	No	No	Yes - high	Never	Yes
P12	Female	70	Asian - Indian	1	Newly diagnosed	No	No	Yes – high but only on atorvastatin 40mg	Never	No
P13	Male	69	White British	5	Newly diagnosed	No	No	Low – not taking any medications	Ex smoker (recent)	Yes
P14	Male	48	Asian - Indian	3	Newly diagnosed	No	No	Low – not taking any medications	Current smoker	No

P15	Female	72	White British	1	Newly diagnosed	No	No	High adherence antiplatelet – not taking statins	Current smoker	Yes

Abbreviations: PAD: Peripheral Arterial Disease; CLTI: Chronic Limb Threatening Ischaemia

Table 22 Relatives characteristics based on purposive sampling criteria

ID	Gender	Relative of patient	Relationship with patient
1	Female	P3	Wife
2	Female	P2	Grand daughter
3	Female	P10	Daughter
4	Female	P12	Daughter

Of the 18 recruited HCPs, 5 worked in primary care and 13 in secondary care. The sample comprised four vascular surgeons, three vascular nurses, three podiatrists, three physiotherapists/physiologists, two General Practitioners (GPs), two pharmacists and one vascular scientist. Tables 23 and 24 present the professional titles of HCPs and their years of experience looking after patients with PAD. Figure 20 presents the geographic location of recruited HCPs.

Table 23 Professional titles of recruited HCPs

Advanced Vascular Nurse Practitioner	1
Highly Specialist Amputee Rehabilitation Physiotherapist	1
Clinical Lead Physiotherapist	1
Community Vascular Specialist Podiatrist	2
Community Lead Pharmacist	1
Consultant General Practitioner	1
Consultant Vascular Surgeon	4
Diabetic Lead Podiatrist	1
Practice Partner General Practitioner	1
Professor of Clinical Exercise Science	1
Vascular Clinical Nurse Specialist	2
Vascular Scientist	1
Vascular Ward Pharmacist	1

Table 24 Years of professional working experience looking after patients with PAD

Years	Number of participants
1-4	2
5-9	3
10-19	9
>20	4

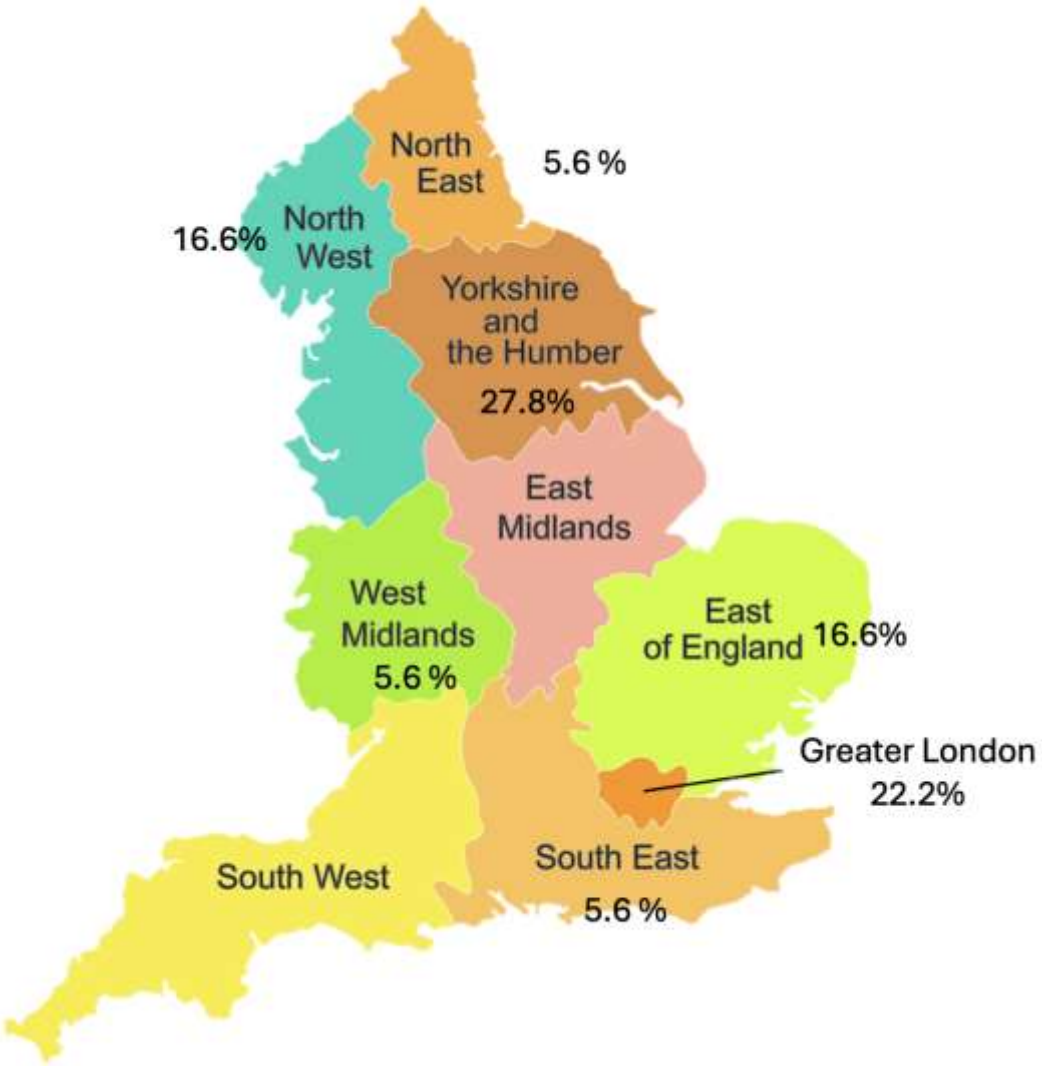


Figure 20 Geographical location of recruited HCPs

4.4.2 Themes & sub-themes derived from interviews

Seven themes were identified, with four mapped to “Perceptions” and three to “Practicalities” (see Figure 21).

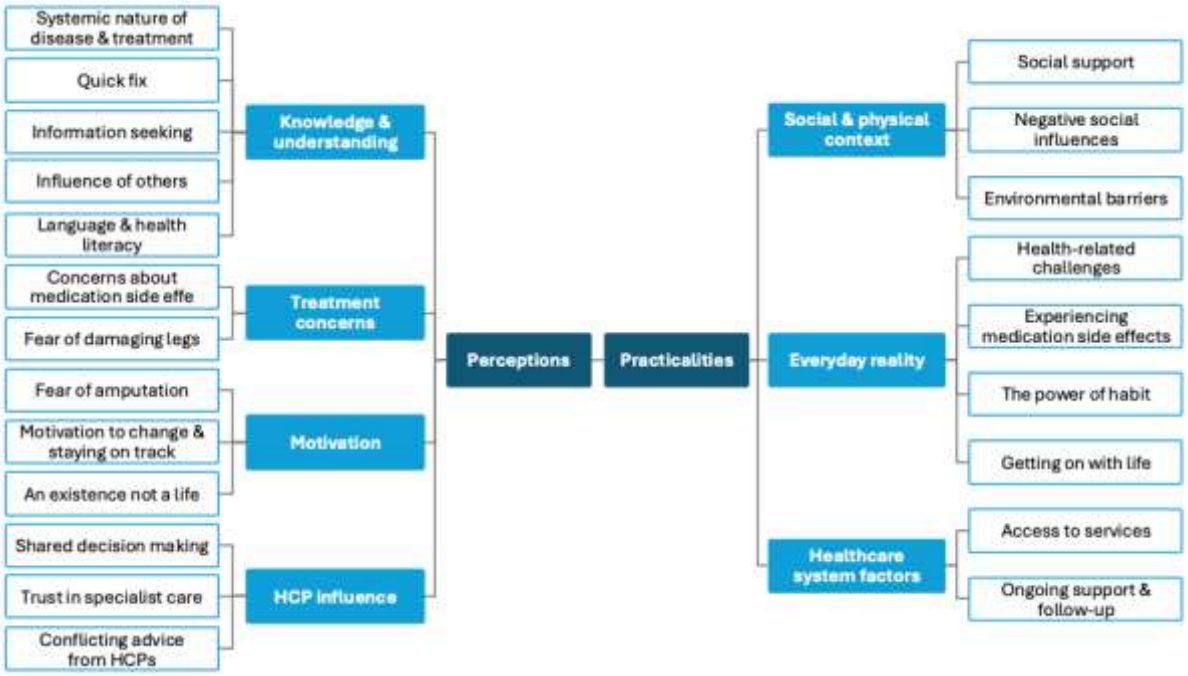


Figure 21 Themes and sub-themes

4.4.2.1 Perceptions

4.4.2.1.1 Theme 1: Knowledge and understanding about disease and treatment

This theme captures the widespread lack of understanding and misconceptions about PAD and its treatment. Knowledge gaps, related to all aspects of treatment, were reported by all participant groups, including patients, relatives, and HCPs. Perceptions regarding disease chronicity, the systemic cardiovascular nature of PAD, medication necessity, and the role of lifestyle changes were reported to influence adherence behaviours. Patients expressed hope for a “quick fix” and preferred this to the reality of needing lifelong treatment and lifestyle change to manage their disease. The lack of appropriate information that patients received heightened these perceptions. Consequently, patients reported seeking information from non-credible resources, which could, in turn, affect their adherence to treatment.

Sub-theme: Systematic nature of disease and treatment benefit

Most patients did not identify PAD as a systemic, chronic condition with cardiovascular implications. Instead, they recognised it as an isolated problem affecting only their limbs. Healthcare professionals highlighted that, based on their experience, patients did not always link PAD with broader cardiovascular risks. This misunderstanding was thought to affect adherence to long-term treatment.

"And from a patient perspective, the challenges are getting people to understand the severity of their condition in terms of an overall cardiovascular risk. They tend to see it quite separately in terms of the limb and the body as separate symptoms. And then their overall body is as two separate things, if that makes sense." (HCP2, vascular surgeon, secondary care)

"On reflection, I think I didn't understand what was going on. I did not realise what PAD means and that I could have a heart attack and die." (P10, high antiplatelet adherence, non-optimised for statins, ex-smoker, walks daily)

Patients' misconceptions about the chronicity of PAD were also identified, with some seeking a definitive cure rather than ongoing management.

"They need to find a cure or some sort of injection, or something that will help to regulate the flow of the blood from the arteries. I think that something needs to be done. Yes, there must be a cure. It's too much taking tablets every day." (P12, high antiplatelet adherence, non-optimised for statins)

These views further underscored the fragmentation in patient understanding, which could result in non-adherence to prescribed medications. Poor understanding of the benefits of medication was identified as a significant barrier to medication adherence. Patients who were non-adherent to medications reported not experiencing immediate benefits or symptom improvement as a reason to stop taking their medications. However, even patients who reported taking their medications daily questioned the

benefit of medications. Most patients were unaware of the functions of their medications and how to assess their effectiveness.

“I was taking the medication, but I wasn’t feeling any better. After a while, I started wondering what the point was, so I just stopped them.” (P4, non-adherence to medications)

“I don’t really know what my tablets do or how to tell if they’re working. I guess they are doing something, otherwise what’s the point in taking them.” (P5, high medication adherence)

Adherent patients appeared to have greater awareness of the medication’s role in preventing further cardiovascular events and maintaining their health. However, most patients had misconceptions about the need for statins, especially if they had normal cholesterol levels. This led some patients to stop taking statins, skip doses or choose not to be on the optimal, prescribed statin dose.

“They said that my cholesterol was borderline. But I didn't understand why I needed to continuously take it [statin].” (P6, high antiplatelet adherence, non-optimised for statins and skipping doses)

All HCPs acknowledged this lack of understanding and they stressed the importance of informing patients of the role of medications and trying to address misconceptions about statins in particular.

“Get the patient to understand better the reasons why they're taking medications, like people always think they're on statins because of the cholesterol and you're like, well, you might not have high cholesterol, but this is why we're asking you to be on it.” (HCP10, physiotherapist, secondary care)

Despite smoking being a well-established risk factor for PAD, smoking cessation was challenging for many patients. Clinicians perceived that patients considered the damage to their legs irreversible, and that is the reason why they did not quit smoking.

“There is a group of patients where they say, well, I've smoked for 60 years, you're not going to stop me now, and they just carry on and take the risk.” (HCP14, vascular nurse specialist, secondary care)

For some patients, the reality of disease progression only became evident after severe complications, and even then, it took a major event, such as amputation, to prompt them to quit smoking for good.

“After they cut my toes, I thought that’s it, I just have to do it [quit smoking]. But it was too late, as then I lost my leg. The doctors told me I had to quit, but I didn’t listen to them. I never thought I would end up like this” (P5, recent ex-smoker, amputee)

The role of exercise in PAD management was frequently misunderstood. Some patients reported limited awareness of the therapeutic benefits of exercise, particularly those with little prior engagement in physical activity. Some HCPs also highlighted that patients with a better understanding of their condition were more likely to attend SET. Attendance at SET then further enhanced their knowledge, encouraged engagement and sustained participation in exercise.

“I think one of the main factors is that they often don't understand, and I think actually we get a better uptake from the people who are more understanding of their condition. And those people tend to engage more in the class and finish the whole six months than the people who don't understand.” (HCP6, physiotherapist, secondary care)

“Sometimes, just saying that exercise is going to actually be the treatment for this can be hard for someone to get their head around. I think once they've been to class and seen it and have experienced it, we've explained it all again to them. They seem a lot more engaged, but sometimes if you don't get them to that point, then actually you

know, if they haven't been someone who exercised a lot in the past, then it can be quite an unusual concept for them that exercise is gonna be treatment." (HCP10, physiotherapist, secondary care)

All patients reported a need for tangible outcomes to help them remain engaged in their treatment. Those who had experienced claudication symptom improvement were more likely to continue exercising. For example: *"I carried on walking and it got better and better and better" (P11, exercises daily).* However, some patients became discouraged if exercise did not produce the expected improvements.

Whilst some relatives recognised the value of exercise in improving circulation, others were not convinced, especially when the patients did not get an improvement.

"It's very important that she keeps up with the walking and the exercise, because that will help her leg. It will help the blood flow." (R4, relative of P12)

"Umm, but unfortunately even the walking just didn't help. So, I understand the scenario of yes, you need to walk more to make it better, but unfortunately for [Name] it didn't. So, he then stopped pushing himself to do more and more." (R1, relative of P3)

Sub-theme: Quick Fix

The lack of understanding regarding the chronic nature of PAD often led to an expectation of a "quick fix". Although HCPs said they regularly discussed the risks and benefits of surgery, many patients and relatives still seemed to believe that surgical intervention was the cure for PAD. Clinicians stressed that this misbelief was strongly linked to patients' limited understanding of PAD as a chronic, systemic disease requiring ongoing management. Clinicians reported frequently encountering patients who expected surgical intervention upon referral to vascular services, believing that procedures would restore normal circulation without further treatment. They also reported that based on their experience, when patients were not offered surgery and

were instead encouraged to take medication and change their lifestyles, they felt cheated by the healthcare system and tended to disengage with their treatment.

“Patients want a quick fix and expect to have surgery to cure or fix them, without having to make lifestyle changes or take medications, especially as they are referred to vascular surgery rather than medicine.” (HCP3, vascular nurse specialist, secondary care)

“I think patients, when they come and you offer them best medical therapy, it feels that it's perhaps a lesser of the two treatments when you compared to surgical intervention. I do think those patient groups are harder to engage. I came here with no tablets and now I'm on these tablets and now you're gonna try this other medicine and it it's still, you know, and can't you just put a stent in? “(HCP4, vascular surgeon, secondary care)

“Patients just want you to do something that has an immediate benefit. They don’t want to take meds for life and quit smoking. They feel scammed when you tell them to exercise.” (HCP8, vascular surgeon, secondary care)

“So I think they have this fallacy and potentially romanticising the idea about stenting, as it's not available for everyone.” (HCP2, vascular surgeon, secondary care)

Similarly, as many patients and their relatives reported perceiving surgery as the "cure", they did not believe they required lifelong medications and lifestyle modifications. Some patients and their relatives reported reading on the internet about surgery as a treatment, expecting this to be offered to them by their vascular surgeon. Having these expectations and beliefs, some patients reported being frustrated and struggling to see why a surgical intervention was not recommended for them, as it seemed like a logical solution for them following diagnostic testing.

“I think from reading on the internet we thought he would just get a stent and then he could get back to normal.” (R1, relative of P3)

“I think it’s an ultrasound which proved that, yes, there’s considerable blockage in both of my legs and he basically said there’s nothing you can do about it. And I was quite shocked as I was sure I was going to have surgery and it will be fixed.” (P2, high antiplatelet adherence, non-optimised for statins, ex-smoker, does not walk daily)

Sub-theme: Information Seeking

All patients talked about receiving no information or non-lay information about their disease and treatment, and that this contributed to non-adherence. Although all HCPs reported providing patients with leaflets, specifically the Circulation Foundation Intermittent Claudication Leaflet, none of the patients interviewed reported being aware of them. All HCPs also emphasised the need for standardised and engaging information. Some patients reported trying to find information about their disease online, which could hinder or facilitate adherence, depending on the information. When asked about the internet sources they used, they reported using Google or the NHS website. Although some patients reported trying to read multiple articles before coming to a conclusion, others did not check whether the information was credible.

“Just in the browser, I would type into Google website. So you type in the phrase and then it would give you hits, but it wouldn't be Google explaining what the hit is. It might be an NHS website or, more often, it's quite often American. But it doesn't matter, I wouldn't just read one. I'd read a couple and I’d go, that's what that term means, and then I'd stop.” (P11, high-medication adherence, never smoked, walks daily)

“I tried to search on the internet. But I found that they gave us too much information. And they are not related. Maybe my condition is not that worse. So for now, I will try to walk more and hope for the best. I don’t think I need to do anything else.” (P4, medication non-adherence, smokers, walks daily)

Some patients also reported finding useful information on social media and in support groups, such as the PAD Facebook group. Specifically, two patients reported that the PAD Facebook group provided positive reinforcement of the benefits of exercise, which in turn facilitated adherence to exercise.

“I didn't know that, if you exercised, then it would improve your legs. Nobody told me that, if you did plenty of exercise, it would improve. Nobody said that, so I've never done that. I work, so I’ve run upstairs and things like that. I joined the PAD facebook group and people there said that you must exercise to get better. Now I push myself because I know it's making me better.” (P8, exercises daily)

Clinicians mentioned that most of their patients used the internet to find out more about their disease, hence, agreed that patients must be provided with reputable links to increase their understanding of the disease and treatment and also facilitate treatment engagement.

“Patients usually don’t have enough experience at doing Google searches to know the reputable stuff from the stuff that isn't actually going to be that helpful.” (HCP18, GP, primary care).

<u>Sub-theme: Influence of others on knowledge and understanding</u>

Some patients and relatives spoke about seeking advice from their social network regarding their disease and treatment. This either helped or hindered adherence, depending on the outcome for their friends/relatives. Sharing insights and experiences with other patients with lived experience of PAD was valuable to patients. Although most patients spoke about the positive benefits, one patient highlighted that his neighbour’s negative experience had led him not to take any medications.

“I just see if I can get advice from other people who have had similar or are going through similar illness, what they have said and what has helped.” (P11, high-medication adherence, never smoked, walks daily)

“I've known people who have told me, and they said it's helped (swimming), it's improved, so I need to try that with my mum.” (R4, relative of P12)

“My neighbour was on aspirin. Next thing I know he’s at the hospital with bleeding and then he died. I’ve seen what happened to him and I don’t want to end up like that.” (P14, not taking any medications).

When asked about the impact of social influences, HCPs agreed that they played a significant role in patients’ lives. Most spoke about the negative media propaganda about statins rather than the influence of the patients’ social networks. However, one clinician felt that the negative influence of the media regarding statins only related to patients of specific demographics, particularly White British patients, as “they're the ones reading that information.” (HCP8, vascular surgeon, secondary care)

“There's always the issue with statins, but it’s mainly from the media. You know, they read the newspapers telling them that, you know, statins are the cause of all the problems and they usually come in already with problems.” (HCP16, pharmacist, secondary care)

<u>Sub-theme: Language and Health Literacy</u>

All clinicians reported that patients from more deprived backgrounds and those who didn’t speak English had more challenges understanding their disease and hence were less adherent.

“We found the patients from the lowest economic demographics had a poor understanding of their condition, how and when to seek health, take their meds and so on.” (HCP4, vascular surgeon, secondary care)

Additionally, most HCPs highlighted that they found it challenging to explain the nuances of PAD and management to non-English speaking patients, even when using an interpreter.

“You know a lot of patients who are using a translator. It’s just not possible to have a nuanced discussion about these things. You know the concept, you can't get the concept across, right? It's very difficult to get the concept across; you know, the

pathology across, right? In a way that the patient can understand it." (HCP12, pharmacist, primary care)

A relative of a non-English speaker echoed this, explaining that she had to attend appointments to translate so her mother could understand decisions and participate in her care.

"I have to go with her, because she, sometimes, doesn't understand. Her English isn't that great, so I go with her." (R4, relative of P12)

All patients specifically spoke about the need for *"layman's language"* to understand their disease. Some patients also suggested ways in which they would like their disease to be explained to them, avoiding medical jargon.

"I'm 60 and older people than myself will go in a consultation. And come out, and they are more confused when they come out than when they went in, because it's jargon, it's non-words. And they don't understand anything. And they've come, and they don't know why they're given a prescription to take, because they didn't understand what was being told to them in the first place." (P9, high medication adherence)

"When you've got interpreters and you're telling people about what is claudication, is that older person going to understand what you're saying, even though there's a translator? All you need to do, if it was me, I would have turned around and said, right, there's a problem with your arteries. They're closing up. What we need to do is open them up a bit so that the blood flows through your legs more freely. That's the better way of explaining it other than some big, long textbook's words." (P1, high medication adherence for aspirin, not on statin, ex-smoker, exercises daily)

4.4.2.1.2 Theme 2: Perceived treatment concerns

This theme describes concerns about treatment, specifically medications and exercise. Some patients expressed concerns about experiencing side effects, particularly from

statins, and the impact of lifelong medications on their bodies. Clinicians perceived that patients worried that exercise could damage their legs and, hence, they avoided exercising.

Sub-theme: Concerns about medication side effects

All patients in this study who were not taking their medications spoke about being worried about developing side effects from taking medications, hence decided either not to start or to stop treatment. Clinicians frequently encountered this concern.

"I've read the leaflet about the clopidogrel, and now I'm worried it'll make me bleed inside. What if I end up in the hospital and don't make it out? I don't want to take tablets. They should make things better, not worse. I haven't taken any of the things they've prescribed. I don't think it's safe. If they can't fix me without causing side effects, what's the point?" (P14, non-adherent to medications)

"Patients are aware of the potential side effects, and they're worried because they know they're probably going to get them, so they stop taking their tablets." HCP12, pharmacist, primary care)

The patients who were non-adherent also expressed concerns about the "long-term impact of medications", believing that even if they didn't have side effects now, they might develop them in the future. Patients who were not on an optimal statin dose reported that they did not wish to be put on a higher, optimal dose, despite being advised to do so by their HCPs, due to their perceived concerns that this would lead to a greater risk of side effects. Clinicians also said that this perception was very frequently reported by their patients.

"I think the [medication] side effects will affect me in the long term." (P4, non-adherent)

"My cholesterol was quite high. They've given me that [statin], because cholesterol could actually narrow your arteries as well. I've got to keep taking those and I know I have to take those. And watch what I'm eating as well. And my cholesterol now is ok. So

I don't think I need to get 80mg, I am quite worried I will get side effects." (P9, high antiplatelet adherence, not-optimised for statins)

"I think they all they usually feel quite worried most of the time. I think they're shocked that they're going up to such a high dose. And obviously worried about the side effects of that." (HCP14, vascular nurse, secondary care)

Sub-theme: Fear of damaging legs

Clinicians noted that many patients feared exercise could worsen claudication or damage their legs, creating a significant barrier to exercise. They emphasised the need to explain that walking through the pain could actually improve claudication symptoms.

"The advice to push into pain with claudication is a direct contradiction to the messages around angina in the chest. And yet we would call claudication angina of the leg, in effect, to get some understanding. So it can be scary for patients." (HCP13, podiatrist, primary care)

Despite HCPs perceiving this misconception as a significant barrier to exercise, patients did not report this belief. Only one patient shared this concern, and it was specifically about walking post-stenting.

"I know the doctors have told me to keep walking with the pain, I sometimes wonder if I am making my leg worse. I am about to have a new stent and I am a bit scared walking after the operation…I just need this stent to work." (P10, high antiplatelet adherence, non-optimised for statins, ex-smoker, does not walk daily)

Most patients were concerned about statins making their leg pain worse, rather than exercise. However, this was not identified by HCPs as a barrier to taking statins.

"The problem I have with statins is that I have been on them and they cause trouble with my legs. And I have cramps anyway. I'm wondering if the cramp in my left leg has been worse because of the… Because I started to get… The cramps have been worse. And

I'm wondering if that's to do with circulatory problems now. I'm not sure. So I don't want to take them." (P1, not on statins)

"I've been told I need to take them, but I feel like they're gonna make me feel worse. My leg is already in pain, why should I take something that will cause me more pain? It says in the leaflet, statins can cause leg cramps. I have these already!" (P14, not taking any meds)

4.4.2.1.3 Theme 3: Motivation

This theme describes factors that could affect patients' motivation for treatment adherence. The fear of losing their legs and being motivated to change and sustain a behaviour seemed to facilitate adherence. On the other hand, the negative psychological impact that patients experienced from their disease could hinder motivation to adherence.

<u>Sub-theme: Fear of amputation</u>

Most ex-smokers and clinicians reported that the fear of amputation was a facilitator for smoking cessation. Clinicians also believed it encouraged exercise uptake, however, no patients mentioned this.

"I think when you're quite blunt with the patients and say, look, you're on the road to limb loss right now. And I think if you're honest with them, I think they do get a little bit of a shock and they stop smoking." (HCP12, pharmacist, primary care)

"I think that fear of losing a limb is what means that they will commit to SET." (HCP6, physiotherapist, secondary care)

"Well, I think it was very much to the shock of when I spoke to the vascular surgeon and he said, well, the best thing you can do for your legs is stop smoking. So, I gave up then, yes, without a problem." (P3, ex-smoker)

Unfortunately, for some patients, the motivation to quit smoking only materialised after adverse events, specifically an amputation. One amputee patient reported that losing his leg influenced him to stop cessation, as he was afraid of losing another limb.

"I don't want to lose another thing, so I have to follow my doctors' advice." (P7, recent ex-smoker, amputee)

Sub-theme: Motivation to change and staying on track

This sub-theme was reported by both patients and HCPs regarding treatment overall. All patients agreed that treatment adherence depended on their motivation to change their behaviour and their ability to stay on track. When they had limited motivation to change, patients could become disengaged with their treatment. This was particularly reported by HCPs regarding exercise and SET attendance.

"I've always been forward-thinking and think before and this helps me stay on track." (P9, high medication adherence, ex-smoker, does not walk daily)

"It's obviously they've got to be quite motivated to get the benefits they need to. I think that if a patient is at the right time of their life and they are willing to make changes, they will." (HCP9, physiotherapist, secondary care)

"I think the motivation to take on some of the more difficult interventions, such as structured exercise, can sometimes go. And patients drop-out." (HCP15, podiatrist, primary care)

In relation to smoking, all HCPs agreed that patients needed to be motivated to quit. Some patients reported smoking as a coping strategy and a means of stress relief; hence, their motivation to quit was low. However, by staying on track and reminding themselves of the benefits of quitting smoking for their disease, smoking abstinence was often achieved.

“Smoking is a habit. It’s difficult to quit. A lot of people don't want to. I think if they were really motivated, they would give it a go.” (HCP5, vascular surgeon, secondary care)

“Smoking was always my way of coping with life. I relapsed once for about a day where I had about three, because I was quite stressed. I had to stay strong, went cold turkey, and never went back to it.” (P9, ex-smoker)

Sub-theme: “An existence not a life”

Most patients talked about the negative impact of their disease on their mental health and motivation. Feeling helpless, stuck, and a burden contributed to feelings of isolation and low mood. Some patients reported giving up, and one said that living with PAD was “an existence, not a life” (P14). Hence, these patients disengaged from their treatment and continued their unhealthy lifestyles, staying indoors, not wanting to prolong what another described as a miserable life.

“To be honest with you, the whole reason I don't stop smoking is because I'm not suicidal. There is a difference, but I actually don't wanna prolong this because it's misery. It's absolute misery.” (P15, current smoker)

All HCPs agreed that PAD significantly impacted patients’ quality of life (QoL). They acknowledged that patients sometimes chose to continue their unhealthy lifestyles, as these might be their only enjoyment in life. They remarked that anxiety and depression often went unsupported due to a lack of psychological services in the NHS. Additionally, HCPs reported that patients often declined to take part in SET due to psychological distress.

“I think that every chronic disease patient has to have some mental health support attached because by the time you get to the stage where you see your body disintegrating, you get that hopelessness and you feel like what's the point? I might as well just enjoy myself and eat what I like right now. At least that for that moment, I feel good.” (HCP1, vascular nurse, secondary care)

“I think a lot of people with mental health problems like anxiety, depression, once you want to mention a class, they just shut down because they can't face going into a room with strangers there. They think, no, no, that's not for me.” (HCP15, podiatrist, primary care)

4.4.2.1.4 Theme 4: Healthcare professional influence

This theme illustrated that clinicians could influence patients' decisions about their disease and treatment. It was emphasised that patients put their trust in vascular specialist clinicians in secondary care. However, receiving conflicting information from different HCPs could be confusing.

Sub-theme: Trust in specialist care

Building rapport and trust between patients and their HCPs was seen as essential for treatment engagement. All patients reported that being treated humanely increased trust in their HCPs.

“I go to my appointments, and, yes, it's my leg. But I get asked about myself as well. Yes, you're treating my leg, but you're asking me, how am I? And all of my daily duties. And sometimes I get asked, what did he do at the weekend? And that makes you comfortable with the person that's giving you care. And I can trust them, I know they genuinely care for me.” (P9, high medication adherence, ex-smoker, does not walk daily)

“So that kind of relationship building that we need to do with our patients to try, it's almost like chronic disease management in a way you know it.” (HCP11, podiatrist, secondary care)

Most study participants agreed that patients trusted their secondary care HCPs more than their primary care clinicians. Patients felt that vascular experts knew more about

their condition than anyone in primary care, perceiving that the only specialist care available was in a hospital setting.

"Yeah, I think that's, yeah. And there is something that patients value from hearing it from somebody other than their GP. They do value that sort of secondary care opinion." (HCP18, GP, primary care)

"For vascular, I prefer to go to the hospital, because they know better. There's no one in my GP that actually knows my problems as much as the hospital does." (P7, high antiplatelet adherence, not optimised for statins, recent ex-smoker, amputee, does not exercise daily)

Sub-theme: Conflicting information from HCPs

This sub-theme was mainly reported by patients and HCPs in relation to medications, particularly statins. Conflicting advice from different professionals was seen as confusing, undermining trust, and hindering informed decisions. This was particularly evident in relation to statin optimisation, with vascular clinicians suggesting that statin doses should be increased to the optimal level for secondary CVD prevention, but patients being unwilling to increase the dose. Often, this was because their primary care clinicians had told them they didn't need a higher statin dose, since their cholesterol levels were not elevated. Vascular HCPs reported often having to "fight with GPs to increase statin dose" *(HCP2, vascular surgeon, secondary care)*.

"But that can be contradicted, that message, sometimes by other health professionals, and including GPs and vascular surgeons, sadly. And we're constantly having to have debates about that with the clinicians, which doesn't help patient understanding when they then get contradicting information." (HCP15, vascular podiatrist, primary care)

Even though most patients reported greater trust in their specialist vascular clinician, when they received conflicting information, they often chose to follow the advice of the person offering the more convenient option. This was usually a primary care clinician.

“Last time I came to the hospital, there's a doctor there [vascular] who told me I should take double dose, but I don't really listen to the doctor sometimes when they tell me about those tablets. Because I've been taking it for I don’t know how many years. My GP said my cholesterol is not high anymore. So, tell me, I should take a double dose now. For what reason?” (P2, not optimised for statins)

Sub-theme: Involving patients in decision making

Some HCPs felt that applying a shared decision-making (SDM) approach for the treatment plan could make people “more likely to engage with their treatment”. They also talked about empowering patients to self-manage; however, they stressed that self-management was not appropriate for all patients, especially those with cognitive challenges.

“An engagement from the patient who is cognitively with it is needed to ensure they will go home and take their medicines and exercise” (HCP15, podiatrist, primary care).

None of the interviewed patients or relatives reported wanting SDM. When specifically asked about their feelings regarding involvement in the decision-making process, most felt it wasn’t their place to make decisions, indicating that this should be the doctors' responsibility. Similarly, HCPs recognised that patients often adopted a passive approach when discussing treatment options.

“Actually, if you reassure them and then empower them to look after their symptoms, they will do it.” (HCP8, vascular surgeon, secondary care)

“Don’t ask me, ask the doctors. I don’t know.” (P2, high antiplatelet adherence, non-optimised for statins, ex-smoker, does not walk daily)

“I feel some patients just don’t want to help themselves. The NHS will sort it out. It’s all about shared decision making, but tell me, how can we do this when people don’t care what happens to them?” (HCP5, vascular surgeon, secondary care).

4.4.2.2 Practicalities

4.4.2.2.1 Theme 5: Social and Physical Context

This theme describes the practical support that patients received from their social circle and how this facilitated treatment adherence. However, not all aspects of social support were seen as facilitators, with patients sharing examples of social influences, such as having friends who smoked, or experiencing feelings of social stigma, which could negatively affect smoking cessation and exercise uptake, respectively. Additionally, environmental barriers, like bad weather and logistics around travelling to exercise classes, were reported as barriers to exercise.

<u>Sub-theme: Social support</u>

Support from the patients' social network could either facilitate or hinder treatment adherence. Patients and HCPs often reported that having an engaging and supportive family, or a dog, was an adherence facilitator for overall treatment and exercise.

"Having my dog keeps me moving. He needs his walks, and that gets me out every day, even when I don't feel like it. It's good for both of us." (P15, walks daily)

"I always think it's good news if a patient's got a dog because they then have to go out and walk the dog." (HCP18, GP, primary care)

When asked about the type of support patients received from family, the majority reported day-to-day tasks, such as household chores and driving around to medical appointments, whilst one patient reported that his wife was in charge of his medications, which facilitated his medication adherence.

"The wife is very supportive and she gives me a good kick up the backside when I get a bit nervous and things like that. She's very much there for me. She doesn't crack the whip or anything like that but she's there to support me and she's effectively my carer.

She does the cleaning and cooking at the house, which is definitely a big help." (P3, high medication adherence, ex-smoker, exercises daily)

"My wife gives me all my medications every morning. Without her, I don't know how I'd manage." (P5, high medication adherence)

"I think it definitely helps if we see the patient attending with their partner. And you can see the partner's listening as well. I think by having someone else there and that family member being onboard as well, it does really help and hinder sometimes, I guess. Yes, I think, definitely, the attitude of the family around the friends around the person definitely makes a difference. If you can get them onboard as well, then I think it does definitely help." (HCP1, vascular nurse specialist, secondary care)

Sub-theme: Negative social influences

Specifically for smoking, all groups reported that patients who smoked within a social circle found it harder to quit. Some patients who managed to quit also spoke about particular times in their lives, where social or work commitments would have made it impossible to quit smoking.

"When I used to work, I would go to the pub and have a fag and all that sort of thing, you know, that's sort of that's what it was like. Everyone was smoking. So even if I wanted to quit, I think it would have been impossible." (P3, ex-smoker)

"I think it's very hard for one person to quit smoking when the other person living in close proximity is still smoking." (HCP2, vascular surgeon, secondary care)

Some patients also spoke about feelings of social stigma due to their disease, which could then influence decisions about their exercise and walking behaviour. They preferred not to leave the house and go for a walk, as they did not want to feel judged and treated differently by other people, because of the way they walked.

“I am not old, so when I need to stop because of the pain, and people ask me if I am ok, offering to help me, it just drives me insane. I don’t want people to see me like that.” (P14, not on medications, current-smoker, does not exercise daily)

Sub-theme: Environmental barriers

Bad weather, prolonged travelling time to exercise facilities and limited time during the day were reported as barriers to exercise by all groups. The motivation to leave the house on a cold, rainy day was limited. Some patients and relatives also reported that it was safer to stay inside when it rained.

“When it gets cold, I feel very cold. And if my legs feel very cold. And I just want to stay in bed.” (P6, does not exercise daily)

“When it’s raining, I don’t want my mum going outside, carrying the umbrella and her stick. She should stay inside.” (R4, relative of P12)

“I think it's just being motivated to get out when the weather is terrible, they just can't be bothered.” (HCP8, vascular surgeon, secondary care)

Specifically for SET attendance, the logistics around travelling, in terms of time, mode of transport, and parking, were reported as barriers by some relatives and most HCPs. Traditionally, SET takes place in hospital settings, which could be some distance for patients. Maintaining regular SET attendance and daily exercise was seen to demand commitment, which could be difficult for people with busy lifestyles to sustain.

“People can't go to hospital-based programmes and pay £5 parking fees if they've even got a car, and they maybe can't afford the bus fare if they live five miles away.” (HCP13, podiatrist, primary care)

“They referred my mum to the exercise programme, but it’s at [Hospital Name], which is too far. So she can’t go there. It would be nice if there was something closer to us. My mum would be able to go more often.” (R4, relative of P12)

"So I think some of those things maybe transport, maybe work life balance, maybe childcare, you know, these some of these people are working 2/3 jobs to keep a roof over their head and said being told to go in excess of 30 minutes is difficult to fit in and they just want the seemingly quick fix, an intervention." (HCP4, vascular surgeon, secondary care)

4.4.2.2.2 Theme 6: Everyday reality

This theme captures the everyday reality of living with PAD. Many of the patients in this study had several health challenges, suffered from claudication pain or medication side effects. Study findings showed that creating routines could lead to habit formation, which in turn facilitated adherence. Additionally, some patients accepted their new reality of living with PAD and simply tried to get on with life.

<u>Sub-theme: Health-related challenge</u>

When talking about health-related challenges, all groups spoke about claudication pain and the existence of other comorbidities and how these could affect adherence. Claudication pain was reported as the main barrier to exercise by all patients, with patients being unable to continue walking due to the pain.

"The pain in my legs was increasing and I just couldn't walk as far. The pain is the main thing that stops me." (P10, exercises daily)

"The bottom calf, it was so painful that when she walked for a little bit, she couldn't, because it was painful. She had to stop." (R3, relative of P10)

"I'm sure some people are in so much pain, they do just find it too difficult." (HCP7, vascular scientist, secondary care)

Besides claudication pain, most patients and relatives reported that symptoms related to other conditions, such as arthritis and balance issues, were also barriers to exercise.

However, some patients reported doing sitting exercises to prevent falls and to stay active.

"The other thing for walking up and sitting, because the foot is numb. When I walk, if there is something on the floor, I don't notice it, I truly don't. My ankle bends and I fall. So I avoid walking for long distance." (P6, does not exercise daily)

"It's the arthritis and the back pain, on top of the claudication pain. It's just hard for her to walk. She doesn't like taking painkillers, she is trying to use a stick, because she feels safer walking with the stick as a balance to help her walk." (R3, relative of P10)

Most HCPs stressed that patients with PAD had multiple comorbidities; hence, they felt that patients were not always focused on the management of PAD until their symptoms worsened or they had a cardiovascular event. Most HCPs reported that patients continued smoking whilst experiencing CLTI symptoms, and that they were only willing to change their lifestyle and quit smoking after having a heart attack or stroke.

"Unfortunately, with our population, there are a lot of other issues and comorbidities. And we see quite a lot of that, that the PAD is only one issue in their lives, and it's not necessarily the dominant issue until the pain gets really bad. So until then, they don't always focus on PAD." (HCP15, podiatrist, primary care)

"Yeah, sometimes, until they get a heart attack or a stroke, they are unwilling to stop smoking. They don't care what happens to their legs. They basically are happy to keep smoking with the blue toes." (HCP2, vascular surgeon, secondary care)

<u>Sub-theme: Experiencing medication side effects</u>

This sub-theme was specific to medication adherence. Patients and relatives identified medication side effects as a barrier to adherence. Patient participants who had previously experienced side effects reported that they were not willing to continue their medications or try alternative options, as they did not want to continue having side effects.

“He can’t take certain medications, and it can really mess him up. The aspirin really messed him up, so he can’t take it ever again.” (R2, relative of P2)

“I used to take statins. They made me so unwell, I had terrible cramps. So I stopped them and I felt so much better! Then I came to vascular and they put me on statins again. I told the doctor I am not going to take them.” (P1, high antiplatelet adherence, not on statins)

Most HCPs reported that statistically only a small percentage of patients got side effects, and these patients should be offered alternative medications. Hence, some HCPs did not perceive medication side effects as a true adherence barrier, rather an “excuse to not take tablets”.

“In my experience, very few patients actually experience side effects. It’s often more about their perception or reluctance, and we can usually offer alternatives if they genuinely have issues. We have so many statin options, ezetimibe, etc. There are always options." (HCP4, vascular surgeon, secondary care)

<u>Sub-theme: The power of habit</u>

Highly adherent patients reported that creating routines helped them stick to medications and exercise. Patients who were taking their medications daily reported strategies to avoid forgetting them, like using a Dosette box, or taking their medications all together.

“I’ve been taking my medications for so long now, it’s part of my life. I never forget to take them.” (P11, high medication adherence)

“Just get up first thing in the morning when I'm having my first cup of tea. My medication is right in front of me, so I just take them. And wherever I get up and sit in the morning, that's where my medication is.” (P9, high medication adherence)

In this study, none of the patients identified forgetfulness as a barrier to medication adherence. Only one patient reported occasionally forgetting one of his medications, but he did not feel it was significant enough to need a strategy in place.

"Sometimes I forget my Warfarin. Maybe once a month, not really." (P2, high adherence for antiplatelets, not optimised for statins)

All patients who reported walking every day noted that having a walking routine facilitated exercise. Patients described walking at specific times during the day, or after meals, as part of their daily plan.

"I try to walk three times a day, first thing in the morning, after lunch and after dinner. I don't go far, just around the house. It can get boring but it's something that I do every day and it keeps me going." (P1, walks daily)

On the other hand, smokers and ex-smokers reported that smoking was part of their life, and that habits were hard to break.

"Human beings are creatures of habit. I've been smoking since I was 12-13 years old. It's part of my life." (P13, recent ex-smoker)

<u>Sub-theme: Getting on with life</u>

This sub-theme was only reported by patients and their relatives. Despite the huge impact PAD had on patients' wellbeing and quality of life, some patients reported that they were simply trying to 'get on with life' and get used to the new reality. Patients and relatives spoke about 'changing things in their lives to avoid the pain'.

"I suppose it was progressively getting worse and I wasn't getting better. I did notice that I was starting to change things in my life to avoid the pain. So, I spent a lot of time in

London in those days, so I got to know the shortest route between tube stations and such like. So, I was actually starting to live with PAD." (P3, exercises daily)

"I am pretty good with walking on a flat surface. One thing I can't do is stairs. A friend suggested to go to this tour and I had to ask how far we have to walk for and if there are any stairs. Going down is easy, but coming back up will be an issue for me. So until I find out the specifics, I cannot commit to it." (P11, exercises daily)

Some relatives also spoke about patients putting up with the pain and trying to continue their day-to-day life, as they felt there was no other choice. Where this was the case, relatives felt that patients had accepted this new reality of living with PAD and did not wish to seek further medical help.

"My husband and I used to take the train to London and go shopping, but after his diagnosis he didn't feel confident doing that. We started planning our journey differently, allowing more time to get to the station, and taking things slow. He had to accept this new reality and get on with it." (R1, relative of P3)

4.4.2.2.3 Theme 7: Healthcare system factors

This theme describes healthcare system-related practical barriers that are linked with treatment non-adherence. It illustrates that access to services and ongoing support are key to patient engagement and treatment adherence in PAD care. Clinicians reported limited availability of PAD-specific services like SET and smoking cessation programmes, alongside long waiting lists and delayed referrals, leading to lost motivation and worsening symptoms. The lack of follow-up care further hinders treatment continuity, highlighting the need for better service access and ongoing support.

<u>Sub-theme: Access to services</u>

This sub-theme was only reported by HCPs to describe the lack of PAD-specific services contributing to poor patient engagement with their treatment. Essentially,

most HCPs believed that patients would engage with whichever services were currently available. Clinicians also spoke about the availability of exercise classes. Despite SET being recommended as a treatment option by national and international guidelines, only a few centres in the UK offered SET. Additionally, some reported there were limited smoking cessation services, making it harder for patients to access such services.

"I suppose it's just patients being able to access services essentially when they need them." (HCP10, physiotherapist, secondary care)

"The fact that most of the population doesn't have access to that [SET] is not acceptable. So we've got to think of other ways to work with selling and providing exercise." (HCP15, podiatrist, primary care)

"The other challenge that we have with these patients with intermittent claudication is maybe getting them to stop smoking and the access to smoking cessation is not universal." (HCP2, vascular surgeon, secondary care)

Clinicians also reported that even when services were available, long waiting lists were an added barrier to engagement. Interviewed primary care clinicians emphasised that the referral process from primary to secondary care was very lengthy, with patients being "stuck in a black hole". By the time patients were seen, their symptoms had worsened. All HCPs stressed that these delays also reduced patients' motivation for lifestyle change.

"Unfortunately, when you now refer to the hospital, the patients are not seen. It takes forever, and by the time they get seen, it's too late." (HCP17, GP, primary care)

"It is also and recommended that we utilise smoking cessation services but the smoking cessation clinic has got such a long sort of waiting list that is very difficult to sort of fit patients in then for them to get contact with the healthcare professional in this clinic and get meaningful intervention in the three to six months that we send them

away. By the time the patient gets to cessation, their motivation to quit isn't just there." (HCP2, vascular surgeon, secondary care)

Sub-theme: Ongoing support & Follow-up

This sub-theme highlights the challenges faced by both patients and HCPs regarding gaps in continuity of care. Interviewed clinicians working in services where no standard outpatient follow-up was offered for patients with PAD reported that they did not know what happened to patients after they got discharged back to primary care. This meant it was impossible to monitor progress and sustained behaviours. Most HCPs felt that follow-ups would support adherence and continuity, by "reiterating the message", but admitted that system pressures limited holistic care. Clinicians saw value in virtual monitoring, while patients preferred face-to-face appointments.

"I think I don't really see what happens to them when they leave clinic. I don't really know. I don't really know how well the actual stop smoking sort of interventions in the community work. It's difficult." (HCP1, vascular nurse, primary care)

"We haven't got space to follow them all up. We don't have the opportunity to see them again, monitor their progress, reiterate the messages. And I think this plays a bit role in their compliance." (HCP8, vascular surgeon, secondary care)

All interviewed patients and relatives reported the need for more continuous support, noting that cancelled appointments or no formal follow-up caused frustration and could lead to treatment disengagement.

"He told me it might get better, it might get worse, but I was left then with no treatment plan. There was no follow-up or anything at all. It was, there you go, you've had your consultation. At the moment I feel that I could do with some one-to-one support in terms of my legs and general fitness level. But I haven't been offered that." (P3, high medication adherence, ex-smoker, exercises daily)

“I'm not going to lie. The way his appointments kept getting cancelled, that was very frustrating. He was ready to give up.” (R2, relative of P2)

4.5 Discussion

4.5.1 Main Findings

This qualitative study explored patients’, relatives’ and HCPs’ perceptions of PAD and its treatment, identifying key barriers and facilitators to treatment adherence. The findings highlight persistent gaps in patient knowledge, treatment concerns, motivation, healthcare system support and service barriers, all of which impact adherence to medications, exercise, smoking cessation, and long-term disease management. The following synthesis focuses on two key areas for discussion: a) perceptions (beliefs and motivation) and b) practicalities (ability) affecting adherence. The key theme throughout the study was patients’ limited knowledge and understanding of disease and management. Many patients and their relatives perceived PAD as a localised limb issue rather than a systemic, chronic cardiovascular condition requiring lifelong management, often expecting a quick fix through surgery. This misconception influenced adherence behaviours and led to inconsistent or no medication use, continued smoking and lack of exercise. Patients who perceived PAD as a chronic condition and perceived their treatment was necessary were more likely to adhere to pharmacotherapy and lifestyle changes. Conversely, some questioned the value of long-term pharmacotherapy, particularly statins, often discontinuing treatment when claudication pain did not improve immediately. Additionally, exercise was also perceived as ineffective for improving their condition. In the absence of clear, patient-friendly guidance, patients often turned to alternative sources, like the internet, social media, and peer networks.

Concerns about treatment, specifically fear of statin side effects, were a prominent barrier. Self-motivation, having daily routines, and a positive mindset facilitated adherence, with fear of amputation being a strong motivator for smoking cessation. Clinician influence was also key; patients trusted vascular specialists more than their

GP. However, conflicting advice, especially for statin dose, led to confusion and suboptimal management.

Besides perceptual barriers, participants also reported practical barriers affecting adherence. Adverse weather and the presence of comorbidities were barriers to exercise. Supportive family involvement, in the form of encouragement and help with day-to-day tasks facilitated treatment engagement. However, patients who had smokers in their social network found it difficult to quit. Undoubtedly, healthcare system issues, including the long NHS waiting list, lack of follow-up and limited PAD services, further hindered adherence.

4.5.2 Interpretation of findings in relation to other studies

The findings of this study align with my pre-doctoral qualitative study and with previous qualitative studies exploring patients' perceptions about PAD. Specifically, patients who considered PAD as an acute instead of a chronic condition felt that self-management was irrelevant, believing instead that surgery could provide a cure or alleviate symptoms (277-279). Beyond knowledge and understanding, patients' beliefs about their illness and treatment play a key role in treatment adherence. A meta-analysis of 94 studies examining the connection between patient beliefs and medication adherence in chronic conditions demonstrated a strong link between high adherence and positive perceptions about the necessity of treatments and fewer concerns about side effects (280). Similarly, my previous qualitative study and research applying the PaPa framework in stroke and HIV populations also identified that patients often discontinue their medications when they are not experiencing symptom relief (139, 166, 281). Conversely, a mixed-methods systematic review on statin adherence found that patients who believed in the protective benefits of statins against heart attacks and strokes were more likely to remain adherent (122). This was evident in the current study amongst highly adherent patients.

Regarding lifestyle changes, participants across all groups in this study reported that patients with PAD frequently struggle to quit smoking, even when aware of the risks, consistent with prior PAD research (92, 139). Clinicians have previously emphasised

that smoking rates typically decline following major cardiovascular or limb events, due to increased awareness of recurrence risk and mortality (282, 283), which is also in line with my findings.

In this study, many patients also viewed exercise as ineffective for improving their condition, echoing findings of previous PAD research (18, 88). A recent umbrella review exploring factors associated with adherence to physical activity in patients with chronic conditions identified that knowledge, expectations, and perceived benefits are key adherence determinants (284). These findings highlight the need for clear communication from HCPs about the systemic risks of PAD, the role of medications and lifestyle changes, and setting realistic expectations regarding surgical outcomes.

In line with the current findings, previous research has shown that media can create uncertainty and confusion around treatment decisions, thereby affecting adherence (122, 285). Limited English proficiency and low health literacy further hinders patients' understanding of PAD, consistent with evidence that health literacy in this population is generally low and strongly shapes illness perception, self-management, and QoL (93, 286). A meta-analysis identified that effective communication by HCPs is strongly associated with treatment adherence (287).

Concerns about treatment consequences were central to adherence challenges reported in this study. Horne et. al also identified that high perceived concerns about treatment adverse events are associated with lower adherence (130). This finding aligns with other qualitative studies in cardiovascular populations, a mixed-methods review of statin adherence, and my previous work on PAD treatment perceptions (122, 139, 281, 288). While clinicians suggested that patients often worry that exercise may worsen leg pain, no patients in our study expressed this view. In another qualitative study, a key exercise barrier was fear of pain when walking, followed by uncertainty regarding the appropriate duration and intensity of activity (278). This highlights knowledge and communication gaps around the safety and therapeutic value of exercise.

This study shows that adherence in PAD is also influenced by both psychological and motivational factors. Consistent with previous research, self-motivation, establishing

routines, and a positive mindset facilitated engagement, while a lack of readiness to change and negative treatment attitudes acted as barriers (88, 139, 289). Fear of amputation emerged as a strong motivator for smoking cessation, supporting previous findings that perceived threat can drive behaviour change (139, 282, 283). However, for some patients, this awareness only followed adverse events, highlighting the need for earlier, targeted risk communication. More broadly, PAD imposes a significant psychological burden, with many patients describing life as an existence. These feelings of low mood and isolation may further embed non-adherence, though limited research is currently available to investigate this association. A mission statement from the American Heart Association stressed that psychological concerns in patients with PAD can reduce motivation for lifestyle changes and supervised exercise therapy, hence, it is essential to further support this population (16, 17). These findings underscore the importance of integrating psychological support into chronic disease management to enhance adherence.

Undoubtedly, the influence of HCPs plays a big role in patient adherence. This study found that trust in specialist vascular clinicians facilitated adherence, while conflicting advice from different professionals reduced it, particularly regarding statin optimisation. Previous research has highlighted that trust in specialist care is correlated with higher adherence in chronic disease management (290). Nevertheless, interprofessional disagreement between primary and secondary care remains a barrier in chronic disease management (291). Although clinicians highlighted SDM as vital for adherence, a recent scoping review found its implementation in PAD was limited by clinicians' poor understanding and patients' passive involvement (292).

Moreover, environmental and social factors can influence adherence. The findings of the current study are in line with my previous qualitative work and systematic reviews in PAD suggesting that practical barriers such as cold weather, rain, and limited access to exercise facilities often lead patients to discontinue activity (18, 88, 139). Social support does not always lead to better health behaviours, highlighting the complex nature of social influence (293). The presence of companionship and family support enables medication use, physical activity, and smoking cessation (122, 139, 294, 295);

while negative behaviours, such as nagging or not offering support, may undermine efforts (296). In our study, experiences and advice from others strongly affected statin adherence. Specifically, hearing about side effects raised anxieties, leading to medication non-initiation or discontinuation (122). Similarly, evidence from the PORTRAIT (Patient-Centered Outcomes Related Treatment Practices in Peripheral Arterial Disease: Investigating Trajectories) registry demonstrated that patients with PAD who have low perceived social support had poorer health status, suggesting that improving support networks could improve clinical outcomes (297).

Participants in this study often spoke about the everyday reality of living with PAD and how this could influence adherence. Previous qualitative studies in patients with PAD also found that claudication pain and other comorbidities limited physical activity (18, 88, 139). While polypharmacy is often cited as a barrier in chronic disease (122), patients in this study did not report this. Although HCPs did not view medication side effects as a true barrier, literature shows strong links between side effects and non-adherence (122, 139). Conversely, routines acted as facilitators, with patients integrating medication-taking into daily habits, such as linking doses to breakfast or bedtime, which supported adherence (122, 139). Similarly, highly adherent patients in the current study emphasised the importance of habit formation.

Lastly, clinicians highlighted the limited availability of PAD-specific services, restricted access to SET and smoking cessation programmes, and long referral waiting times as major barriers to adherence. On the other hand, patients and relatives reported frustration with cancelled appointments and lack of follow-up, which undermined motivation and treatment engagement. Insufficient healthcare provision has been previously identified as an adherence barrier for statins (122). The findings of this study reflect persistent gaps in UK PAD service provision, where care remains inconsistent despite guideline recommendations (298). Implementing structured follow-up could reinforce education, support habit formation, and improve patient engagement in long-term disease management.

4.5.3 Strengths and Limitations

This is the first study to explore barriers and facilitators to PAD treatment adherence from the perspective of patients, their relatives and HCPs. Participants were recruited across England to capture a wide range of perspectives, ensuring representation across different genders, ages, ethnicities and social deprivations. The inclusion of clinicians from various professional backgrounds, within primary and secondary care, provided a holistic overview of clinicians' perceptions on factors affecting adherence, supporting the design of future interventions within current clinical practices. This broad representation also strengthens the generalisability of study results across different settings in England.

To ensure high methodological standards, this study was designed and reported in accordance with qualitative guidelines. The COREQ checklist was used to guide the reporting of this qualitative study (299). A systematic approach to data collection was adopted, using a structured topic guide based on the PaPa to ensure that both perceptual and practical adherence barriers could be explored. The theoretical framework (PaPa) also informed the data analysis, to allow themes to be systematically organised, following inductive analysis. Additionally, PPI and stakeholder engagement was strong throughout the study, ensuring the findings were relevant and meaningful to service users.

The study limitations should also be acknowledged. First, self-selection bias may have occurred, as patients and relatives who participated may have been more engaged than the wider PAD population. Although efforts were made to recruit participants from primary and secondary care, no patients were recruited from primary care. Only three patients from North West London primary care networks expressed interest in taking part in the study, but none met the eligibility criteria, as they did not have PAD. Moreover, the sample size of relatives was small (N=4), reflecting challenges I have previously encountered in engaging relatives of patients in PAD research. Similarly, clinicians with a specialist interest in PAD care may have been more inclined to take part. Despite recruitment targeting clinicians from different levels of seniority, unfortunately, only senior clinicians participated in the study. The study was advertised

to less senior team members (e.g. band 5 and 6 nurses, SHOs and Regs), but none expressed interest in participating. Some reported a lack of confidence in their clinical knowledge or busy clinical schedules as reasons not to participate. Lastly, the findings are also specific to the NHS England context and may not be generalisable to other healthcare systems that operate in a different way than the NHS.

4.5.4 Implications for future research

This study identified barriers and facilitators to PAD treatment adherence. These factors should be taken into consideration when designing interventions to support patients with PAD with their self-management and treatment adherence, in both clinical practice and future research. Although patients who had previously experienced CLTI were interviewed during this study, the topic guide was focused on conservative treatment for intermittent claudication, rather than CLTI management. In light of this study's limitations, the findings may not be generalisable to the CLTI population. Hence, future research is required to explore barriers and facilitators in patients who have experienced CLTI and amputation.

This study also demonstrated how healthcare system factors can affect adherence. While it provided valuable insights into the current system, further research is required to capture the evolving clinical context through more targeted systems-level studies. It is important to note that this study was conducted before the announcement of the 2025 NHS 10-year plan, which emphasises a shift towards delivering care within community settings and expanding the use of digital health, in order to allow secondary care to focus on more acute conditions and emergencies (249). Notably, all patients in this study expressed a preference for in-person hospital-based care with their vascular team and were sceptical about digital interventions, which suggests that implementing the new NHS plan may be challenging. Future research should focus on how this new NHS direction can affect patient perceptions, engagement and adherence for the PAD population.

4.5.5 Implications for this work

This chapter provides a systematic exploration of the barriers and facilitators influencing treatment adherence in PAD. The next stage of this work includes triangulating the data from my pre-doctoral projects (a survey and a qualitative study) and the doctoral qualitative study to identify the key influences on treatment adherence. This synthesis will enable the identification of potential interventions and components, in preparation for the co-design workshops. This will be discussed in Chapter 6. Although this study included interviews with relevant service users (patients, relatives and HCPs) across England, a purposive qualitative sample cannot fully capture the structure and delivery of vascular services for PAD across the country. To ensure that the proposed intervention is feasible and implementable with existing care pathways, I decided to explore current service provision more broadly before conducting the co-design workshops. This exploration was undertaken through a Freedom of Information Request, which will be discussed in Chapter 5.

4.6 Conclusion

This is the first qualitative study to explore treatment adherence in PAD from the perspectives of patients, relatives, and HCPs. The findings reveal that adherence is shaped by multifaceted factors, including patient knowledge, motivation, social and environmental influences, and healthcare system structures. Misconceptions of PAD as an acute rather than chronic, systemic condition, concerns about medication side effects, claudication pain, and inconsistent professional advice undermined adherence, while trust in specialist care, daily routines, and supportive relationships facilitated it. Gaps in communication, information resources, health literacy, and service provision further limited long-term management. Addressing these challenges requires a patient-centred approach, combining clear education about the disease and treatment, psychological and social support, consistent interprofessional communication, and structured follow-up. Embedding these strategies into care pathways offers the potential to improve adherence, clinical outcomes, and quality of life for patients with PAD.

Chapter 5: Understanding the clinic context of intermittent claudication services in England: insights from a freedom of information request (FOIR)

5.1 Introduction

This chapter presents results from a freedom of information request (FOIR) about the availability and structure of intermittent claudication (IC) services in England. A pragmatic approach was employed to better understand current service provision prior to selecting the key intervention ingredients and undertaking the co-design workshops for an intervention to address adherence in PAD. Below, I explain the rationale behind undertaking a FOIR.

As discussed in previous chapters, for patients with IC, timely diagnosis and access to appropriate care and disease management, including vascular specialist clinics and supervised exercise therapy (SET) programmes, are essential for improved outcomes. Despite this, research has shown that service provision across the UK remains inconsistent, with limited availability of SET programmes (300-302). Previous research on claudication services in England has solely focused on SET provision, without fully addressing other key aspects of care, such as structured smoking cessation support or the organisation and setup of dedicated claudication clinics. A more comprehensive understanding of the breadth and quality of these services is therefore required.

Additionally, whilst I was conducting the qualitative interviews with healthcare professionals (HCPs) across the country, I realised that each vascular centre has a different service set-up. Although I was already aware of this, actually conducting the research and better understanding the issue of adherence in relation to the clinical context made me worry about the feasibility and implementation of the intervention I proposed to develop within the NHS. To ensure that the intervention would be relevant

and feasible within the current healthcare system, a better understanding of claudication services provision was required before conducting the co-design workshops.

Freedom of information requests have emerged as a valuable tool for researchers to access detailed, system-level data in healthcare (13, 14). In the context of the UK healthcare system, which is complex and continually evolving, FOIRs offer a valuable method for acquiring a clear picture of available healthcare provision, including specialised services for specific conditions, such as claudication.

5.2 Aim and Objectives

Aim: To explore the availability and structure of services for the management of patients with IC in England.

Objectives:

1. To assess and describe the availability and structure of IC clinics in England
2. To assess the structure of SET for patients with IC in England
3. To assess access to lifestyle support for patients with IC in England
4. To assess the referral process to IC clinics

5.3 Methods

5.3.1 Study design

A pragmatic FOIR approach was used to explore the structure and delivery of IC services across England. The FOIR consisted of a structured questionnaire covering various aspects of service provision. The questionnaire was specifically developed for this study and, although not previously validated or published, it was designed in accordance with questionnaire development guidance (303, 304). Its content was informed by the study aim, relevant national guidelines (8), and previous studies on vascular SET services (301), in line with best practice recommendations (303, 304).

The questionnaire (see Appendix 5) consisted of 22 items, both multiple-choice and open-ended questions. Each item included an “Other” option with space to provide a written response, allowing respondents to accurately reflect local service configurations when predefined options were insufficient. Free-text responses also enabled clarification of responses and provided insight into potentially poorly constructed or unclear questions, supporting future questionnaire development (303).

All questions were carefully structured to minimise response bias. This included consideration of the order of items, allowing a logical flow of the questions (303). A definition of vascular services was also provided alongside the questionnaire to ensure consistency in interpretation (305, 306). To ensure clarity and relevance, the questionnaire was piloted with a small group of vascular clinicians (two vascular nurse specialists, two vascular surgeons, one exercise physiologist) and two vascular administrators and refined accordingly before dissemination.

The questionnaire covered the following areas:

- The existence and structure of IC management services within organisations
- The range of healthcare professionals involved in IC care (vascular surgeons, vascular nurses, physiotherapists, etc.)
- The extent of SET availability, including whether it is delivered in hospital-based, community-based, or virtual settings
- The inclusion of smoking cessation programmes, dietary counselling, and psychological support for patients with IC
- The referral process to IC services

5.3.2 Ethics

The Freedom of Information Act 2000 enables access to publicly held, non-identifiable information (307). No human participants or human data were collected in this study. Hence, ethical approval and consent to participate were not required. All methods were carried out in accordance with the Freedom of Information Act 2000 (307).

5.3.3 The current set-up of vascular services

The National Health Service (NHS) England, established in 1948, is founded on the principles of universal access, equity, and care based on clinical need rather than ability to pay (14). Funded primarily through general taxation, the NHS provides comprehensive healthcare services across primary, secondary, and tertiary care (14). Increasing demand, rising costs, and staff shortages have led to major reforms. These changes aim to improve efficiency and integration, with greater emphasis on local planning and coordination between NHS Trusts, Integrated Care Boards (ICBs), and community services (15).

In 2015, the Vascular Society of Great Britain and Ireland (VSGBI) published a guide outlining how vascular services should be set-up and delivered (306). According to this guide, vascular services in England are largely delivered within this framework by specialist multidisciplinary teams within acute NHS Trusts and are coordinated through regional vascular networks (305, 306). These networks were established to centralise complex care, improve outcomes, and ensure continuity across the patient pathway (305, 306). These services encompass the diagnosis, medical management, and surgical treatment of conditions affecting the arterial, venous, and lymphatic systems (305, 306). Patients with IC may be reviewed in either a specialised IC clinic or a generic vascular clinic, depending on the set-up of each organisation (305, 306).

Care is organised using a Hub and Spoke model, with each network comprising one Hub centre supported by several Spoke centres (305, 306). Hub centres are designated arterial centres and provide comprehensive specialist services, including complex arterial and endovascular procedures, and 24-hour emergency care, such as for ruptured abdominal aortic aneurysms (305, 306). These centres also have access to advanced imaging, interventional radiology, and critical care (305, 306). On the other hand, Spoke centres are typically non-arterial centres and focus on outpatient assessment, diagnostics, risk factor management, SET, and post-operative follow-up, with established referral pathways to the hub for patients requiring specialist intervention (305, 306).

Vascular services are delivered by multidisciplinary teams (305, 306). Core staff include consultant vascular surgeons, interventional radiologists, vascular nurse specialists, vascular scientists/sonographers, anaesthetists, and allied health professionals (AHPs), such as exercise physiotherapists and podiatrists (305, 306). Administrative and coordination staff support pathway management across the network (305, 306).

In recent years, vascular services have undergone significant re-organisation to consolidate specialist expertise and resources into fewer high-volume centres, supported by evidence suggesting improved patient outcomes through centralisation (305, 306). Despite progress, challenges remain, including variations in service provision, workforce shortages, and unequal access to care across regions.

5.3.4 Participants and data collection

The FOIR was sent to NHS Trusts across England on the 21st of January 2025, requesting information on services provided for patients with IC. A list of NHS trusts was obtained from the NHS England provider website (https://www.england.nhs.uk/publication/nhs-provider-directory/). Trusts solely providing mental health, cancer, women's or paediatric services were excluded from the FOIR. The list was hand-searched to identify organisations that were not eligible. All eligible Trusts were compiled into an Excel spreadsheet.

The request was sent to eligible Trusts via email or submitted via Trust-specific electronic forms to the designated FOIR teams at NHS Trusts, in accordance with the official procedures outlined in the Freedom of Information Act 2000 (307). Trusts that provided incomplete responses were contacted to obtain the missing information. Non-responding institutions were sent reminders after the statutory 20-working-day period, and thereafter at four-week intervals, to encourage participation (307). Where possible, additional contact was made with key personnel within vascular services. Reminder emails continued up to three times over 12 weeks unless a response was received earlier. The study was conducted and documented in accordance with the guidelines

outlined in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist (308).

5.3.5 Data analysis

All responses were collected, recorded, and stored in a secure Microsoft Excel spreadsheet for preliminary organisation. The data were then cleaned for consistency. Using the IBM Statistical Package for Social Sciences (SPSS) (v.29) software, descriptive statistics, including percentages, were used to summarise the quantitative data. While the primary aim of the study was to present the distribution of available services, I considered conducting more complex analyses, such as t-tests, as these could potentially reveal patterns that percentages alone might overlook. However, I decided not to pursue these approaches to maintain simplicity and focus on getting real-time NHS data on a timely manner.

5.4 Results

5.4.1 Responders

From 21 January 2025 to 21 May 2025, 138 Trusts were sent a FOIR. The response rate was 89.9%. At least three reminders were sent to the 14 Trusts that did not respond. Of the 124 Trusts that responded to the FOIR, 12 (9.6%) were primary care Trusts that reported not providing vascular services, and 30 (24.2%) were secondary care Trusts that reported not providing vascular services. Therefore, 82 (66.2%) were secondary care Trusts that reported providing vascular services.

5.4.2 Regional variation

The 82 Trusts included in the analysis were distributed across the integrated care systems in England, as shown in Figure 22. Fewer than half offered dedicated claudication clinics (n = 38), and fewer still provided SET (n = 24). Only 16 Trusts nationally reported delivering both claudication clinics and SET (see Table 25). The FOIR demonstrated a broadly even geographical distribution of vascular services within

England, with the North East and West Yorkshire contributing the highest proportion of responses (18.3%).

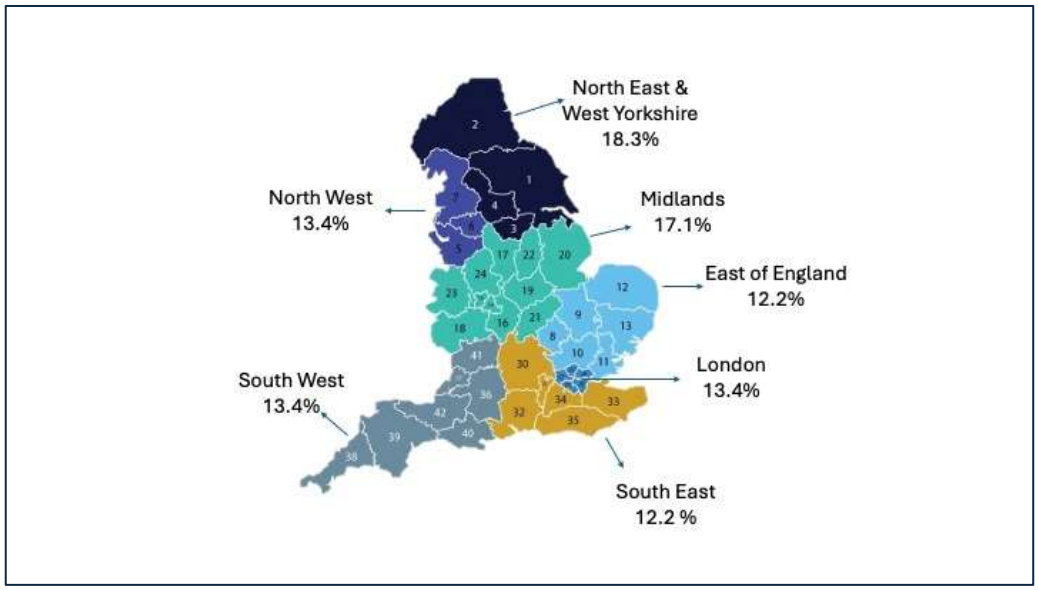


Figure 22 Geographical distribution of the 82 NHS Trusts with vascular services that responded to the FOIR

Specifically looking into the set-up of services in each area, there was a marked regional variation (see Table 25). In the South East, 10 of 12 Trusts (83%) provided vascular services, one of the highest proportions nationally. Seven of these (70%) offered claudication clinics, but only three (30%) provided SET, and only one Trust (10%) delivered both. In London, of 17 responding Trusts, 13 (76%) provided vascular services. Eight (62%) offered claudication clinics, and five (38%) offered both clinics and SET. In the North East & Yorkshire, 27 Trusts responded, of which 15 (56%) reported providing vascular services. However, only eight of these vascular Trusts (53%) offered claudication clinics, five (33%) provided SET, and just four (27%) delivered both services. In the East of England, 10 of 13 Trusts (77%) reported vascular services. Of these, three (30%) offered claudication clinics, four (40%) provided SET, and two (20%) delivered both.

Table 25 Regional distribution of claudication clinics and SET across responding Trusts

Region	Trusts Responding to the FOIR	Trusts with Vascular Services	Trusts with Claudication Clinics	Trusts with SET	Trusts with both claudication clinics & SET
North East & Yorkshire	27	15	8	5	4
North West	16	10	3	2	1
Midlands	20	13	3	4	1
East of England	13	10	3	4	2
South West	19	11	6	2	2
South East	12	10	7	3	1
London	17	13	8	5	5
Total	124	82	38	24	16

In the South West, 11 of 19 Trusts (58%) had access to vascular services. Six Trusts (55%) offered claudication clinics, but only two (18%) provided SET, with two (18%) delivering both services. In the North West, 10 of 16 responding Trusts (63%) provided vascular services, but only three (30%) offered claudication clinics and two (20%) provided SET. Only one Trust (10%) delivered both, representing one of the lowest levels of integrated service provision. The Midlands showed a similar pattern. Of 20 responding Trusts, 13 (65%) provided vascular services, but only three (23%) had claudication clinics and four (31%) provided SET. Only one Trust (8%) offered both services.

5.4.3 Claudication clinics

Of the 82 responding Trusts that provide vascular services, 38 (46.3%) reported offering specific claudication clinics. Of these, 19 (50%) were nurse-led, 11 (29%) were jointly run by doctors and nurses, and eight (21%) were jointly run by vascular nurse specialists and AHPs (see Figure 23). Regarding services offered, two clinics (5.3%) provided disease counselling, treatment planning, lifestyle management, and verbal exercise advice; 20 clinics (52.6%) offered these services along with diagnostic testing; and 16 clinics (42.1%) provided the full range of services, including diagnostic testing

and structured exercise programmes. In terms of clinic frequency, one (2.6%) ran once a month; six (15.8%) every 2–4 weeks; 23 clinics (60.5%) ran weekly; seven (18.4%) three times a week, 1 (2.6%) once a month, and one (2.6%) daily. Follow-up intervals were most commonly determined by clinician decision (24 clinics, 63.2%), while others offered follow-up every 3–6 months (11 clinics, 28.9%), once a year (2 clinics, 5.3%), or had no formal follow-up (1 clinic, 2.6%).

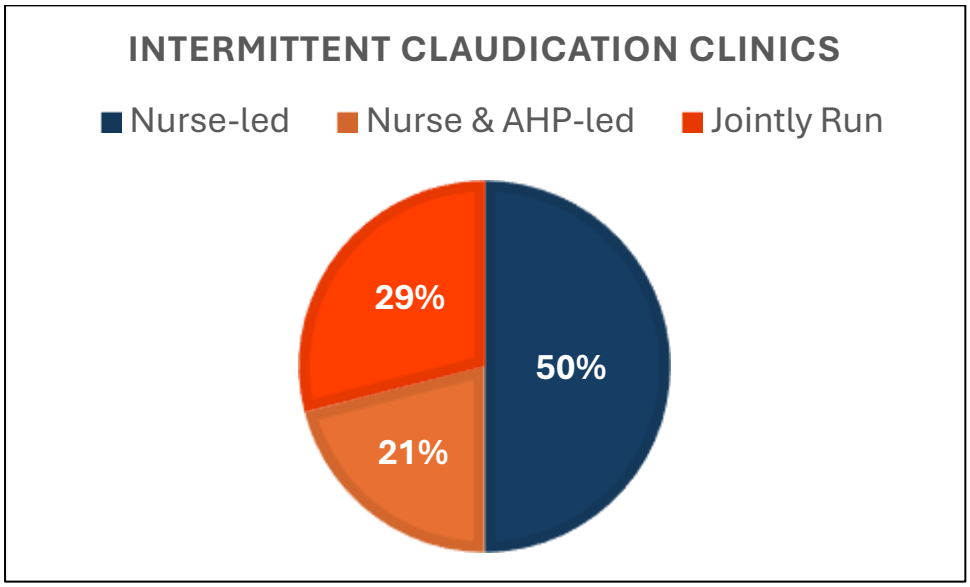


Figure 23 Distribution of healthcare professionals leading claudication clinics.

Abbreviation: AHP: allied health professional

Regarding waiting times from referral to first vascular specialist clinic appointment for patients with IC, 47 out of 82 respondents (57.3%) did not provide an answer. Among those who did, two (2.4%) said it depended on urgency, eight (9.8%) reported a waiting time of less than 4 weeks, 14 (17.1%) reported a waiting time of 4–12 weeks, and 11 (13.4%) reported a waiting time of more than 12 weeks.

5.4.4 Exercise programmes

Of the 82 Trusts responding to the FOIR, 24 (29.3%) reported offering SET programmes and structured exercise advice for patients with IC, whereas the remaining 58 Trusts (70.7%) provided only verbal exercise advice without a formal SET programme. Of the

24 Trusts offering SET, 16 offered claudication clinics and SET; however, in eight Trusts offering SET, patients may have been seen in generic vascular clinics rather than dedicated claudication clinics.

Among the 24 Trusts delivering a structured exercise intervention (see Table 26), the format of the exercise programme varied as follows: eight Trusts (33.3%) offered supervised classes exclusively in a hospital or community setting; 12 (50%) combined supervised classes in hospital or community settings with home-based, unsupervised exercise; two (8.3%) paired supervised classes with an app-based home programme; one (4.2%) combined supervised classes with virtual (home-based) supervised sessions; and one (4.2%) provided an app-directed exercise programme only. Programme location was predominantly within a secondary care setting: 16 Trusts (66.7%) delivered SET in hospital, four (16.7%) referred patients to a different hospital, two (8.3%) referred patients to a primary care setting outside the Trust, and two (8.3%) referred to a private setting outside the Trust, specifically in a university and a local charity.

Table 26 Characteristics of exercise provision for patients with IC in responding Trusts

Characteristics	**n (%)**
Exercise Format	
Supervised classes (hospital or community)	8 (33.3)
App-based home exercise only	1 (4.2)
Supervised + home-based unsupervised	12 (50.0)
Supervised + app-based home	2 (8.3)
Supervised + virtual supervised at home	1 (4.2)
Programme Location	
Within own Trust	16 (66.7)
Another hospital/Trust	4 (16.7)
Referral to primary care (outside Trust)	2 (8.3)
Referral to private setting	2 (8.3)
Programme Duration	
4-8 weeks	7 (29.2%)
12-16 weeks	16 (66.7)
6 months	1 (4.2)
Session Length (minutes)	
30-60	17 (70.8)

60-90	6 (25.0)
90	1 (4.2)
Session Frequency (times/week)	
Once per week	10 (41.6)
Twice per week	4 (16.7)
One or two times per week	3 (12.5)
>3 times per week	3 (12.5)
Dependent on clinical decision making	1 (4.2)
Every 2-4 months	1 (4.2)
No response	2 (8.3)
Staffing	
Physiotherapist alone	6 (25.0)
Exercise professional alone	5 (20.8)
Physiotherapist + nurse	4 (16.7)
Physiotherapist + nurse + exercise professional	2 (8.3)
Nurse + exercise professional	1 (4.2)
Physiotherapist + physio aide	1 (4.2)
Nurse + sonographer	1 (4.2)
Nurse alone	1 (4.2)
Nurse + vascular scientist	1 (4.2)
Exercise professional + cardiac rehabilitation exercise physiologists	1 (4.2)
Vascular surgeons + vascular nurses + vascular scientists	1 (4.2)

In terms of programme duration, seven Trusts (29.2%) offered programmes lasting 4-8 weeks, 16 (66.7%) reported that supervised exercise programmes typically lasted 12–16 weeks; and one (4.2%) had a 6-month programme. The length of the exercise classes was most commonly 30–60 minutes, as specified by 17 Trusts (70.8%); six Trusts (25%) ran 60–90 minute classes; and one (4.2%) conducted a 90-minute session.

The frequency of supervised classes also varied: one Trust (4.2%) based frequency on clinical decision-making; one (4.2%) scheduled classes every 2–4 months; 10 (41.6%) held sessions once per week; three (12.5%) met one or two times per week; four (16.7%) twice weekly; three (12.5%) held sessions three times per week; and two (8.3%) did not provide an answer.

Shorter programmes (4-8 weeks) were limited in frequency, with only four delivered once per week, and sessions were typically 30-60 minutes (five programmes) or 60-90 minutes (three programmes) (see Table 27). Programmes taking place for 12–16 weeks

ran once per week (five programmes), 1-2 times per week (three programmes), or 2-3 times per week (three programmes each), with one programme delivered very infrequently (every 2–4 months). Session lengths were mainly 30-60 minutes (nine programmes), with a few longer sessions of 60-90 minutes (three programmes) and over 90 minutes (one programme). Longer programmes (>16 weeks) were rare, with only one delivered twice a week and one with a 60–90 minute session.

Regarding compliance with the NICE guidelines (12-16 weeks, two hours) (8) only three out of 24 Trusts (12.5%) were delivered in accordance with national guidance (see Table 27). According to the updated 2024 European Society for Vascular Surgery (ESVS) clinical practice guidelines on exercise therapy for PAD (11), another three of 24 Trusts (12.5%) delivered exercise therapy in accordance with these guidelines.

Table 27 Distribution of exercise programmes by duration and format

Programme Duration	**Frequency**					**Length of session (minutes)**		
	1/week	**1-2/week**	**2/week**	**3/week**	**Every 2-4 months**	**30-60**	**60-90**	**>90**
4-8 weeks	4*	-	-	-	-	5	3	-
12-16 weeks	5	3	3	3	1	9	3	1
>16 weeks	-	-	1	-	-	1		-

*The numbers represent the number of exercise programmes that fit the characteristics

Finally, the multidisciplinary composition of the teams delivering SET varied, with physiotherapists being the most common profession running the classes, either alone in 6 hospitals (25%) or together with another professional in seven hospitals (29.2%) (see Table 26). Four Trusts (16.7%) combined a physiotherapist and a nurse, whilst two Trusts (8.3%) had a team of a physiotherapist, a nurse, and an exercise professional.

5.4.5 Lifestyle and psychological support services

Regarding smoking cessation services within their own organisation, 18 respondents (22.0%) reported providing smoking cessation support, while three (3.7%) referred to

another hospital or Trust outside their organisation. The most common pathway was referral to a primary care setting outside the organisation, reported by 34 respondents (41.5%). Additionally, 5 (6.1%) referred patients to private services, and 16 (19.5%) used a combination of hospital services and primary care referrals. Two out of 82 Trusts (2.4%) reported offering cessation advice only, two (2.4%) did not formally refer patients, and two (2.4%) did not answer the question.

For dietetic services, 21 Trusts (25.6%) reported providing services within their own organisation, while two (2.4%) referred to another hospital or Trust outside their organisation. Referral to a primary care setting was offered by 21 Trusts (25.6%), two (2.4%) referred to a private setting, and six (7.3%) reported offering both hospital support and referral to primary care. Seven of 82 Trusts (8.5%) did not respond to the question. Two (2.4%) offered advice only, and 23 (28.0%) stated they did not provide any referral or dietetic service. Psychological support services for patients with claudication were notably limited, with only one Trust (1.2%) reporting that they provided such services.

5.4.6 Referral process for IC services

Most responding organisations (94%) reported using electronic referral systems for patients with IC. A small minority relied exclusively on alternative methods, including secure email (n = 3) or paper-based referral (n = 1), while one organisation did not respond to this question in the FOIR. When asked whether a standardised referral proforma was in use, only 28 organisations (34%) reported having an established template, with an additional two (2.4%) indicating that a specific vascular referral proforma was under development. The remaining majority (64%) did not use a standard proforma.

5.5 Discussion

5.5.1 Summary of main findings

This FOIR was the first to examine the availability and structure of claudication services across NHS England, including the provision of lifestyle support and SET. The findings reveal marked disparities in care provision, despite the NHS's commitment to universal access to healthcare. Fewer than half of centres offer dedicated claudication clinics, less than a third provide SET programmes, and even fewer provide integrated support services such as smoking cessation, dietary or psychological counselling. These service gaps suggest that many patients with IC may not receive guideline-recommended, holistic care, raising concerns about equity, consistency, and long-term outcomes.

5.5.2 Findings in relation to current literature

Existing literature on claudication services in England is limited, yet the results of this FOIR align with earlier studies highlighting poor availability of SET (300, 301) and further underscore the systemic variation in vascular service delivery across the country. Although we have moved beyond the pandemic era, during which vascular services primarily provided emergency procedures only (309), limitations remain. The continued limited availability of claudication services and SET, despite their strong evidence base, suggests a persistent gap between clinical guidelines and real-world practice.

A previous retrospective cohort study evaluated the effects of the 2012 NICE guideline on the management of PAD in NHS England, using Hospital Episode Statistics data from 2009 to 2019 (310). The study highlighted that the introduction of the NICE guidelines was linked to a reduction in hospital admissions for revascularisation, particularly among patients with moderate IC (310). Unfortunately, there are no data on the provision of medical management or lifestyle services for patients with IC since the implementation of the guidelines.

This FOIR revealed that all claudication clinics and most SET programmes are delivered exclusively within secondary care, limiting accessibility for many patients, particularly those in rural or underserved areas. To ensure equitable access, services should be available in both primary and secondary care settings. Although such a care pathway was proposed by NHS Scotland in 2024 (311), NHS England has yet to approach a similar model. The new 2025 NHS 10-Year Plan promotes moving services closer to patients in the community and prioritising prevention to identify and address risks earlier, making healthier choices easier and more accessible (249). A new service provision for vascular services may be expected following the announcement of the NHS Plan. However, clinicians and patients may have different beliefs about this. As presented in Chapter 4, secondary care clinicians advocate for the chronic management of vascular patients within primary care to allow secondary care to focus on acute and complex cases, however, primary care clinicians have indicated that they do not currently have the relevant equipment or expertise to diagnose and manage vascular patients in the community. From the patient perspective, there is a strong preference for being treated by specialist vascular clinicians rather than GPs, due to higher levels of trust and confidence in secondary care expertise. Finally, the absence of dedicated, vascular-specific community services has emerged as a major barrier to patient engagement and treatment adherence, reinforcing the need for system-wide changes to support prevention, integration, and equitable access.

The recently published Commissioning for Quality and Innovation (CQUIN) for the best clinical practice management of PAD emphasises the importance of cardiovascular risk factor management but offers little guidance on how to deliver services optimally to meet these goals (302). Models from other chronic disease pathways, such as cardiac rehabilitation and oncology, have demonstrated that nurse-led clinics can improve patient outcomes, enhance quality of life, and provide cost-effective care through personalised education, regular monitoring, and psychosocial support (312, 313). Similarly, a recent study assessing the impact of a nurse-led IC clinic revealed that such clinics can streamline vascular services by accurately diagnosing and managing PAD, therefore reducing demand on doctor-led clinics and prioritising specialist input for patients with more urgent surgical needs (314). Given these proven benefits, nurse-

led clinics should be positioned as a cornerstone of care for patients with IC, particularly during early management. These clinics could support cardiovascular risk reduction and lifestyle modification, provide early education, and enable timely referral to SET programmes or other vascular specialists. To deliver a more optimal service, future care models should also include closer integration with primary care, standardised referral pathways, and robust data collection on outcomes to inform continuous improvement. Such steps are essential for reducing regional variation and ensuring that all patients with IC receive timely and comprehensive care.

With regards to SET, this FOIR found a wide variation in programme format, setting, duration, session length, frequency, and staffing. Although SET is recommended for all patients with IC, limited NHS commissioning (315) means that many Trusts do not offer it at all. Since the Covid-19 pandemic, there has been a rise in digital interventions aimed at improving SET availability and adherence. The use of smartphones and wearable devices enables real-time monitoring, personalised feedback, and accessibility without geographic constraints (316). A systematic review has shown that mobile health (mHealth) for PAD is associated with improved adherence and effectiveness (317). However, only four Trusts in our FOIR reported utilising digital health approaches to SET. While limited use of technology may reflect assumptions about frailty, high comorbidity, and digital literacy in the PAD population, digital options should still be made available to more technologically able patients and those who would benefit from a flexible, virtual exercise programme that fits into their daily routines.

As for the structure of SET programmes, compliance with NICE guidance was substantially lower when programme length was considered. The NICE guidance recommends a minimum of 12 weeks of SET, for approximately two hours per week (28). A previous Cochrane review highlighted that SET programmes that meet the recommended frequency and duration are associated with significant improvements in pain-free and maximum walking distances, whereas less structured or lower-dose interventions show smaller or no such benefits (29). These findings are consistent with previous literature. A national audit performed before the Covid-19 pandemic (between

July and December 2019) revealed that only 46% of vascular centres offer SET, with just 6.8% of these centres delivering SET fully compliant with NICE guidelines. Another observational study, conducted after the Covid-19 pandemic, found that only 48% of vascular units had access to SET programmes, with just five out of 23 meeting the NICE dose recommendations (301). Compared with earlier reports, our findings suggest that a higher proportion of centres now offer SET, which may indicate some progress in provision. However, there is still substantial room for improvement in aligning practice with NICE recommendations. It should also be noted that this apparent increase should be interpreted cautiously, as changes in the total number of vascular units nationally could affect these percentages and may not necessarily reflect an absolute increase in service provision.

However, even if the programme duration is optimal, inadequate programme frequency does not constitute compliance with guidelines. Importantly, international guidelines further stress the need for an adequate exercise dose. The latest ESVS PAD guidelines suggest a training frequency for patients with IC should be three times per week to achieve a meaningful improvement in their walking distance (11). The results from this FOIR make it difficult to directly compare trends in service provision over time. While some Trusts have achieved the previous benchmark, further improvement is needed to meet the newest guideline recommendations. A similar trend has been identified regarding the provision of other vascular services in NHS England, such as varicose vein interventions, with many local varicose vein commissioning policies not being compliant with NICE guidance (318).

Besides the SET programme dose, it is also important to consider programme attendance and completion rates when thinking about the clinical effectiveness of SET. Although this FOIR did not assess SET uptake, attendance, or completion, previous literature indicates that actual uptake among patients with IC is often low, with only 24.2% of eligible patients attending SET (301). In my pre-doctoral survey, fewer than 20% of patients attended and completed SET (71). This suggests that even when SET programmes are delivered in accordance with national guidance, poor attendance or high dropout rates may substantially limit their clinical impact.

Compared with previous studies, a large variation in the professional backgrounds of staff leading SET was observed in this FOIR. Physiotherapists were the most common group leading SET (25%), whereas in a recent study conducted by Harwood et al, nurses (42%) most commonly led these programmes, followed by physiotherapists (21%) (301). Regarding the professional background of staff leading IC clinics in this FOIR, half were nurse-led. Only approximately one in five adopted a multidisciplinary approach, utilising vascular nurse specialists and physiotherapists. This contrasts with cardiac rehabilitation models, which typically feature a cardiac nurse specialist leading a broader multidisciplinary team comprising exercise specialists, dietitians, and a visiting cardiologist (319, 320). It is important to note that cardiac rehabilitation is traditionally funded by ICBs (321), unlike IC services that are not always funded by the ICB across England. This difference in funding arrangements may help explain the variation in services offered between the two.

Although guidelines recommend a holistic cardiovascular approach, including support for smoking cessation and dietary changes, such services are rarely available to vascular patients in secondary care. In this FOIR, fewer than half (41.5%) of the 82 Trusts offering vascular services reported referring patients to smoking cessation support. While lifestyle interventions are standard in cardiac rehabilitation and are also endorsed by the PAD CQUIN (302), their absence in vascular care highlights a persistent disconnect between clinical guidelines, service delivery, and commissioning. Notably, smoking cessation interventions are underutilised in vascular clinical care. Although many smokers express a desire to quit and make a quit attempt, long-term abstinence rates remain low, particularly in the absence of structured support (67, 322). Previous research has shown that cessation interventions that combine clinician advice, behavioural counselling, and pharmacological treatment substantially increase abstinence rates compared with brief verbal advice alone (323, 324). Hence, all patients should be offered such smoking cessation support. However, as presented in this FOIR, the implementation of these strategies in clinical practice is limited.

Previous studies have highlighted the burden of PAD diagnosis on wellbeing, such that patients with PAD experience significantly more mental health disorders compared to the general population (16, 325). Depression in patients with PAD is associated with higher mortality, reduced physical function, and worse outcomes after revascularisation, including major amputation (326). Despite this, only one of the Trusts that responded to this FOIR reported providing psychological services for patients with PAD. Unfortunately, current care systems for PAD often overlook the integration of mental health support, health behaviour management and the complex nature of living with the disease (17). These gaps, alongside persistent disparities in PAD care, indicate the need to move beyond the current fragmented care model towards a more integrated, multidisciplinary, patient-focused approach. Further research is essential to develop evidence-based interventions that support holistic patient management and tailored, equitable, and sustainable care pathways.

Last but not least, data from this FOIR showed that about a third of Trusts have dedicated referral proformas that primary care clinicians can use to refer patients directly to IC services. A previous review found that referral proformas can improve both referral rates and appropriateness (327), however their availability and use within PAD remains limited. Across clinical specialities, substantial variations persist in referral rates, alongside inappropriate referrals, poor communication and collaboration between primary and secondary care (328, 329). This is evident across PAD, where primary care assessments of IC are based solely on clinical history, leading to considerable diagnostic inaccuracy (330). A recent systematic review on referral interventions highlighted that although proformas are useful, they are most effective when combined with staff education and wider system-level changes (331). When used in isolation, their implementation is often hindered by time pressures and staff preconceptions about the necessity of referral (331).

5.5.3 Strengths and Limitations

A key strength of this study is that it offers the first comprehensive overview of IC services in England based on publicly available, real-time NHS data. Additionally, the FOIR questionnaire was designed in line with guidance on questionnaire development

and was piloted to ensure its relevance (303, 304). However, this study has several limitations. Despite best efforts to obtain responses from all NHS Trusts in England, with a high response rate (89.9%), some Trusts did not respond to the FOIR; hence, the data may not be representative of all NHS services. However, compared with the National Vascular Registry (NVR) data on arterial centres in England (332), the FOIR presented here includes information from 61 of the 79 centres in the 2023 NVR update. Moreover, a particularly good response was observed in regions with high levels of cardiovascular and peripheral arterial disease, such as the North East coastal regions (333).

Another limitation is that the data collected are specific to the questions asked, precluding detailed insights into day-to-day clinical practices. Some NHS Trusts provided overlapping time ranges in their free-text responses (e.g. 2–3 weeks or 3–4 weeks). To maintain the integrity of the original data, these responses were retained as reported rather than reclassified into mutually exclusive categories. Consequently, there is some uncertainty in the interpretation of the SET frequency distributions presented in this chapter. The undisclosed identity of FOIR responders (either administrative staff or clinicians) within each NHS Trust introduces potential variability in responses, as answers could be influenced by the responder's understanding. I did not instruct Trusts to consult clinical teams when completing the FOIR; however, based on experience and pilot testing, it is standard practice for administrative staff to seek input from clinical colleagues when unsure of the answer. This assumption, while reasonable, cannot be verified and introduces potential variability in internal validity. To mitigate this, FOIR questions were pilot-tested, and clinical terms were clearly defined. Although attempts were made to seek clarification on some Trust responses, this proved impossible due to the inherent restrictions of the FOIR process, a recognised methodological challenge in such requests (334). A further limitation was that FOIRs may be considered resource-intensive because they heavily rely on administrative support. When the FOIR was distributed, the NHS was undergoing significant restructuring, with many administrative and management functions closing down. Yet it is important to note that there is dedicated administrative support for FOIRs within the NHS, a legal requirement that each Trust must comply with.

5.5.4 Implications for future research

As noted in the limitations, some vascular centres may not have responded to the FOIR; hence, these results do not provide a fully comprehensive picture of IC services in England. Further nationwide research is needed to better understand the structure of vascular networks. Additionally, while this FOIR is focused on NHS England, it is important to note the lack of comparable international literature. There are currently limited published data on the availability and structure of claudication services across other healthcare systems, making direct comparisons difficult. This highlights an urgent need for international research and benchmarking to better understand global variations in PAD care and to inform the development of best-practice models.

To better understand regional variation, it is important to examine the characteristics of regions with the highest service provision and explore whether these could be adapted in other areas to enhance delivery. Finally, understanding the barriers to successful guideline implementation is essential to developing well-considered, effective solutions for patients with PAD. Future research should focus on multidisciplinary integration to ensure equitable and sustainable IC management across the NHS. Targeted policy interventions, standardised claudication service provision, and strategic investment in vascular care are paramount to improving patient outcomes and aligning clinical practice with established guidelines.

5.5.5 Implications for this work

As suspected when I started this FOIR project, the findings highlighted significant variability and gaps in service provision, which informed the co-design process by emphasising the need for a flexible, scalable intervention that could be adapted to local contexts and delivered by existing clinical teams. Additionally, given the current NHS challenges, a low-cost intervention would be most preferable. The results of this FOIR and the triangulation data from Chapter 6 were presented to the stakeholder group and the Society of Vascular Nurses (SVN) to discuss potential intervention ideas addressing

key adherence influences, whilst taking into consideration the challenges in optimal service provision.

5.6 Conclusion

The findings reveal regional variation and inconsistencies in the provision of IC services across England, with many not meeting guideline-recommended levels. The limited availability of specialised claudication services offering medical management, lifestyle interventions and SET is a major obstacle to delivering optimal care for patients with PAD. Only a few Trusts offered comprehensive IC care. Even when SET programmes were available, only a minority of these were delivered in line with national guidance. Understanding the barriers to successful guideline implementation should allow the development of well-considered, effective solutions for patients with PAD. Future work should focus on bridging the gap between policy and practice, expanding access to evidence-based interventions, and ensuring equitable, holistic care pathways for patients with IC.

Chapter 6. Intervention Development Phase 1: Triangulation of theory and evidence to generate outline intervention

6.1 Chapter Summary

This chapter triangulates and consolidates findings on the modifiable influences on PAD treatment adherence from my pre-doctoral and doctoral work (presented in Chapter 4); identifies intervention content and Behavioural Change Techniques (BCTs) (102) to address these influences; and outlines intervention ideas that could utilise the identified BCTs. Additionally, the intervention guiding principles and logic model are presented, as per the Person Based Approach (PBA).

6.2 Aims and Objectives

Aim: To triangulate evidence from my pre-doctoral and doctoral work to identify modifiable influences on PAD adherence, and to generate the guiding principles for the intervention and its outline.

Objectives:

1. Create a list of the most important determinants affecting adherence to the guideline-recommended treatment plan for the management of PAD, by triangulating findings from three methodologically distinct studies (Pre-doctoral projects and doctoral study in Chapter 4)
2. Identify relevant BCTs to target these adherence determinants
3. Draft intervention ideas to deliver the relevant BCTs

6.3 Methods

6.3.1 What is triangulation?

Triangulation is the process of using multiple methods or data sources to develop a comprehensive understanding of phenomena (335, 336). It is based on the idea that no single research methodology can fully address a research question (335, 336). Utilising different methods allows researchers to capture different versions of reality and better answer the research questions (335, 336). In this way, triangulation enhances the quality and credibility of study results (335, 336).

Four types of triangulation have been identified: 1) methodological triangulation, combining more than one methodology to study a phenomenon; 2) data triangulation, combining multiple data sources to answer the same research question; 3) theory triangulation, using multiple theory approaches to understand a phenomenon; and 4) investigator triangulation, where multiple researchers collect and/or analyse the same research question (335, 336). It is important to note that although adopting a triangulation approach can be beneficial, it can be resource-intensive in terms of time and funding, and also relies on the researcher's expertise (335, 336)

For this PhD project, I utilised methodological triangulation to assess the consistency of findings across different data collection methods (see section 6.3.2). Although I have not conducted a triangulation study before, I received bespoke training from my supervisor, Dr Judah, who has completed and supervised multiple triangulation studies. Additionally, at each stage of the process, I had group supervisor meetings to get guidance and support from my supervisory team.

6.3.2 Overview of studies used for triangulation

Three studies exploring barriers and facilitators to treatment adherence for the management of PAD were used in the triangulation process (Table 28):

1. A survey of patients with PAD exploring adherence rates and sociodemographic and clinical factors, as well as illness perceptions affecting adherence (pre-doctoral study) (71)
2. Inductive/deductive thematic analysis of semi-structured interviews with patients with PAD underpinned by the PaPa (pre-doctoral study) (139)
3. Inductive/deductive thematic analysis of semi-structured interviews with patients with PAD, their relatives and HCPs underpinned by the PaPa (Chapter 4).

All studies aimed to identify factors affecting patient-related adherence to the guideline-recommended plan for the management of PAD. Table 28 summarises the key features of each study included in the triangulation exercise, in terms of methods employed, use of theory, sample size, clinical setting, participant selection, data collection and data analysis.

Table 28 Key features of studies included in triangulation

	Patient survey (71)	**Patient semi-structured interviews (139)**	**Semi-structured interviews (Chapter 4)**
Method	Survey of patients with PAD	Semi-structured interviews with patients with PAD	Semi-structured interviews with patients with PAD, their relatives and HCPs
Sample size	105 patients	12 patients	17 patients, 4 relatives and 18 HCPs
Clinical setting	Secondary care: patients recruited from ICHNT vascular surgery outpatient clinics	Secondary care: patients recruited from ICHNT vascular surgery outpatient clinics	Primary and secondary care (ICHNT, Leicester NHS Trust, Mid Yorkshire NHS Trust and Hull NHS)
Method of data collection	Survey	Face-to-face, Remote via video (MS Teams) and via Phone	Face-to-face, Remote via video (MS Teams) and via Phone
Use of framework for data collection	Validated Morisky Medication Adherence Scale	Yes – topic guide based on PaPa	Yes – topic guide based on PaPa

	(MMAS-8) questionnaire (221) Validated Brief Illness Perceptions Questionnaire (B-IPQ) (90)		
Participants	Patients with PAD, at any stage of their disease	Purposively sampled patients with PAD with different sociodemographic data and different levels of adherence	Purposively sampled i) patients with PAD with different sociodemographic data and different levels of adherence, ii) relatives of patients, iii) healthcare professionals with different professional backgrounds (e.g. nurses, doctors, physiotherapists) involved in the care of patients with PAD
Analysis	SPSS software Descriptive statistics and t-tests	Professionally transcribed transcripts uploaded onto NVivo Combination of inductive and deductive (PaPa) thematic analysis	Professionally transcribed transcripts uploaded onto NVivo Combination of inductive and deductive (PaPa) thematic analysis

Abbreviations: HCP: Healthcare Professionals; ICHNT: Imperial College Healthcare NHS Trust; PAD: Peripheral arterial disease; PaPa- Perceptions and Practicalities approach

Each approach and study has distinct strengths and limitations, which are described in Chapter 4 and in the relevant published papers (71, 139). The strengths and limitations are summarised in Table 29. With each subsequent study, I tried to address the limitations of the previous one. For example, a limitation of the pre-doctoral qualitative study (139) was that I only interviewed patients from a single centre (Imperial College Healthcare NHS Trust). For the PhD qualitative study (Chapter 4), I also included relatives of patients with PAD and healthcare professionals involved in their care; and opened the recruitment to other sites outside London, to capture a broader demographic and better understand the issue of adherence from the views of different participants.

Table 29 Strengths and weaknesses of studies included in the triangulation process

Study	Strengths	Weaknesses
Patient Survey (pre-doc)	• Data collection from diverse participants • The use of validated questionnaires • No previous relationship with the patients • Stressed that there is no right or wrong answer	• Single-centre study • Potential for responder bias (i.e. participants providing responses they think they should provide, or responses they think I am expecting to hear, rather than what they truly think or feel) • Unable to explore in-depth beliefs about adherence
Patient semi-structured interview study (pre-doc)	• The first qualitative study in PAD to explore adherence barriers and facilitators • The use of the PaPa framework • Expert qualitative supervisor • Reflexivity • Discussed data with wider research team (MW, AHD) • No pre-existing relationship with participants • Employed a "no-blame" approach during the interviews.	• Single-centre study • Only including the views of patients • One researcher collecting data leading to potential observer bias • Novice qualitative researcher • Potential for responder bias (i.e. participants providing responses they think they should provide, or responses they think I am expecting to hear, rather than what they truly think or feel)
Patient, relative and HCPs interview study (Chapter 4)	• The first qualitative study in PAD involving patients, relatives and HCPs • Diverse sample • UK wide study • The use of PaPa framework • More experienced qualitative researcher	• Potential for responder bias (i.e. participants providing responses they think they should provide, or responses they think I am expecting to hear, rather than what they truly think or feel) • Only four relatives were interviewed, hence, their

	• Expert qualitative supervisors • Reflexivity • Discussed data with wider research team (MW, GJ, AHD) • No pre-existing relationship with participants • Employed a "no-blame" approach during the interviews.	perceptions may not have been captured fully

6.3.3 Triangulation of study findings

To conduct the triangulation exercise, I created tables on Microsoft Word for each target behaviour: 1) overall PAD treatment, 2) medication adherence, 3) smoking cessation and 4) exercise uptake (See Tables 30, 31, 32, 33). Each table summarises how findings from multiple data sources (survey and qualitative interview studies), patient and public involvement (PPI) and stakeholder input (see Section 6.3.4) were systematically compared and contrasted to prioritise key behavioural influences relevant to PAD management. For each treatment domain (overall treatment, medication adherence, smoking cessation, and exercise), factors were mapped as perceptual or practical barriers and/or facilitators and examined across data sources to assess consistency, differences, and gaps. When factors were both barriers and facilitators, the context for each categorisation was explained. For example, the lack of motivation was a barrier, whilst the presence of motivation was a facilitator. Factors identified in only one data source were highlighted, while overlapping influences were synthesised to strengthen confidence in their relevance. If any conflicting information between resources was identified, this was discussed with the supervisory team to reach a consensus. I also coded factors that were not in the survey or topic guides and were not examined.

Each factor was then rated as high, medium or low for its potential impact on behavioural change, perceived importance to healthcare professionals, and feasibility

of change within the proposed intervention. A factor was voted as “high” when there was strong evidence from the studies included in the triangulation and the PPI group validated it; as “medium” if some participants mentioned it and it was not relevant to everyone, but could be important for some; and as “low” if the evidence was limited and was only applicable to a small number of patients, but not important. I combined these ratings through structured voting to identify final intervention priorities (see Section 6.4.1). This was then discussed with the supervisory team (MW and GJ), before agreeing on a final vote. The end result was a list of the most important influences for each target behaviour for PAD (see Section 6.4.1).

6.3.4 Patient and Public Involvement and Stakeholder Engagement

Once adherence influences had been identified across data sources, they were presented to PPI and stakeholder groups for prioritisation, based on the impact and feasibility of change. Separate online meetings were held with the PPI and stakeholder groups via Microsoft Teams, each lasting approximately two hours. The PPI group rated the potential impact of changing each influence and ranked influences from most to least important within each target behaviour (medication taking, smoking exercise, exercise). The stakeholder group completed the same prioritisation exercise but also assessed the feasibility of addressing each influence within the proposed intervention and the constraints of the current NHS system. All voting and ranking activities were conducted using Mentimeter. An example of the ranking is shown below in Figure 24. The groups also discussed draft intervention ideas to address these influences (see Section 6.3.5).

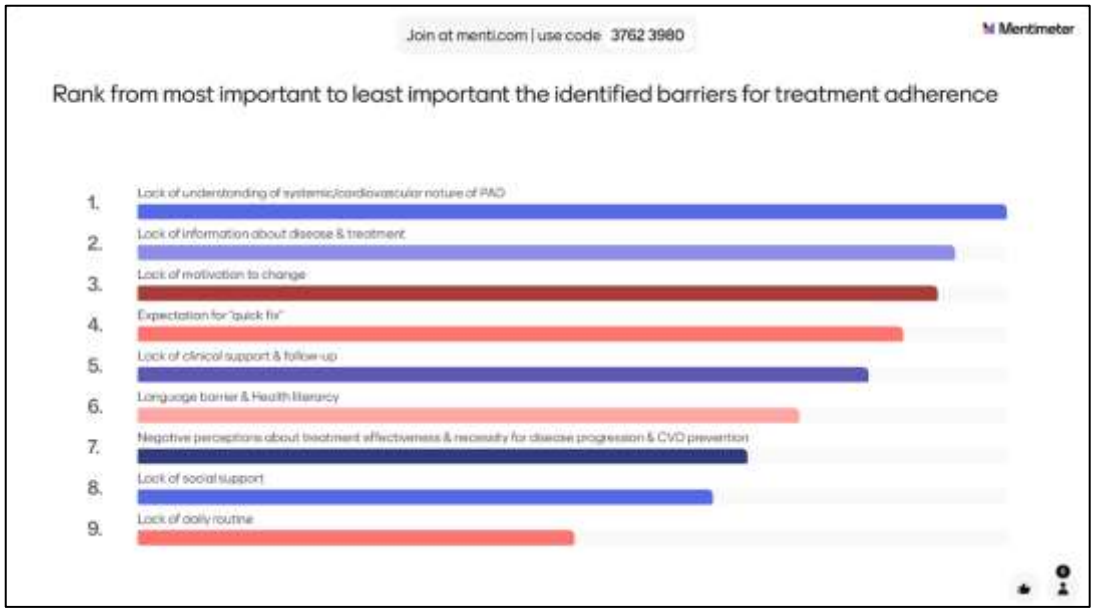


Figure 24 Ranking of adherence influences for treatment adherence by the stakeholder group regarding the impact of change

6.3.5 Intervention ideas

As described in Chapters 1 and 2 (See Sections 1.6 and 2.6.2), I had undertaken preliminary work to discuss potential intervention formats and ideas with the PPI and stakeholder groups. Both groups stressed the importance of addressing the gap regarding patient-friendly information about PAD and treatment. These issues were informed further through the qualitative work (Chapter 4), the freedom of information request (Chapter 5) and the triangulation exercise. Finally, it was agreed that a leaflet intervention would be the most appropriate format for this intervention.

I developed preliminary outlines of intervention ideas to illustrate how the candidate BCTs could be delivered within a PAD adherence intervention. These ideas were discussed and iteratively refined with the supervisory team (MW, GJ and AHD). Each intervention idea was initially generated from individual BCTs. For example, BCT 11.3 *Conserving mental resources* led to the consideration of practical reminders, such as diaries. At this stage, intervention ideas were intentionally broad to allow flexibility and further development during the co-design workshops (see Chapter 7). I conducted this activity for each PAD target behaviour. Through this process, I generated a set of

intervention ideas, presenting how each BCT could be utilised to address specific adherence influences.

6.3.6 Identification of BCTs

After synthesising influences from all three studies, potentially relevant BCTs were identified using the online Theory and Techniques Tool (TATT) (134). The TATT presents a heat map linking 74 BCTs with 26 mechanisms-of-action (MoAs), producing 1924 possible BCT-MoA pairings (134). Each cell represents the strength of evidence for a specific link, with stronger links shown in green (see Figure 25). These links are already established from the work done to develop the TATT. The strength of a link is based on triangulation evidence from a literature synthesis and an expert consensus study, and is categorised as established, inconclusive, a non-links, or no evidence of association (134).

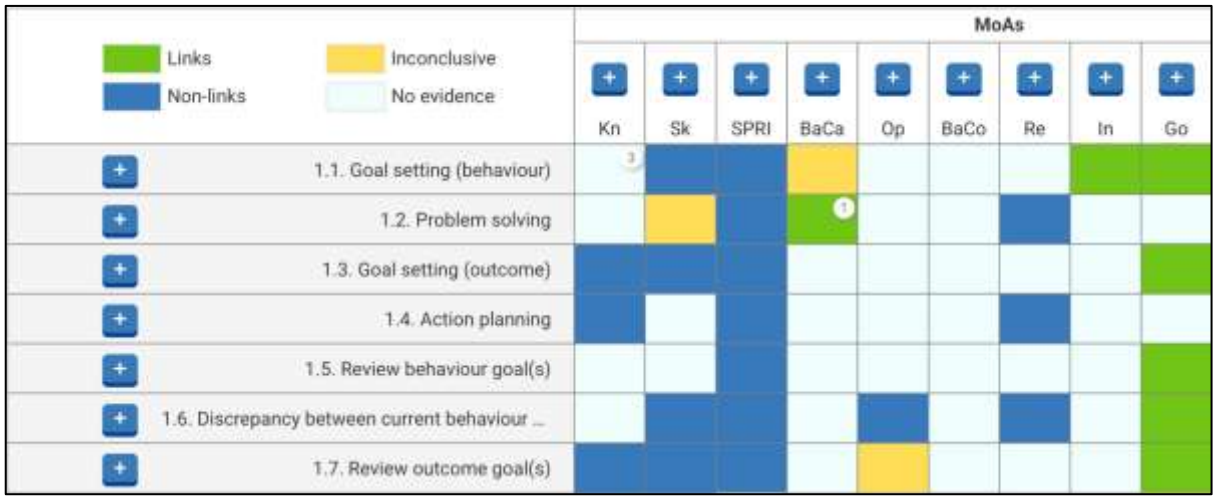


Figure 25 The Theory and Techniques Tool (Adapted by Johnston, 2021) (134).

Abbreviations: Kn: Knowledge; Sk:Skills; SPRI: Social/Professional role and identity; BaCa: Beliefs about capabilities; Op: Optimism; BaCo: Beliefs about consequences, Re: Reinforcement; In: Intention; Go: Goals

The mapping of influences to MoA was conducted by conceptually aligning each influence with its underlying theoretical construct using established behavioural science frameworks and definitions of MoAs provided within the TATT. Specifically, influences were examined to determine what would need to change for the target behaviour to occur (e.g. gaps in knowledge mapped to the MoA knowledge; misconceptions mapped to beliefs about consequences). This process ensured that MoA selection was theory-driven rather than assumption-based.

When using the TATT, I only included BCTs with established links to relevant MoAs. Those with inconclusive links or non-links, or no evidence of association, were not considered. The appropriateness and feasibility of each candidate BCT, in relation to the identified influences, target behaviours, and study context, were then discussed with the supervisory team (MW and GJ). Each BCT was reviewed in detail and excluded only where it was clearly infeasible or inappropriate for the intervention context (see Section 6.4.3).

6.3.7 Developing guiding principles

Guiding principles summarise two central considerations that inform both the development and evaluation of an intervention: 1) key intervention design objectives, which define the intervention's aims in relation to user needs and contextual challenges, and 2) key intervention features, which describe the specific content, delivery methods, and implementation strategies intended to meet those objectives (7). This phase aimed to ensure that the intervention was firmly grounded in the development work described in Chapters 3, 4, and 5 and to articulate how it would support people with PAD to engage with and adhere to treatment.

Guiding principles were developed using an established person-based approach (158). First, the overarching objective of the intervention was defined: to support individuals with PAD to adhere to treatment in ways that are acceptable, feasible, and sustainable within their daily lives. Following that, key issues, needs, and challenges that could influence adherence were identified, as described in the triangulation exercise. For each key influence, specific design objectives were formulated, explaining what the

intervention needed to achieve to address that issue. These objectives were then translated into practical intervention features intended to operationalise them in the intervention content and delivery. The guiding principles were treated as iterative and reviewed and refined through ongoing discussions with the supervisory team, the PPI group, and stakeholders, ensuring alignment with current clinical practice (see Section 6.4.4).

6.4 Results

6.4.1 Intervention format

Intervention ideas were discussed in detail when preparing for PhD funding application and during my PhD with my PPI and stakeholder groups. It was very clear that there was a lack of patient-friendly information, hence the need to address this gap. The most popular options were a booklet or a video intervention. Most patients preferred a booklet version (physical copy and/or electronic version), whilst more clinicians voted for a video intervention. Patients spoke about having resources they could use daily and make notes on. They were not as keen on the video intervention, as they felt that a smartphone or access to a digital device would be required. Patients also noted that a leaflet should be the first choice, with a video developed later. Most clinicians felt that it was essential to shift to more digital health resources, however, our patients may not be ready for that. My core principle throughout this PhD was to represent patients' voices and co-design an intervention with them, for them. Hence, I opted for the booklet intervention. All decisions made for the selection of BCTs, discussed in the section below, were based on the fact that I was developing a booklet intervention. The materials generated and distributed at the co-design workshops to vote on the most relevant intervention content using BCTs will be discussed in Chapter 7. Finally, the NICE PAD guidelines for IC (8), with a focus on improving IC symptoms, were followed throughout. Given the format of this intervention and following PPI and stakeholder feedback, it was decided that for the exercise component of the booklet, the focus should be on walking with claudication pain, rather than supervised exercise therapy.

6.4.2 Methodological triangulation to generate lists of the most important influences on PAD treatment adherence

6.4.2.1 Treatment as a whole

Across the *treatment as a whole* domain, eight influences were identified in the pre-doctoral qualitative work and 12 in the main qualitative study presented in Chapter 4 (see Table 30). Across all overlapping influences from the two qualitative studies, no significant disagreements were observed. These influences were mapped onto the perceptual and practical components of the PaPa framework, with nine corresponding to perceptions and three to practicalities. The influences were then categorised as high, medium or low importance, following the metrics discussed in Sections 6.3.3 and 6.3.4.

Four high-priority perceptual influences were identified: 1) Knowledge and understanding of PAD, 2) Expectation of a quick fix, 3) Lack of information about the disease and treatment, and 4) Positive mindset and motivation to change and stay on track. None of the practical influences were rated as high priority by patients or clinicians. Knowledge and understanding of PAD was voted the top priority by HCPs and the one most likely to be impactful. The findings of the qualitative study (Chapter 4) showed that most patients do not perceive PAD as a chronic cardiovascular condition and therefore do not understand why they need to make long-term changes. Related to this was the expectation of a quick fix. Although this was rated as medium priority in the triangulation exercise, I categorised it as high priority because of its importance for understanding PAD as a chronic disease. Lack of information was prioritised because the existing information was considered neither meaningful nor patient-friendly. Lastly, motivation was voted the third-highest priority by HCPs, whilst all patients spoke about the need for motivation to change.

It is important to note that although some influences were voted as medium priority, such as health literacy and language barrier, these were not disregarded during the intervention development process. Although the intervention was not explicitly designed to address health literacy, I ensured that the language used throughout the information leaflet was lay and included many visual elements. Additionally, some

medium priority influences were interconnected with high priorities and could be addressed in tandem. For example, the perception of the necessity of treatment is related to knowledge of the cardiovascular nature of PAD, so it can be addressed at the same time. Once people understand that PAD is a chronic disease and that treatment is for cardiovascular management, they are likely to learn more about its benefits. Similarly, habit formation first requires motivation for behaviour change, and so motivation was seen as more important to address as a necessary precursor to change. Regarding trust in specialist care, although this intervention does not specifically focus on mechanisms to increase patients' trust in HCPs, I aimed to ensure that the information included was trustworthy and credible.

Only two influences were voted as low priority: support from HCPs and follow-up, and social support. Although both influences are important, they are outside the scope of an information leaflet and cannot be directly addressed by it. This intervention is intended to be used within the existing healthcare system and cannot influence the restructuring of current healthcare services to offer more follow-up appointments and HCP support options (e.g., additional services, psychological support). However, the provision of a patient-centred information leaflet by HCPs may improve perceptions of support by patients and families. This will be further discussed during the co-design workshops. Similarly, an information leaflet cannot directly address or improve social support, but it could provide a mechanism through which patients and families can discuss and share knowledge and understanding of PAD.

Table 30 Triangulation of studies to identify influences for PAD treatment

PaPa	Factor	Pre-doc qualitative	PhD qualitative	Impact of change (patients)	Impact of change (HCPs)	Feasibility of changing (HCPs)	Final voting/ priority
Perceptions	Knowledge & understanding about PAD as a chronic cardiovascular condition	Facilitator when knowledge is present and Barrier when there is lack of knowledge	Facilitator when knowledge is present and Barrier when there is lack of knowledge	High	High	High	High
	Expectation about "quick fix"	Not examined	Barrier	Medium	High	Medium	High
	Perceiving treatment as necessary & effective	Facilitator when having positive perceptions and Barrier when having negative perceptions	Facilitator	High	Medium	Medium	Medium
	Concerns about treatment (even if believing treatment is important)	Barrier	Barrier	High	Medium	Medium	Medium
	Lack of information about disease & treatment	Barrier	Barrier	High	Medium	Medium	High

	Language barrier	Not examined	Barrier	Medium	Medium	Low	Medium
	Low health literacy	Not examined	Barrier	Medium	High	Low	Medium
	Positive mindset & Motivation to change & staying on track	Facilitator	Facilitator	High	High	High	High
	Trust in specialist care	Not examined	Facilitator	Low	Medium	Low	Medium
Practicalities	HCP support & follow-up	Facilitator	Facilitator	Medium	Low	Low	Low
	Daily routine / habit formation	Facilitator	Facilitator	Medium	Low	Medium	Medium
	Positive social support & engagement	Facilitator	Facilitator	Medium	Low	Low	Low

6.4.2.2 Medication Adherence

Across the *medication adherence* domain, six influences (including one non-significant influence) were identified in the pre-doctoral survey, 13 in the pre-doctoral qualitative study, and 13 in the main qualitative study (see Table 31). Only two influences were identified across all three data sources, and 12 influences were identified across both qualitative studies. Following synthesis and final voting, five high-priority, six medium-priority and seven low-priority influences were identified.

The following high-priority influences were identified: 1) Understanding about the cardio-protective role of treatment, 2) Perceiving medical therapy as less effective, 3) Concerns about medication side effects, 4) Fear of damaging the legs due to statins, 5) Influence of others – negative experiences with taking medications. The first two were ranked as equal top priorities. It is essential for patients to understand that medications protect them from cardiovascular events, such as heart attack and stroke, and their main role is not claudication symptom relief. In turn, their perception about treatment necessity will be addressed. Concerns about side effects was voted as the second top priority, and concerns about statins damaging the legs or making claudication pain worse was voted as the third highest priority. This was mainly reported during the large qualitative study (Chapter 4), and some PPI members validated it. Clinicians also noted that most patients discuss how the media and opinions from wider society can affect opinions about medication side effects, hence it is important to address them when discussing medication side effects.

Similarly to the *treatment as a whole* domain, some medium priority influences are interconnected with high priorities, hence the intervention will not explicitly target these but may address them indirectly. For example, univariate analysis in the pre-doctoral survey showed that patients with low medication adherence had lower levels of perceived personal control over health ($p < 0.05$) (71). However, in the interview studies, this factor was a barrier reported as being affected by motivation. Supporting patients to feel more in charge of their health may be achieved by increasing motivation. Following the final vote, it was decided that this influence is not a key ingredient of this

specific intervention. Moreover, the influence “lack of information” is connected to treatment understanding and will be addressed by providing an information booklet. The influence “mixed information from different HCPs” was highlighted as an important factor, but it was decided that this could not be directly addressed by an information booklet. Although a booklet cannot influence what HCPs say to patients, it may help to standardise the information being received. Although several of the practical influences presented in Table 31, such as “forgetfulness” and “creating routines”, are medium or low priority, they are easily addressed in an information leaflet and have been included where possible.

Some of the low priority factors identified in Table 31 could not be easily addressed in an information leaflet e.g. perceptions about “not being a tablets person” and swallowing problems. The practical experience of medication side effects was identified as less important than concerns about side effects. Clinical factors such as previous vascular intervention or cardiovascular event were voted as low priority and were less likely to be addressed by an intervention intended for newly diagnosed patients. Older age was also voted as low priority and was not found to be an important factor in the qualitative studies. However, as described in Chapter 7, efforts were made to include patients of all ages in the co-design workshops, to ensure the intervention was relevant across age groups.

Table 31 Triangulation of studies to identify influences for medication adherence

PaPa	Factor	Survey	Pre-doc Interview	PhD interview	Impact of change (patients)	Impact of change (HCPs)	Feasibility of changing	Final voting/ priority
Perceptions	Lower perceived control over health	Barrier	Barrier but mainly connected to motivation	Barrier but mainly connected to motivation & everyday reality	Medium	Low	Low	Medium
	Low perceived control over treatment	Barrier	Not reported	Not reported	Low	Low	Low	Low
	Understanding about cardio-protective role of treatment	Not examined	Barrier when there is lack of understanding & Facilitator when there is understanding	Barrier when there is lack of understanding & Facilitator when there is understanding	High	High	High	High
	"It doesn't make me feel better" / Perceiving medical therapy as less effective	Barrier	Barrier	Barrier	High	High	High	High
	Lack of information about treatment	Not examined	Barrier	Barrier	High	Medium	High	Medium
	Concerns about medication side effects	Not examined	Barrier	Barrier	High	Medium	High	High
	Fear of damaging the legs due to statins	Not examined	Barrier	Barrier	Medium	High	High	High

	Concern of long-term impact of meds on body	Not examined	Barrier	Barrier	High	Low	Medium	Medium
Perceptions	"Not a tablets person"	Not examined	Barrier	Not reported	Low	Low	Medium	Low
	Influence of others – negative experiences with taking meds	Not examined	Not reported	Barrier	Medium	High	High	High
	Mixed information about statins from different HCPs causing confusion to patients	Not examined	Barrier	Barrier	High	Medium	Low	Medium
Practicalities	Older age	Facilitator	Not reported	Not reported	Low	Low	Low	Low
	Previous vascular intervention	Facilitator	Not reported	Not reported	Low	Low	Low	Low
	Previous cardiovascular event & related comorbidities	Not statistically significant	Facilitator	Facilitator	Medium	Low	Low	Low
	Experiencing side effects	Not examined	Barrier	Barrier	Medium	Low	Low	Low
	Swallowing problems	Not examined	Barrier	Not reported	Low	Low	Low	Low
	Forgetfulness	Not examined	Barrier	Barrier	Low	Medium	Medium	Medium
	Creating routines/habits: dossett box, taking meds all together, placing meds in visible places	Not examined	Facilitator	Facilitator	High	Medium	High	Medium

6.4.2.3 Smoking Cessation

Within the *smoking cessation* domain, fewer influences were identified compared with other target behaviours, especially in the pre-doctoral survey data**.** Only one influence was identified in the survey, and 10 overlapping influences were identified across the pre-doctoral and PhD qualitative studies (see Table 32). Only one influence was reported across all three studies. In total, eight influences were mapped under perceptions and two under practicalities. Following the final categorisation of influences, two were coded as high priority, five as medium and three as low priority.

A strong motivation to quit smoking and negative perceptions about the importance of smoking cessation were identified as high priorities. Motivation to quit was voted as the top priority by HCPs. They all highlighted the need for realistic goals to quit smoking. As for the importance of quitting smoking, this was mainly related to the belief that it is too late to benefit from quitting, especially for those who have been smoking for many years.

Although the fear of amputation to quit smoking was perceived as a strong facilitator for cessation, it was coded as a medium priority influence. Following the stakeholder meeting and supervisory team discussions, it was agreed that it was strongly linked to motivation to quit and did not need to be a separate intervention component. Other medium priority influences were smoking as a coping mechanism, as a habit, or as a way out of misery. Although an information leaflet cannot provide specific psychological and smoking cessation support, it was decided that the co-design workshops could consider how best to touch upon these topics. The stakeholder groups also highlighted that some of these influences could be addressed by increasing patients' motivation. The final influence voted as a medium priority was the patients' social network, but this was not something that could be addressed through an information booklet. As discussed in relation to medication adherence influences, some of the low priority influences in Table 32 could be indirectly addressed by increasing motivation to quit smoking and improving knowledge and understanding about PAD.

Table 32 Triangulation of interview studies to identify influences for smoking cessation

PaPa	Factor	Survey	Pre-doc interview	PhD interview	Impact of change (patients)	Impact of change (HCPs)	Feasibility of changing	Final voting/ priority
Perceptions	Feeling less in control of treatment	Barrier	Barrier, mainly related to motivation	Barrier, mainly related to motivation	Low	Medium	Low	Low
	Negative perceptions about the importance of smoking cessation	Not examined	Barrier	Barrier	High	Medium	High	High
	Only convinced about the importance of smoking cessation after amputation	Not examined	Not examined	Facilitator	Low	Low	Low	Low
	Fear of amputation	Not examined	Facilitator	Facilitator	High	Medium	Medium	Medium
	Strong mindset & motivation to quit	Not examined	Barrier when lack of motivation, Facilitator when there is motivation	Barrier when lack of motivation, Facilitator when there is motivation	High	High	High	High
	Smoking as a coping mechanism & pleasure	Not examined	Barrier	Barrier	Medium	High	Medium	Medium
	Smoking as a habit	Not examined	Barrier	Barrier	Medium	High	Medium	Medium

	“An existence not a life” so continue to smoke to not prolong misery	Not examined	Barrier	Barrier	Medium	High	Medium	Medium
Practicalities	Saving money from quitting smoking & not buying cigarettes	Not examined	Facilitator	Not reported	Low	Low	Low	Low
	Having smokers family members & friends	Not examined	Barrier	Barrier	Medium	High	Low	Medium

6.4.2.4 Exercise Uptake

In the *exercise* domain, seven influences were identified in the pre-doctoral survey (and two non-statistically significant ones), and 16 overlapping influences were identified by both qualitative studies (see Table 33). Half (8/16) of the influences were mapped under perceptions and half under practicalities. Four high-priority influences were identified, ten medium and five low priority.

The perceptual influence "perceived treatment necessity" was identified as a key priority. This mainly focused around knowledge about the purpose and safety of walking through pain. Clinicians also emphasised the need for measurable outcomes (e.g. improvement in walking distance) to demonstrate the benefits of walking in addressing this influence. Environmental barriers, including adverse weather, travel time to exercise, and a lack of exercise spaces, were voted the highest priority barriers to exercise uptake by HCPs. Following discussion with the supervisory team, I decided that although an information leaflet cannot directly address these barriers, for example, by creating a community-based exercise programme, it would be possible to generate helpful suggestions during the co-design workshops.

Similar to the other treatment domains, medium priorities were not disregarded, but were considered in relation to higher priorities. For example, motivation is highly important for behaviour change. Specifically for exercise, the data and discussions with the PPI and stakeholder groups indicated that motivation is typically more present when patients understand the benefits of exercise. Hence, addressing their lack of understanding of the purpose and benefits of exercise could, in turn, affect their motivation. The negative impact of PAD on people's mental health is also highly relevant, but could not be directly addressed through an information leaflet. However, the aim of the leaflet was to provide realistic, patient-centred, positive and motivational support for behaviour change.

As for low-priority factors, although some were voted as such due to perceptions of limited impact or feasibility of behaviour change, they were still considered during the co-design phase (Chapter 7).

Table 33 Triangulation of studies to identify influences for exercise uptake.

PaPa	Factor	Survey	Pre-doc interview	PhD interview	Impact of change (patients)	Impact of change (HCPs)	Feasibility of change	Final voting/ priority
Perceptions	Lower perceived identity – perceiving claudication symptoms as less severe	Facilitator	Facilitator mainly around ability to do things if symptoms are not bad	Facilitator mainly around ability to do things if symptoms are not bad	Low	Low	Low	Low
	Lower perceived personal control over treatment	Barrier	Barrier mainly related to motivation	Barrier mainly related to motivation	Low	Low	Low	Low
	Higher concerns about disease & treatment	Barrier	Barrier concern that exercise might damage legs after surgery	Barrier concern that exercise might damage legs after surgery	Medium	Low	Medium	Medium
	Perceived Treatment necessity & effectiveness	Barrier specifically for lower perceived treatment effectiveness	Barrier when not aware of exercise benefit & Facilitator when aware	Barrier when not aware of exercise benefit & Facilitator when aware	High	Medium	High	High
	Disease understanding	Not statistically significant	Barrier when not knowing about disease &	Barrier when not knowing about disease &	High	Medium	Medium	Medium

			Facilitator if have knowledge	Facilitator if have knowledge				
	Positive mindset & motivation to change	Not examined	Facilitator	Facilitator	High	Low	Low	Medium
	Embarrassment/stigma due to claudication	Barrier Higher emotional distress	Barrier	Barrier	High	Low	Low	Low
	Negative impact of disease on QoL & feelings of isolation	Barrier Higher disease impact on daily quality of life	Barrier	Barrier	High	High	Medium	Medium
Practicalities	Claudication pain	Barrier	Barrier	Barrier	High	Medium	Low	Medium
	Bad weather	Not examined	Barrier	Barrier	Medium	High	Medium	High
	Travel	Not examined	Barrier	Barrier	Medium	High	Medium	High
	Limited access to exercise areas	Not examined	Barrier	Barrier	Medium	High	Medium	High
	Other comorbidities affecting exercise (e.g. back pain, COPD)	Not statistically significant	Barrier	Barrier	Medium	Medium	Low	Low
	Having a daily routine	Not examined	Facilitator	Facilitator	Medium	Medium	Medium	Medium
	Having a dog	Not examined	Facilitator	Facilitator	Medium	Medium	Low	Low
	Support from HCPs (mainly to offer guidance & build confidence)	Not examined	Facilitator	Facilitator	Medium	Medium	Low	Medium

Abbreviations: COPD: Chronic Obstructive Pulmonary Disease; HCP: Healthcare Professional; QoL: Quality of life

6.4.3 Identification of relevant BCTs

The BCT mapping using the TATT was done for all the high priority influences identified above. For the key influence "lack of knowledge that PAD is a chronic disease", two MoAs (knowledge and belief about consequences) and 13 candidate BCTs were identified, using the TATT (134) (see Table 34). Of the 13 possible BCTs, eight were deemed relevant for this intervention. BCTs *2.6 Biofeedback, 10.1 Material incentive (behaviour), 10.8 Incentive (outcome)* and *10.10 Reward (outcome)* were not applicable for a booklet intervention. Biofeedback requires real-time physiological monitoring and feedback that cannot be delivered via a booklet. Incentives were also ruled out because they require external resources, reinforcement, or delivery mechanisms beyond the scope of this intervention. Additionally, BCT *4.1 Instructions on how to perform a behaviour* were not relevant to address poor understanding of PAD, but might be relevant to other influences (e.g. exercise instructions).

For the key influence "lack of motivation to change behaviour and staying on track for overall treatment plan", four MoAs (motivation, belief about capabilities, behavioural regulation and goals) and 22 candidate BCTs were identified. Of these, 15 were relevant to this intervention. Specifically, BCTs 10.8 *Incentive (outcome)* and 10.10 *Reward (outcome)* were excluded as they cannot be delivered or sustained through a booklet. BCT 2.2 *Feedback on behaviour* was also excluded, as it typically requires real-time monitoring or personalised feedback from a clinician or digital system, which falls outside the scope of a printed resource. In contrast, BCTs that support self-regulation and internal motivation (e.g., BCTs 1.1, 1.2, 1.4, 1.6) were retained because they can be effectively operationalised through reflective exercises, examples, and prompts in written materials.

As for the key influence "belief that medications offer claudication symptom relief", two MoAs (knowledge and belief about consequences) and 13 candidate BCTs were identified. The principles applied for the influence "lack of knowledge that PAD is a chronic disease" were also maintained for this influence, and the same BCTs were

excluded for the same reasons. The selected BCTs focused on health consequences, reframing expectations, and credible explanations of the preventive cardiovascular role of medications, which are well-suited to booklet delivery and directly address the discrepancy between patient expectations and clinical intent.

For the key influece “concerns about medication side effects” four MoAs (Beliefs about consequences, negative attitudes towards behaviour, perceived vulnerability and social influences) and 18 candidate BCTs were identified, of which six were excluded. As with other influences, BCTs on incentives were excluded. As for social influences, *BCTs 3.1 Social support (unspecified), 6.3 Information about others’ approval*, and *10.4 Social reward* were excluded because it is hard to address social influences that provide information that contradicts what the intervention is trying to communicate. With that in mind, I will ensure that other MoAs for this influence are strengthened to help overcome the social influences about side effects.

Regarding key influence “negative beliefs about necessity of smoking”, two MoAs (knowledge and negative attitudes towards behaviour) and eight candidate BCTs were identified. BCTs *2.6 Biofeedback* and *4.1 Instructions on how to perform a behaviour* were excluded because they are incompatible with a booklet format and challenging to implement without ongoing clinical support. Instead, BCTs focused on providing information about health consequences, and reframing beliefs about the benefits of quitting smoking can be effectively communicated through a booklet intervention.

For the influence “lack of motivation to quit smoking”, four MoAs (motivation, belief about capabilities, behavioural regulation and goals) and 22 candidate BCTs were identified. The principles applied for the influence “lack of motivation to change behaviour and staying on track for overall treatment plan” were also maintained for this influence, and the same BCTs were excluded for the same reasons.

Regarding influence “lack of education on the safety and purpose of walking with the pain” three MoAs (knowledge, beliefs about consequences and perceived vulnerability) and 13 BCTs were identified. Of those, 10 BCTs were selected. As with other influences, BCTs on biofeedback and incentives were not appropriate for this intervention. BCT *4.1*

instructions on how to perform a behaviour was initially excluded because walking through pain in PAD is highly individual and ideally requires professional supervision to ensure safety; attempting to model this behaviour within a booklet could be misleading or unsafe. However, after further discussion with the stakeholder group, it was decided to keep this BCT and work with the HCPs to specifically word the text, in line with NICE guidance to offer clear guidance on how to perform a walk that aims to improve claudication symptoms.

For the influence "environmental barriers (weather, time, location) for exercise", one MoA (environmental context & resources) and six BCTs were identified. Of these, only BCT 7.1 *Prompts/cues* was relevant for this intervention. BCTs *12.1 Restructuring physical environment* and *12.5 Adding objects to the environment* that involve physical changes to the environment (e.g. altering facilities, providing equipment, or modifying access to spaces) were excluded, as a booklet cannot directly change environmental conditions such as weather, exercise facilities, or availability of safe walking areas.

Table 34 Selection of BCTs using the TATT

Influence	**Mechanisms of Action**	**Potential BCT (NB those scored out were excluded for the intervention)**
Lack of knowledge that PAD is a chronic disease (that requires chronic CVD management and not a quick surgical fix)	Knowledge	• 2.6 Biofeedback, • 4.1 Instructions on how to perform a behaviour, • 4.2 Information about antecedents, • 5.1 Information about health consequences, • 5.3 Information about social and environmental consequences
	Belief about consequences	• 5.1 Information about health consequences • 5.2 Salience of consequences • 5.3 Information about social and environmental consequences • 5.5 Anticipated regret • 5.6 Information about emotional consequences • 9.2 Pros and Cons

		• 9.3 Comparative imaging of future outcomes • 10.1 Material incentive (behaviour) • 10.8 Incentive (outcome) • 10.10 Reward (outcome)
Lack of motivation to change behaviour and staying on track for overall treatment plan	Motivation	• 1.3 Goal setting (outcome) • 2.2 Feedback on behaviour • 9.2 Pros and Cons • 10.8 Incentive (outcome) • 10.10 Reward (outcome) • 15.4 Self-talk
	Beliefs about capabilities	• 1.2 Problem solving • 4.1 Instructions on how to perform a behaviour • 6.1 Demonstration of behaviour • 8.1 Behavioural practice/rehearsal • 8.7 Graded tasks • 15.1 Verbal persuasion about capability • 15.3 Focus on past success • 15.4 Self-talk
	Behavioural regulation	• 1.2 Problem solving • 2.3 Self-monitoring of behaviour • 5.2 Information about antecedents • 8.2 Behaviour Substitution • 11.2 Reduce negative emotions • 11.3 Conserving mental resources
	Goals	• 1.1 Goal setting (behaviour) • 1.3 Goal setting (outcome) • 1.5 Review behavioural goals • 1.6 Discrepancy between current behaviour & goal • 1.7 Review outcome goals
Belief that medications offer	Knowledge	• 2.6 Biofeedback, • Instructions on how to perform a behaviour, • Information about antecedents, • 5.1 Information about health consequences, • 5.3 Information about social and environmental consequences
	Belief about consequences	• 5.1 Information about health consequences • 5.2 Salience of consequences

claudication symptom relief		• 5.3 Information about social and environmental consequences • 5.5.Anticipated regret • 5.6 Information about emotional consequences • 9.2 Pros and Cons • 9.3 Comparative imaging of future outcomes • 10.1 Material incentive (behaviour) • 10.8 Incentive (outcome) • 10.10 Reward (outcome)
Concerns about medication side effects	Beliefs about consequences	• 5.1 Information about health consequences • 5.2 Salience of consequences • 5.3 Information about social and environmental consequences • 5.5 Anticipated regret • 5.6 Information about emotional consequences • 9.2 Pros and Cons • 9.3 Comparative imaging of future outcomes • 10.1 Material incentive (behaviour) • 10.8 Incentive (outcome) • 10.10 Reward (outcome)
	Negative attitudes towards behaviour	• 5.1 Information about health consequences • 5.3 Information about social and environmental consequences • 9.1 Credible source • 9.2 Pros and Cons • 13.2 Framing/reframing
	Perceived vulnerability	• 5.1 Information about health consequences • 5.2 Salience of consequences
	Social influences	• 3.1 Social support (unspecified) • 3.2 Social support (practical) • 6.2 Social comparison • 6.3 Information about others' approval • 10.4 Social reward
Negative beliefs about necessity of	Knowledge	• 2.6 Biofeedback • 4.1 Instructions on how to perform a behaviour

smoking – "too late to quit"		• 4.2 Information about antecedents • 5.1 Information about health consequences • 5.3 Information about social and environmental consequences
	Negative attitudes towards behaviour	• 5.1 Information about health consequences • 5.3 Information about social and environmental consequences • 9.1 Credible source • 9.2 Pros and Cons • 13.2 Framing/reframing
Lack of motivation to quit smoking	Motivation	• 1.3 Goal setting (outcome) • 2.2 Feedback on behaviour • 9.2 Pros and Cons • 10.8 Incentive (outcome) • 10.10 Reward (outcome) • 15.4 Self-talk
	Beliefs about capabilities	• 1.2 Problem solving • 4.1 Instructions on how to perform a behaviour • 6.1 Demonstration of behaviour • 8.1 Behavioural practice/rehearsal • 8.7 Graded tasks • 15.1 Verbal persuasion about capability • 15.3 Focus on past success • 15.4 Self-talk
	Behavioural regulation	• 1.2 Problem solving • 2.3 Self-monitoring of behaviour • 4.2 Information about antecedents • 8.2 Behaviour Substitution • 11.2 Reduce negative emotions • 11.3 Conserving mental resources
	Goals	• 1.1 Goal setting (behaviour) • 1.3 Goal setting (outcome) • 1.5 Review behavioural goals • 1.6 Discrepancy between current behaviour & goal • 1.7 Review outcome goals
Lack of education on the safety and purpose of walking with the pain	Knowledge	• 2.6 Biofeedback • 4.1 Instructions on how to perform a behaviour • 4.2 Information about antecedents

		• 5.1 Information about health consequences • 5.3 Information about social and environmental consequences
	Belief about consequences	• 5.1 Information about health consequences • 5.2 Salience of consequences • 5.3 Information about social and environmental consequences • 5.5 Anticipated regret • 5.6 Information about emotional consequences • 9.2 Pros and Cons • 9.3 Comparative imaging of future outcomes • 10.1 Material incentive (behaviour) • 10.8 Incentive (outcome) • 10.10 Reward (outcome)
	Perceived vulnerability	• 5.1 Information about health consequences • 5.2 Salience of consequences
Environmental barriers (weather, time, location) for exercise	Environmental context & resources	• 3.2 Social support (practical) • 7.1 Prompts/cues • 7.5 Remove aversive stimulus • 12.1 Restructuring physical environment • 12.5 Adding objects to the environment

The next step of the intervention design was to create intervention wording (in lay language) to address the influences, based on each of the selected BCTs. These messages could then be discussed, selected and iterated in co-design workshops. This process is described in Chapter 7.

6.4.4 Guiding principles

The priorities identified through the triangulation exercise described above were then used to develop guiding principles to reflect the main adherence challenges in patients with PAD. It was important that the intervention addressed the lack of knowledge and understanding of PAD as a chronic condition, the cardiovascular benefits of medicines

and the benefits of quitting smoking and exercising, while also tackling concerns and motivation.

The objective of the intervention is to support treatment adherence in newly diagnosed patients with PAD. Patients lack the knowledge and understanding that PAD is a chronic condition, expecting a quick fix. They are not aware of the preventive cardiovascular benefits of medicines, the benefits of quitting smoking, or the benefits of exercise. This is not helped by the lack of patient-focused educational resources. Patients are also concerned about medication side effects and lack motivation to sustain healthier behaviours. Finally, environmental barriers are seen as barriers to exercise. Table 35 below presents the guiding principles for the intervention, incorporating the intervention design objectives and key features of the intervention. The intervention design objectives were to: 1) strengthen understanding of PAD as a cardiovascular disease, 2) provide clear, patient-focused information that avoids medical jargon, and 3) actively support motivation to engage with long-term treatment. The key features of the intervention are designed to ensure that the intervention is supportive, engaging and closely aligned with patients' lived experiences of PAD.

Table 35 Guiding Principles of PAD & Me intervention

Intervention Design Objectives	**Key features**
Strengthen understanding of PAD as a cardiovascular disease	• Use educational material (texts and images) to ensure patients with PAD can gain an appropriate understanding of their condition, the treatment options and rationale for each treatment • Provide information about surgical interventions and risk of surgery, emphasizing it is an option only for those with severe PAD • Provide simple information on how patients could exercise safely • Provide credible and trustworthy information, including credible resources that patients could use for further information • Address concerns, misconceptions and beliefs about PAD and treatment

Provide clear, patient-focused information that avoids medical jargon	• Reduce reading burden, only include relevant information, in a lay language, using the appropriate rate of text and images per page • Ensure the reading age is less than 13 • Involve patients, their relatives and healthcare professionals in the development of content for the intervention
Actively support motivation to engage with long-term treatment	• Include section on goal setting and interactive resources, such as planning/habit forming routines and self-monitoring using a diary • Use images that are encouraging and engaging and relatable • Provide examples for each activity, for example tips to be consistent with taking medications, or exercises to do when time is limited

6.4.5 Logic model

A logic model was created (see Figure 26) to diagrammatically represent the mechanisms of action of the intervention (337, 338), consisting of:

- Intervention aim: the aim of the intervention to address the identified problem
- Inputs: the information gathered in Chapters 3,4 and 5, any resources/facilities that will be used
- Intervention components: the main intervention content and mechanisms of action
- Outcomes: short-term, medium-term and long-term changes that can be attributed to the intervention
- Impact: patient and healthcare system benefits of the intervention

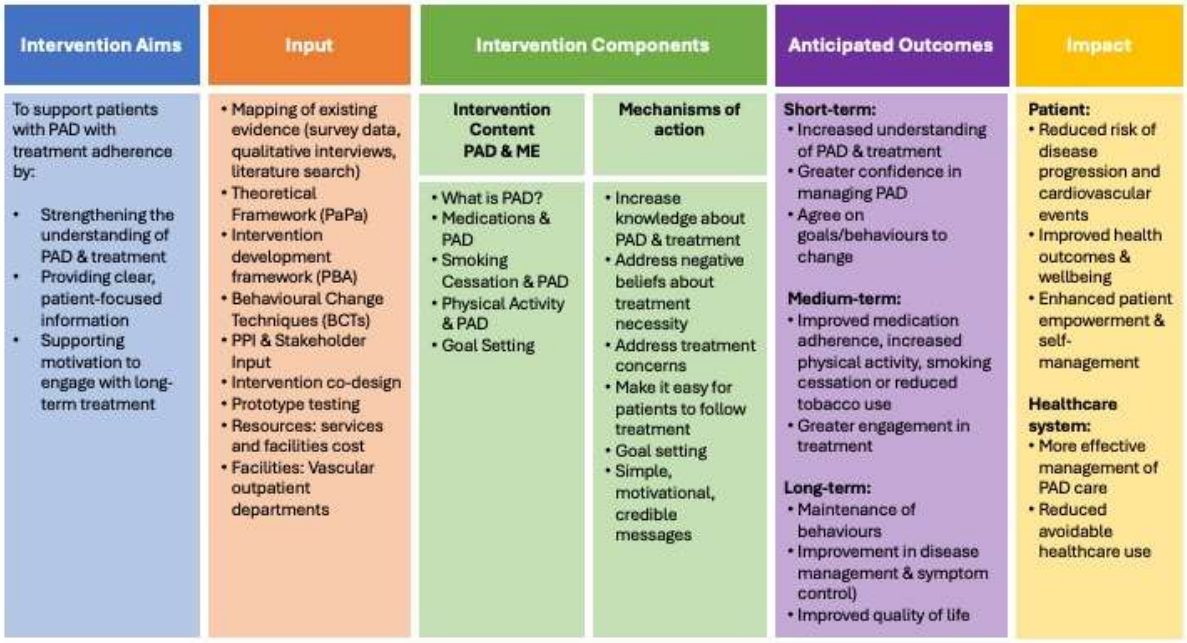


Figure 26 PAD & Me intervention logic model

6.5 Discussion

6.5.1 Main findings

Triangulation of findings from the pre-doctoral survey and the two qualitative studies generated a comprehensive set of influences on adherence to treatment for PAD, thereby completing the behavioural diagnosis stage of intervention development. Integrating evidence across these studies enabled the identification of key behavioural influences across multiple treatment domains, including overall treatment adherence, medication adherence, smoking cessation, and exercise uptake. Using the TATT, I mapped these influences to relevant MoAs and selected relevant BCTs, a structured approach to identify key intervention components.

By conducting this methodological triangulation, I was able to utilise multiple sources of data that provide complementary insights into why adherence to PAD treatment is often suboptimal. While the studies shared similar overarching aims, each contributed distinct perspectives on patients' experiences and adherence barriers and facilitators.

The triangulation also ensured that influences identified were corroborated as important in more than one study.

Influences related to knowledge and understanding of PAD as a cardiovascular condition were consistently identified across data sources, reinforcing the importance of addressing misconceptions about disease progression and the necessity of treatment. Findings from the qualitative studies offered a greater understanding of how these misconceptions shaped motivation, beliefs about necessity, and engagement with long-term treatment plans, highlighting the added value of in-depth qualitative approaches.

Following the behavioural analysis, candidate BCTs were identified by mapping the prioritised influences onto an established behavioural science framework (the TATT). Although more candidate BCTs were initially identified, only those deemed feasible, acceptable, and appropriate for a booklet intervention were selected. This process emphasised the importance of context-specific decision-making in intervention development, particularly given the constraints in current NHS service delivery.

The intervention ideas generated at this stage are intentionally broad and preliminary, reflecting their role as a bridge between theory and practical design rather than as fully specified solutions. Evidence from systematic reviews has highlighted that existing adherence interventions in cardiovascular disease, specifically in cardiac rehabilitation (339, 340), uptake of physical activity (341), and in diabetes medication adherence (342) commonly include educational materials, information about health consequences, reassurance about treatment safety, feedback on progress, and motivational messaging, all of which align with the BCTs selected in this study. As discussed in Chapter 3, previous multi-component interventions for PAD adherence have not used BCTs in their design from the intervention development stage. Only the study by Cucato et al. reported using BCTs during the intervention development stage in its protocol (78). The recently published Textpad pilot RCT indicated that BCTs goal-setting, problem-solving, and self-regulation were used (343). However, it impossible to

assess whether these BCTs were effective or not. Hence, this PhD project is addressing this gap in the literature.

In summary, a list of adherence influences and relevant BCTs to address these have been identified. It is important to note that influences were prioritised, consistent with the intervention's aim, and that BCTs were selected for a booklet intervention. Hence, future researchers could utilise this existing list but tailor it to their context, aims, and intervention format.

6.5.2 Strengths and Limitations

The methodological triangulation described in this chapter has several strengths. Combining three studies and two distinct methodologies (quantitative and qualitative) offset some of the weaknesses of each study and allowed a comprehensive behavioural analysis. In addition to evidence from the triangulation, the opinions of the PPI and stakeholder groups were also taken into consideration when prioritising the list of influences, thereby making the intervention user-focused. The use of the TATT to select relevant BCTs provided a clear rationale for selecting intervention components that could lead to behaviour change. Additionally, the selection process for the key influences and BCTs was fully transparent, enabling replication of the intervention.

It is important to note that there are several limitations. Two of the three studies included in the triangulation were undertaken in a single-centre, which could influence the generalisability of the findings. However, the qualitative study was undertaken across four centres, and so offsets this limitation. Additionally, although I followed a systematic approach to triangulation, I did not use a specific triangulation methodology; hence, this could affect the rigour of the analysis. Lastly, although using the TATT was a strength, the tool has some limitations. The TATT has been criticised for the lack of empirical evidence linking MoA and BCTs to specific behaviours or contexts (134). Additionally, there is a lack of empirical knowledge about whether BCTs will in fact lead in behaviour change (134). Hence, any research using the TATT needs to

consider which BCTs are suitable for their specific context and population, as has been done here.

6.5.3 Next steps

The next stage of this work involves conducting co-design workshops with patients with PAD and their relatives, to develop the booklet intervention, in line with the PBA approach and informed by the results of this chapter. The content of the intervention and the materials for the co-design workshops will be based on the identified BCTs. Particular attention will be paid to ensure the intervention is user-focused, feasible, acceptable, engaging and perceived as useful for patients, whilst respecting the guiding principles of the intervention. This work will be discussed in Chapter 7.

6.6 Conclusion

The triangulation process outlined in this chapter combined the results of three distinct studies (pre-doctoral projects and qualitative study described in Chapter 4) conducted to understand the influences on PAD treatment adherence. Using behavioural science frameworks, including the TATT, relevant BCTs were identified for each treatment domain (overall treatment, medication adherence, smoking cessation, and exercise uptake). Additionally, it was highlighted that it is important to consider the context and population when selecting appropriate BCTs. The guiding principles and the logic model for the intervention were also developed. The next step is to conduct co-design workshops with patients with PAD to develop an educational, behavioural booklet intervention to support treatment adherence in newly diagnosed patients.

Chapter 7. Intervention Development Phase 2: Co-production of the PAD & Me Booklet

7.1 Introduction

7.1.1 Chapter Summary

This chapter describes the development of the adherence intervention, the PAD&Me booklet. It summarises three rounds of co-design workshops with patients with PAD and their relatives, based on co-production and participatory research methods, in line with the Person Based Approach (PBA) (162). The activities and materials used for each workshop will be presented, and the chapter will conclude with a detailed description of the PAD&Me intervention, ready for user-testing.

7.1.2 The principles of participatory research, co-production and co-design in healthcare interventions

Participatory research is a term used to describe the active involvement of individuals affected by the problem being studied, to better understand their perspectives and effectively address the issue (344). Participatory research includes a range of approaches, such as co-production, patient and public involvement (PPI), and stakeholder engagement (344). The National Institute for Health and Care Research (NIHR) has emphasised the importance of participatory research, specifically PPI (345, 346). In their guidance, they stress that PPI should be a mandate for all research projects; research should be "carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them" (346).

In recent years, co-production has been considered best practice in health care research, particularly in the design of services and interventions (347, 348). The NIHR acknowledges that some may consider co-production research to be "really good PPI"

(346). However, it is more accurately understood as a comprehensive approach in which lay members and professionals collaborate as equal partners at every step of the research cycle (346). This dual interpretation has contributed to ongoing ambiguity regarding its definition and scope (347, 348).

In their recent 2024 guidance, the NIHR offers the following definition for co-production: "Co-producing a research project is an approach in which researchers, practitioners and the public work together, sharing power and responsibility from the start to the end of the project, including the generation of knowledge" (345). This definition also includes the following principles (345):

- Power sharing: joint ownership and shared understanding
- Including all perspectives: include everyone who can make a contribution
- Respect and valuing others: everyone has a say; all forms of experience are equal
- Reciprocity: learning from each other
- Building relationships: knowing and utilising what each person has to bring

Co-production is an umbrella term for several different approaches. The Social Care Institute for Excellence suggests that there are four types of co-production (349):

- Co-design: including planning of services (or writing a protocol, designing an intervention or product)
- Co-delivery: of services (carrying out the research)
- Co-decision making: in the allocation of resources (or prioritisation of areas for research/ identifying additional funding opportunities)
- Co-evaluation: of the service (evaluating the coproduction process, research analysis and dissemination)

Reflecting this breadth, the NIHR recommends that researchers should question why they are undertaking co-production, what they are coproducing and what the benefits are (345). Ultimately, co-production is less about adhering to single definition and more about enacting key values and principles (350). It is a transparent, open, and ongoing

process with constant critical reflection throughout the research cycle. To provide further guidance for researchers on points to consider for effective implementation of co-production principles, the NIHR Applied Research Collaborations (ARC) West developed a useful guide (see Figure 27) (351):

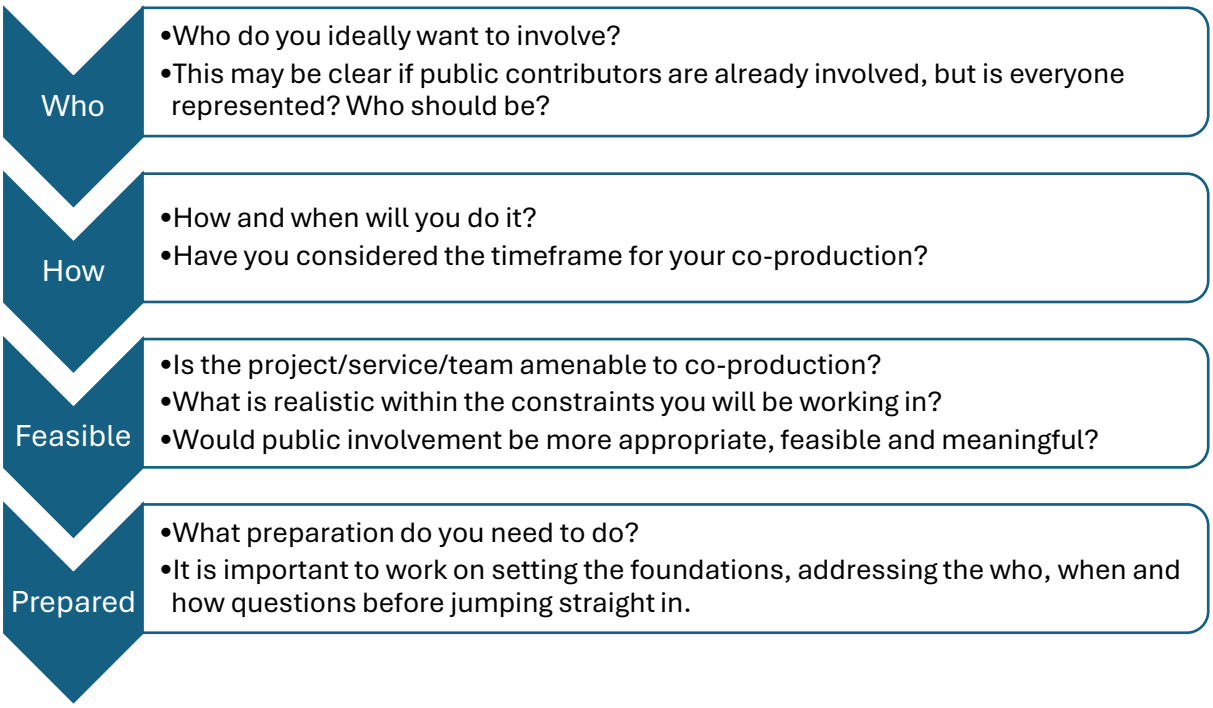


Figure 27 Putting co-production into practice (adapted from NIHR ARC West, 2020) (351).

Evidence from a systematic review of 55 studies exploring the evidence on the links between patient experience and clinical safety and effectiveness outcomes, found that user involvement in healthcare interventions is associated with user satisfaction, clinical effectiveness and patient safety (352). However, co-production can be challenging to implement due to resource constraints (e.g., funding, facilitators) (353), engaging with service users and building long-term relationships with them to reduce drop-outs (354).

Taking these points into consideration, for my project, it was essential to include the perspectives of patients with PAD whose voices are often underrepresented, making a co-production approach to intervention development appropriate. In line with the PBA and the NIHR co-production guidance, the overarching principles were based on co-production, whilst specifically for the workshops, co-design was used.

Co-design is the process of creating or developing a product and is grounded in design theory (355). It brings together people with lived experience and expertise, cultural insight, and professional knowledge to learn from one another and improve outcomes through intentional design (355). As a method of co-production, co-design includes principles of power-sharing, prioritising relationships, using participatory methods, and building capacity (355). The approach rests on both collective participation and structured design processes; each is essential, and neither alone is sufficient to generate meaningful solutions (355). Using co-design was made feasible through NIHR funding, which covered costs, including participant vouchers, catering and refreshments, and printed materials. As the activities were delivered online or at NHS facilities, there was no charge for using venues. In addition, existing professional networks and established collaborations made identifying and recruiting suitable facilitators straightforward.

7.1.3 Power dynamics in participatory research

Inclusivity and user involvement throughout the research process are at the core of participatory research. However, it is important to acknowledge power imbalances that can manifest through interpersonal tension and challenging conversations (356). Hence, considering and addressing power dynamics between service users and researchers during the intervention design phase is an important step.

Power imbalances may hinder effective co-production (357), but are not in themselves a participatory research problem (358). Power imbalances have always been present in societal structures and academia (358). In the field of clinical research, a certain hierarchy is often perceived: that researchers' and clinicians' opinions matter more than patients', as they have the privilege of knowledge and authority (358, 359). Previous evidence has indicated that service users do not usually speak the language of research and can be silenced (358, 359). Co-production approaches should take this into consideration and make active efforts to bring balance between service users and clinicians (358). Williams et al recommend that co-production researchers consider: 1)

the people involved, 2) the structure within which participation is set, specifically the environment and the level of involvement, and 3) the social interactions, how conflict is managed and how contributions are valued (358). By doing so researchers can avoid falling into what has been termed the "dark side" of co-production implementation (such as reinforcing inequalities, not promoting accountability or treating co-production as a transactional activity), whilst support an ongoing, transparent process (358).

Although it is crucial to address power imbalances, researchers also need to consider how service-user input aligns with the intervention's theoretical and evidence-based foundations. The PBA explicitly acknowledges and seeks to manage power dynamics among researchers, clinicians, and service users by promoting transparency and reflexivity rather than adopting all user suggestions without critical evaluation (162). Participatory research approaches are seen as complementary but an essential step to better understand the problems addressed through PBA. However, it is important that they do not override theoretical or clinical expertise (162). Following a structured PBA approach, including a detailed behavioural analysis and the development of guiding principles, enables researchers to make a critical decision on whether to implement a change advocated by participants (162). Therefore, the PBA promotes a collaboration between researchers and service users, whilst maintaining scientific rigour (162).

Based on these considerations, I based my co-design approach on the following principles:

1) Involving service users and clinicians equally
2) Separating service users and clinician workshops to reduce power imbalances and increase patient confidence
3) Respecting different opinions and following a no-blame, open approach to service users' opinions
4) Explaining to service users that some solutions proposed may not be feasible within the current project or current healthcare system, but that all opinions would be noted and could be used for future projects

5) Presenting myself as a patient advocate and researcher, keen to understand the service users' perspectives, rather than an authoritative figure or an expert clinician
6) Respecting the guiding principles
7) Reflecting and discussing any challenges with the supervisory team
8) Being transparent and documenting decisions made

7.2 Aim and Objectives

Aim: To co-design the PAD&Me booklet intervention to support adherence to medications, uptake of exercise and smoking cessation in newly diagnosed patients with PAD.

Objectives:

1. Conduct co-design workshops with patients and their relatives to discuss the intervention format, timing, delivery and messaging
2. Conduct stakeholder meetings to discuss the intervention and ensure it is consistent with current clinical guidance and compatible with clinical practice
3. Finalise the intervention prototype of the PAD&Me booklet

7.3 Methods

7.3.1 Co-design workshops schedule and materials for the PAD&Me Intervention

The intervention development process included three rounds of workshops, each comprising two sessions (one face-to-face (F2F) and one online) lasting approximately 2 hours (see Figure 28). The content and structure of each round of workshops were developed to address its aims. Following discussions with the PPI group, each workshop included only patients and relatives, rather than HCPs, to allow patients to express themselves freely without feeling judged.

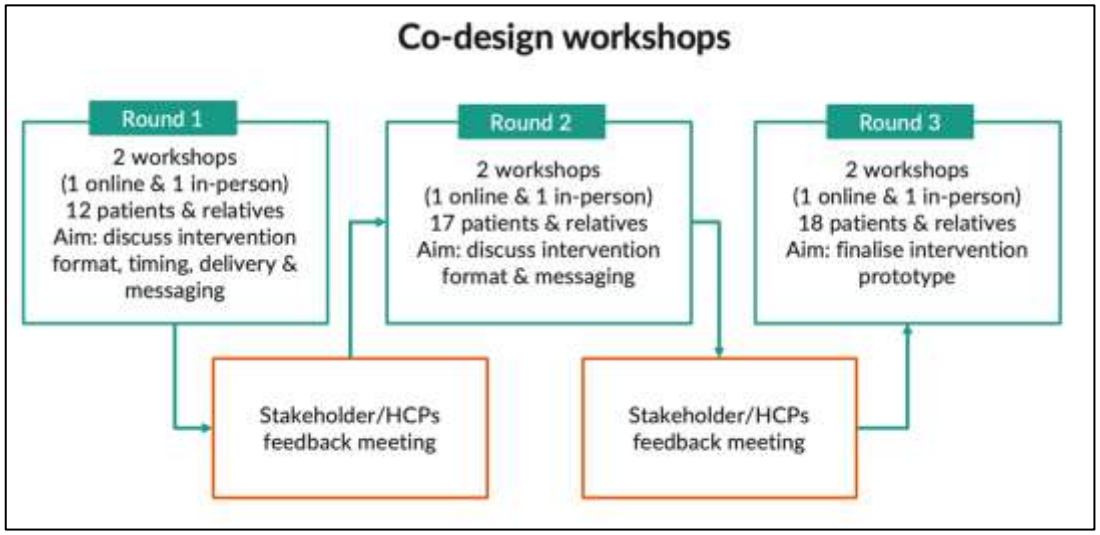


Figure 28 Co-design workshops schedule

Eligible participants were patients with PAD and their family members/friends. To ensure diverse representation of participants from different backgrounds, purposive sampling was adopted where possible, and new participants were invited to each workshop. The workshop opportunities were advertised through NHS collaborating sites, the PAD Facebook groups and VOICE platform. Specifically for Leicester, eligible participants were identified by the Leicester PAD PPI Group Lead. The PPI group suggested that workshops were held on different dates and times, one in the morning and one in the afternoon, to increase inclusivity and representation.

The F2F workshops took place at Charing Cross Hospital (London) and Glenfield Hospital (Leicester), and the online ones were conducted via Microsoft Teams. In line with the principles of the PBA and NIHR PPI guidance, lay language was used to enhance participation and engagement (45). A four-week interval was timetabled between each round of workshops to allow sufficient time to update the draft intervention.

The workshop format included introductions (name, area of the UK, patient/relative), an ice breaker exercise (say three words that come in mind about PAD), a small overview of the project aims, three activities, a 10-minute comfort break after the first hour of the workshop (usually at the end of Activity 2), and a wrap-up stage. Within each workshop,

activities requiring voting for consensus were conducted as a bigger group. Activities that required detailed feedback were conducted in smaller groups of 3-4 participants to encourage discussion, with opportunities to rephrase and refine proposed intervention messages and reach a consensus on preferred messages. The workshop concluded with a summary of next steps and an explanation of how participant input would be used to refine the intervention, ensuring transparency and meaningful patient involvement throughout the development process. Both F2F and online workshops in the same round included the same activities. The F2F workshop was held first, followed by the online session later that week, with a two- to three-day interval to review notes and determine whether any major changes were needed before the online workshop.

I was the lead facilitator for all workshops. Each smaller group had a co-facilitator and an additional individual taking notes to ensure that all feedback was adequately captured. Participants were given a £50 shopping voucher upon completion of the workshop as a thank-you for their time. At the start of each workshop, participants were informed that only those who could actively participate, i.e., offer feedback, participate in all activities, and keep their cameras on during online meetings, would be eligible for a voucher.

7.3.1.1 Messages used for workshops based on BCTs

The intervention messages were drafted based on the key influences identified in Chapter 6. They included BCT and Mechanism of Action (MoA), identified for each message using the Theory and Techniques Tool (TATT) (134). Initial drafts were written in line with BCT guidance and then reviewed with supervisors (MW and GJ) through an iterative process. Each BCT was initially represented as a standalone message. During the workshops, messages were discussed in detail, with opportunities to combine overlapping content where appropriate. Participants were asked to select their top three messages and rephrase these to ensure they were meaningful to them. They were also asked to re-organise the remaining messages if they liked aspects of them, but felt they could be improved. The final selected messages were inserted into the draft

booklet and reviewed during the third round of workshops, and were further rephrased to ensure the intervention was adequately user-focused.

7.3.1.2 Co-design workshop – Round 1 (Patients & Relatives)

The first workshop was designed to inform the format, timing, delivery of the PAD & Me intervention, as well as content regarding *treatment as a whole* and *medication adherence*. The face-to-face workshop took place at Glenfield Hospital in Leicester, and the online workshop included participants from London and Leicester. The co-facilitators for this round were: a vascular nurse specialist/qualitative researcher, a trainee vascular surgeon, a PPI co-ordinator, and a research nurse.

Activity 1 sought feedback on i) the format of the intervention (text only, or text and images), ii) whether they preferred a leaflet (single folder sheets of A4) or a booklet, iii) the number of pages (<4, 4-10, >10, other), iv) the text style (first or third person) and v) where and from which HCP would they prefer to receive this booklet (primary care from GP or secondary care from vascular specialist). The aim was to reach consensus, but all answers were recorded.

For Activity 2, participants reviewed two sets of BCT-informed messages: the first explaining that PAD is a lifelong condition (see Appendix 6 – Table 6.1), and the second that PAD requires lifelong management and that surgery is not the solution (see Appendix 6 – Table 6.2). For Activity 3, participants reviewed two sets of BCT-informed messages addressing medication-related beliefs and concerns. One set of messages explained that aspirin and statins do not improve claudication symptoms directly, but they reduce the risk of heart attack or stroke (see Appendix 6 – Table 6.3). The second set of messages addressed the misconception that statins will worsen claudication (see Appendix 6 – Table 6.4).

7.3.1.3 Co-design workshop – Round 2 (Patients & Relatives)

The aim of this workshop was to further develop the intervention's format and content. The face-to-face workshop took place at Charing Cross Hospital in London (see Figure

29), and the online workshop included participants from London, Leicester, Yorkshire and Scotland. Co-facilitators for this round of workshops were: a vascular nurse specialist/qualitative researcher, one vascular advanced nurse practitioner, a PPI co-ordinator, a clinical trials co-ordinator, a psychologist/PhD candidate, one research nurse, and a behavioural scientist/supervisor (GJ).



Figure 29 Face-to-face co-design workshop at Charing Cross Hospital - June 2025 (Co-design participants gave permission for this photo to be used)

In Activity 1, participants were asked to vote for their preferred photograph/visual graph to add to the booklet for each section (PAD, medications, smoking cessation, and exercise) (See Figures 30, 31, 32, and 33). In Activities 2 and 3, participants reviewed BCT-informed messaging for smoking cessation (see Appendix 6 – Table 6.5, 6.6) and exercise uptake (see Appendix 6 – Table 6.7, 6.8).

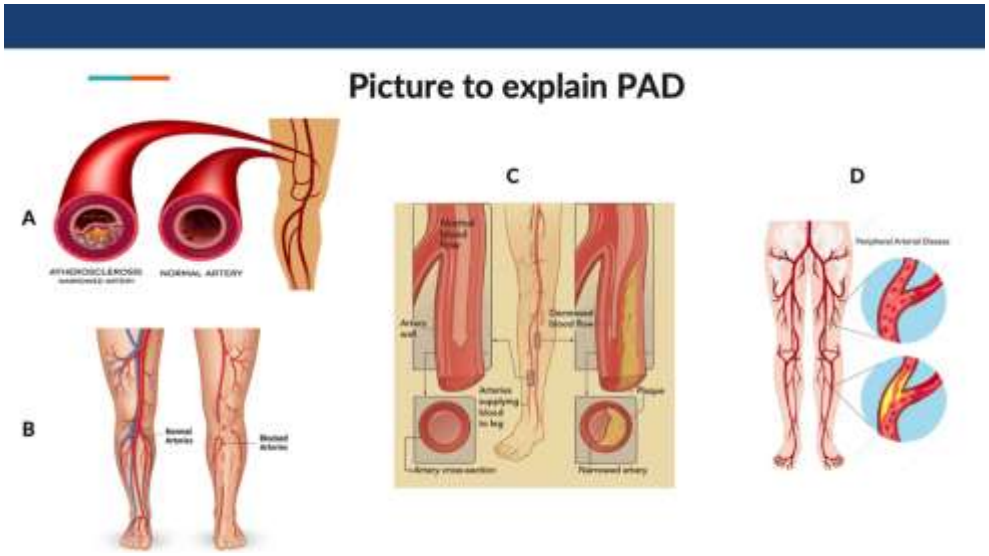


Figure 30 Slide used in Round 2 - Activity 1 - Pictures for PAD

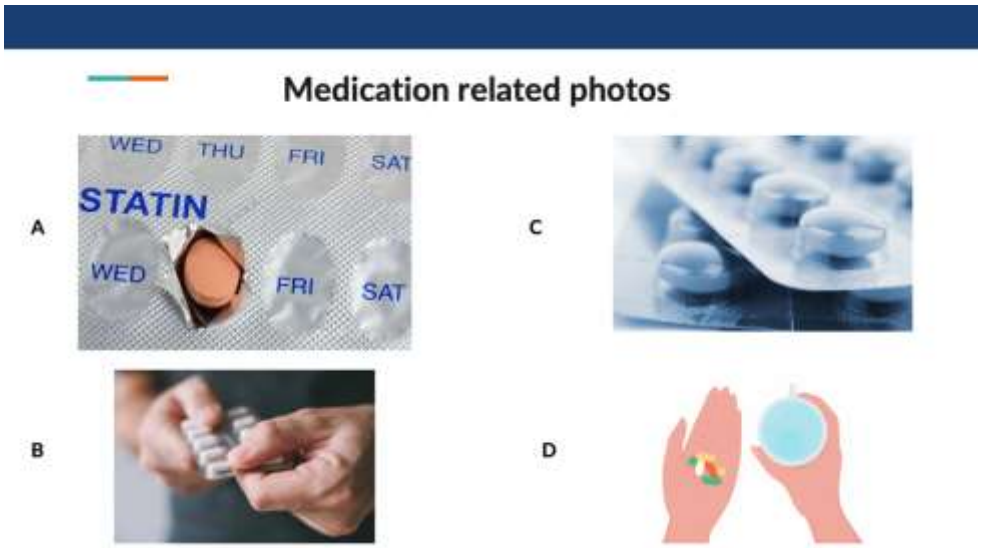


Figure 31 Slide used in Round 2 - Activity 1 - Pictures for Medications

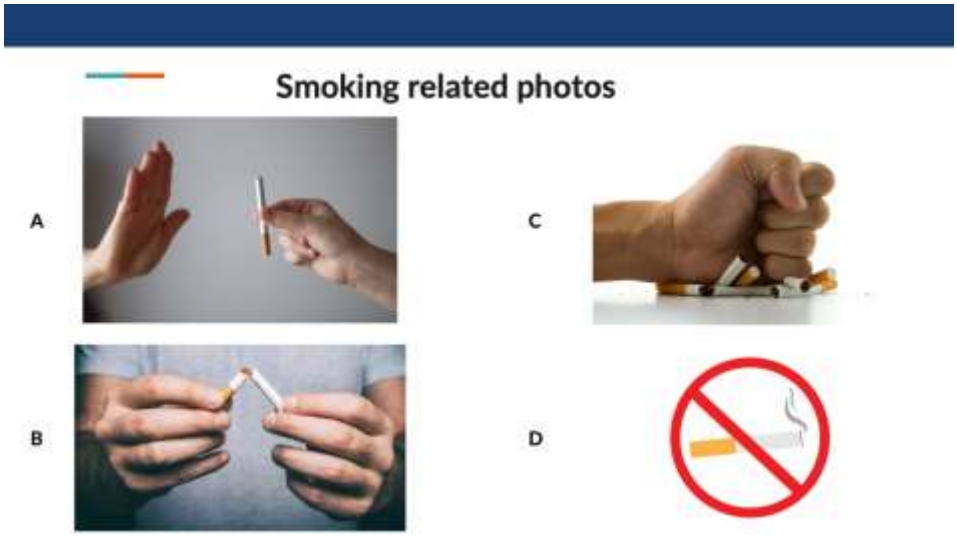


Figure 32 Slide used in Round 2 - Activity 1 - Pictures for Smoking cessation



Figure 33 Slide used in Round 2 - Activity 1 - Pictures for Exercise

7.3.1.4 Co-design workshop - Round 3 (Patients & Relatives)

The aim of this workshop was to finalise the intervention prototype and discuss any changes required before the Optimisation Phase (think-aloud interviews, discussed in Chapter 8). As in Round 2, the face-to-face workshop took place at Charing Cross Hospital in London, and the online workshop included participants from London, Leicester, Yorkshire and Scotland. Co-facilitators for this round were: a vascular nurse specialist/qualitative researcher; one vascular advanced nurse practitioner; a medical doctor/PhD student; two research assistants; a research practitioner; a PPI co-ordinator; and a research nurse.

In Activity 1, participants voted for their preferred cover photo and colour scheme for the booklet (see Figures 34, 35, and 36). Activity 2 involved reviewing the Goal Setting section of the booklet in small groups and providing feedback. The goal setting section included messages about setting goals, a planner/goal setting diary and tips to fill in this diary. This was developed in line with existing support booklets for aortic aneurysm (360) and home-based exercise for PAD. For Activity 3, each smaller group reviewed a different section of the booklet: one group reviewed the section on PAD & medications, one on smoking, and one on exercise. Participants were allocated to these groups based on their adherence levels and preferences. For example, current smokers were assigned to the group that reviewed information on smoking cessation. In this way, participants reviewed the most relevant information to them and provided constructive feedback.



Figure 34 Slide used in Round 3 - Activity 1 - Front Page Options

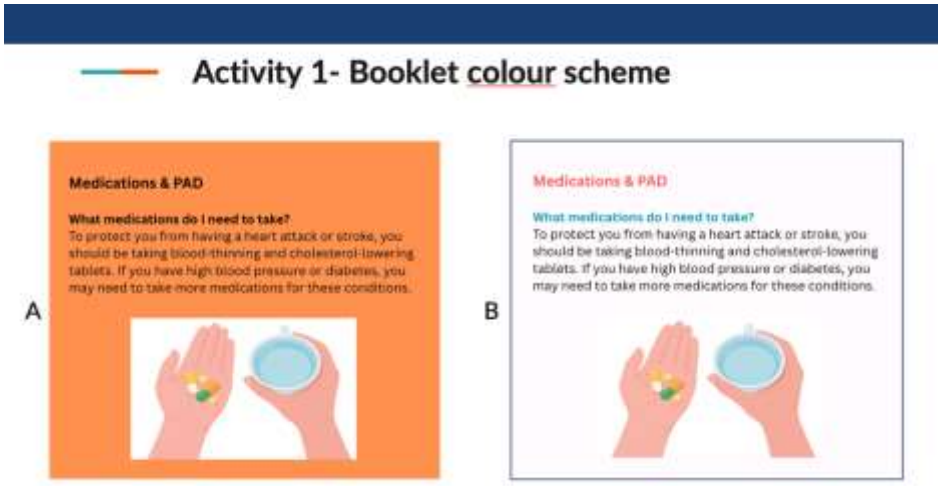


Figure 35 Slide used in Round 3 - Activity 1 - Colour scheme - Part one

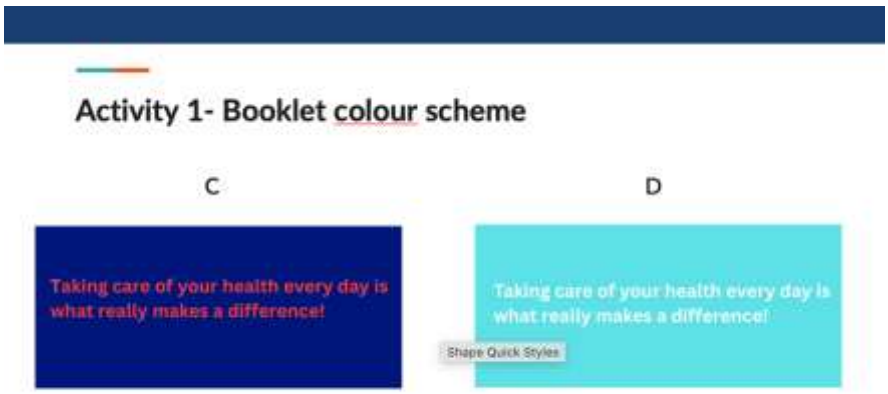


Figure 36 Slide used in Round 3 - Activity 1 - Colour scheme - Part two

7.3.2 Stakeholder feedback meetings

Between each round of workshops, I organised stakeholder meetings with key clinician experts and behavioural scientists to evaluate the appropriateness and feasibility of the intervention co-designed by patients. Stakeholder workshops were advertised through the Vascular Society, Society of Vascular Nurses, PAD Specialist Interest Group, and X (Twitter), and through networks of clinicians at collaborating sites.

Eleven experts took part in the stakeholder feedback meetings: three exercise physiologists, three vascular surgeons, one exercise therapist, one vascular nurse

consultant, one vascular advanced nurse practitioner, one general practitioner (GP), and one behavioural scientist. At each meeting, the top messages selected by patients were presented, allowing stakeholders to provide feedback and ensure that relevant clinical information was not excluded. Stakeholders were also asked to provide guidance on the most effective methods for delivering the intervention within various care pathways and offer strategies for addressing potential barriers to implementation within the NHS.

Meetings were held via Microsoft Teams and lasted approximately two hours. Two breakout groups were formed to ensure all participants had the opportunity to contribute. The meeting was supported by a co-facilitator familiar with the intervention, and two note-takers. Meetings were transcribed via Teams so that facilitator notes could be checked for accuracy and completeness.

7.4 Results

In total, 29 participants (six of whom participated in all workshop rounds) and 11 stakeholders participated in three rounds of co-design workshops between May and July 2025. The results of each workshop round, including details on participants, the intervention format, and the chosen wording for the booklet, are discussed below.

7.4.1 Results from Round 1

7.4.1.1 Participants

In total, 12 participants (age range 52-82, female n=8) took part in the first round of workshops, with six participants attending each workshop. Eleven were individuals living with PAD, and one was a relative providing a carer perspective. All participants identified as White British. Regarding clinical characteristics, one participant was newly diagnosed with PAD at the time of the workshop, two reported a history of chronic limb-threatening ischaemia (CLTI), and two had previously undergone surgical vascular interventions. Three participants reported non-adherence to statin therapy. Two participants were current smokers, and seven were ex-smokers. All reported walking

most days of the week, but none met the recommended 30 minutes of exercise per day due to claudication. None of the included patients had previously attended a SET programme.

7.4.1.2 Format

Overall, there was a strong consensus across most domains, indicating clear and shared expectations among participants. Regarding the format, six patients voted for text-only, and six for the inclusion of images. There was unanimous agreement that the resource should take the form of a booklet rather than a leaflet. Participants highlighted the practicality of an A5 format, noting that it would be easier to handle while still suitable for conversion to PDF, thereby accommodating both paper-based and digital reading preferences. All participants agreed that the booklet should be concise, with a maximum of 10 pages recommended. Participants also suggested specific structural features to enhance usability, including a table of contents and clear definitions of PAD and claudication, underscoring the importance of information clarity and accessibility. Most participants (11/12) voted for a second-person writing style that addressed the reader directly ("you") rather than third-person language to increase relevance and engagement.

7.4.1.3 Messages

For Activity 2 (messages about PAD – see Appendix 6, Table 6.1), participants generally favoured messages that used simple, patient-friendly language and specific framing styles, particularly when presenting numerical information (e.g., preferring "1 in 2 people" over "50%"). Several message options were combined to reflect preferred wording elements, resulting in revised sentences that incorporated the most acceptable phrasing. Additionally, participants highlighted specific wording they wished to retain in the booklet.

The consensus on messages that surgery is not the solution is presented on Appendix 6 – Table 6.2. Overall, participants favoured simple, clear wording. Participants also suggested combining elements from selected messages to improve clarity and

acceptability. Some concerns were raised about how surgical risks were presented, particularly where risk information felt overly detailed or potentially alarming. There was general agreement that risk information should be included, but communicated in a balanced way. One patient at the online workshop recommended adding percentages for each risk of surgery, but the rest of the participants did not think it was necessary, as they wanted to know all potential risks. This was further discussed at the stakeholder meeting and informed refinement of the final wording.

For Activity 3, participants selected the messaging about PAD & Medications. The consensus for messages explaining the role of medications is presented in Appendix 6, Table 6.3; whilst the consensus for messages to address the concern about statins is presented in Appendix 6, Table 6.4. Specifically, for messages explaining the role of medications, Option B received the most votes (9/12), with participants requesting that the word “aspirin” be replaced with “blood-thinning tablets”. Additionally, they preferred the word “protection” over “prevention”. Participants did not feel the need to combine any sentences, but they liked specific messages, such as “people who take control of their health”, as this made them feel empowered. Participants reported that if I decided to keep option H for the booklet, I should not mention which healthcare professional prescribes medications, but simply say “you have been prescribed…” It was felt that specifying the healthcare professional might cause confusion, especially in people with multimorbidity and polypharmacy, who might be seeing several different people.

As for messages addressing the concern that statins would damage patients’ legs, although most participants preferred option F (8/12), there was no clear preference for the other messages. For example, all participants liked the first part of options B and E, but they felt the overall messages were not impactful enough. For option H, participants requested that a specific HCP should be described rather than using the generic term HCP, as this could cause confusion. Participants preferred to mention a doctor or a nurse, not a pharmacist, because none said they would go to their pharmacists to change their medications. Finally, some participants at the F2F

workshop requested combining option F&H; participants at the online workshop liked this idea and also requested adding the sentences from B and E that they liked.

7.4.2 First Stakeholder Meeting

During this meeting, the selected messages from the first round of patient workshops were reviewed and restructured to ensure that all the relevant clinical information was included. Overall, clinicians found the messages that patients had selected meaningful and impactful. They made a few suggestions to simplify the text and provide some definitions (e.g. claudication). Additionally, they recommended incorporating this message, "Research in people taking statins has found that over 90% of the muscle pain or discomfort patients reported was not caused by the statin itself", into the text about statins, so that patients are offered data-driven information that could reassure them about statins, and hence facilitate adherence.

Following discussion in smaller groups and a review by the whole group, the following text was selected for inclusion in the booklet section on "What is PAD?":

Peripheral arterial disease (PAD) is a lifelong condition. It happens when blood doesn't travel properly from your heart to your legs. This can lead to serious problems like heart attack, stroke, and even leg amputation. In fact, 1 in 2 people like you could face another blockage or have a heart attack or stroke within five years.

Over time, your arteries (the tubes that carry blood) can get narrowed and blocked. This can happen faster if you smoke, don't exercise, or have an unhealthy diet. Medications can help slow the process, but they can't replace healthy habits. Being active, eating well, and stopping smoking protect your heart and brain, improve blood flow and mobility, and help you stay independent for longer. There isn't a quick fix. It takes daily effort to look after your health and prevent new blockages or serious events.

Surgery in patients with PAD might not be needed to improve symptoms in the long term or reduce the risk of amputation, heart attack or stroke. Surgery can be risky, leading to

nerve damage, new blockages, heart attack and stroke. This can be different for each patient. Taking care of your health every day is what really makes a difference!

The BCTs for this text are: 4.2 – Information about antecedents, 5.1- Information about health consequences, 5.2 – Salience of consequences, 9.2 – Pros & cons, and reflect MoA Knowledge and Beliefs about consequences.

For the section "Medications & PAD", the following text was selected for testing in the prototype workshop:

While blood thinning and cholesterol tablets don't help with the leg pain from PAD (called claudication) directly, they protect your blood vessels and lower your risk of a heart attack or stroke by nearly 40%. Think of them like a protection plan. Patients who take control of their health by taking medications often feel more confident and less anxious. Even though you may not feel the effect physically, knowing you're actively preventing something serious, can bring peace of mind.

Worried that statins might make your leg pain worse? Statins don't cause PAD symptoms, so can't make your claudication pain worse. Research in people taking statins has found that over 90% of the muscle pain or discomfort patients reported was not caused by the statin itself. Statins help protect your arteries and lower your risk of heart attack, stroke, leg wounds and amputation. They are an important part of keeping you healthy for life, not the cause of your pain. Like any other medication, some people may have an allergy and/or intolerance to specific statins. If you have any concerns or questions, speak to your doctor or nurse. Most patients can switch to a type of statin that may work better for them. You don't have to figure it out alone.

The selected text utilised the following BCTs: 3.2 – Social support (practical), 5.1- Information about health consequences, 5.2 – Salience of consequences, 5.6 – Information about emotional consequences, 9.1- Credible source, 13.2- Framing/reframing. The relevant MoAs were Knowledge, Beliefs about consequences, Vulnerability, Negative attitudes and Social influence.

Lastly, the stakeholder group discussed patients' requests to remove the wording about surgery and to avoid using the word "amputation", as both were felt to be triggering and scary. All clinicians stressed the need to include information about surgery and amputation, as they felt that a strong barrier to adherence was the perception that there was a quick fix through surgery, often accompanied by a lack of knowledge that PAD could progress to amputation.

7.4.3 Refinements prior to Round 2

Overall, the recommendations from the first round of co-design workshops and the stakeholder group aligned with the intervention's guiding principles and the logic model. I reviewed the recommendations with my supervisors and began working in Canva to develop a prototype of the booklet, incorporating the selected images and text, so that this could be presented to participants during the third round of workshops.

Following the workshops, I realised there was confusion about which medications each patient needed to take; some patients were not prescribed statins, and others were taking medications for diabetes or blood pressure, so it was important to clarify this. Hence, I added the following paragraph in the Medications & PAD section:

What medications do I need to take?
To protect you from having a heart attack or stroke, you should be taking blood thinning and cholesterol lowering tablets. If you have high blood pressure or diabetes, you may need to take additional medications to manage these conditions.

Additionally, during the workshops, adherent patients shared tips with those who were not taking their medications. Although forgetfulness was not identified as a key influence following the data triangulation exercise (see Chapter 6), a key aspect of the PaPa framework is to make it easier for people to adhere to their treatment by reducing practical barriers. Hence, the following section was added:

How can I make it easier for me to take my medications?

- *Keep a medication tracker so you stay on top of your doses*
- *Try setting reminders on your phone or use sticky notes, or linking your medication to daily habits, like brushing your teeth or having breakfast*
- *Ask your pharmacist about packaging options, like a Dosette box for easier organisation*

7.4.4 Results from Round 2

7.4.4.1 Participants

Seventeen participants (age range 50-86, female n=9) took part in the second round of workshops: seven attended the F2F workshop and 10 attended online. Six of the participants also took part in the first round of workshops. Thirteen participants were individuals living with PAD, and four were relatives of patients. Around half (9/17) identified as White British, with the remaining participants identifying as individuals of minority ethnic backgrounds. Regarding clinical characteristics, two participants were newly diagnosed with PAD at the time of the workshop, three reported a history of CLTI, four had previously undergone surgical vascular interventions, and one had a major (above-knee) amputation. One patient reported not taking any of their prescribed medications and four patients reported non-adherence to statin therapy. Seven patients and one relative were current smokers, and six patients were ex-smokers. Five patients reported walking daily for 30 minutes, whilst the rest were not meeting the recommended 30 minutes of exercise per day due to claudication pain. The amputee reported performing bed and chair exercises daily and attending amputee rehabilitation classes. Only one of the included patients had previously attended a SET programme.

7.4.4.2 Format

Although patients were asked to vote for only one option in each section, some had multiple preferences and suggested combining elements. For the PAD artery illustration (see Figure 30), option A was the most favoured (10/17), with participants

preferring its simplicity and clarity. There was strong support for combining option A with other versions (e.g., A&C, n=10 votes) to retain visual simplicity while improving explanatory detail.

Regarding the images for medications (see Figure 31), options A and D received seven votes each. Option A was perceived as fresh and acceptable, although some participants cautioned against specific medication labels to avoid confusion. Option D reflected the lived experience of polypharmacy for some, but others found it visually overwhelming.

Smoking-related images (see Figure 32) generated the most diverse views. Option A received the most votes (7/17), while option D (6/17) was considered the clearest but less engaging. No participants voted for options B or C. None of the smokers liked the four options; they preferred more graphic, factual images (e.g. cigarette packet warnings). However, the rest of the participants cautioned that such images could be distressing and not necessarily effective for behaviour change.

Lastly, for exercise-related images (see Figure 33), option A was preferred (12/17), described as positive, motivating, and emotionally engaging, particularly because it included a dog, which offered them feelings of happiness and encouragement. Participants stressed that if selected, it should represent greater diversity in age and ethnicity to enhance relatability.

7.4.4.3 Messages

For Activity 2, the consensus on messages about smoking cessation is presented in Appendix 6- Table 6.5 and 6.6. For messages addressing the misconception that it is "too late to quit smoking" after PAD diagnosis (Appendix 6, Table 6.5), option B was the most popular (12/17). Participants favoured messages that were encouraging, supportive, and conversational in tone. All smokers liked option B as it mentioned amputation, and it made them feel "shocked" and "scared", which they felt was appropriate for such a serious issue. Smokers also requested the option to cut down rather than quit, and to incorporate this into the selected messages. Some patients

also suggested combining options B and C to strengthen the message about smoking cessation.

For motivational smoking cessation messages (Appendix 6, Table 6.6), preferences varied. Participants proposed combining elements from selected messages and incorporating social support framing and references to NHS resources. One combined version (J&G&K) received unanimous support in the online workshop.

Appendix 6 Tables 6.7 and 6.8 summarise preferences for exercise-related messages. Participants favoured statements that clearly explained the safety and purpose of walking with pain and suggested combining selected wording elements to produce a simple, factual, and encouraging message. For messages addressing environmental barriers (e.g., weather, time, location), option A was generally preferred, particularly because it promoted manageable strategies, such as short daily walks and habit formation. Minor wording refinements were suggested, and participants endorsed additional practical alternatives for adverse weather, such as chair-based or bed exercises.

7.4.5 Second Stakeholder Meeting

During this meeting, the selected messages from the second round of patient workshops were reviewed and restructured to ensure that all relevant clinical information was included. Following discussion in smaller groups and then a review of the text with the whole group, clinicians advised adding further information to the "Smoking & PAD" section, specifically an opening paragraph, information about vaping, and the perceived link between smoking and stress. Clinicians agreed that it would be useful to add relevant NHS smoking cessation resources. Based on the text selected from the patient workshops, clinicians voted for the following messages to be included in the booklet:

I've smoked for years, would quitting now even make a difference?

Quitting smoking, even after being diagnosed with PAD, lowers your risk of needing surgery, slows artery damage, and you are less likely to have a heart attack, stroke and amputation. Within two weeks, your circulation will begin to improve, making exercise and walking feel easier. By quitting now, you can take more control over your future.

Do I really need to quit?
Many people with PAD have done it, and so can you. Quitting is hard, and it is a personal decision. You don't have to quit smoking all at once. Start by cutting down, delay your first cigarette, smoke fewer each day, or set a quit date and work towards it.
Many people smoke when they feel stressed, tired, or overwhelmed. These are common triggers. Spotting your triggers is the first step. Once you know what sets off the urge, you can plan how to respond. Cravings will come, especially in social situations or when someone offers you a cigarette. Practice what you'll say in advance. Having a plan makes it easier to stay confident and in control.

When the urge hits, swap the cigarette for something healthier: have a glass of water, a walk, or a light snack. Replacing the habit helps build long-term change. Every cigarette that you don't smoke helps your body get better.

The BCTs used in the paragraph titled "I've smoked for years, would quitting now even make a difference?" are: 5.1- Information about health consequences and 13.2- Framing/reframing, with MoA Knowledge, Beliefs about consequences and Negative attitudes. In the paragraph titled "Do I really need to quit?", the BCTs included are: 1.3 – Goal setting (outcome), 8.7 – Graded tasks, 15.1 - Verbal persuasion about capability, and MoA Beliefs about capabilities and Goals.

For the "Physical Activity & PAD" section, it is important to note that the PAD IC guidelines (8) were followed with an aim to improve IC symptoms. The term physical activity instead of exercise was used as a title for this section, following advice from the stakeholder and PPI group. This was to ensure that the text was inviting, friendly and less daunting for the patients.

Clinicians liked the text that patients selected, but exercise physiologists stressed the need to include a paragraph about the recommended activities and what counted as a 30-minute walk. Although they liked the paragraph about exercising when the weather is bad, they felt that some patients might think they only needed to do these activities, and skip their 30-minute walk. Therefore, following this, I sought further advice from two physiotherapists, which will be discussed below (see Section 7.4.6).

It hurts when I walk, won't that damage my legs?
It's normal to worry, but walking with claudication is safe and one of the best things you can do for your legs. If you avoid walking because of pain, your muscles get weaker, your blood flow slows down even more, and it becomes harder to walk as far. Although walking with the pain can feel uncomfortable or frustrating at first, it helps. Walking to the point of discomfort, and continuing a little before resting, encourages your body to build new blood pathways around the blocked areas. Over time, this improves circulation, strengthens your legs, and helps reduce the pain over time. With regular walking, you'll likely find it easier to go farther without stopping, and stay more active and independent in daily life.

How can I fit exercise into my day when I don't have time?
Walking and staying active every day can make a real difference. Look at your daily routine and pick a time that works best for you to go for your exercise walk. Making it part of your routine helps it become a habit that's easier to keep up. Small changes to your daily routine can help you form a habit of being more active and healthier.

For the paragraph titled "It hurts when I walk, won't that damage my legs?", the following BCTs were utilised: 4.2 – Information about antecedents, 5.1- Information about health consequences, 5.2 Salience of consequences, 5.6 – Information about emotional consequences and 9.2 – Pros & cons; and MoA Knowledge and Beliefs about consequences. In the paragraph titled "How can I fit exercise into my day when I don't have time?", the text applies BCT 7.1 – Prompts/cues and MoA Environmental context & resources.

7.4.6 Refinement of booklet prior to Round 3

Feedback from the workshops and the stakeholder group was discussed with the supervisory team. It was agreed to include the clinicians' suggestions and further assess the patients' preferences during the third round of workshops. Input was sought from other experts to further refine the materials prior to the next workshops.

A behavioural scientist and a vascular surgeon who had previously designed an educational booklet for aortic aneurysms and smoking cessation (360) were consulted on the selection of appropriate text. The wording that their PPI group selected to support smoking cessation was adapted for the PAD & Me intervention. It was stressed that the same message should be shared among vascular patients. The following paragraphs were added (which will then be reviewed by patients in the third round):

We are not here to tell you to quit smoking, that is your choice. This section is about the benefits of quitting smoking for to your PAD and where to find help if you are thinking about quitting or cutting down.

What about vaping and e-cigarettes?
While they might seem like a different choice, the healthiest choice is to avoid smoking and vaping. If quitting smoking is hard, switching to vaping may be a bit better for your health since it usually has fewer harmful chemicals than regular cigarettes. But quitting completely is the best option!

Smoking and stress
Some people think smoking helps them relax or reduces stress. But that's actually a myth! Smoking can make you more stressed in the long term. When you light up a cigarette, you might feel a little calmer for a short time. That's because your body is getting a quick hit of nicotine. But once that feeling wears off, you'll feel even more stressed than if you didn't smoke at all.

Are you thinking of cutting down or quitting smoking?

Everyone is different, so the best way to quit is the way that fits you and your lifestyle. But you don't have to do this alone!
The NHS Stop Smoking Service is free, supportive, and designed to help you find what works best for you, not force you to follow one set plan. Support might include:

- *One-to-one or group sessions*
- *Medicines to reduce cravings*
- *Nicotine replacement therapy (like patches or gum)*
- *Vaping*

Using NHS support and stop-smoking treatments together can make you up to 4 times more likely to quit for good!
To get started, call 0300 123 1044, search "NHS Stop Smoking Service," or visit the NHS website, which also offers a stop-smoking app and help to create your own quit plan.

As for the exercise section, two physiotherapists advised on the relevant wording. The following addition was made in the "Physical Activity & PAD" section:

What activities should I be doing?
Walking for exercise every day for 30 minutes helps build a habit. This walk should be focused on exercise, building your walking strength and should not include walking you'd do anyway (like shopping or housework).

You can use a timer to keep track:
1. Start the timer when you begin your walk.
2. Walk at your usual pace until you feel pain – keep going for as long as you can tolerate.
3. When you need to stop and rest, pause the timer.
4. Start the timer again when you resume walking.
5. Repeat this until you've walked for a total of 30 minutes (rest time doesn't count).

It may take longer than 30 minutes overall, because you'll need to stop and rest along the way, and that's okay. Over time, as you practice walking through some discomfort, you will find you can walk longer before needing to rest. To feel confident, try to walk in a safe, familiar place and keep a water bottle with you.

The following section was refined following the physiotherapy input:

What can I do to stay active during bad weather?
If the weather is bad or too hot to go outside, there are still plenty of ways to keep moving indoors! While these suggestions won't directly improve your claudication, as you need to walk for 30 minutes every day to do that, staying active in general is really important for your health. Here are some simple things you can do around the house:

- *Going up and down the stairs,*
- *Doing chair exercises,*
- *Try standing up to work, by putting your laptop on a box or shelf, or even getting a standing desk,*
- *Marching on the spot while watching TV,*
- *Walk around the house when adverts are on the TV.*

7.4.7 Results from Round 3

7.4.7.1 Participants

In total,18 participants (age range 50-80, male n=12) took part in the third round of workshops, nine in each workshop. Seven of the participants also took part in the second round of workshops. Five more participants were invited to the workshop but three were unable to attend due to emergency medical issues (one experienced CLTI); and two due to last minute working responsibilities. However, the two patients that could not attend due to work requirements, agreed to review the prototype booklet and provide written feedback on the materials.

Fifteen participants were individuals living with PAD, and three were relatives of patients. Half of the participants (9/18) identified as White British, with the remaining

participants identifying as individuals of ethnic minority backgrounds. Regarding clinical characteristics, three participants were newly diagnosed with PAD at the time of the workshop, four reported a history of CLTI and five had previously undergone surgical vascular interventions.

Regarding medication adherence, one patient reported not taking any of their prescribed medications and five patients reported non-adherence to statin therapy. Six patients were current smokers, and six patients were ex-smokers. Four patients reported walking daily for 30 minutes, whilst the rest were not meeting the recommended 30 minutes of exercise per day due to claudication. Three of the included patients had previously attended a SET programme, all of whom reported maintaining their activity levels following the end of the programme.

7.4.7.2 Format

Regarding participants' preferences for the front page photograph of the booklet (see Figure 34), most preferred option B (14/17 votes) because it was positive and encouraged exercise. All participants stressed the importance of using inclusive images that represented diverse skin tones. As for the booklet's colour scheme, there was strong consensus to include high-contrast options to accommodate colour blindness and visual impairment. All participants voted for Option B (see Figure 35), a colour scheme with a white background and coloured text. The rest of the options (A,C and D in Figure 35 and 36) did not receive any votes. Nine participants voted for the traditional NHS white and blue colour scheme, but the remainder felt it was not innovative enough and had seen it before.

7.4.7.3 Wording of booklet

Overall, participants liked the clarity and tone of the written content across sections. Some offered insightful refinements, including: strengthening messages around daily medication adherence; removing content perceived as potentially misleading (e.g. vaping); reframing exercise recommendations to acknowledge variability in capacity;

and balancing honest discussion of surgical risks with supportive motivational messaging.

More specifically, all participants liked the contents page and suggested adding a space to enter their NHS number so they could gather all their clinical information in one place. As for the section “What is PAD?”, most participants (n=13) liked the main text. Whilst all participants in the F2F group were happy with the existing photo, the online participants requested a clearer representation of the arterial system. Three patients felt that information about surgery was scary, as they were not aware of the risks. Others (15/18) felt that fear of surgery and its associated complications would help them stay on track and remain adherent. Hence, the consensus was to keep the surgery-related text. All participants suggested that it would be good to connect the text about surgery with a message explaining why it is important to do healthy things every day, so that it felt more encouraging and less threatening.

Regarding the medications section, all participants liked the text's simplicity. Some requested that the importance of taking medications daily be further emphasised. A patient at the face-to-face workshop also suggested adding a bullet point about the prescription certificate in the section “How to make it easier to take your medications daily”. I incorporated this recommendation before the online workshop, and all participants liked it. A few patients were unsure what a Dosette box was; hence, they suggested adding a visual representation of it if there was space in the booklet.

The smoking section received the most conflicting feedback. Although most participants liked the text and found it encouraging, none of the smokers liked the photos, even though they had voted for them in previous workshops. Five participants (three ex- and two never-smokers) suggested using the standard NHS smoking cessation photos, whereas three (including two smokers) suggested using a more amusing, cartoon-type image. One smoker recommended adapting the images of diseased organs from cigarette packs, whilst the rest of the smokers disagreed. Overall, smokers felt the content was encouraging, non-patronising, and they liked that it acknowledged the difficulty of quitting smoking. They felt supported and not judged as

they were given the option to cut down if they were not ready to quit. Finally, all participants suggested removing the information about vaping. This contradicted a previous round, where two smokers who switched to vaping asked to include vaping. Following the group discussion, it was agreed that people should not be encouraged to vape, as there is not enough evidence for its safety.

For the exercise section, most patients liked the content and the information about the benefits of exercise. Some patients were concerned about the recommended 30 minutes of daily exercise, as they had not been previously given such guidance. Additionally, those with claudication felt this might be overwhelming, as they were unable to walk for more than 5 minutes. They stressed the need to tone down the language and make it more encouraging. Regarding the exercises during bad weather, we were unable to reach a consensus on whether people preferred the term “adverse” or “extreme” weather; hence, it was agreed this would be further explored during the next stage of this work (see Chapter 8). Additionally, none of the patients liked the suggestion about marching on the spot. They felt the image was positive and elicited a feeling of happiness, but also suggested adding people to the photo, including older people.

Regarding the goal setting section, all participants found it useful and encouraging. Some suggested including an opening sentence stating that the booklet covered a variety of treatment areas and emphasising that people could set different goals. Most participants also recommended adding a sentence about involving family members or healthcare professionals when setting goals. Most participants found the table layout difficult. They recommended adding more space, making it more interactive by adding different days of the week, so they could tick boxes. Some people felt the ticking would facilitate habit formation and maintenance of behaviours. All participants requested that one example be added for each behaviour. Three patients in the face-to-face group found the “Challenges & Solutions” column unnecessary, whereas the rest of the participants liked it.

Finally, some patients felt it was essential to include resources and links to vascular charities, as well as mental health and lifestyle resources, so they could access further information about their condition and how to manage it.

7.4.8 Stakeholder input

As there were no major changes to the booklet following the final round of workshops, stakeholders thought it was best to review the booklet and provide written feedback rather than hold a meeting. Additionally, most stakeholders were on annual leave between July-September, hence, logistically it was hard to plan a meeting. Five of the stakeholders agreed to review the booklet and offer written feedback: one vascular nurse consultant, one vascular surgeon, one behavioural scientist and two exercise physiologists. Clinicians were informed that patients had suggested removing the vaping section and agreed that this was appropriate. Overall, they were happy with the revised version and did not wish to make any further changes.

7.4.9 Final refinements

Based on the feedback from the final round of workshops, the booklet was updated and reviewed by the supervisory team. No major changes were made following the workshops, but some of the text was re-organised, to ensure that it flowed well and was not repetitive. To develop a more professional-looking version of the booklet before user-testing, I collaborated with a professional design and printing company (Harlow Printing Ltd). The process took almost two months and included an initial meeting with the designer, sending them the current version and all relevant visual changes that needed to be made, and two rounds of iteration from the designer to ensure the recommendations from the co-design workshops and stakeholder meetings had been fully incorporated.

7.5 Discussion

7.5.1 Main findings

To my knowledge, this was the first co-design activity with patients with PAD and their relatives to design a booklet intervention to support them with treatment adherence. Three rounds of co-design workshops (six workshops in total) were undertaken with 29 patients and relatives, and two stakeholder meetings were conducted with 11 HCPs to develop the PAD & Me booklet intervention. Half the workshops were conducted face-to-face and half online, and each workshop lasted 2 hours. Each workshop round had a specific aim. The workshops resulted in detailed, actionable changes to the booklet's content and format, enhancing its acceptability, relevance, and usability while maintaining alignment with clinical guidance and behavioural principles. Stakeholder input ensured that the intervention aligns with current clinical guidance.

Following the selection and refinement of the wording, the following 13 BCTs were included within the education booklet: 1.1 Goal setting (behaviour); 1.3 Goal setting (outcome); 4.2 Information about antecedents; 5.1 Information about health consequences; 5.2 Salience of consequences; 5.3 Information about social and environmental consequences; 7.1 Prompts/cues; 8.7 Graded tasks; 9.1 Credible source; 9.2 Framing/reframing; 11.2 Reduce negative emotions; 12.3 Avoidance/reducing exposures to cues for the behaviour; and 15.1 Verbal persuasion about capability. Participants prioritised clear, encouraging and relatable images; simple, supportive and non-patronising text; and stressed the importance of including credible PAD-related resources. Being co-designed with patient and stakeholder input, this intervention has the potential to be feasible and scalable within the current healthcare system.

7.5.2 Interpretation of findings in relation to other studies

As presented in Chapter 3, none of the current multi-component interventions supporting PAD adherence have utilised co-design approaches to address specific adherence influences. Hence, there is limited comparative literature. The use of co-design approaches is growing in other chronic disease specialities, including cardiology

(361) and diabetes (362). A scoping review exploring the use of co-design in the development of cardiovascular disease secondary prevention interventions demonstrated that although more studies are employing co-design, there is limited consensus on its definition and description, and a lack of transparency in reporting participants' involvement (361). The authors stressed the need to further evaluate the effectiveness of such interventions in future research (361). A recent scoping review examining the engagement of target users in the development of self-management diabetes app interventions found that users were mainly involved in the evaluation stage rather than the early stages of intervention development (362). This raises the question of whether these interventions are truly co-designed and user-focused (362).

However, the adoption of co-design methods in PAD and in vascular surgery more broadly is limited. When searching the literature for studies reporting the use of co-design in the intervention development phase, only two were identified. The CREATE study was identified on the HRA website (2023 registration); however, beyond this registration, the study's co-design process or results have not yet been published, and attempts to contact the PI by email were unsuccessful (363). The study registration reports plans to use a structured co-creation approach, bringing together patients with PAD, carers, clinicians, and researchers to collaboratively design a physical activity intervention for IC through a series of workshops (363). A consensus approach is described in order to determine the intervention components, content, design, and delivery model (363). Additionally, a preprint study was found describing a design thinking project to identify solutions to improve diagnosis and secondary prevention of PAD (364). The study included co-design workshops with patients with PAD, carers, clinicians and stakeholders (364). System-level barriers to effective care delivery and priority solutions were identified, focusing on improved funding, government support systems, and technological applications (364). The authors concluded that the next step of their work will be to implement, evaluate and optimise the identified solutions to improve PAD care (364).

A booklet format was chosen for the PAD&Me intervention for a number of reasons, including the lack of patient-friendly resources, the feasibility of using a booklet within

the current healthcare system and its low cost. An umbrella review identified that patient leaflets can improve patients' knowledge and satisfaction, as well as short-term treatment adherence (365). The authors of this review highlighted that the impact on adherence also depends on the intervention's content and context, and they encouraged a case-by-case adherence assessment (365). To ensure booklets are relatable, simple language and engaging images should be used (365), principles that I employed throughout the co-design workshops. A review assessing the role of images in health communication found that their use can improve adherence by enhancing understanding and clarifying complex information (366). Combining text with relevant images can increase motivation to change behaviour and ability to recall information, especially for patients with low literacy levels (366). Images can be more effective when carefully designed and selected to meet the target population's needs and requests, and tested with target users (366).

Although a booklet intervention was the most requested option by the PPI group in this PhD study, previous literature has indicated that written information may not be relevant to all patients (367). A critical commentary targeted at researchers and policymakers stressed that information alone is insufficient to change behaviour (223). Additionally, evidence from a randomised trial indicates that information booklets alone, without additional support, have no effect on healthcare services utilisation (368). Treatment information should be presented in a way that considers the patient's beliefs and addresses any disconnect between these beliefs and the evidence-based recommendations (133), which is in line with the principles of the PAD&Me booklet. With that in mind, leaflets and booklets should not replace clinician consultations; rather, they should complement them (367). Clinicians can personalise booklets for patients by highlighting relevant sections during consultations, reinforcing key messages, and supporting patients in focusing on their individual goals (365). Nevertheless, it is important to highlight that according to the intention–behaviour gap, even when patients plan to modify their behaviour, this does not guarantee action, as behaviour is also shaped by contextual, cognitive, and environmental influences (369). Therefore, interventions should not focus solely on motivation or intention formation

but should address multiple determinants using a range of evidence-based BCTs to increase the likelihood that intentions translate into sustained change.

Previous behavioural interventions have also utilised a booklet mode, including an intervention aiming to increase adherence to tamoxifen in the treatment of breast cancer (370) and a self-management intervention for reducing the impact of chemotherapy-induced peripheral neuropathy symptoms (371). Similar to my study, both interventions were co-designed with patients to ensure their needs were addressed, but their effectiveness was not assessed (370, 371). In vascular surgery, although there are currently no other educational booklet interventions to support treatment adherence, a recent study of a cardiovascular risk-reduction intervention for patients with aortic aneurysm utilised booklets to educate patients about lifestyle changes (360). To date, the effect of the booklets on behaviour change has not been tested (360). Additionally, a recent study described the development of a leaflet checklist for GPs to help them improve the medical management of patients with PAD (95). The leaflet was found acceptable and the authors state that it has the potential to be widely adopted in clinical practice to streamline the prescription of best medical therapy (95). However, as presented in Chapter 4, even if patients are prescribed the appropriate treatment, they might not adhere due it due to knowledge barriers and treatment concerns. Hence, greater efforts are required to comprehensively tackle adherence barriers.

Regarding other modes of educational interventions for PAD, a recent study explored patients' perspectives on an online video education tool (372). In total, 20 patients were included in the study; after watching a 20-minute video on the definition, presentation, associated risks, and treatment of PAD, patients' knowledge gaps did not improve (372). The authors concluded that such a video could be used as an additional tool for clinician education (372). Other education interventions have mainly focused on exercise behaviours. The Group Oriented Arterial Leg Study home-based behaviour change exercise intervention incorporated health education and cognitive-behavioural support to increase walking activity in patients with PAD (373). Specifically,

the cognitive support component focused on strengthening participants' psychological and self-regulatory skills to sustain behaviour change, by supporting them to self-monitor their behaviours, thoughts and emotions, as well as develop personalised strategies to maintain activity over time (373). The results demonstrated improvements in 6-minute walking distance and physical activity, illustrating how integrating education into behaviour change interventions can impact outcomes (373).

The Motivating Structured Walking Activity in People With Intermittent Claudication (MOSAIC) multicentre randomised controlled trial tested a home-based behaviour change and education intervention delivered by physical therapists to improve walking capacity in patients with intermittent claudication (77). The behaviour change component was informed by 15 BCTs (77). It was a structured, multi-session intervention combining education, motivational support, and practical self-regulation strategies to promote walking (77). It included building readiness to change, setting personalised goals, action planning, problem-solving barriers, and self-monitoring progress (77). Follow-up sessions reinforced skills, reviewed goals, addressed challenges, and supported relapse prevention and integration of walking into daily life to encourage maintenance of behaviour change (77). The study found that at 3-month follow-up, the walking exercise behaviour change group showed a significant improvement in 6-minute walking distance compared with usual care, as well as an improvement in the illness perception questionnaire scores (77). The authors concluded that further research is needed to explore the long-term effects of such interventions on exercise behaviours (77). A systematic review of patient education interventions for physical activity in PAD identified potential benefits, including improved activity and patient empowerment (374). However, the included evidence was limited and inconclusive regarding improvements in walking capacity and daily activity, highlighting the need for more rigorous evaluations of educational interventions (374).

Regarding the BCTs selected in the current study, the findings align with those in Chapter 3, highlighting the need to use alternative BCTs beyond '*instructions on how to perform a behaviour'* and *'goal setting'*. It is, however, unclear whether the selected

BCTs will indeed be effective in improving adherence in patients with PAD. There is limited data on the effectiveness of BCT interventions during the intervention development stage, and these studies are mainly focused on exercise behaviours. A systematic review that classified which BCTs were included in behaviour change interventions to promote physical activity in people with intermittent claudication found that the most frequently used BCT was *'goal setting (behaviour)'*, followed by '*Instruction on how to perform a behaviour'* (104). Additionally, the BCT domains most frequently used were: Goals and planning (89% of interventions); 'Feedback and monitoring' (89% of all interventions); 'Repetition and substitution' (64% of all interventions); 'Shaping knowledge' (62% of all interventions) and 'Social support' (53% of all interventions) (104). However, the review did not evaluate which BCTs were associated with effective behavioural change.

7.5.3 Strengths and Limitations

A strength of this project was the use of a robust co-production approach, underpinned by NIHR co-production principles and the PBA. Patients were central to the intervention development process, with their lived experiences actively shaping the content, format and tone of the PAD&Me intervention. Co-design workshops were delivered both online and face-to-face, across different locations. This pragmatic approach maximised accessibility and allowed individuals with varying preferences and mobility limitations to participate. Stakeholder involvement, including clinical and behavioural science expertise, ensured that patient preferences were balanced with clinical relevance, feasibility, and evidence-based practice. Additionally, participant feedback indicated high levels of satisfaction with the co-design process. Patients consistently reported feeling listened to and valued, and many described gaining a clearer understanding of PAD and its management by the end of the workshops. Practical support, including participant vouchers for participation, available parking at workshop locations, and provision of refreshments, reduced participation barriers (375) and aligned with NIHR recommendations for inclusive patient involvement (346).

However, several limitations should be acknowledged. Recruiting new patients for each workshop proved challenging, reflecting broader difficulties in engaging people with PAD in research. However, having the same participants attend multiple workshops could also be considered a strength, as it can enhance data depth and credibility by building trust, enabling reflection across sessions, and supporting iterative refinement of ideas (376). Additionally, although efforts were made to recruit participants from diverse ethnic backgrounds, the majority (17/29) were White. One patient from a minority ethnic background and low socioeconomic status expressed a strong interest in participating but was ultimately unable to attend due to transport barriers. Unfortunately, organisational constraints prevented real-time reimbursement of travel costs in this case, highlighting the structural limitations that can exclude underserved populations, even within fully funded co-production efforts.

A further limitation is potential participation bias. It is possible that some individuals were motivated to take part primarily by the financial incentive offered, rather than genuine interest in the project. This risk is increasingly recognised in participatory research, particularly when vouchers are used to reimburse time and expertise (377). Recruitment via online platforms also presented specific challenges. Although online recruitment methods are increasingly recognised as efficient and cost-effective compared with traditional approaches, such as hospital-based recruitment (378), they are not without risk. In this project, no participants were ultimately recruited via the VOICE platform, as all expressions of interest received through this route were identified as inauthentic and thus posed a threat to the project's research integrity. Fake participants were successfully detected during the eligibility screening stage. Warning signs included identical or irrelevant answers to screening questions, repeated typographical errors, early focus on financial incentives, and non-response when asked to speak by phone to discuss the workshops further. When asked to have an initial call to discuss the workshop, all people who expressed interest via VOICE declined; hence, they were not included in the workshops. Additionally, although participants enjoyed the participation at the workshops, I did not formally assess whether their involvement led to improved understanding of PAD, empowerment, and emotional wellbeing.

Finally, this booklet was co-designed for newly diagnosed patients with PAD, and it is not entirely relevant for patients with CLTI. Although it could be utilised by all patients with PAD, adjustments would have to be made for each disease stage.

7.5.4 Implications for future research

This study identifies several topics that should be further explored in future research. Future interventions should continue to embed patients as active partners throughout the research lifecycle. Given the limited use of co-design in vascular surgery, future studies should incorporate it in their methodology and explore its impact. Moreover, such studies should explicitly evaluate whether involvement in co-design improves patients' understanding of their condition, empowerment, and emotional wellbeing. Understanding these potential benefits would strengthen the use of co-design as a research method in vascular research.

Given the difficulty in identifying new participants for each workshop, future studies should focus on developing and testing more effective strategies to engage people with PAD in research and intervention development. There is a need to explore innovative and flexible recruitment approaches, including closer collaboration with primary and community care, and partner organisations, as well as enhanced support for transport and appropriate compensation of participants.

Finally, future research must move beyond intervention development to formally evaluate effectiveness. The PAD&Me booklet incorporates multiple theoretically informed BCTs, yet the extent to which these components influence adherence behaviours in PAD remains unknown. Rigorous evaluation studies, including feasibility studies and adequately powered effectiveness trials, are needed to assess which BCTs, or combinations of BCTs, are most effective in improving adherence outcomes. Such work will help refine intervention content and strengthen the evidence base for behaviourally informed, patient-centred interventions in PAD.

7.5.5 Next steps for this work

According to the PBA, once the intervention development phase is complete, the next steps include intervention optimisation and evaluation (162). The next stage of this work involves optimising the PAD & Me intervention through think-aloud interviews with newly diagnosed patients with PAD (described in Chapter 8), in line with the PBA approach. As discussed in Chapter 2, the time constraints of this PhD fellowship mean that the intervention has not yet been evaluated, however, this will be conducted in post-doctoral work.

7.6 Conclusion

This chapter describes the co-production of the PAD&Me adherence intervention. Through a rigorous, transparent process, key adherence influences were translated into a patient-centred educational booklet co-designed with patients, relatives, and healthcare professionals. The co-design approach ensured that the intervention was acceptable, relevant, and grounded in lived experience, while remaining aligned with evidence-based practice and behavioural theory. Patients valued clear language, engaging images, credible information, and supportive messaging, reinforcing the importance of designing interventions that are non-patronising and accessible. The inclusion of multiple BCTs reflects the complexity of adherence behaviour and the need for multifaceted solutions, particularly when addressing multiple behaviours. Although this work did not evaluate clinical effectiveness, it provides a strong methodological and theoretical foundation for future testing. Overall, this research demonstrates the value of co-produced interventions in PAD and underscores the importance of involving patients as equal partners in developing solutions to improve long-term adherence and outcomes.

Chapter 8. Intervention optimisation through think-aloud interviews

8.1 Chapter Summary

This chapter describes the optimisation of the PAD&Me booklet intervention through think-aloud interviews, in line with the Person Based Approach (PBA). Think-aloud interviews are valuable for eliciting immediate reactions to each intervention component and for observing its use in a real life context (158). The aim of think-aloud interviews is to gather detailed insights into the intervention's active ingredients and content, rather than focusing solely on its functionality and usability, which will then lead to intervention refinement from the target users' perspective before feasibility testing (158). This intervention was designed for newly diagnosed patients with PAD who are the target users.

8.2 Aims and Objectives

Aim: To user-test and assess the acceptability of a person-based, theory-informed behavioural intervention prototype to support patients with PAD with their treatment adherence.

Objective: To explore patients' responses to and perceptions of the intervention booklet to identify components that might require modification to maximise engagement, acceptability, and practicality.

8.3 Methods

8.3.1 Design

A think-aloud qualitative study, following the PBA guidance (162), was conducted using semi-structured interviews to observe and record participants' responses to the booklet's content.

8.3.2 Ethics

A substantial ethics amendment was submitted to the ethics application, under the qualitative study described in Chapter 4, to undertake this study (REC REF 24/WA/0075).

8.3.3 Participants

Patients for the think-aloud study were recruited following the same process as the qualitative study (see Chapter 4). Similar eligibility criteria also applied. The key difference in the eligibility criteria was the inclusion only of patients with newly diagnosed (<1 year) PAD, as the intervention was targeted to them. Additionally, none of the patients recruited to the think-aloud study had previously participated in the project, so they had fresh perspectives.

8.3.4 Sample size

Recruitment continued until no further changes in the intervention prototype were required. The sample size calculated was based on the PBA think-aloud literature (158, 379). It was anticipated that four to six patients would participate in each round of interviews to provide sufficient feedback, and that at least two rounds would be completed. Similar to the qualitative study in Chapter 4, a purposive, maximum variation sampling strategy of approximately 12 patients was planned to ensure a diverse group, enabling comparative analysis (258).

A varied patient sample aimed to include the following;
- Participants of different sociodemographic backgrounds (age, gender, ethnicity, socio-economic deprivation)
- Participants differing in levels of adherence. This was assessed via medical records and the screening questionnaire, as described in Chapter 4.

8.3.5 Procedure

This was an iterative process involving interviews with different patient groups to gain a detailed understanding of how they perceived and engaged with the intervention (158). This process helps ensure that the intervention is user-focused and engaging (158). The

think-aloud study was designed to gather feedback on the PAD&Me booklet intervention, rather than explore patients' perceptions and experiences of their condition. It was planned that different patients would participate in each of the two rounds. Iterations to the intervention were conducted between each round, based on the interview findings. The purpose of multiple rounds was to assess whether the refinements made following the previous round had successfully addressed the issues previously identified, hence, maximising the usability and acceptability of the booklet.

Participants were invited to take part in a single one-to-one interview to give their overall feedback about the PAD&Me booklet intervention. Interviews took place between October 2025 and November 2025, face-to-face or online via Microsoft Teams. Patients who took part in face-to-face interviews were shown the paper version of the booklet, whilst those who were interviewed online were shown the electronic, PDF version. Patients were allowed to keep the booklet version they used during the interview for their own use after the interview. Interviews lasted approximately 30 minutes and they were audio-recorded and transcribed verbatim. All patients received a £20 thank you voucher at the end of the interview.

8.3.6 Topic guide

The topic guide was developed in line with the research questions and the PBA. It asked patients for their immediate thoughts about the draft intervention and any feedback they wanted to share. The topic guide questions are presented below in Table 36.

Table 36 Think-aloud topic guide questions

Stage	Questions and Prompts
Think-aloud	• What are your first impressions? • What are you thinking now? • What made you choose that option? • What do you think about [this information]? • Can you tell me a bit more about why you think that? • What is it you like/don't like about that? • That's really interesting.....
Post think-aloud	• Overall, what do you think about the booklet?

	• Can you tell me about anything you thought was particularly good about the booklet? • Can you tell me anything about the booklet that you did not like as much? • What do you think should be changed or improved? • How do you think it would feel to get a booklet like this from your doctor or nurse? • How would you want to receive a booklet like this? Would you prefer someone to guide you through it, or would you rather read it at your own pace?

8.3.7 Patient and Public Involvement and Stakeholder Engagement

Patient and public involvement (PPI) was integral to this project, as the booklet was co-designed with patients with lived experience and their relatives. Similar to the qualitative study, the PPI group reviewed the topic guide to ensure the questions were easy to understand and to assess if changes were required.

Additionally, between rounds 1 and 2 of the think-aloud interviews, I met with the PPI and stakeholder group to discuss suggestions that conflicted with previously discussed ideas during the co-design workshops. Separate meetings were conducted with the PPI and stakeholder groups. These were conducted online on Microsoft Teams and lasted for an hour. I presented to them the PAD&Me booklet used in Round 1 and the suggested changes from the participants in the think-aloud interviews. The point of these meetings was to clarify any uncertainties about changes to the booklet's content.

8.3.8 Analysis

A rapid and practical approach was used to analyse the data, in line with the PBA (158). Field notes from the interviews and verbatim transcripts were reviewed in Microsoft Word to identify feedback and suggestions. Positive and negative feedback, as well as suggestions for improvement from the think-aloud interviews, were summarised in a table of changes. This iterative process enabled me to identify issues likely to influence

engagement and/or the effectiveness of the intervention and to track decisions about whether and how to implement modifications.

Changes were made between rounds and were coded as per the PBA coding framework (see Table 37) (158). The feedback was reviewed and assigned to categories based on its likely contribution to behaviour change, feasibility, alignment with guiding principles and frequency across participants (158). The changes were then prioritised based on the must-have, should-have, could-have, and won't-have (MoSCoW) criteria (158, 159). This model, widely used in intervention development, offers a simple, flexible way to focus on modifications most likely to influence usability and impact.

Not all suggestions were implemented; some were out of scope or not essential for achieving the intervention's aims. The table of changes, therefore, served as both a record of feedback and a transparent rationale for decisions made between rounds. Using this approach, the PAD & Me booklet was progressively refined, and any remaining suggestions for future improvement were clearly prioritised using MoSCoW.

Table 37 Coding framework following the PBA guidance (Adapted from Yardley et al., 2015) (158).

Coding framework		
Code	**Stands for**	**Means**
IMP	Important for behaviour change	This is an important change that is likely to impact behaviour change or a precursor to behaviour change (e.g. acceptability, feasibility, persuasiveness, motivation, engagement), and/or is in line with the Logic Model, and/or is in line with the Guiding Principles. For example, participants appear unconvinced by an aspect of the intervention, so you decide to add motivational examples.
EAS	Easy and uncontroversial	An easy and feasible change that doesn't involve any major design changes. For example, a participant was unsure of a technical term, so you add a definition.
REP	Repeatedly	This was said repeatedly, by more than one participant.
EXP	Experience	This is supported by experience. Please specify what kind of experience, for example: 1. PPIs agree this would be an appropriate change.

		2. Other stakeholders (e.g. practitioners, providers, topic specialists) agree that this would be an appropriate change. 3. Literature: This is supported by evidence in the literature.
NCON	Does not contradict	This does not contradict experience (e.g. evidence), or the Logic Model, or the Guiding Principles
NC	Not changed	It was decided not to make this change. Please explain why (e.g. it would not be feasible; or only one person said this).

8.3.9 Refinements between rounds

A recognised challenge in intervention development is that not all feedback from target users can be incorporated, largely due to financial and time constraints. Additionally, some of the feedback might be contradictory or not clinically appropriate/accurate. Acknowledging these challenges, intervention developers advocate establishing a cut-off point and clear prioritisation criteria to ensure that the development process remains both practical and transparent (158, 159). With that in mind, the PAD&Me booklet and the table of changes were reviewed by the supervisors to finalise the changes between rounds. To guide decisions on whether to amend specific intervention elements and the sequence of changes, a benchmark was set in line with the PBA and MoSCoW criteria (158, 159).

8.4 Results

Twelve patients were included, in two rounds of think-aloud one-to-one interviews. The think-aloud study was completed after the second round, as the study participants recommended no new suggestions of importance at that stage. The results of the interviews have been organised into changes that relate to specific pages or features of the booklet or to target behaviours.

8.4.1 Round 1

8.4.1.1 Participant characteristics

Six patients completed the first round of interviews, between the 2nd and 17th of October 2025. The participants' demographics and adherence levels are reported below in Table

38. Three patients were recruited from Imperial Healthcare NHS Trust and three from Glenfield Hospital, Leicester.

Overall, the six participants represented a diverse group with a fair representation of genders, ages and ethnic backgrounds. All patients had been diagnosed with PAD for less than 12 months. Most patients had previously undergone a surgical intervention for PAD and two of these had an intervention due to CLTI. Medication adherence varied across the group, with most patients not on optimal management and two not taking any medications. Smoking status also differed across the group, with four current smokers, one ex-smoker, and one never smoker. Regarding daily exercise, only two participants (P1 and P6) reported walking daily, while the remaining four did not.

Table 38 Think-aloud interview Round 1 participant characteristics.

ID	Gender	Age	Ethnicity	CLTI	Previous Intervention	Medication adherence	Smoking status	Meeting activity goal
TA-P1	Female	73	White - Other	No	No	High	Never	Yes
TA-P2	Male	70	Other	No	No	Does not take any medications	Current	No
TA-P3	Male	75	White British	No	Yes	Not optimised for statins	Current	No
TA-P4	Male	65	South Asian	Yes	Yes	Not optimised for statins	Ex-smoker	No
TA-P5	Male	70	White - Other	Yes	Yes	Does not take any medications	Current	No
TA-P6	Female	69	Other	No	Yes	Not on statins	Current	Yes

8.4.1.2 Booklet feedback

A detailed description of the findings is presented below, in the form of quotes. The positive and negative feedback from the first round of the think-aloud study is

presented in Appendix 7, Table 7.1. Table 39 in section 8.4.3 presents all agreed changes for the booklet.

8.4.1.2.1 Overall impressions and design

The overall response to the PAD&Me booklet was encouraging, as all participants believed that engaging materials would be beneficial for people with PAD. All participants found the language used simple to understand and the overall information being the right amount.

"This is excellent! Can I keep it? You know after I left the doctor, I got nothing, I was just left, so I am pleased something like is now available!" (TA-P 1)

"This is just brilliant. Everything you need to know, not too much text, simple language, it's like talking to your friend." (TA-P3)

However, one patient seemed concerned that this booklet might be used to replace clinical appointments.

"I guess, yes, it can be useful, it has a summary of everything you need to know. But is this now a way to not see the doctor? Don't get me wrong, it's good stuff, but I just want to discuss this with someone who knows what they're doing, I am not the doctor." (TA-P5).

Regarding the overall design and graphics, most people were happy with the prototype version. They all liked the A5 booklet style and most patients were positive about the current colour scheme, with only one patient commenting that the use of red was alarming. All participants wanted the text to be bigger to ensure that it was readable for individuals with visual problems.

"I really like the blue, it's calming and it reminds me of the NHS. The colour scheme works well." (TA-P4)

“The red tones make me think something is wrong, it’s like a red traffic light.” (TA-P5)

“The text is too small. For older people or anyone with visual problems, it’s a bit hard to read.” (TA-P1)



Figure 37 Round 1, Front and content pages

Most participants liked the cover page and found the picture positive and encouraging (see Figure 37).

“I like the title PAD & Me, because at the end of the day, it is about me.” (TA-P6)

“Looking at this photo and the people smiling makes me wanna walk again.” (TA-P4)

However, one patient, who recently experienced CLTI did not share the same feelings regarding the photo.

“This photo doesn’t represent people like me. Everyone in it looks happy and walking, but I feel stuck because of my toe amputation and my mental health. Seeing others

smiling isn't helpful, it just makes me feel misunderstood, almost as if the image assumes I'm not aware of my own situation or undermines my intelligence." (TA-P5)

Regarding the contents page (see Figure 37), all patients found it useful and did not wish to make any changes.

"Everything on this page is useful. It's great having all the important vascular numbers in one place." (TA-P2)

8.4.1.2.2 Information about PAD

As for page 3 (see Figure 38), all patients found the information and the photo useful, and some made suggestions for improvement.

"The information is easy to follow. The picture is helpful. I only understood what PAD actually is after seeing this, so it's really useful." (TA-P1)

"Hmm, after you explained the photo, I only then fully understood it. I think you should make it very clear, for people like me, that has never visualised what a blockage looks like. You should add some text next to the image and spell out blockage." (TA-P2)

Specifically, although most patients agreed it was important to include the information about surgical intervention, one felt it was not appropriate as it should be included within a discussion between patients and doctors.

"It's important to include this [surgery]. People assume surgery fixes everything, and trust me, I've been there. So this helps set realistic expectations." (TA-P3)

"Talking about surgery here doesn't feel appropriate. That should come from a doctor, not from a booklet. You should remove it." (TA-P5)



Figure 38 Round 1, Pages 3 and 4

8.4.1.2.3 Medications & PAD

As for pages 4-5 (see Figure 38 and 39), most patients found this section useful, and some offered suggestions for improvement, such as adding information about free prescriptions for diabetics. When prompted, other patients also agreed that this would be useful. Some patients also adding pharmacists as relevant healthcare professionals to talk to about medication and not limit it to doctors and nurses.

"The wording is really clear and encouraging. I like the photo and the section about making meds easier to take, especially the Dosette box idea." (TA-P4)

"The last sentence needs to be clearer, so we know it's still talking about medication." (TA-P6)

"As I'm diabetic, I get my prescriptions for free. So maybe you could add something about it there, be mindful of the cost of living." (TA-P1)

“Yeah, so maybe you can add here about pharmacists too. Especially in the community and in many medical practices, now pharmacists do your medication review, I know mine does. So I think it's a good inclusion.” (TA-P6)

However, patients who were not taking their medications or who were not on statins had mixed feelings when reading the booklet.

“The wording is clear, but I don’t know if I am ready yet to start taking tablets every day. Reading this is encouraging, but I also thought that taking medications would make me feel better, and you’re saying it won’t?” (TA-P2)

“So, as you know, I am not taking statins because I have a healthy diet, I am slim, I exercise daily, so I am not convinced I need them. I must say that the information here is really good and makes me double-think about restarting my statins.” (TA-P6)

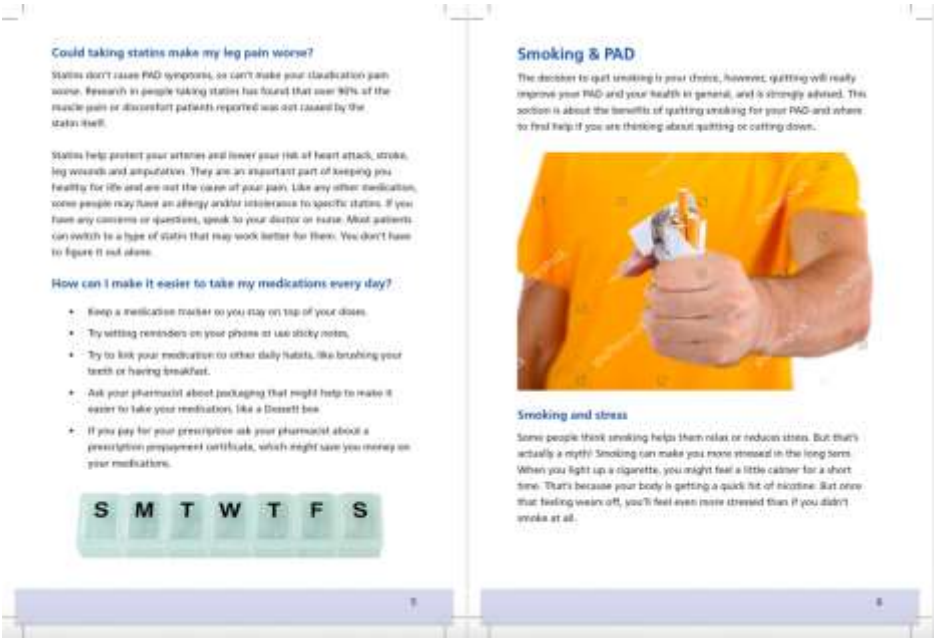


Figure 39 Round 1, Pages 5 and 6

8.4.1.2.4 Smoking & PAD

Regarding pages 6-8 (See Figure 39 and 40), patients shared mixed feelings. Overall, patients found the language simple, encouraging, and not patronising. However, patient TA-P1, who was a never-smoker, felt that she was unable to fully comment on

this section as it was not relevant for her, although she agreed it was necessary to have a section about smoking. The four current smoker patients who took part in the study suggested improvements to this section. All four liked the suggestion to cut down, but they felt the image was not impactful enough and that the paragraph about stress was not representative. The patient who previously quit smoking (TA-P4) also agreed with the above suggestions.

"I guess because I'm coming from being a smoker, I'm all for encouragement. I like that it talks about cutting down instead of just quitting. It's great, supportive, it doesn't make you feel judged." (TA-P6)

"The stress paragraph doesn't really say much. Smoking for me is just a long term habit, not about stress." (TA-P3)

"The triggers section really made me think about my smoking habits." (TA-P2)

"Oh yes, perfect, you have the NHS information here and the phone number. It's good, people can read about it, they're in the moment, thinking about cutting down, the NHS number is there, you have to take advantage of the opportunity." (TA-P6)

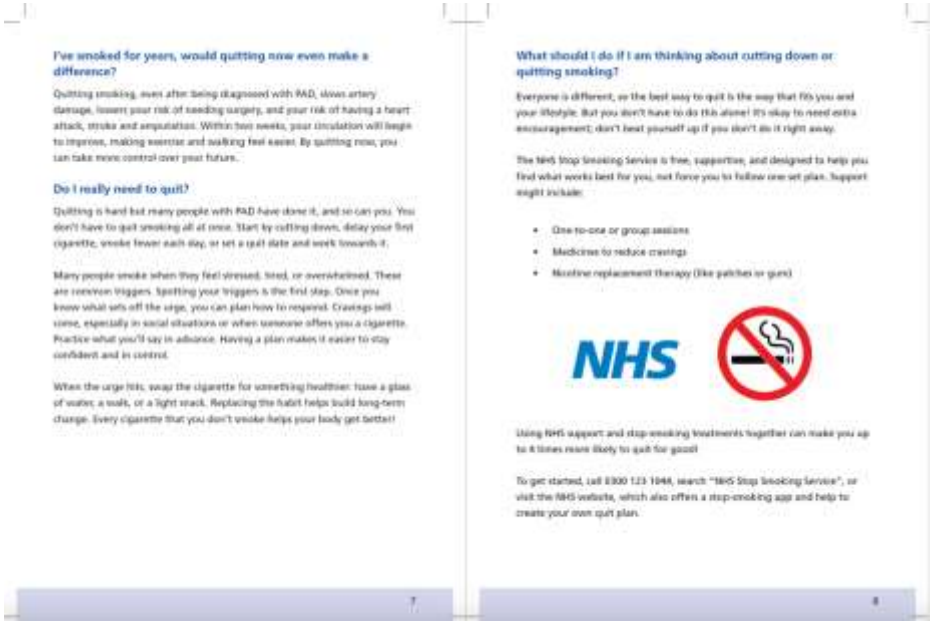


Figure 40 Round 1, Pages 7 and 8

None of the current smoker patients liked the photo. A patient suggested an alternative image, and then I specifically asked the other patients what they thought about that suggestion. They agreed it could be a good suggestion and more impactful for quitting smoking.

"The photo doesn't motivate me to stop smoking, it looks like someone offering a cigarette and I am not going to say not to them." (TA-P2)

"You know what you could do? Here, where you talk about the benefits of smoking in the body, you could add that in a figure. Like I know that I'm supposed to quit to help with my circulation, but I think that if I had a visual timeline, showing me what will happen to my body after I quit would be great. Yes, it would make me think twice about lighting a cigarette." (TA-P3)

"Oh, yes. I wasn't aware of that, but that would be useful [timeline of smoking cessation] because it would be more explanatory and more visual." (TA-P4)

"To me, the photo looks like someone is crushing a pack of cigarettes, but I guess the intention could be made clearer. It's not really doing anything for me. But I think that suggestion about the timeline of quitting could be a good replacement. You need to make it visual." (TA-P5)

8.4.1.2.5 Physical Activity & PAD

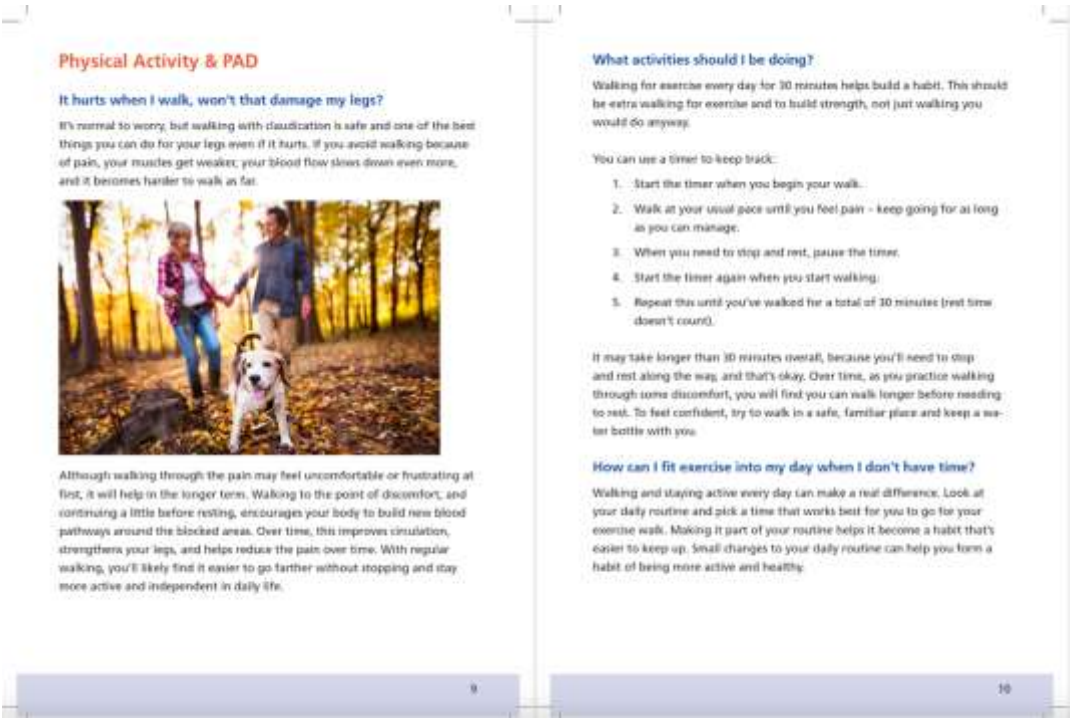
Specifically for pages 9-11 (see Figures 41 and 42), Physical Activity & PAD, most patients found this section useful. One patient stressed the importance of highlighting that walking with claudication pain is not harmful, and gave a suggestion on how to improve the flow of the text.

“I just really this section and I like the photo of the dog, it’s something happy. I really like the guide about walking for exercise, I haven’t seen that before so it’s definitely something I will be doing.” (TA-P1)

“I think it's important to stress that, you know, that walking through the pain is not harmful.” (TA-P6)

Some patients also reported receiving mixed information about walking frequency, and that 30 minutes of daily walking might be overwhelming for those who were really struggling with claudication.

“Walking every day for 30 minutes can be quite a challenge for some people, myself included. Maybe say the goal is to do that, but we understand it will take a while. That’s more encouraging, I think.” (TA-P2)



Physical Activity & PAD

It hurts when I walk, won't that damage my legs?

It's normal to worry, but walking with claudication is safe and one of the best things you can do for your legs even if it hurts. If you avoid walking because of pain, your muscles get weaker, your blood flow slows down even more, and it becomes harder to walk as far.

Although walking through the pain may feel uncomfortable or frustrating at first, it will help in the longer term. Walking to the point of discomfort, and continuing a little before resting, encourages your body to build new blood pathways around the blocked areas. Over time, this improves circulation, strengthens your legs, and helps reduce the pain over time. With regular walking, you'll likely find it easier to go farther without stopping and stay more active and independent in daily life.

9

What activities should I be doing?

Walking for exercise every day for 30 minutes helps build a habit. This should be extra walking for exercise and to build strength, not just walking you would do anyway.

You can use a timer to keep track:

1. Start the timer when you begin your walk.
2. Walk at your usual pace until you feel pain – keep going for as long as you can manage.
3. When you need to stop and rest, pause the timer.
4. Start the timer again when you start walking.
5. Repeat this until you've walked for a total of 30 minutes (rest time doesn't count).

It may take longer than 30 minutes overall, because you'll need to stop and rest along the way, and that's okay. Over time, as you practice walking through some discomfort, you will find you can walk longer before needing to rest. To feel confident, try to walk in a safe, familiar place and keep a water bottle with you.

How can I fit exercise into my day when I don't have time?

Walking and staying active every day can make a real difference. Look at your daily routine and pick a time that works best for you to go for your exercise walk. Making it part of your routine helps it become a habit that's easier to keep up. Small changes to your daily routine can help you form a habit of being more active and healthy.

10

Figure 41 Round 1, Pages 9 and 10

Regarding tips about fitting exercise into daily activities and exercising during adverse weather, most patients found the suggestions useful. Some patients also suggested potential amendments to improve the booklet.

“These are really useful tips. Just a few small typos need correcting.” (TA-P1)

“Fitting exercise into your day can be hard. I think you should add a few more practical examples, like if you're regularly travelling somewhere and get off the bus a stop earlier, or something like that. So some examples, I think, so that because if you were saying, I don't have time, well, these are kind of possibilities to consider.” (TA-P4)

“I feel like it might not be clear for everybody. So I mean, I know what chair exercises are, but I don't think we should assume that. So maybe we should, instead of having that exercise bike, you could potentially have, an example of a chair exercise, everyone knows what a bike is.” (TA-P6)

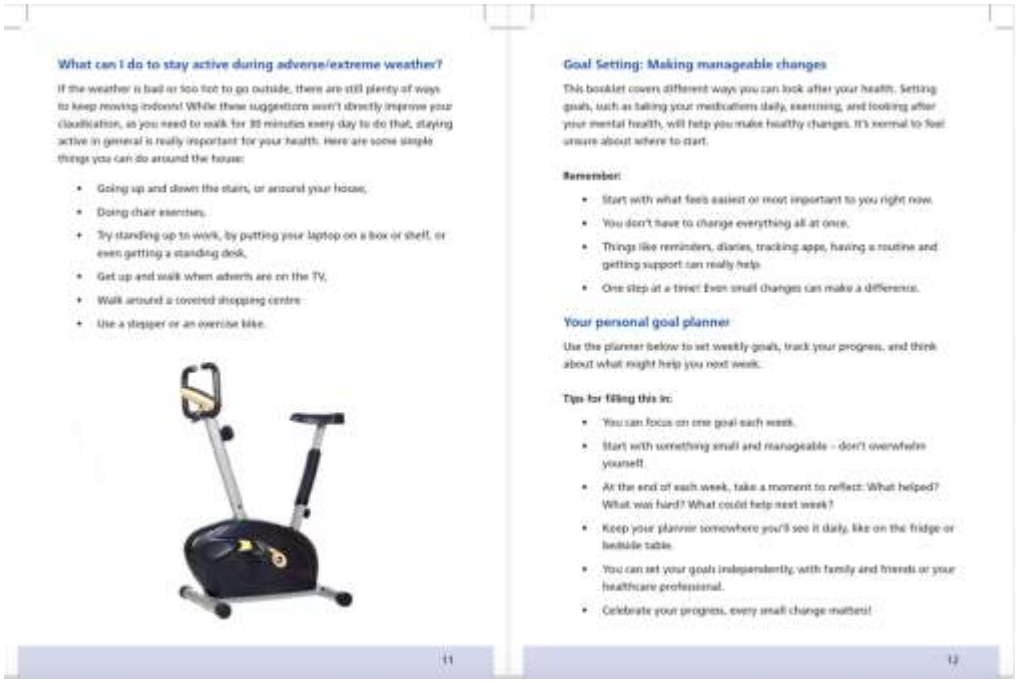


Figure 42 Round 1, Pages 11 and 12

8.4.1.2.6 Goal Setting

All patients found pages 12-14 (see Figures 42 and 43) really encouraging. They particularly liked the concept of setting small, realistic goals and they found the table useful.

“This table is so helpful. I’m thinking of cutting it out for my fridge. The suggestion about cutting down cigarettes is really useful, you know it makes me think that I can do it.” (TA-P3).

“All the examples make sense, it covers all the real-life things we deal with.” (TA-P1)

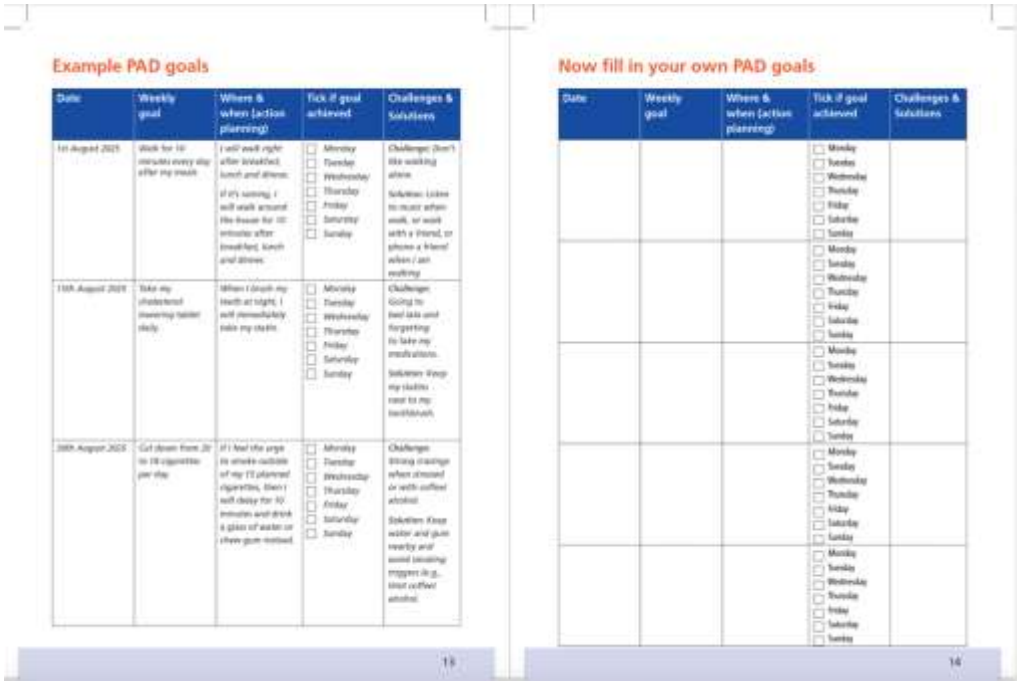


Figure 43 Round 1, Pages 13 and 14

8.4.1.2.7 Support resources

Regarding the support resources (see Figure 44), all patients found them useful. However, two recommended including information about red flags and CLTI.

“I didn’t know about some of these resources before. The mental health support is especially helpful.” (TA-P4)

“There should be something about recognising CLTI and what to do. That information is missing.” (TA-P5)

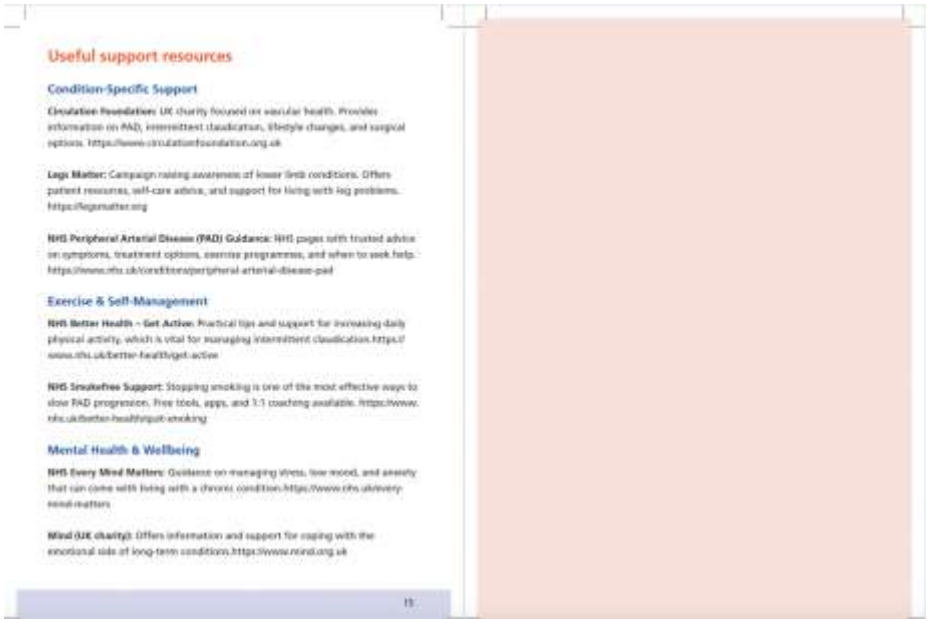


Figure 44 Round 1, Page 15

8.4.2 PPI and Stakeholder feedback following Round 1

The PPI (n=4) and stakeholder (n=5) groups were consulted following Round 1. Specifically, we focused on the following topics:

A) **Changing the cover photo** to specifically show an amputee, like the PAD Awareness National Gallery photos. Both stakeholders and the PPI group suggested that this would not be appropriate, given that the booklet is designed for newly diagnosed patients with PAD.

B) **Removing the information about surgery for PAD.** Both groups agreed that it was important to have this information, given the perception about a quick fix through surgery being a strong barrier for adherence to pharmacotherapy and lifestyle changes.

C) **Adding information about CLTI**. Both groups agreed that this would be a good addition to the support resources and we should have a separate page about red flags. Following this, I then contacted the Society of Vascular Nurses (SVN) to discuss adopting the SVN CLTI Patient information (https://svn.org.uk/wp-content/uploads/2025/02/SVN-RING-POSTER.pdf). We agreed to maintain the

same language, to avoid confusion and ensure that patients receive the same message from different sources.

8.4.3 Refinement of intervention between Round 1 and Round 2

As most recommended suggestions were easy to implement and aligned with the intervention's logic model, it was agreed to make most of the changes to ensure the intervention was engaging (see Table 39). The changes to the front page and PAD & Surgery were not altered following feedback from the PPI and stakeholder group. Regarding the recommended colour scheme change, although this was not directly amended in the booklet, a page with a different colour scheme was created, and patients were asked for their preference in the Round 2 interviews. The same approach was employed for the smoking cessation photo; participants were shown an updated version, as well as the photo from Round 1 and asked to vote for their preference. This version was further evaluated by a new group of patients, as described in the subsequent section.

Table 39 Agreed changes following Round 1 of interviews

	Intervention element	**Possible Change**	**Reason for change**	**MoScoW**	**Agreed change / Not changed**
1	Front page	Change front page photo & colour scheme. P5 suggested that we have a photograph of an amputee and not have "actors".	NCON	C/W	Not changed
2	Overall booklet	Make the text bigger	EAS, NCON	M	Agreed change
3	Colour scheme	Suggestion to have a warm pink or a lavender colour, as these colours are liked by most people and are associated with	NCON	C/W	Not changed

		calmer thoughts and feelings.			
4	PAD – Page 3	Move photo after 1st paragraph so it flows better. Add text about blockage in the photo.	REP, EAS, NCON	M	Agreed change
5	Meds & PAD – Page 4	"Even though you may not feel the effect of the medications physically, knowing you're actively preventing something serious, can bring peace of mind." *	EAS, NCON	C	Agreed change
6	Meds & PAD – Page 5	"If you have any concerns or questions, speak to your doctor, nurse or pharmacist." *	EAS, NCON,	C	Agreed change
7	Meds & PAD – Page 5	Rephrase 2nd bullet point: post-its instead of sticky notes	EAS, NCON	C	Agreed change
8	Meds & PAD – Page 5	Add an extra bullet point "If you are diabetic, speak to your pharmacist / ask your pharmacist about a medical exemption certificate to get your prescriptions for free" – or something along these lines	EXP, EAS,NCON	C	Agreed change
9	Smoking & PAD	Replace that photo or add an extra one showing the timeline of quitting smoking and the benefits for the body (P3). Simple facts in non jargon language. We have a sentence about it in the text but patient thinks it would be really useful to also have that in a visual format. If this photo is added it should go in page 7, after the relevant	IMP, REP	M	Agreed change

		text “I’ve smoked for years, would quitting now even make a difference?”			
10	Smoking & PAD	Re-organise section about do I really need to quit smoking.	EAS, NCON	S	Agreed change
11	Exercise – page 9	“Although walking through the pain may feel uncomfortable or frustrating at first, it is not harmful and it will help in the longer term.” *	EAS	M	Agreed change
12	Exercise – page 11	1)Change to “Here are some simple things you can do home or indoors” 2)Move bullet point 5 to last and make sure there are commas, full stops in the right places	EAS, REP	M	Agreed change
13	Exercise – page 11	Replace photo of bike with someone doing a chair exercise.	EAS, IMP, NCON	S	Agreed change
14	Goals Table – Page 13	Correct typo.	EAS, NCON, REP	M	Agreed change
15	Support resources	Add a separate page about CLTI – adopt SVN RING poster	IMP, REP, EXP	M	Agreed change

*The highlighted text represents the changes in the text suggested by participants

8.4.4 Round 2

8.4.4.1 Participant characteristics

Six new patients (different from Round 1) completed the second round of interviews, between the 4th and 19th of November 2025. The participants’ demographics and adherence levels are reported in Table 40 below. Five patients were recruited from Imperial Healthcare NHS Trust and one from Mid Yorkshire NHS Trust.

Variability in gender, age, and ethnic background was present. All patients were newly diagnosed with PAD (for less than 12 months). In this cohort of patients, no one had previously experienced CLTI. Regarding medication adherence, three patients were highly adherent, and three patients were not optimised for statins. In terms of smoking status, one patient never smoked, two were current smokers and three ex-smokers. Finally, most patients reported walking daily.

Table 40 Think-aloud interview Round 2 participant characteristics

ID	Gender	Age	Ethnicity	Previous CLTI	Previous intervention	Medication adherence	Smoking status	Meeting activity goal
TA-P7	Male	76	Other	No	No	High	Ex	Yes
TA-P8	Male	86	White British	No	Yes	High	Ex	No
TA-P9	Male	79	South Asian	No	No	Not optimised for statins	Current	No
TA-P10	Male	71	White British	No	No	Not optimised for statins	Recent ex-smoker	Yes
TA-P11	Female	54	White British	No	Yes	High	Current	Yes
TA-P12	Female	64	Other	No	Yes	Not optimised for statins	Never	Yes

8.4.4.2 Booklet feedback

A detailed description of the findings is presented below, in the form of quotes. The positive and negative feedback from the second round of the think-aloud study is presented in Appendix 7, Table 7.2. Table 41 in section 8.4.6 presents all agreed changes for the booklet.

8.4.4.2.1 Overall impressions and design

The reaction to the second version of the PAD & Me booklet was positive, and overall, no suggestions were made to change its contents. All participants found the booklet engaging and encouraging.

“I really like the front page, the title, the colours, the photo, the smiling faces, the diversity. It feels encouraging, and it makes the booklet feel more welcoming.” (TA-P7)

“I think, yeah, I think it's so important to have as much information out there, because there is so little. I actually had to go online, and you know, when I first got the diagnosis, because it made no sense to me.” (TA-P9)

8.4.4.2.2 Information about PAD

The participants liked the information about PAD (see Figure 45) and found the updated photo diagram useful.

“Yeah, it's accurate and concise. All the information you need to know. It's just advised on what you should do. Take your medication, do exercise, follow a healthy lifestyle. It also explains that surgery is not the solution, so you have definitely done a good job here. I wouldn’t add anything else.” (TA-P8)

“I've come to realise that, you know, there's no fast fix for claudication..It's something that you're going to be living with. This booklet really touches upon that.” (TA-12)

One patient suggested re-designing the image on Page 3 to make it more illustrative and vibrant.

“The colours look a bit muted, could you make them more vibrant and make the figure more professional?” (TA-P10)

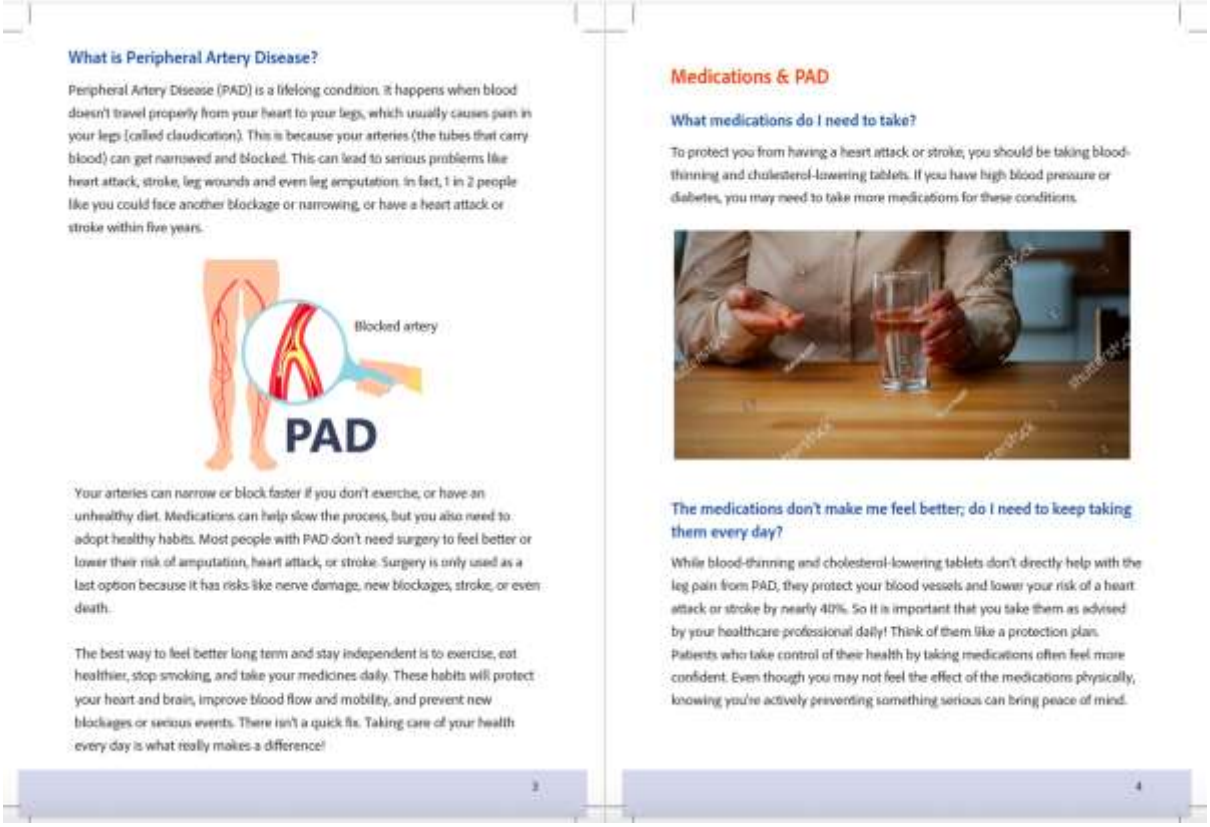


Figure 45 Round 2, Pages 3 and 4

8.4.4.2.3 Medications & PAD

All participants found the medication & PAD section (see Figure 45 and 46) useful and did not wish to change anything.

"The photo is nice, the text is easy to follow, I don't think there's a need to change anything here." (TA-P7)

"I like that you have here as well that if you have other conditions, you may need to take more tablets, because most of us do, and everyone is different." (TA-P8)

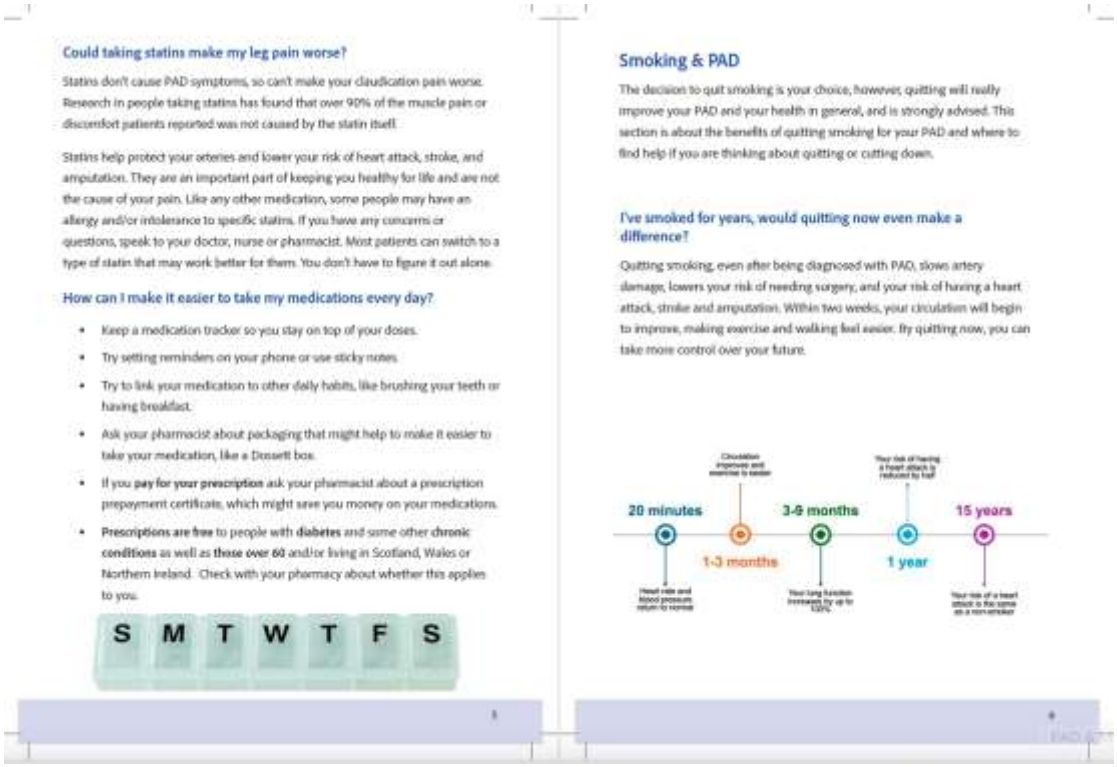


Figure 46 Round 2, Pages 5 and 6

8.4.4.2.4 Smoking & PAD

Regarding the smoking section (see Figure 46), all patients found it useful, and some suggested that the figure (smoking timeline) be improved so it was more engaging compared to the previous image used in Round 1.

"I like that it talks about cutting down, not just quitting." (TA-P11)

"The text in the image (smoking timeline) is a bit small, it could use some polishing." (TA-P8)

8.4.4.2.5 Exercise & PAD

All participants found the section encouraging to keep walking and the practical tips useful.

“All the information is helpful and encouraging; it makes me feel like walking won’t be harmful and this is something that I have really been worrying about.” (TA-P10)

8.4.4.2.6 Goal setting

The goal-setting section was useful for most patients. One patient felt it was not exactly relevant to them as they already had a daily routine, but they felt it was encouraging and did not think it should be removed or altered.

“This doesn’t really apply to me because I’m already very organised, but it’s reassuring to know I’m doing the right things, and it will help people who don’t have a routine.” (TA-P11).

8.4.4.2.7 Information about CLTI and support resources

Regarding the newly added section about CLTI (page 14) (see Figure 47), although most patients thought it was helpful to know about adverse events and how to recognise if they were developing CLTI, some felt that it was very concerning as they had not discussed this information with their clinicians.

“It’s great information, but it can be a bit alarming. I didn’t know about this before, and I am quite concerned.” (TA-P11)

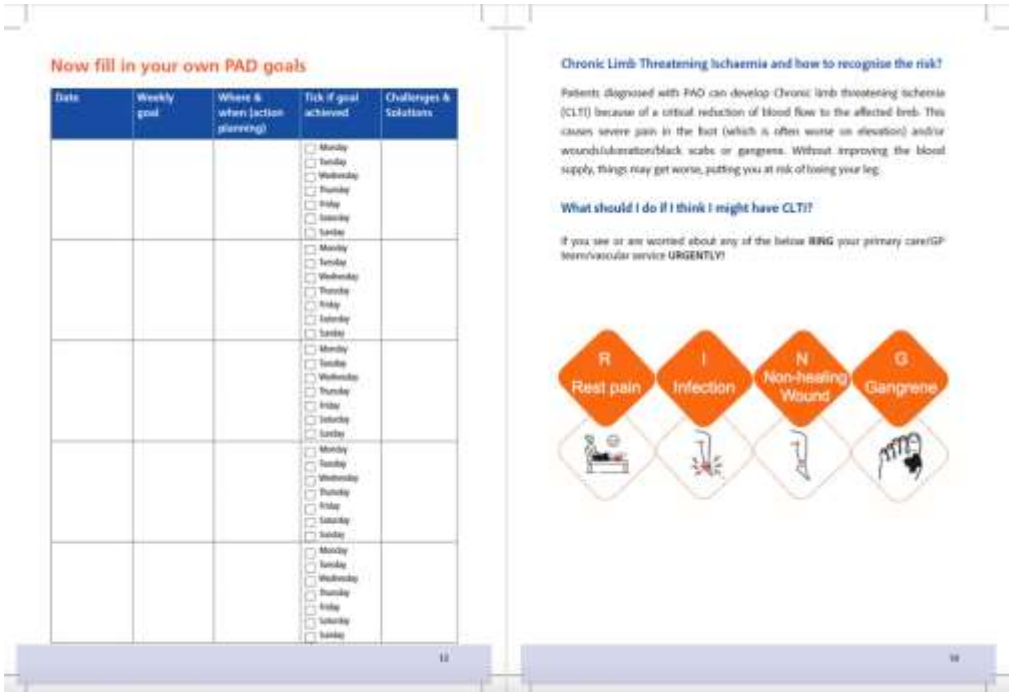


Figure 47 Round 2, Pages 13 and 14

Finally, all patients found the support resources useful and felt that all the necessary information was included.

"I really like all the resources, especially the ones about mental health and healthy eating." (TA-P8)

8.4.5 PPI and Stakeholder feedback following Round 2

Similar to the PPI and stakeholder meetings following Round 1, the groups met to discuss the findings of Round 2 interviews. Both groups agreed with the recommended changes and felt that the booklet was now ready for utilisation in clinical practice. Additionally, we specifically discussed amending the information about amputation and CLTI to make it less alarming. Both groups agreed that we should not amend the language in this section, as this could confuse patients who receive different message from different sources. Regarding changing the word "amputation," this was discussed at length during the co-design workshops. The overall agreement following the co-design workshops and the PPI and stakeholder groups was to keep the word "amputation" as all patients should be informed about it, given the high rates of CLTI.

8.4.6 Refinement of intervention following Round 2

Following the PPI and Stakeholder meetings, I presented the table of changes to my supervisors. As most of the recommended suggestions focused on the booklet's graphic design, it was agreed to implement them according to patient feedback (see Table 41). As all involved parties felt it was not necessary to make further amendments to the intervention, the study was concluded. To prepare the final version of the booklet, I collaborated with a graphic designer to ensure it looked professional and included high-resolution photos and graphs. The final version of the PAD&Me booklet is shown in Appendix 8.

Table 41 Agreed changes following Round 2

	Intervention element	**Possible change**	**Reason for change**	**MoScoW**	**Agreed change / Not changed**
1	Overall booklet	Make the text bigger	EAS, NCON	S	Agreed change
2	PAD- Page 3	Change “amputation” to a less scary word.	-	-	Not changed
3	PAD – Page 3	To update figure	EAS, NCON	M	Agreed change
4	Smoking & PAD – Pages 6&7	To update figure	EAS, NCON	M	Agreed change
5	Exercise – Page 8-10	Suggested change: “Use a stepper, an exercise bike or a treadmill”. Correct typo.	EAS	C	Agreed change
6	CLTI – Page 14	The wording is alarming, consider softening it.	-	-	Not changed

8.5 Discussion

8.5.1 Main findings

A co-produced multicomponent behavioural intervention to facilitate PAD treatment for newly diagnosed patients with PAD was optimised through patient user-testing. The findings from the think-aloud studies 1 and 2 were used to optimise the intervention. Although most suggested changes were easy to implement and aligned with the intervention's logic model, some were not adopted because they were inconsistent with clinical guidance. Specifically, the suggestions that were not implemented were i) removing the text about surgical interventions; ii) removing the text about amputation; and iii) including a photo of an amputee on the cover page. Overall, patients reported that the PAD&Me booklet intervention was acceptable, engaging and motivating for newly diagnosed patients with PAD. All patients found the information useful, effective for behaviour change and the language clear, patient-friendly and encouraging. The intervention also ensured that patients had all the resources they needed for PAD management, including medications, smoking cessation, exercise, how to recognise signs and symptoms of CLTI and support resources. Following each think-aloud interview round, the intervention was further discussed with PPI and stakeholder groups to ensure its acceptability. From a clinical perspective, the intervention was consistent with current clinical guidance to optimise patient safety. Below, the findings are discussed in relation to the broader literature.

8.5.2 Findings in relation to wider literature

Employing a think-aloud strategy is a novel, efficient and systematic way to rapidly analyse qualitative data during the intervention optimisation process and make acceptable modifications to the intervention. Although this methodology has not been previously used in vascular surgery, studies that have used the PBA for multiple conditions, including hypertension management (380) and postpartum blood pressure self-management (381), have identified that think-aloud interviews are an effective way to improve the acceptability, credibility, and persuasiveness of interventions.

The PAD&Me booklet was designed to complement routine vascular care, acting as a tool that nurses, vascular surgeons, physiotherapists, and podiatrists could integrate into consultations for newly diagnosed patients with PAD. The intention was that clinicians could introduce the booklet, and patients would then use it independently at home to reinforce key messages about treatment, address misconceptions, practise goal-setting, and reflect on their progress. This model is consistent with evidence showing that self-management education interventions, particularly those that are interactive rather than purely informational, can improve health behaviours by strengthening motivation and problem-solving skills (382). Unlike traditional educational materials, self-management interventions encourage patients to identify their own challenges and adopt feasible strategies to address them. Additionally, a previous review of psychological interventions for newly diagnosed patients found that education, problem-solving, and goal setting are essential techniques to support patients in navigating this journey in their lives and adjusting to the new reality of living with a chronic condition (383).

Patients in our study reported that the PAD&Me intervention is acceptable and has the potential to facilitate behaviour change for medication, exercise uptake, and smoking cessation. A previous Cochrane review identified that mixed educational and behavioural interventions may increase treatment adherence (384). However, as presented in Chapter 3, existing multicomponent interventions for patients with PAD are not effective, and only two studies have assessed acceptability from a patient perspective.

Two recent studies have evaluated interventions to improve health behaviours in patients with PAD. The co-designed Textpad telehealth counselling and remote exercise intervention was effective in addressing patients' concerns and improving their understanding of PAD (215). Similarly, the qualitative evaluation of the FASTIC nurse-led surgical follow-up for PAD intervention showed that the intervention was effective in increasing patients' awareness of PAD-related health behaviours, such as physical activity and smoking (214). The FASTIC study also highlighted that the patients found the intervention to be effective in increasing their motivation for behaviour change

(214). The Textpad study found that many patients with PAD preferred home-based exercises, due to convenience, easier access and mobility issues (215). Patients in the current study also indicated that the indoor exercise tips were particularly useful.

Although clinical guidelines for PAD emphasise the importance of patient education, adherence and self-management support, these approaches are not routinely implemented in practice. Yet several systematic reviews indicate that self-management interventions can improve confidence, symptom management, and engagement across long-term conditions (219, 233, 235-237, 382).

Regarding the format of the interventions, patients in this study found the booklet format acceptable. Adherence and self-management interventions delivered via booklets have been particularly well-received across diverse patient populations (370, 385, 386). Currently, in vascular surgery, there is a growing trend to design and deliver digital interventions. However, the Textpad tele-intervention stressed that while most participants managed the digital technologies well, several experienced issues with devices, connectivity, or using Zoom, relying on family, friends, or programme staff for support. This reflects broader evidence that access to technology alone is insufficient; digital literacy and social support strongly influence engagement (215).

Previous qualitative research also suggests that the success of booklet interventions depends on patients' beliefs about their condition and the perceived usefulness of the material, as well as clinicians' endorsement (385). Patients who viewed their illness as untreatable or doubted the relevance of the resource were less likely to engage with it. Similarly, lack of clinician encouragement reduced uptake. This highlights the importance of designing interventions that directly target patient concerns, of involving stakeholders early in the development process and of working with clinicians to embed booklets into usual practice.

This conclusion was reinforced in the PAD&Me development. Involving vascular patients and clinicians from the earliest stages led to concrete design improvements and greater acceptability. Patients shaped the tone, layout, and clarity of the content,

for example, requesting larger text, clearer diagrams, and reassurance around potentially alarming topics such as amputation risk. Clinicians expressed interest in adopting PAD&Me in their practice and recognised its potential to fill a gap in accessible PAD-specific information. Their engagement is likely to support the intervention's uptake and implementation into regular clinical practice.

Overall, the PAD&Me project demonstrates that a carefully designed, interactive, and user-informed self-management booklet could play a valuable role in supporting behaviour change in people with PAD. By addressing both perceptual and practical barriers and grounding the intervention in evidence-based behaviour change methods, the final booklet has strong potential to be implemented successfully into routine vascular care.

8.5.3 Strengths and limitations

A key strength of the PAD&Me booklet intervention was its systematic, theory-informed approach throughout the process. To my knowledge, no previous PAD self-management or adherence-focused intervention has used the PBA and the PaPa frameworks. The study followed the PBA methodology and the MoSCoW criteria to prioritise realistic and feasible changes, focusing on designing a user-focused intervention. This allowed me to explore engagement challenges and better understand acceptability across different patient groups. Feedback was gathered from individuals who had not been previously involved in this study and were all newly diagnosed with PAD. This allowed me to gain fresh perspectives and a broad understanding of potential barriers and limits of the PAD&Me booklet.

The choice to use a booklet as the main mode of delivery offered several advantages, such as low cost and ease of distribution, but also had limitations. Some patients may not engage with written materials, and those with lower health literacy may find the content challenging. Specifically for this PhD study, low health literacy was identified as a medium-priority influence on adherence during the data triangulation process (Chapter 6). With that in mind, the booklet used very simple language and visual

representations to ensure that patients with low literacy could engage with the intervention. However, it should be noted that I did not use a reading age software to ensure the language used is simple enough. Additionally, because the booklet is intended for use during the first PAD appointment in secondary care, clinicians involved in delivery may require training in BCTs, which adds to resource implications.

Another limitation is that I have led both the intervention development and optimisation studies, which may have influenced the findings. To reduce my individual bias and enhance reflexivity, I actively invited both positive and negative feedback, carefully worded interview questions, kept detailed field notes, and discussed emerging insights with the wider research team. Moreover, although patients were encouraged to offer their honest opinions and feedback, and the intervention received both positive and negative feedback, some participants may not have been transparent and could have provided socially desirable answers.

Regarding the sample, it was mainly from London, although efforts were made to recruit participants from the other collaborating NHS sites. This may limit transferability to other regions. Finally, although participants in the second round did not identify major new issues, this version of the PAD&Me booklet should not be considered definitive, as further refinement may be needed before being tested in wider clinical settings.

8.5.5 Implications for clinical practice

The stakeholder and the PPI groups have advised using the PAD&Me booklet during the initial diagnosis appointment, with input from the vascular clinicians. The booklet could potentially be utilised in primary care consultations; however, it was stressed that an experienced clinician, familiar with the condition, should present the booklet and be able to answer any questions the patients might have.

8.5.6 Implications for future research

The focus of this study was to gain patients' immediate thoughts regarding the intervention. Hence, we were unable to explore their experiences of the intervention within usual clinical practice. Moreover, clinicians' experiences of implementing the booklet were not assessed. This would be a vital next step to assessing the acceptability and feasibility of using the PAD&Me intervention in reality. Future researchers can adapt or extend this think-aloud approach across populations, delivery formats, and outcome targets, and examine how specific development steps enhance intervention quality and engagement.

8.6 Conclusion

This study described the optimisation process of PAD&Me, a co-designed booklet designed to support newly diagnosed patients with PAD. Through two iterative Think-Aloud studies, refined with input from PPI and clinical stakeholders, the intervention was adapted to improve usability and acceptability. Newly diagnosed patients with PAD found the PAD&Me booklet helpful, simple and encouraging for understanding PAD and supporting adherence to medications, exercise uptake and smoking cessation. Therefore, the PAD&Me booklet intervention represents a meaningful contribution to improving patient education and behavioural support in vascular care.

Chapter 9: Discussion, Implications and Conclusions

9.1 Chapter summary

In this chapter, I discuss the overall contribution of the thesis, synthesise findings across the individual studies, and reflect on what they reveal about improving adherence in PAD. Additionally, I present implications for future research and policy, as well as ways to utilise the findings of this work in current clinical practice. Strengths and limitations are also presented. Finally, I conclude by summarising the key messages from this thesis and proposed next steps.

9.2 Overall contribution of the thesis

9.2.1 Contribution to PAD care research

This thesis contributes new knowledge by providing the first comprehensive behavioural exploration of treatment adherence in PAD, incorporating the perspectives of patients, relatives, and healthcare professionals (HCPs). Using this approach allowed the exploration of perceptual, practical and healthcare system level influences on adherence. The findings demonstrate that adherence is a complex process shaped by patients' knowledge and beliefs about the disease, concerns, their motivation and everyday reality, as well as the organisation of care pathways and the support available within the healthcare system. This work reframes adherence in PAD as a broader behavioural and health systems challenge, rather than a patient issue.

9.2.2 Contribution to behavioural intervention development

This thesis also contributes methodologically by demonstrating how behavioural science frameworks can be systematically applied to develop adherence interventions in PAD. It presents a novel approach to intervention development, utilising the Person-Based Approach (PBA) (162) and the Perceptions and Practicalities Approach (PaPa) (133), applying principles of behavioural science to understand and address

adherence. The thesis also integrates behavioural theory through the use of the Theory and Techniques Tool (TATT) (134) and Behaviour Change Technique Taxonomy v1 (102) to develop the intervention content. Each study presented in this thesis builds on the results of the previous chapter, consistent with the sequential process of intervention development. The integration of findings across studies, alongside the application of behavioural science frameworks, has enabled an in-depth examination of the complex, multifactorial issue of treatment adherence and informed the development of the PAD&Me booklet. This structured approach improves transparency, replicability, and theoretical grounding compared with many existing PAD interventions.

9.2.3 Contribution to clinical innovation

Finally, the thesis resulted in the development of PAD&Me, a theory-informed, co-designed educational booklet aimed at supporting treatment adherence for newly diagnosed patients with PAD. Unlike existing interventions, PAD&Me targets multiple behaviours simultaneously, addresses specific adherence determinants identified in this research, is co-designed with patients and clinicians and is designed to be low-cost, scalable and compatible with current NHS structures. Together, these contributions advance both the scientific understanding of adherence in PAD and the development of practical tools to support patient self-management.

9.3 Summary of main findings

The aim of this thesis was to co-design a person-based, theory-informed behavioural intervention to support patients with PAD with their adherence. In line with the PBA (162), the following stages of intervention development were undertaken during this thesis:

9.3.1 Stage 1: Planning - identification of key behavioural issues, needs, and challenges

During this stage, the following work was completed:

9.3.1.1 A scoping review of existing multi-component interventions designed to support patients with PAD in adhering to guideline-recommended treatment (Chapter 3)

Out of 15 studies (2,462 patients, 60.4% male) included in this review, only two addressed all guideline-recommended treatment aspects, limiting holistic support for patients with PAD. Key intervention components included structured exercise (12/15) and education programmes (10/15). Most interventions were delivered by multidisciplinary teams in hospital settings over three months. Only one study employed behavioural theory in its development, and most interventions (14/15) focused on the BCT "instruction on how to perform a behaviour" rather than diverse BCTs. No interventions significantly increased adherence to all PAD therapies. Few studies measured the intervention's impact on adherence, hindering recommendations regarding effective intervention characteristics. Most interventions lacked behavioural science approaches and were not designed to address specific adherence determinants.

Based on these findings, the following points were further explored during this PhD:

1) Gaps in multidisciplinary care and clinicians' uncertainty about available referral pathways were further explored in the qualitative study to identify opportunities for improved collaborative patient management.
2) The optimal care settings for patients with PAD from the perspectives of patients, as well as specialist and primary care clinicians, were explored during the qualitative study and stakeholder engagement discussions.
3) Determining the most effective point in patients' disease journey (e.g. diagnosis, post-surgical intervention), to introduce the adherence intervention was explored during the qualitative study, the patient and public involvement (PPI) and stakeholder engagement discussions.

9.3.1.2 A qualitative interview study of barriers and facilitators to treatment adherence from the perspectives of patients with PAD, their relatives, and HCPs (Chapter 4)

Fifteen patients (eight men and seven women, aged 48-82, 8/15 White British), four relatives (all women) and 18 HCPs (five from primary and 13 from secondary care) were interviewed. Seven themes were identified: (1) Knowledge & understanding, (2) Treatment concerns, (3) Motivation, (4) HCP influence, (5) Social & physical context, (6) Everyday reality, (7) Healthcare system factors. The findings demonstrated that patients' adherence to PAD treatment is a complex process shaped by their personal understanding, motivation and daily lives, as well as support from HCPs and the wider system. To enhance adherence, future interventions should focus on improving patient education, addressing misconceptions about the necessity of conservative treatment, fostering individual motivation through practical goal setting, and strengthening collaborative care across the healthcare system. Based on these findings, during this PhD I further explored the structure and delivery of services for PAD, specifically intermittent claudication (IC) across England (see Chapter 5).

9.3.1.3 A Freedom of Information request (FOIR) of available services for IC in England (Chapter 5)

In England, 82 Trusts reported providing vascular services. Fewer than half (46.3%) offered dedicated claudication clinics, and only 29.3% provided structured SET programmes. Yet of these SET programmes, only 12.5% of were delivered in line with national guidelines. Most clinics were nurse-led, whereas most SET programmes were physiotherapy-led. Lifestyle support was limited: only 22% provided smoking cessation services internally, 25.6% offered dietetic support within the Trust, and just one Trust reported access to psychological services for PAD patients.

This FOIR highlighted substantial regional variation and gaps in claudication service provision across England. Many Trusts did not consistently deliver care aligned with national clinical guidelines, particularly in offering SET and integrated lifestyle care. This finding was particularly important in relation to the co-design workshops. In line with my pragmatism approach, it was essential that throughout this PhD I co-designed a flexible, scalable intervention that could be adapted to local contexts and delivered by

existing clinical teams. Additionally, given the current NHS challenges, a low-cost intervention would be most preferable. In this way, the intervention would most likely not add extra burden to the NHS.

9.3.2 Stage 2: Development and design of the intervention

During this stage, the following work was completed:

9.3.2.1 Data triangulation and development of guiding principles (Chapter 6)

Seven influences were identified: Lack of knowledge that PAD is a chronic disease; lack of motivation to change behaviour and staying on track; false beliefs that medications offer symptom relief for PAD; concerns about statins side effects; negative beliefs about necessity of smoking; lack of education on the safety and purpose of walking with the pain (recommended to improve PAD symptoms); environmental barriers to exercise. Candidate BCTs were identified for each treatment domain (overall treatment, medication adherence, smoking cessation, and exercise uptake), and these were further prioritised to ensure that only relevant BCTs for this intervention were selected.

The next stage of this work involved co-design workshops with patients with PAD and their relatives to develop an educational, behaviourally informed booklet intervention to support treatment adherence in newly diagnosed patients with PAD (see Chapter 7).

9.3.2.2 Intervention co-design (Chapter 7)

Three rounds of co-design workshops were undertaken with 29 patients and relatives, and two stakeholder meetings with 11 HCPs to develop the prototype PAD & Me booklet intervention. Workshops took place in London, Leicester, or online via Microsoft Teams. Stakeholder meetings were held between the patient workshops to ensure the intervention aligned with current NHS practice. Each workshop round had a specific aim, and participants worked on the intervention's format and content. The workshop materials and intervention content were informed by the identified BCTs, with particular emphasis on ensuring the booklet is user-centred, feasible, acceptable, engaging, and perceived as useful, while remaining aligned with the intervention’s guiding principles.

Following the workshops, the following BCTs were included within the education booklet: 1.1 Goal setting (behaviour); 1.3 Goal setting (outcome); 4.2 Information about antecedents; 5.1 Information about health consequences; 5.2 Salience of consequences; 5.3 Information about social and environmental consequences; 7.1 Prompts/cues; 8.7 Graded tasks; 9.1 Credible source; 9.2 Framing/reframing; 11.2 Reduce negative emotions; 12.3 Avoidance/reducing exposures to cues for the behaviour; and 15.1 Verbal persuasion about capability.

Participants prioritised clear, encouraging and relatable images; simple, supportive and non-patronising text; and stressed the importance of including credible PAD-related resources. Being co-designed with patient and stakeholder input, this intervention has the potential to be scalable and applicable within the current healthcare system. The next step of this work was to user-test the booklet with newly diagnosed patients with PAD (see Chapter 8).

9.3.3 Stage 3: Optimisation of the intervention

9.3.3.1 Intervention user-testing (Chapter 8)

Two rounds of qualitative think-aloud interviews (n=12) were conducted with newly diagnosed patients with PAD to observe and describe their reactions to each element of the intervention. Overall, patients reported that the PAD&ME booklet intervention was acceptable, engaging and motivating for newly diagnosed patients with PAD. All patients found the information useful, effective for behaviour change and the language clear, patient-friendly and encouraging. The intervention also ensured that patients had all the resources they needed for PAD management, including medications, smoking cessation, exercise, how to recognise signs and symptoms of CLTI and support resources. Following the final round of interviews, the booklet was refined with designer input. Finally, although the PAD&Me booklet presented in Appendix 8 has been user-tested, it should not be considered definitive, as further refinement may be needed before being evaluated and in wider clinical settings prior to implementation.

9.4 General findings from this thesis in relation to PAD adherence

9.4.1 Adherence in PAD

The findings of this thesis provide important insights into how PAD treatment adherence should be understood. First, adherence is driven by a combination of perceptual and practical factors. For example, adherence can be influenced by the following perceptual factors: patients' beliefs about PAD as a chronic condition; misconceptions about the necessity and purpose of medications, smoking cessation and exercise; concerns about statin side effects, and challenges in maintaining motivation. Additionally, practical barriers, such as environmental limitations to exercise, claudication pain and lack of comprehensive HCP support were commonly reported. These findings suggest that improving adherence requires addressing both patients' perceptions and their ability to engage in recommended behaviours.

The research also highlights persistent knowledge gaps and misconceptions about PAD among patients. Many participants did not fully understand that PAD is a chronic condition requiring long-term management. Some believed that medications should provide immediate symptom relief, while others were uncertain about the safety and purpose of walking with pain, which is commonly recommended to improve symptoms of intermittent claudication. Some patients also believed that "it's too late to quit smoking", as they already had established disease. These findings indicate that patient education and information is often insufficient or not designed with behavioural principles in mind, leaving patients to develop their own interpretations of the condition and its treatment.

Moreover, the findings demonstrated that adherence is also influenced by the organisation of healthcare services. The FOIR revealed substantial variation in service provision across England, with limited access to claudication-related services. This suggests that patients' ability to adhere to recommended treatments may depend in part on the services available within their local healthcare system. Adherence should

therefore be understood as influenced by healthcare system structures, as well as patient-level factors.

Finally, the findings suggest that early stages of the disease pathway represent an important and currently underutilised opportunity for intervention. As presented in Chapter 3, existing studies focus on patients following surgical endovascular interventions, whereas this thesis highlights the importance of providing behavioural support at the point of diagnosis. Early engagement may help patients develop an accurate understanding of their condition, address misconceptions, and establish positive health behaviours. Taken together, these findings suggest that improving adherence in PAD requires interventions that address behavioural, educational, and healthcare system factors, and that early intervention may be particularly valuable in supporting long-term disease management.

9.4.2 Behaviour change interventions in practice

This thesis also provides several important lessons for the development of behaviour change interventions in PAD. First, the use of behavioural theory played a key role in improving the focus of the intervention. By systematically mapping identified adherence influences to MoAs and corresponding BCTs, it was possible to ensure that the intervention content directly addressed the determinants of behaviour identified in the empirical data. This structured approach strengthened the theoretical grounding of the intervention and helped move beyond generic educational materials towards a more targeted strategy for supporting adherence.

Additionally, the co-design process substantially improved the relevance and acceptability of the intervention. Through the workshops, patients and relatives highlighted the importance of presenting information in a supportive and non-patronising tone, using simple and accessible language, incorporating relatable images, and providing practical strategies that could be integrated into everyday life. These preferences shaped both the format and the content of the PAD&Me booklet and ensured that the intervention aligned with patients' experiences and needs. Such

elements may not have been identified through researcher-led design alone, demonstrating the value of meaningful patient involvement in intervention development.

Finally, this work highlighted the importance of adopting a pragmatic perspective when designing interventions intended for real-world healthcare settings. The findings of the FOIR revealed considerable variation in service provision and limited resources across many NHS Trusts. As a result, it was essential that the intervention was designed to be low cost, adaptable to different service contexts, and deliverable by existing clinical teams without requiring additional infrastructure. These considerations demonstrate that effective intervention development must balance behavioural theory with practical feasibility, ensuring that interventions are not only theoretically sound but also implementable within the constraints of continuously evolving healthcare systems.

9.5 Updated literature on multicomponent adherence interventions

Since my review on multicomponent interventions was completed and published, a few studies have emerged. An updated search of the literature (2024-February 2026), identified three studies describing multicomponent interventions.

Cucato's study (Textpad) (78), from the protocol that was identified in my review, was recently completed, and the results of the pilot randomised trial (RCT) study have been published (343). The digitally delivered, home-based telehealth intervention for socioeconomically disadvantaged patients with PAD was feasible, and the authors concluded that it could potentially influence functional capacity and health behaviours (343). Specifically, results indicated improvements in subjective functional capacity [walking speed and stair-climbing ability ($p< 0.01$)] and quality of life ($p < 0.01$) in the intervention group compared to the control group; as well as a 50% reduction in smoking rates in the intervention group (343). However, the study was underpowered (36 patients recruited instead of the target of 60); only 13 patients in the intervention

and 12 in the control group completed the study, hence, the results should be interpreted with caution (343). The study presented a high drop-out rate, mainly due to patients not attending their review appointments or wishing to discontinue with the study (343). The authors concluded that further research is required to explore the long-term impact of adherence promoting interventions (343). Compared to my study, Textpad did not address medication adherence behaviours and it was also digitally delivered, which could have added an extra barrier to participation, as seen by the high drop-out rates.

A secondary analysis of the FASTIC study (196), previously discussed in Chapter 3, indicated that the person-centred, nurse-led post-revascularisation follow-up contributed to better perceived quality of care (387). Specifically, patients who took part in the study had a better understanding of self-management, a better relationship with their clinicians, and they felt more respected and involved in their care (387). Although this secondary analysis indicates an improvement in patient satisfaction (387), as presented in Chapter 3, the intervention was not effective in improving adherence (196). The authors concluded that nurses are well positioned to manage vascular patients and recommended that vascular units could consider transitioning follow-up care from surgeons to nurses (387). This is in line with my findings and the feedback from stakeholders on how to best delivery the PAD&Me intervention: utilising existing nurse-led pathways.

The “Keep Pace!” pilot study of 20 patients with PAD found that a telehealth, nurse-supported home-based intervention was effective in improving patients’ well-being and walking distance (388). The intervention included remote walking training for PAD, as well as text messages on walking training and lifestyle optimisation (including a healthy diet) (388). The intervention significantly improved pain-free walking distance (from 76.26±36.82 metres in baseline to 188.42±81.17 at the end of follow-up, $p<0.001$); and 6-minute walking distance (from 308.79±82.62 meters in baseline to 425.94±107.09 meters at the end of the study, $p<0.001$) (388). Additionally, the study found that most patients (95%) reported implementing individual health behaviour changes following their interactions with the intervention (388). However, no detail was provided about

what behaviour change constituted; hence, it is impossible to assess the effectiveness of the intervention on specific adherence behaviours. Compared to my study, the “Keep Pace!” study did not address medication adherence behaviours, hence, did not focus on all aspects of the conservative management plan.

In summary, these studies included small sample sizes, did not focus on all aspects of the conservative PAD treatment plan, the adherence outcomes were unclear, and there was limited use of behavioural theory. Although Textpad incorporated BCTs in its content (343), the effect of these BCTs on behaviour change could not be ascertained. Moreover, although digital health interventions might be considered as more practical to deliver, patients in my study had a preference for in-person services. This reinforces the need for comprehensive theory-informed interventions like PAD&Me.

9.6 Implications for future research and policy

Future research and policy should prioritise advancing the development, evaluation, and implementation of interventions to support treatment adherence in PAD. In this section, implications for future research and policy are discussed.

9.6.1 Research directly linked to this PhD project

Future research must move beyond intervention development to formally evaluate effectiveness. An essential next step for this work is to evaluate the feasibility and acceptability of implementing the PAD & Me intervention within routine clinical practice. Subsequent research should progress to a rigorous evaluation of effectiveness, cost-effectiveness, and acceptability. The first step would be a feasibility study to assess whether the intervention is feasible before scaling up to a randomised controlled trial (RCT). Further pilot testing and an adequately powered RCT are then needed to determine intervention effectiveness, identify which BCTs or combinations are most impactful, and assess outcomes such as adherence, quality of life, and cardiovascular risk reduction. Such work will help refine intervention content and strengthen the evidence base for behaviourally informed, patient-centred interventions in PAD.

9.6.2 Research in PAD adherence more broadly

Beyond this project, there is a clear need for methodological advancement in PAD adherence research. As presented in Chapter 1, there is no gold standard method for measuring adherence. Hence, a major priority is to establish consistent terminology for adherence and validated methods for measuring adherence across different treatment aspects, as identified in Chapter 3. This can support future studies in deciding on intervention outcomes for measuring the effectiveness of adherence interventions.

Additionally, as presented throughout this work, there is limited research on the development of multicomponent PAD adherence interventions, and only a few studies have incorporated theory in their development. Hence, larger, theory-driven studies using structured intervention development frameworks are needed to strengthen rigour, transparency, and testing. Future studies should assess how specific development stages contribute to intervention engagement, usability, and overall rigour. Finally, as presented in Chapter 3, the current literature has focused mainly on the white population, without considering how culture and ethnicity may influence adherence. Although efforts were made to have representation of participants from diverse ethnic backgrounds in this study, most of the population was white. Additionally, in the qualitative study, I was unable to explore whether ethnicity influenced adherence. Future studies should include diverse patient populations to improve generalisability and further explore the unique challenges they experience. Moreover, there is a gap relating to patients with chronic limb-threatening ischaemia (CLTI), who remain underrepresented in adherence research despite having complex needs and high morbidity. Although this study was focused on IC, patients who have previously experienced CLTI were recruited; however, exploring and addressing their unique adherence issues was beyond the scope of this PhD.

9.6.3 Health services research priorities

Future research should also focus on health-system and service-level factors influencing adherence and outcomes. This includes identifying optimal care pathways for PAD management, understanding regional variation in service provision, and examining how multidisciplinary models can be implemented effectively in clinical practice. As discussed in Chapter 5, further national and international studies are needed to map service structures for IC, benchmark provision, and identify transferable features of high-performing regions. Research should also investigate barriers to guideline implementation and ways to offer equitable, holistic care pathways for patients with PAD. Finally, in line with the new 10-year NHS plan, future research should explore how optimal care for patients with PAD can be delivered effectively in the community, whilst taking into account how this shift may affect patient engagement, preferences, and adherence, particularly given evidence that many patients prefer specialist-led secondary care.

9.6.4 Policy

From a policy perspective, findings highlight the need for coordinated action to ensure equitable, evidence-based PAD care. Priorities include commissioning standardised services across regions, addressing inequalities in access between PAD and other cardiovascular specialties, such as cardiac rehabilitation, and investing strategically in PAD care infrastructure. Policymakers should also prioritise the integration of multidisciplinary teams and support the implementation of proven interventions to bridge the gap between clinical guidelines and routine practice. Future service design and policy development should embed patient involvement from the outset to ensure that pathways are acceptable, accessible, and aligned with patient needs.
Together, these research and policy directions will be critical for improving adherence, reducing disparities, and enhancing long-term outcomes for patients with PAD.

9.7 Implications for clinical practice

Findings from this PhD have several important implications for clinical practice. The qualitative study revealed that many patients have limited knowledge and understanding of PAD, which can contribute to poor treatment adherence. In the absence of accessible, patient-friendly resources, patients often develop their own views of their condition and rely heavily on clinicians or the internet for information and guidance. The PAD&Me booklet was developed to address this gap and is intended to be used as both an educational guide and a practical support tool to help patients navigate their condition. The booklet has the potential to help patients make informed decisions about their care and self-management, therefore feeling more empowered and engaged in their treatment.

In addition to supporting patients, the intervention may also benefit clinicians. Insights from this research highlight key adherence barriers and facilitators that clinicians can use to tailor their consultations and deliver more patient-centred care. The booklet can be integrated into initial diagnostic consultations to facilitate structured discussions, support goal-setting, and reinforce the message that PAD is a chronic condition requiring lifelong management. The stakeholder group and the PPI have advised using the PAD&Me booklet during the initial diagnosis appointment, with assistance from the vascular clinicians. The booklet could potentially be utilised in primary care; however, it was stressed that an experienced clinician, familiar with the condition, should present the booklet and be able to answer any questions the patients might have.

It is important to situate these implications within the evolving healthcare context. This research programme began in October 2021, prior to recent structural changes in the NHS and the announcement of the new 10-year plan. Based on Chapter 4 and stakeholder discussions, perspectives differed across professional groups regarding where PAD management should be delivered. While vascular clinicians acknowledged that PAD is a chronic condition that could, in principle, be managed in primary care, they also highlighted the current lack of clear pathways, resources, and specialist expertise. Primary care clinicians felt that they could manage this population if they had

the expertise and equipment. On the other hand, patients emphasised the value of specialist input from hospital-based clinicians and expressed concerns about what they perceived as non-specialist management. These findings highlight a broader systems issue: limited integration and communication between services that support people with PAD.

Without coordinated care pathways and effective multidisciplinary collaboration, patients are at risk of inadequate support in managing their condition. Although the PAD&Me booklet could potentially be used in primary care settings, it was designed for secondary care settings and its feasibility and effectiveness in routine practice remain to be established. Further implementation research is therefore needed to determine how best to embed this intervention across care pathways and ensure equitable access to structured adherence support.

9.8 Strengths and Limitations

The strengths and limitations of each study for this PhD have been presented within each chapter. A summary of the thesis' key strengths and limitations is presented in this section.

9.8.1 Strengths

The main strength of this PhD was employing a rigorous intervention development process, underpinned by behavioural science using validated frameworks, strengthening the results of this work. The PBA offered a person-centred approach to intervention development, which is ideal for this project, exploring perceptions of an under-represented cardiovascular population. Additionally, the PaPa, a framework specifically designed to understand and address adherence behaviours, was used to allow the exploration of perceptual and practical barriers to adherence. Moreover, the use of the TATT while selecting relevant BCTs facilitated the consideration of evidence-based intervention components relevant for each adherence influence for my intervention. Last but not least, the use of the TIDieR framework in Chapter 3,

supported the description of available multicomponent interventions in a systematic way, enabling me to methodically identify gaps in current literature.

The logical, stepwise process of this PhD demonstrates clear reporting of each intervention development step and the decisions made. This transparent approach can enable future researchers to determine whether and how this research is relevant to their own clinical context. The qualitative study (Chapter 4), is the first of its kind within PAD research, exploring adherence barriers and facilitators from the perspectives of patients, their relatives and HCPs. Inductive thematic analysis, and mapping onto the PaPa, allowed me to organise findings in a systematic way, providing a detail description of adherence barriers and facilitators.

The inclusion of the FOIR enabled a pragmatic exploration of current IC services and was the first study to examine the holistic provision of IC services in England. By conducting a FOIR, I was able to get a snapshot of service provision and plan a feasible, scalable intervention. Another strength of this thesis is the triangulation of findings across three studies to identify key adherence influences. Combining different methodologies to answer the same research question further strengthens the findings of this study and the overall intervention design. Throughout the triangulation exercise, all relevant adherence influences were identified, but only the ones relevant to this project were addressed by the PAD&Me intervention. This comprehensive list of adherence influences can be utilised by PAD researchers and adapted within their respective context.

This project was developed with patients for patients. The involvement of PPI throughout all stages of the research project, stakeholders and the co-design activities, ensures the intervention is user-focused and aligned with patient needs and priorities. A robust co-production approach, underpinned by NIHR co-production principles and the PBA, was employed. Additionally, I set rules regarding power dynamics, to ensure transparency in the decision-making process. A mix of face-to-face and online activities were undertaken to ensure diverse representation. Patients taking part in this study felt listened to and valued, and felt that they were getting some clarity about their condition

and treatment. Following the co-design workshops, the intervention was further refined in the think-aloud interviews with newly diagnosed patients with PAD, new to this research, offering fresh perspectives to this work. This optimisation process ensured that the intervention is user-focused, engaging and acceptable to patients.

Finally, this project, addressed important gaps in PAD care: i) supporting patients at the beginning of their disease journey, ii) offering patient-friendly resources. As discussed in previous chapters and highlighted by PPI discussions, patients lack sufficient support at this crucial stage, and to date most research has been focused on management post-surgical intervention. Additionally, patients stressed the need for lay, patient-friendly resources about their disease and management. This project addresses these gaps through the PAD&Me intervention being designed for newly diagnosed patients, offering information and their disease and treatment, addressing common misconceptions and supporting goal setting. Being theory-informed and co-designed with patients, this intervention has the potential to positively influence adherence, and to be acceptable and implementable within the current healthcare system.

9.8.2 Limitations

Although the use of behavioural science frameworks strengthened the theoretical grounding of this work, it also comes with limitations. Firstly, the PBA heavily relies on PPI and stakeholder engagement, which can add time and financial constraints during the intervention development process. Additionally, the PaPa was originally designed for medication adherence, so it may not have fully captured the nuances of lifestyle behaviours. However, this was not evident in the present study. The suggested BCTs for each MoA are limited by available evidence. Several MOAs-BCT pairs are lacking in evidence. Therefore, while it is a tool to suggest suitable BCTs based on existing research, there are evidence gaps, so the suggested BCTs are not fully comprehensive. More broadly, there remains limited evidence confirming that specific BCTs reliably produce behaviour change across contexts. Although triangulation was conducted

systematically, no formal triangulation methodology was applied, which may affect analytical rigour.

The structured, theory-driven approach used to design the intervention enhanced transparency and reproducibility but may have limited flexibility to pursue novel or exploratory ideas outside those indicated by the data. It is also important to note that stakeholder discussions and co-design workshops took place during a period of transition at the NHS, with workforce shortages, a hiring freeze, and political change affecting the health system. These contextual pressures appeared to foster pessimism about resource-intensive innovations and may have constrained creative input from participants. While this reflected genuine system-level barriers, it may also have narrowed the scope of intervention possibilities considered.

The format of this intervention is a booklet, which might not be appropriate for all patients (367), particularly non-English-speaking patients or those with low literacy levels. However, to overcome this issue, the work conducted during the co-design workshops ensured the booklet has minimal text, is visually engaging, and uses simple language. Although lay language was used for the booklet, this was not cross-checked with a reading age software, which is an additional limitation. Moreover, the findings of this work may not be generalisable to the PAD population as a whole. Firstly, two of the three studies used in triangulation were conducted in single-centre settings, which may limit generalisability. Furthermore, the intervention and the qualitative work focused on IC and newly diagnosed patients, meaning findings may not apply to patients with CLTI. The co-designed booklet, while potentially adaptable, was not specifically developed for later disease stages.

Although efforts were made to ensure inclusivity, most participants were White British, which limits the transferability of the findings to more diverse populations. Recruiting patients from primary care was unsuccessful because none of those who expressed interest in the study had PAD, restricting the representation of earlier diagnostic pathways. In addition, including multiple professional groups enriched the data but reduced the sample size within each subgroup (e.g. nurses, doctors, etc), therefore

may have limited effective comparisons across professions. Recruitment for co-design workshops was also challenging, reflecting broader difficulties engaging people with PAD in research. Finance-related barriers, such as my organisation's inability to authorise payment to reimburse travel promptly for participants from underserved backgrounds, may have unintentionally excluded underrepresented voices.

Finally, participation bias is also possible, as financial reimbursement may have motivated some individuals to participate primarily for the incentives. Additionally, patients who were more adherent or were interested in changing their behaviour may have been more likely to participate in this study.

9.9 Conclusion

To conclude, this thesis addressed a key gap in the management of patients with PAD by developing a theory-informed, person-centred behavioural intervention to support adherence to guideline-recommended therapy for PAD. Adopting the PBA allowed the development of the intervention in a rigorous, person-based way. The use of the PaPa provided a comprehensive exploration of behavioural, practical and healthcare system factors affecting adherence and how to address these. These insights informed the co-design of the PAD&Me booklet intervention. The scoping review identified that existing multicomponent interventions that support treatment adherence in PAD do not incorporate intervention development frameworks or theories of behaviour change in their development and they are not effective in improving adherence across all treatment domains. Additionally, they do not focus on newly diagnosed patients with PAD. The qualitative study showed that adherence is influenced by a complex combination of perceptual and practical factors. Patients often had limited understanding of PAD as a chronic condition, misconceptions about the necessity and purpose of medications, exercise, and quitting smoking, and concerns about side effects. The lack of patient-friendly resources also added to the lack of understanding and misconceptions. Motivation for behaviour change was also affected by everyday challenges, social context, and the level of support received from healthcare professionals. The FOIR revealed substantial variation in the availability and structure

of claudication services across England, with limited access to SET and lifestyle support in many NHS Trusts. By utilising behavioural science approaches, I comprehensively explored the influences on adherence and the mechanisms by which these can be addressed, which informed the PAD&Me booklet. Through co-design and user-testing, the booklet was refined to ensure that it was clear, supportive, engaging, and relevant to patients' experiences. The intervention was designed to address gaps in knowledge and misconceptions about treatment, support motivation for behaviour change, and provide practical strategies to help patients adhere to their treatment plan. To conclude, the PAD&Me booklet is a novel, scalable intervention that directly targets the barriers identified in this thesis and provides patients with accessible, evidence-informed support for managing their condition. Having been co-designed, it has the potential to be engaging and practically implementable within the NHS, as well as facilitate treatment adherence and improve outcomes for PAD.

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Appendices

Appendix 1. Behavioural Change Technique Taxonomy (version 1, Michie et al 2013)

Group	Behavioural change technique
1. Goals and planning	1.1. Goal setting (behaviour) 1.2. Problem solving 1.3. Goal setting (outcome) 1.4. Action planning 1.5. Review behaviour goal(s) 1.6. Discrepancy between current behaviour and goal 1.7. Review outcome goal(s) 1.8. Behavioural contract 1.9. Commitment
2. Feedback and monitoring	2.1. Monitoring of behaviour by others without feedback 2.2. Feedback on behaviour 2.3. Self-monitoring of behaviour 2.4. Self-monitoring of outcome(s) of behaviour 2.5. Monitoring of outcome(s) of behaviour without feedback 2.6. Biofeedback 2.7. Feedback on outcome(s) of behaviour
3. Social support	3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional)
4. Shaping Knowledge	4.1. Instruction on how to perform the behaviour 4.2. Information about Antecedents 4.3. Re-attribution

	4.4. Behavioural experiments
5. Natural consequences	5.1. Information about health consequences 5.2. Salience of consequences 5.3. Information about social and environmental consequences 5.4. Monitoring of emotional consequences 5.5. Anticipated regret 5.6. Information about emotional consequences
6. Comparison of behaviour	6.1. Demonstration of the behaviour 6.2. Social comparison 6.3. Information about others' approval
7. Association	7.1. Prompts/cues 7.2. Cue signalling reward 7.3. Reduce prompts/cues 7.4. Remove access to the reward 7.5. Remove aversive stimulus 7.6. Satiation 7.7. Exposure 7.8. Associative learning
8. Repetition and substitution	8.1. Behavioural practice/rehearsal 8.2. Behaviour substitution 8.3. Habit formation 8.4. Habit reversal 8.5. Overcorrection 8.6. Generalisation of target behaviour 8.7. Graded tasks
9. Comparison of outcomes	9.1. Credible source 9.2. Pros and cons 9.3. Comparative imagining of future outcomes
10. Reward and threat	10.1. Material incentive (behaviour) 10.2. Material reward (behaviour)

	10.3. Non-specific reward 10.4. Social reward 10.5. Social incentive 10.6. Non-specific incentive 10.7. Self-incentive 10.8. Incentive (outcome) 10.9. Self-reward 10.10. Reward (outcome) 10.11. Future punishment
11. Regulation	11.1. Pharmacological support 11.2. Reduce negative emotions 11.3. Conserving mental resources 11.4. Paradoxical instructions
12. Antecedents	12.1. Restructuring the physical environment 12.2. Restructuring the social environment 12.3. Avoidance/reducing exposure to cues for the behaviour 12.4. Distraction 12.5. Adding objects to the environment 12.6. Body changes
13. Identity	13.1. Identification of self as role model 13.2. Framing/reframing 13.3. Incompatible beliefs 13.4. Valued self-identify 13.5. Identity associated with changed behaviour
14. Scheduled consequences	14.1. Behaviour cost 14.2. Punishment 14.3. Remove reward 14.4. Reward approximation 14.5. Rewarding completion 14.6. Situation-specific reward

	14.7. Reward incompatible behaviour 14.8. Reward alternative behaviour 14.9. Reduce reward frequency 14.10. Remove punishment
15. Self-belief	15.1. Verbal persuasion about capability 15.2. Mental rehearsal of successful performance 15.3. Focus on past success 15.4. Self-talk
16. Covert learning	16.1. Imaginary punishment 16.2. Imaginary reward 16.3. Vicarious consequences

Appendix 2. Guidance for Reporting Involvement of Patients and the Public (GRIPP2) Short Version Checklist (Staniszewska et al., 2017)

Section and topic	Item
1: Aim	Report the aim of PPI in the study
2: Methods	Provide a clear description of the methods used for PPI in the study
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience

Appendix 3. Interview Topic guides

[Before turning on the recorder]

- Introduce myself
- Ask the participant how they would like to be called (first or last name)
- Go through the participant information sheet and the consent form and confirm participants are happy to continue participation
- Explain that I'm going to note down things I want to come back to
- Reiterate there's no right or wrong answer etc.
- The interview will take about an hour. Questions before we start?

PATIENTS

[Turn on the recorder]

Introduction

1. Can you tell me a bit about yourself?

Prompts:

    - Place of origin
    - Occupation
    - Living conditions
    - Current health

2. Can you tell me a little bit about when you were first diagnosed with PAD?

Prompts:

    - When? Where? What happened?
    - When you first started feeling symptoms that led you to seek care? What happened?

- How were you told about your condition?
- How was your diagnosis communicated to you by your medical team?
- What can you remember being told about the complications of PAD?

Exploring patients' perceptions of PAD and experience living with PAD

3. What does PAD mean to you?

Prompts:

- What did you know about PAD before you found out you had the disease?
- Has anyone you know have PAD?

4. Can you tell me about how it is for you living with PAD?

Prompts:

- What does your condition mean to you?
- Quality of life
- Employment

Treatment

5. What is your current treatment plan?

Prompts:

- What did your healthcare provider (GP, Vascular doctor, vascular nurse) recommend for you?
- What do you think about your current plan?
- What do you understand about how the treatment works?
- What do you understand about the importance of your treatment plan?
- Meds, exercise, smoking
- Who is currently looking after you? Who is involved in your care?

- Where do you usually seek care? E.g. community Vs hospital
- Do you have any concerns about your treatment?

6. Who has provided you with this treatment plan?

Prompts:

- Healthcare professional background & setting
- What did they say? How did they explain the plan?
- What materials did they use? How did you find these?
- Did you use any other sources of information?

Information

7. Do you feel you have enough information about your disease and treatment?

Prompts:

- Yes -> that's great, would you like to tell me about the info you've received?
- No -> what have you received so far? If nothing, what would you need? If you received something but you were not satisfied, why was that?

Location

8. Where do you currently receive vascular care for your PAD? Where do you feel is the best place for you to receive vascular specialist care and why?

Prompts:

- Community / GP
- Hospital
- Home

Adherence perceptions (necessity beliefs and concerns) & practicalities

9. What are your personal views about your treatment plan? (this is different to the previous question, which is more about what the treatment plan is)

Prompts:

- What parts of your treatment plan do you think are more important to you?
- How easy is it to follow your treatment plan?
- Can you tell me more about any problems you have?

10. How important do you think it is for you to be on this treatment?

Prompts:

- QoL
- Clinical outcomes
- Limb salvage
- Has this changed over the years?
- Explore perceptions in different stages of the disease

11. What do you think happens if someone does not follow their treatment plan?

Prompts:

- Explore the patient's understanding regarding natural disease progression, CVD and limb complications
- "Balance" between lifestyle & med management (e.g. healthy diet & exercise so no need for statins)

12. What concerns you about your treatment and disease? What worries you the most?

Prompts:

- E.g. claudication pain while exercising, medication side effects
- Do you worry about not taking your meds? Not quitting smoking? Etc

13. What makes it difficult to follow the treatment plan?

Prompts:

- What aspects of your plan do you find difficult/challenging to follow?
- Tell me about the times you found it difficult to follow your treatment plan. What caused this?
- Remembering to take meds
- Claudication pain
- Resources barriers, e.g. opportunities/space to exercise
- Social support
- Environment

14. What helps you follow your treatment plan?

Prompts:

- Can you start with your meds and then tell me about smoking and exercise?
- What are the available resources in your area? E.g. SET, specialised vascular clinic
- How about family support?
- Text message, reminders, Dossett box

15. What sort of things would you find helpful in supporting you to follow your treatment plan?

Prompts:

- What could the medical team do differently?
- What could your family do differently?

- How about the government/NHS (e.g. facilitate more SET programmes, paid sick leave to attend SET, paid NRT to quit smoking, paid medication prescriptions)?
- How would you like to receive information about your care? (e.g. group session, leaflet, video)

Support

16. How do you cope with your disease and treatment?

Prompts:

- Does anyone help you? If yes, what do they do? If not, what support do you need?
- Family? Friends?
- Do you know other patients with PAD? What do you discuss with them?
- HCPs – how have you felt regarding the support you received? (check on language & health literacy)
- In what ways does the clinic support your treatment currently? What are they doing to help you stay on treatment?

17. Finally, are there any lessons gained from your experience of living with PAD and being on treatment that you could share with others who are starting treatment?

RELATIVES

Introduction

1. Please tell me a little bit about yourself and your situation.

Prompts:

- Background/ Origin
- Employment/occupation

2. What is your relationship to X? (If not related, ask: how long have you known x, and in what capacity?)

Diagnosis & living with PAD

3. When and how did you find out about X's current PAD diagnosis?

4. Please can you tell me a bit about your experience as a relative/friend of a patient (X) with peripheral arterial disease?

Prompts:

- Years since patient's diagnosis
- Day-to-day activities
- Changes in relationship with the patient

5. Do you feel you have enough information about the disease to support X?

Prompts:

- Yes -> that's great, would you like to tell me about the info you've received?
- No -> what have you received so far? If nothing, what would you need?

6. What kind of support, if any, are you currently offering to your relative/friend?

Prompts:

- Emotional
- Day-to-day task based (e.g. cleaning, cooking, etc)
- Formal carer
- In charge of medications management or medical management in general

7. What would you say are the main challenges that you have experienced supporting X?

Prompts:

- Individual patient difficulties
- System/organisation/NHS
- Personal difficulties
- Relationship or social difficulties

Treatment & Management

8. What do you know about the treatment X is taking? What are your thoughts regarding X's current treatment plan?

Prompts:

- It works / it doesn't
- What part(s) of the treatment plan do you think is/are more important for the patients?
- Guidance / information
- Easy/hard for patients to understand/follow
- Appropriateness
- Concerns
- Communication of plan

9. If you are involved in the medical management, can you please tell me more about your role in it?

Prompts:

- Responsibilities
- Challenges
- Support/training to do this role
- Importance of the role

10. In your opinion and experience, how good is the patient at following their treatment plan?

Prompts:

- Good -> what helps them?
- Bad -> move to next question about challenges

11. In your opinion and experience, what might be the challenges/difficulties and concerns the patient has regarding their disease and treatment management?

Prompts:

- Disease specific (e.g. medication side effects, claudication pain)
- Personal/life specific (e.g. work, family)
- Other comorbidities
- System (e.g. difficulty getting an appointment, long waiting list)
- Lack of knowledge/capacity to understand
- Lack of skills (practical skills)
- Social identity / optimistic personality
- Emotional (fear)
- Memory

Considerations for change

12. How do you think the treatment/disease management plan for the patient could be improved?

Prompts:

- What could the clinical team do differently? Who should be involved?
- What could the patients do differently?
- What could the family/carers do differently?
- How about the government/NHS (e.g. facilitate more SET programmes, paid sick leave to attend SET, paid NRT to quit smoking, paid medication prescriptions)?
- Available information resources (e.g. group session, leaflet, video)
- Location of disease management
- Role of technology
- Personalisation
- Promote more independence in disease management.

HEALTHCARE PROFESSIONALS

Introduction

13. Please can you tell me a bit about your experience of working with patients with peripheral arterial disease and any challenges that you experience supporting them?

Prompts:

- Profession
- Interest in PAD

- Years in practice
- Individual patient difficulties
- System/organisation pressures
- Personal difficulties

Treatment

2. What are your thoughts regarding the current guideline-recommended best medical therapy plan?

Prompts:

- It works / it doesn't
- What part(s) of the treatment plan do you think is/are more important for the patients?
- What do you aim to achieve by offering this plan?
- Do you feel you have enough guidance / protocols / guidelines to base your practice on this?
- Easy/hard for patients to understand

3. In your opinion and experience, what things are important to ensure that treatment with a PAD patient is effective?

Prompts:

- Clinical Vs PROMS/QoL needs
- Conservative treatment Vs surgical
- Treatment duration

4. What are your thoughts regarding the current structure of clinical appointments in your setting?

Prompts:

- What works? What doesn't?

- How often do you see patients?
- What is the duration of the clinical appointments?
- MDT Vs single HCP
- Information given & mention patients' beliefs about info
- Focus on clinical Vs patient outcomes

Professional roles

5. Who do you think is the right HCP to provide care for PAD patients?

Prompts:

- GP/ Primary care clinician
- Vascular specialist clinicians or surgeons
- Nurses (specialists), community/district nurses, Practice nurses
- Other allied HCP (Physio)
- MDT

Location

6. Where do you think PAD patients should be managed?

Prompts:

- Primary care
    1. Specialist clinics inserted in integrated care systems
    2. GP surgery / practice
    3. Patient's homes – for those housebound
- Secondary care
- Vascular surgery / vascular medicine / cardiac rehab

Communication

7. What factors are important to consider when communicating a treatment plan with a PAD patient?

Prompts:

- Verbal / Written
- Tools used (e.g. visual material, leaflets)
- Language used (lay, technical, body language)
- Role of technology/apps

Training

8. Clinicians with a variety of experience and professional backgrounds are treating PAD patients. What skills do you think HCPs should have to effectively manage PAD patients in a clinical environment?

Prompts:

- Formal learning
- Working experience
- Advanced practice learning
- CVD risk management

Adherence Barriers & Facilitators

9. In your opinion, what are the barriers and facilitators that patients face regarding following their treatment plan?

Prompts:

- Personal issues
- System/organisational
- HCPs issues
- Carer/support

Considerations for change

10. Is there anything we need to particularly think about when thinking about the management of PAD patients?

Prompts:

- Who should be involved / human resources (how many in a team and how big a caseload per HCP)
- Location
- Information
- Time
- Budget

11. What can be done differently within the current healthcare system to better support PAD patients following their treatment plan?

Prompts:

- What could the clinical team do differently?
- What could the patients do differently?
- What could the family/carers do differently?
- How about the government/NHS (e.g. facilitate more SET programmes, paid sick leave to attend SET, paid NRT to quit smoking, paid medication prescriptions)?
- Available information resources (e.g. group session, leaflet, video)

Closing

- Look at notes- are there any questions to revisit?

So, we are coming to the end of the interview now and I have asked you everything that I wanted to. Is there anything else you would like to tell me about?

How do you feel about being involved with this research? What do you think about the questions asked? Is there anything else you would like to add or think I should have asked? Is there anything you would like to ask me?

Thank you very much for taking the time to give us your views. Your contribution to this research will help us to think about how best to support patients with PAD with their adherence.

Turn off recorder:

- Give thanks
- Vouchers/ travel expenses
- Reiterate what happens next

Appendix 4. Qualitative interview study coding tree

Themes	Sub-themes	Codes
Knowledge & Understanding about disease & treatment	Systematic nature of disease and treatment benefit	Lack of understanding of systemic nature of disease; Chronic Vs acute; unusual concept that exercise and lifestyle changes is the treatment; Patients with better disease understanding engage better with their treatment; benefit of walking; CVD systemic nature; why take statins; link of smoking and PAD; understanding disease process & aetiology
	"Quick fix" / surgery is the treatment	Quick fix; expectations; expectation that referral to vascular surgery equals having surgery; perception that surgery is the treatment; magic pill
	Information Seeking	Information about disease and treatment; available info resources
	Influence of others on knowledge & understanding	Media; misinformation; negative relative experiences
	Language & Health Literary	Patient characteristics; deprivation and understanding; language barrier; medical terminology
Treatment concerns	Concerns about medication side effects	High statin dose equals higher side effects; concerns about med side effects; anxiety about statins; concerns

		about long-term impact of medications in the body; depend on meds; not a meds person
	Fear of damaging legs	Walking with the pain; perception that walking can harm legs; statins & fear of cramps
Motivation	Fear of amputation	Fear of amputation
	Motivation to change	Motivation; mindset; empowerment; wanting to quit smoking; keep going
	A life not an existence	A life not an existence; Fear or discomfort leaving the house; Embarrassment; Impact on quality of life
HCP influence	Shared decision making	Decision making; patient involvement
	Trust in specialist care	Patients want to get specialist opinion from secondary care; lack of GP trust; building rapport & trust
	Conflicting info from different specialties or primary & secondary care	Conflicting info from vascular & primary care causing confusion to patients
Social & physical environment	Environmental barriers	Weather as a barrier to exercise; travel; transport
	Social support	Family support; family influence; HCP support; social interactions; dog; getting family onboard
	Negative social influence	Family can hinder or facilitate adherence; family influence re smoking

Everyday reality	Health-related challenges	Balance/falls; arthritis; polypharmacy; previous MI facilitates adherence; claudication pain; pain as a barrier to exercise
	Experiencing medication side effects	Experiencing med side effects
	The power of habit	Daily routine; talking all meds together; keeping meds them together; creating a walking routine; habit; smoking as a habit; people are creatures of habit
	Getting on with life	New life; acceptance; balance between quality of life and symptoms
Healthcare system factors	Access to services (B)	Lack of services PAD services; access to smoking cessation; access to services; lack of uniformed services
	Waiting times and FU (B)	Lack of FU; long waiting list; unable to monitor progress; long waiting lists for SET; long waiting list for smoking cessation

Appendix 5. Freedom of Information Request: Claudication Services Questionnaire

Services

Q1. Does your Trust currently provide a vascular service for the diagnosis and treatment of vascular diseases, specifically including vascular surgery and interventional vascular radiology?

☐ Yes

☐ No

Q2. If vascular services are available, is your organisation designated as a specialist vascular care centre or a hub centre within the network of care providers? (please select all that apply)

Hub centre: providing diagnostics and expert advice in an outpatient setting and providing elective and 24/7 emergency vascular services.

Spoke centre: providing diagnostics and expert advice in an outpatient setting.

☐ Hub

☐ Spoke

☐ Other (Please specify) .....

Claudication clinics

Intermittent claudication: Intermittent claudication is the most common clinical symptom associated with peripheral arterial disease — walking (exercise) induced pain in the lower limbs caused by diminished circulation that is relieved by rest.

Q3. In your organisation, are there specific claudication clinics for patients with intermittent claudication?

 Yes

 No – If no please skip to question Q10

Q4. If yes, which healthcare professional usually sees patients in these clinics? Please select all that apply.

 Vascular surgeon/medical doctor

 Vascular nurse specialist

 Allied health professional

 Other (Please specify) .....

Q5. In your organisation, what is the format of claudication clinics? Please select all that apply.

 Diagnostic testing

 Disease counselling and treatment planning

 Offer lifestyle management

 Offer exercise

 Other (Please specify) .....

Q6. How frequently are claudication specialist clinics held?

 Weekly

 Every 2–4 weeks

 Every 2–4 months

 Less frequently than all the above options

 Other (Please specify) .....

Q7. What is the standard interval for routine follow-up for patients diagnosed with intermittent claudication?

- Every 1 month,
- Every 3–6 months
- Every 12 months
- Determined by clinical need
- No formal follow-up
- Not Known

- Other (Please specify) .....

Q9. In your organisation, what is the current waiting time for patients with intermittent claudication between referral and 1st appointment in the vascular specialist clinics?

Please specify .....

Exercise

Q10. Are patients with intermittent claudication who attend your Trust offered a supported exercise programme specifically designed for claudication? Please select all that apply.

- Yes
- No
- Verbal advice only

Q11. What is the format of the exercise programme for patients with claudication? Please select all that apply.

- Supervised classes in hospital or community setting

 Virtual Supervised classes at home

 App based directed exercise at home

 Home/Unsupervised

 Don't Know

Q12. If a structured programme exists, where is this programme provided?

 Your hospital/ Trust, i.e within your organisation

 Another hospital/ Trust, i.e outside your organisation

 Referral to primary care setting outside your organisation

 Referral to a private setting outside your organisation

 Other (Please specify) .....

Q13. Over what duration do these supervised exercise programmes typically last for patients diagnosed with claudication?

 4-8 weeks

 12–16 weeks

 More frequently than all the above options (Please specify) .....

 Less frequently than all the above options (Please specify) .....

Q14. How long are the classes (in minutes)?

 30-60 minutes

 60–90 minutes

 More frequently than all the above options (Please specify) .....

 Less frequently than all the above options (Please specify) .....

Q15. How often/frequently (times per week) do the classes meet?

 Once per week

 Every 2–4 weeks

 Every 2–4 months

 Less frequently than all the above options

 Other (Please specify) .....

Q16. Which healthcare professionals are involved in delivering the classes? Please select all that apply.

 Physiotherapist

 Nurse

 Exercise professional

 Other (Please specify) .....

Smoking

Q17. In your organisation, where do you offer a smoking cessation service to patients with intermittent claudication?

 Your hospital/ Trust, i.e within your organisation

 Another hospital/ Trust, i.e outside your organisation

 Referral to primary care setting outside your organisation

 Referral to a private setting outside your organisation

 Other (Please specify) .....

Dietetics

Q18. In your organisation, where do you offer a dietetics service to patients with intermittent claudication?

 Your hospital/ Trust, i.e within your organisation

 Another hospital/ Trust, i.e outside your organisation

 Referral to primary care setting outside your organisation

 Referral to a private setting outside your organisation

 Other (Please specify) .....

Psychology

Q19. Does your organisation offer a psychology service specific for patients with intermittent claudication?

 Yes

 No – If no please skip to question Q21

Q20. Is there a screening pathway for patients with intermittent claudication to be referred to a psychologist?

 Yes

 No – If no please skip to question Q21

Referral

Q21 What are the available pathways or methods by which patients with intermittent claudication are referred to the vascular service in your organisation? Please select all that apply:

 Vascular staff screen lists of hospital ward patients

 A telephone/pager referral system

 A paper referral form (collected in person/faxed/posted)

 Secure email system

 Electronic computerised system (e.g. patient record system)

 Other (Please specify) .....

Q22. Is there a standard proforma for referral to vascular?

 Yes

 No

 Other (Please specify) .....

Appendix 6. Messages used for co-design workshops

Table 6.1 Messages explaining that PAD is a lifelong condition

Option & voting	Suggested message	BCT	MoA
A - 10	PAD is a lifelong condition. It happens when blood doesn't travel properly from your heart to your legs. Half of patients with PAD who don't follow their treatment plan are at risk of a heart attack or stroke. To improve blood flow, you need to do things to keep your heart healthy, like exercise, healthy eating and stopping smoking. So just treating your legs won't make your PAD better.	5.1- Information about health consequences	Knowledge, Belief about consequences
B - 1	PAD is a lifelong condition, caused by years of fatty build-up in the arteries. Smoking, high cholesterol, high blood pressure and unhealthy lifestyle can lead to PAD.	4.2 – Information about antecedents	Knowledge
C -4	Without ongoing care, your PAD can get worse. In fact, 1 in 2 people like you could face another blockage or even have an amputation within five years. Regular walking, medications, and healthy habits can reduce your risk.	5.2 - Salience of consequences	Belief about consequences
D -9	PAD is a lifelong condition. If it gets worse, you may struggle with walking, working, or other activities. That could put pressure on your family and home situation, and even your ability to get out and about on your own. Having a healthier lifestyle and taking your medications can help you stay independent.	5.3 – Information about social and	Knowledge, Belief about consequences

		environmental consequences	
E - 0	Imagine it's a year from now and you're back in hospital, unable to walk far or needing an amputation. How would you feel knowing you had a chance to act earlier, but didn't?	5.5 – Anticipated regret	Belief about consequences
F - 1	If your condition gets worse, you might feel upset or angry at yourself because you didn't take your medications or adopt a healthier lifestyle. Walking regularly, taking your meds and stopping smoking will make you feel better about yourself and your health.	5.6 – Information about emotional consequences	Belief about consequences
G -9	Adopting a healthier lifestyle and taking your medications daily for PAD protects your heart and brain, improves your mobility and can keep you independent. But it takes daily effort and it's not a 'quick fix'.	9.2 – Pros and cons	Belief about consequences
H – 0	Imagine two versions of yourself in five years. One walks daily, takes medications and avoids smoking. The other one doesn't do any of these things. What does each version of you look like? Are you walking independently, or using a walking aid? Are you often in hospital?	9.3 – Comparative imagining of future outcomes	Belief about consequences
A&C - 10	PAD is a lifelong condition. It happens when blood doesn't travel properly from your heart to your legs. In fact, 1 in 2 people like you could face another blockage or even lose their toe or their leg within five years within five years. Without ongoing care, your PAD can get worse. To improve blood flow, you need to do things to keep your heart healthy, like exercise, healthy eating and stopping smoking.	5.1- Information about health consequences & 5.2 – Salience of consequences	Knowledge, Belief about consequences

A&D - 10	PAD is a lifelong condition. It happens when blood doesn't travel properly from your heart to your legs. If it gets worse, you may struggle with walking, working, or other activities. That could put pressure on your family and home situation, and even your ability to get out and about on your own. To improve blood flow and stay independent for longer, you need to do things to keep your heart healthy, like exercise, healthy eating and stopping smoking.	5.1- Information about health consequences & 5.3 – Information about social and environmental consequences	Knowledge, Belief about consequences
A&C&D - 10	PAD is a lifelong condition. It happens when blood doesn't travel properly from your heart to your legs. In fact, 1 in 2 people like you could face another blockage or even lose their toe or their leg within five years within five years. Without ongoing care, your PAD can get worse and you may struggle with walking, working, or other activities. That could put pressure on your family and home situation, and even your ability to get out and about on your own. To improve blood flow and stay independent for longer, you need to do things to keep your heart healthy, like exercise, healthy eating and stopping smoking.	5.1- Information about health consequences & 5.2 – Salience of consequences & 5.3 – Information about social and environmental consequences	Knowledge, Belief about consequences

Table 6.2 Messages explaining that PAD requires lifelong management – surgery is not the solution

Option & voting	Suggested messages	BCT	MoA
A -9	If your symptoms are very bad, surgery might help with your walking, but surgery won't lower your risk of heart attack or stroke. Taking your medications and having a healthier lifestyle will help lower this risk.	5.1- Information about health consequences	Knowledge, Belief about consequences
B - 1	Surgery might help your leg pain for a little while, but it doesn't fix PAD completely. If PAD isn't looked after over time, it can get worse. Some people find it harder to walk, take care of themselves, or may even need an amputation. This can also affect their family and job or daily activities.	5.3 – Information about social and environmental consequences	Knowledge, Belief about consequences
C -8	Surgery might help with your symptoms, but it doesn't cure PAD. If we don't treat the causes, other arteries can get blocked too, leading to heart attack, stroke or amputation. That's why taking medication, walking, healthy eating and stopping smoking are really important to reduce your risk of your disease getting worse.	4.2 - Information about antecedents	Knowledge
D -6	If your symptoms are very bad, surgery might offer symptom relief and easier walking . But it can be risky, leading to nerve damage, heart attack, stroke and new blockages. Surgery doesn't stop your PAD and there is a risk of re-blockage.	9.2 – Pros and cons	Belief about consequences
E - 3	Imagine it's next year, and your leg pain is back. Or worse, you're told surgery isn't possible. How would it feel to know it might have been prevented if you had managed	5.5 – Anticipated regret	Belief about consequences

	your condition differently through exercise, medications and stopping smoking every day?		
F -4	Some people think surgery will fix PAD completely, but that's not true. Even after surgery, PAD can become worse if it's not managed properly. Serious problems like heart attack, stroke or blocked arteries can still happen. Surgery doesn't stop PAD. It might help with severe symptoms, but only for some people. Taking care of your health every day is what really makes a difference.	5.2 - Salience of consequences	Belief about consequences
G -3	Many people feel disappointed after PAD surgery because they thought it would get rid of their pain. When the pain comes back, or when they find out they still need to take medications and walk every day, they may feel upset or confused. Making lifestyle changes now can help you make the best choices for your health and avoid that frustration later.	5.6 – Information about emotional consequences	Belief about consequences
H - 3	Imagine two versions of your future self. In one, you have had surgery, but you continue to smoke and don't take your medications regularly. A few months later, your pain is worse, and you're back in hospital. In the other, you don't need surgery because you walk every day, take your meds, and stop smoking. Your pain is more manageable, and you stay out of hospital. You can't control everything, but you can choose the path that gives you the best chance to stay independent for longer.	9.3 – Comparative imagining of future outcomes	Belief about consequences
A&F - 6	Some people think surgery will fix PAD completely, but that's not true. If your symptoms are very bad, surgery might help with your walking, but surgery won't lower your risk of heart attack or stroke. Even after surgery, PAD can become worse if it's not managed properly. Serious problems like heart attack, stroke or blocked arteries can still happen. Surgery doesn't stop PAD. It might help with severe symptoms, but only for some people. Taking care of your health every day is what really makes a difference.	5.1- Information about health consequences & 5.2 – Salience of consequences	Knowledge, Belief about consequences

Table 6.3 Messages explaining that aspirin and statins do not improve claudication symptoms directly, but they reduce the risk of heart attack or stroke

Option & voting	**Suggested messages**	**BCT**	**MoA**
A - 5	PAD starts because of long-term damage to your blood vessels, often from cholesterol, smoking, and high blood pressure. Statins and aspirin help treat the *cause,* not the leg pain itself. They also stop the disease from getting worse in other parts of your body, like your heart or brain.	4.2 - Information about antecedents	Knowledge
B – 9	While aspirin and statins don't help with the claudication pain directly, they protect your blood vessels and lower your risk of a heart attack or stroke by nearly 40%. Think of them like a protection/prevention plan.	5.1- Information about health consequences	Knowledge, Belief about consequences
C - 3	You might not notice a difference while taking aspirin and statins, but without them, your risk of a heart attack or stroke goes up. PAD means you already have narrowed arteries. It's not just about your legs, it's about your whole body.	5.2 - Salience of consequences	Belief about consequences
D - 1	If your condition gets worse without medication, it could affect your ability to live independently, work, care for loved ones, or continue activities you enjoy. Taking aspirin and statins helps you stay active, avoid hospital stays, and reduces the strain on you and your family.	5.3 – Information about social and environmental consequences	Knowledge, Belief about consequences
E – 0	Imagine you didn't take the medication because you didn't think it made a difference. Then months later, you have a stroke. Many patients in that position say, 'I wish I'd known how serious PAD really was, even though I couldn't feel it.'	5.5 – Anticipated regret	Belief about consequences

F – 0	Imagine in a year from now, you're back in hospital with worse symptoms. Would you look back and wish you had stayed on the statin or spoken to your doctor before stopping it?	5.5 – Anticipated regret	Belief about consequences
G – 8	Patients who take control of their health by taking medications often feel more confident and less anxious. Even though you may not feel the effect physically, knowing you're actively preventing something serious, like a heart attack or losing your leg, can bring peace of mind.	5.6 – Information about emotional consequences	Belief about consequences
H - 6	Your doctor/nurse prescribed aspirin and statins for you to slow down the blocking of your arteries that carry blood around your body. By taking these tablets, your risk of a heart attack or stroke will be lower, even if the tablets don't stop the pain in your legs.	9.1- Credible source	Belief about consequences
I - 7	Aspirin and statins help protect your heart and blood vessels in the long run. However, they don't fix claudication pain from PAD, and there is a chance they might cause mild side effects. These medications treat the cause of PAD, not just the symptoms, reducing your risk of having a heart attack, stroke or amputation.	9.2 – Pros and cons	Belief about consequences
J – 1	Imagine two versions of your future. One where you continue taking your medications, you avoid losing your leg, stay mobile, and live independently. The other version where you stop your medications because you didn't feel different. Months later, you have a heart attack and face a long recovery. Which future do you want?	9.3 – Comparative imagining of future outcomes	Belief about consequences

Table 6.4 BCT Messages to address the concern that "Statins will make my claudication pain worse"

Option & voting	**Suggested messages**	**BCT**	**MoA**
A - 6	Statins don't make PAD worse, they're actually protecting you from having a heart attack or stroke. The pain might be from walking more or your PAD getting worse, not the statins. If you are experiencing more pain, speak to your doctor, nurse, or pharmacist.	5.1- Information about health consequences	Knowledge, Belief about consequences Negative attitudes, Vulnerability
B - 3	Statins help protect your arteries, improving blood flow and reducing your risk of heart attack and stroke. Most people don't find their claudication pain worsens with statins, and some even notice improved walking. Taking statins can help you stay active and independent for longer.	5.2 – Salience of consequences	Knowledge, Belief about consequences Negative attitudes, Vulnerability
C - 2	If you don't take your statins your PAD may get worse. This can affect your ability to work, walk to the shops, or stay independent. It can put pressure on your family too.	5.3 – Information about social and environmental consequences	Knowledge, Belief about consequences, Negative attitudes
D – 2	Many people feel frustrated or guilty when they stop medication and later find out their condition has got worse. Staying on your statin can give you peace of mind and confidence that you're doing the right thing.	5.6 – Information about emotional consequences	Belief about consequences
E - 3	Statins lower your risk of heart attack and stroke, help protect your arteries, and they can keep you healthier for longer. Some people may experience mild muscle aches, but this doesn't happen to everyone and doesn't mean your claudication pain will get worse.	9.2 – Pros and cons	Belief about consequences, Negative attitudes

F – 8	Statins do not make PAD worse. If you think you have side effects from your statins, talk to your doctor. Most patients can switch to a type of statin that may work better for them. Don't just stop taking them on your own.	9.1- Credible source	Negative attitudes
G - 6	Statins don't cause PAD symptoms, so can't make your claudication pain worse. Statins actually help protect your arteries. They are an important part of keeping you healthy for life, not the cause of your pain.	13.2- Framing/ reframing	Negative attitudes
H - 3	If you get leg pain whilst taking statins, book an appointment with your doctor or pharmacist. They can help work out if a different statin might be better for you, or if you need more care for your PAD. You don't have to figure it out alone.	3.2 – Social support (practical)	Social influence
I - 3	George, who also has PAD, thought the statin was causing his leg pain. Turns out it was his circulation getting worse. Once his statin medication was adjusted, he was walking further and felt reassured about staying on the statin.	6.2- Social comparison	Social influence
B&E&F&H	Worried that statins might make your leg pain worse? Statins do not make PAD worse. They lower your risk of heart attack and stroke, help protect your arteries. If you think you have side effects from your statins, book an appointment with your doctor or nurse.	3.2 – Social support (practical) & 5.2 – Salience of consequences & 9.1- Credible source & 9.2 – Pros & cons	Belief about consequences, Vulnerability Negative attitudes, Social influence

Table 6.5 BCT Messages for negative beliefs about the necessity of smoking – 'too late to quit'

Option & voting	**Suggested messages**	**BCT**	**MoA**
A – 8	PAD doesn't appear overnight. It develops over years due to things like smoking, high blood pressure, and cholesterol. Quitting smoking now helps stop the damage continuing. You may not be able to change your past, but you can control your future.	4.2 – Information about antecedents & 5.1- Information about health consequences	Knowledge
B - 12	Quitting smoking, even after being diagnosed with PAD, lowers your risk of needing surgery, slows artery damage, and you are less likely to have heart attack, stroke and limb loss. Your circulation can start improving in just weeks. It's never too late to give your body a chance to get better.	5.1- Information about health consequences	Knowledge, Belief about consequences
C - 6	Because smoking affects your blood flow/circulation, it can also affect how much you can do with your family and friends, how independent you can stay, and whether you'll need help walking or looking after yourself in the future. Quitting protects your quality of life and your loved ones too.	5.3 – Information about social and environmental consequences	Knowledge, Belief about consequences
D – 3	Your doctor will tell you that even people who smoked their whole lives felt better after they quit. They could walk more and had better blood flow. It's not true that it's 'too late' to stop. Every cigarette you **don't** smoke is good for you.	9.1- Credible source	Negative attitudes
E – 4	Quitting smoking slows PAD, reduces the risk of heart attack or stroke, and helps your lungs and legs work better, even though it might make you feel frustrating or uncomfortable in the short-term.	9.2 – Pros and cons	Belief about consequences
F – 8	Some damage from smoking is already done. But quitting stops new damage from happening every day. By quitting now, you can take more control over your future	13.2- Framing/ reframing	Negative attitudes

B&C	Quitting smoking, even after being diagnosed with PAD, lowers your risk of needing surgery, slows artery damage, and you are less likely to have heart attack, stroke and amputation. Your circulation will start improving in just weeks. It's never 'too late' to cut down or stop smoking. Every cigarette you **don't** smoke is good for you.	5.1- 5.1 Information about health consequences & 5.3 – Information about social and environmental consequences	Knowledge, Beliefs about consequences

Table 6.6 BCT Messages to address the lack of motivation to quit smoking

Option & voting	**Suggested messages**	**BCT**	**MoA**
A - 2	Set a clear quit plan. This could be: 'I will stop smoking in 2 weeks and remove cigarettes from my home the night before.' Setting specific goals and writing them down helps make it real.	1.1 – Goal setting (behaviour)	Goals
B – 4	Think ahead about when you're most likely to smoke, for example after meals, when bored, or stressed. Make a list of things you could do instead, like taking a short walk, drink water, or call someone. Planning helps you stay in control.	1.2 - Problem solving	Motivation, Belief capabilities, Behavioural regulation

C – 8	Think about your end goal: avoiding losing your leg, walking without pain, living longer independently. Quitting smoking will help you improve your health and avoid serious complications from PAD.	1.3 – Goal setting (outcome)	Goals
D – 2	Check in with yourself once a week: How many cigarettes did I cut down/avoid this week? What got in the way? What went well? Reviewing your goals helps you adjust and keep improving.	1.5 – Review behaviour goal(s)	Goals
E – 3	If your goals are to avoid losing your leg, improve your circulation, reduce pain, and avoid surgery, but you're still smoking, ask yourself what you could do differently to reach your goals.	1.6 - Discrepancy between current behaviour and goal	Goals
F – 0	Try keeping track of each day you don't smoke using a calendar or app. Seeing your smoke-free days add up can help you stay motivated and remind you how far you've come.	2.3- Self-monitoring of behaviour	Behavioural regulation
G – 4	Most people smoke when they are tired, stressed or busy. Spot the triggers that get in your way and then make a plan to deal with them when they show up.	4.2 – Information about antecedents	Knowledge
H – 2	Before quitting, practise what you'll say if someone offers you a cigarette or if you have a craving. Planning what you will say helps you feel more confident when cravings hit, or you are under or social pressure.	8.1 – Behavioural practice/ rehersal	Beliefs about capabilities

I – 2	When you feel the urge to smoke, swap it for a healthy alternative, like a healthy snack, a drink of water, or a short walk. Replacing a bad habit with a healthy one helps create healthier long-term plans.	8.2 – Behaviour substitution	Behavioural regulation
J – 8	You don't have to quit smoking all at once. Start by cutting down, delay your first cigarette, smoke fewer each day, or set a quit date and work towards it. Every cigarette that you don't smoke helps your body get better.	8.7 – Graded tasks	Beliefs about capabilities
K – 4	You might feel like smoking helps right now, but quitting has big benefits. It can help your blood flow, make walking easier, and lower your chance of a heart attack, stroke or losing your leg.	9.2 – Pros and Cons	Motivation
L – 0	Quitting smoking can make you feel upset or sad at first. That's normal. Try breathing exercises, short walks, or listening to music to improve your mood and stay on track.	11.2 – Reduce negative emotions	Behavioural regulation
M – 0	Trying to make too many changes at once can be overwhelming. Focus on quitting smoking first, and keep your daily routines simple, like using reminders and reducing stress where possible.	11.3 – Conserving mental resources	Behavioural regulation
N – 2	Quitting is hard, but many people with PAD have done it, and so can you. Every time you resist a cigarette, you're proving to yourself that you can change.	15.1 - Verbal persuasion about capability	Beliefs about capabilities
C&J&N	Quitting is hard, but many people with PAD have done it, and so can you. You don't have to quit smoking all at once. Start by cutting down, delay your first cigarette, smoke fewer each day, or set a quit date and work towards it. Think about your end	15.1 - Verbal persuasion about capability & 1.3 –	Beliefs about capabilities &

	goal: avoiding losing your leg, walking without pain, living longer independently. Quitting smoking will help you improve your health and avoid serious complications from PAD. Every cigarette that you don't smoke helps your body get better.	Goal setting (outcome) & 8.7 – Graded tasks	Goals & Beliefs about capabilities
J&G&K and use social aspects of G-J & add NHS resources to the message	You don't have to quit smoking all at once. Start by cutting down, delay your first cigarette, smoke fewer each day. Many people smoke when they feel stressed, tired, or overwhelmed. These are common triggers. Spotting your triggers is the first step. Once you know what sets off the urge, you can plan how to respond. Cravings will come, especially in social situations or when someone offers you a cigarette. Practice what you'll say in advance. Having a plan makes it easier to stay confident and in control. When the urge hits, swap the cigarette for something healthier: try a glass of water, a walk, or a light snack. Replacing the habit helps build long-term change. It might feel like smoking helps in the moment, but quitting has big benefits: better blood flow, easier movement, and a lower risk of heart attack, stroke, or amputation. Every small step counts, you're not alone. Are you thinking of cutting down or quitting smoking? Look at these resources.....Link NHS quitting smoking	8.7 – Graded tasks & 9.2 – Pros & Cons & 4.2 – information about antecedents	Beliefs about capabilities & Motivation & Knowledge

Table 6.7 BCT Messages to address the lack of education on the safety and purpose of walking with the pain

Option & voting	**Suggested messages**	**BCT**	**MoA**
A – 6	PAD means you have less blood supply to your legs and this is why it hurts when you walk. If you walk until it hurts and then rest, your body starts to build new paths for blood to flow. This helps your legs get stronger and makes walking easier over time.	4.2 – Information about antecedents	Knowledge
B – 4	The reason why it hurts when you walk, is because of problems with blood supply to your legs. When you walk until it hurts and then rest, your body starts to build new paths for blood/ new blood pathways to flow. This helps your legs get stronger and makes walking easier over time.	4.2 – Information about antecedents	Knowledge
C – 8	Walking to the point of pain, and then resting, actually helps your body build new blood pathways around the blocked vessel. Over time, this means you can walk further with less pain. It's one of the best ways to manage PAD safely and naturally.	5.1- Information about health consequences	Knowledge, Belief about consequences
D – 6	If you avoid walking because of pain, your leg muscles get weaker, your circulation/ blood flow slows even more and it will be harder to walk as far. But pushing bit by bit through the discomfort can reduce your claudication pain and help you stay more independent.	5.2 –Salience of consequences	Belief about consequences
E – 4	Not walking can mean relying on others for shopping or daily tasks. Regular walking helps you stay active and less dependent on others for longer.	5.3 – Info about social and environmental consequences	Knowledge, Belief about consequences

F – 3	Imagine if in a year from now, you are unable to walk, even for a short distance, and you're told you need surgery or that nothing can be done to improve your walking. You might regret that you had the chance to strengthen your legs, but you avoided it as you didn't want to walk with some pain. By walking now, even when it's tough, you're helping give your future self the best chance.	5.5 – Anticipated regret	Belief about consequences
G – 6	At first, walking with claudication pain can feel scary or frustrating, but as you keep going, you'll feel stronger and more confident because you're helping your body get better.	5.6 – Information about emotional consequences	Belief about consequences
H – 5	Walking with claudication pain might be painful and requires daily efforts to see results. But it is the best way to improve claudication pain, improve leg circulation, build strength, and delay or avoid surgery.	9.2 – Pros and cons	Belief about consequences
I – 5	Imagine two versions of your future. In one you walk 5 times a week through manageable pain, and over time, you're able to walk to the park, visit friends and stay active. In the other version, you avoid walking, your legs get weaker, you are unable to walk independently, and you may need surgery. Which path would you want to choose?	9.3 – Comparative imagining of future outcomes	Belief about consequences
A,B,C,D &G	Do you continue walking if you have pain? You pain is cause because of bad circulation in your legs. At first, walking with claudication pain can feel scary or frustrating. Walking to the point of discomfort, and continue walking through the pain instead of resting, helps your body build new blood pathways around the blocked vessel. Over time, this process improves circulation, strengthens your legs, and gradually makes walking easier and less painful. Avoiding exercise due to pain can weaken your muscles and worsen your symptoms, but consistently pushing through mild to moderate discomfort helps manage PAD naturally, improves mobility, and supports your independence. Walking every day makes it a habit.	4.2 – Information about antecedents, 5.1- Information about health consequences, 5.2 – Salience of consequences, 5.6 – Information	Knowledge, Beliefs about consequences

		about emotional consequences	
G&H	At first, walking with claudication pain can feel scary or frustrating, but it is the best way to improve claudication pain, improve leg circulation, build strength, and delay or avoid surgery.	5.6 – Information about emotional consequences, 9.2 – Pros & cons	Beliefs about consequences
A, D &H	PAD means you have less blood supply to your legs, and this is why it hurts when you walk. If you walk until it hurts and then rest, your body starts to build new paths for blood to flow. This helps your legs get stronger and makes walking easier over time. If you avoid walking because of pain, your leg muscles get weaker, your circulation/ blood flow slows even more and it will be harder to walk as far. But pushing bit by bit through the discomfort can reduce your pain and help you stay more independent. Walking with claudication pain might be painful and requires daily efforts to see results. But it is the best way to improve claudication pain, improve leg circulation, build strength, and delay or avoid surgery.	4.2 – Information about antecedents, 5.2 - Salience of consequences, 9.2 – Pros & cons	Knowledge, Beliefs about consequences

Table 6.8 BCT Messages to address environmental barriers (weather, time, location) for exercise & support walking

Option & voting	**Suggested messages**	**BCT**	**MoA**
A – 11	Even short walks are helpful, and you can do these inside or outside. Think about your daily routine and when is the most convenient time for you to go for a walk. Set up a reminder so you don't forget. A simple alarm on your phone or a sticky note can remind you to walk. Walking everyday makes it a habit, so it is easier to stick to over time.	7.1 – Prompts/cues	Environmental context & resources
B - 0	If cold, wet, or dark weather puts you off walking, try indoor options like walking in a shopping centre, community centre, or even around your home. Wearing comfortable and/or waterproof clothes and shoes, and listening to music while you walk, can make it feel easier and more enjoyable.	11.2 – Reduce negative emotions	Environmental context & resources
C – 0	If cold, wet, or dark weather puts you off walking, try indoor options like walking in a shopping centre, community centre, or even around your home. Walking on the spot, or marching while sitting watching TV is better than not walking at all.	11.2 – Reduce negative emotions	Environmental context & resources
D – 0	If cold, wet, or dark weather puts you off walking, try indoor options like walking in a shopping centre, community centre, or even around your home. If you're speaking on phone, consider walking around your home while you talk.	11.2 – Reduce negative emotions	Environmental context & resources

E	Certain routines, like always sitting on the sofa after lunch, can make it less likely that you will keep active. Try keeping your walking shoes by the door as a visual reminder, or change your routine slightly so that you always take a walk before you sit down and rest. Small changes to your routine can help you form a habit to walk more and be healthier.	12.3 – Avoidance/reducing exposures to cues for behaviour	Environmental context & resources
E & Suggestions	Small changes to your routine can help you form a habit to walk more and be healthier. • Try keeping your walking shoes by the door as a visual reminder • Take a walk before you sit down and rest • Listening to music or a podcast while you walk • Going up and down the stairs, • Doing chair or bed exercises, • When working or using your laptop, try switching to a standing desk • Standing and walking to get a glass of water instead of having it near you	7.1 – Prompts/cues & 11.2 – Reduce negative emotions & 12.3 – Avoidance/reducing exposures to cues for behaviour	Environmental context & resources

Appendix 7. Feedback from think-aloud interviews

Table 7.1 Positive and negative feedback following Round 1 of think-aloud interviews.

	Intervention element	**Negative Comments**	**Positive Comments**	**Possible change**
1	Front page	The photo isn't representative of the general PAD population as they are all happy and walking, especially those who have experienced previous amputation.	Patients really like the front page. They like the colours, the titles and photo. Like the diversity & that people smile. It's encouraging	Change front page photo & colour scheme. P5 suggested that we have a photograph of an amputee and not have "actors".
2	Overall booklet	The text is a bit small and not very easy to read for older people or those with visual problems.	Very positive, simple & effective language, non-jargon, feels friendly and encouraging. A friendly guide, useful resource, that will cover the current gap of info resources.	Make the text bigger
3	Colour scheme	Remove red tones as this means danger.	5/6 patients happy with the current colour scheme, they like blue, it's calming, reminds them of the NHS.	Suggestion to have a warm pink or a lavender colour, as these colours are liked by most people and are associated with calmer thoughts and feelings.

4	Content - Page 2	N/A	All patients happy with this page. Good to have vascular numbers etc in one place.	N/A
5	PAD - Page 3	The photo isn't crystal clear.	Right info, easy to follow. Nice photo.	Move photo after 1st paragraph so it flows better. Add text about blockage in the photo.
6	PAD - Page 3	One patient (P5) felt that it is not appropriate to talk about surgery in that text as I am not a doctor and this should be down to the doctor's discretion to discuss about it. Pt suggested to remove that section.	Overall info easy to follow. 5/6 patients reported it's important to talk about it.	N/A
7	Meds & PAD - Page 4	Rephrase last sentence so it's very clear that we are still talking about meds.	Really useful, easy to understand.	"Even though you may not feel the effect of the medications physically, knowing you're actively preventing something serious, can bring peace of mind." *
8	Meds & PAD - Page 5	Section "Could taking statins make my leg pain worse?" – 2nd paragraph also add pharmacist as community pharmacists can help		"If you have any concerns or questions, speak to your doctor, nurse or pharmacist." *

9	Meds & PAD – Page 5	Section "How can I make it easier to take my medications every day" – suggestion to make it clear		Rephrase 2nd bullet point: post-its instead of sticky notes
10	Meds & PAD -Page 5	Not a negative comment, more of a suggestion from P1 (who is diabetic) to add about free prescriptions.	Really clear and easy wording. Encouraging, addresses points on statins concerns, appealing photos, really like idea of Dossett box.	Add an extra bullet point "If you are diabetic, speak to your pharmacist / ask your pharmacist about a medical exemption certificate to get your prescriptions for free" – or something along these lines
11	Smoking & PAD- page 6	Photo – not effective for behaviour change, doesn't even focus on it. Implies that someone invites you to have a cigarette instead of actually avoid it.	Overall wording is good and relatively encouraging. Doesn't feel patronising. Smokers like the fact that it talks about cutting down. Patients who haven't smoked also found this section clear and informative. Although it's not applicable to them, it could help other patients.	Replace that photo or add an extra one showing the timeline of quitting smoking and the benefits for the body (P3). Simple facts in non jargon language. We have a sentence about it in the text but patient thinks it would be really useful to also have that in a visual format. If this photo is added it should go in page 7, after the relevant text "I've smoked for years, would quitting now even make a difference?"
12	Smoking & PAD – page 6	Not sure about smoking & stress, it's mainly habit/boredom, rather	Likes this section about triggers and cutting down. Feels that it's	Re-organise section about do I really need to quit smoking.

		than stress. Ideally we should remove the section, or merge it with the rest of the text about triggers.	effective and has made him think about how he could cut down (P3).	
13	Exercise – page 9	It is not 100% clear that we are saying that exercise isn't harmful so we will have to spell it out.	Really encouraging, right amount of information.	"Although walking through the pain may feel uncomfortable or frustrating at first, it is not harmful and it will help in the longer term." *
14	Exercise – page 11	"Here are some simple things you can do around the house" we have examples that aren't just in the house.	Very useful but need to correct minor typos.	1)Change to "Here are some simple things you can do home or indoors" 2)Move bullet point 5 to last and make sure there are commas, full stops in the right places
15	Exercise – page 11	Offer clarity around chair exercises.	Same as above.	Replace photo of bike with someone doing a chair exercise.
16	Goals Table – Page 13	Minor typo for cigs cut down to 15 not 18.	Really useful examples and like variation in different behaviours.	Correct typo.

17	Support resources – page 15	Important info on how to recognise CLTI & what to do is missing.	Like all resources, especially mental health. Was not previously aware of CF or Legs Matter.	Add a separate page about CLTI – adopt SVN RING poster

*The highlighted text represents the changes in the text suggested by participants

Table 7.2 Positive and negative feedback following Round 2 of think-aloud interviews.

	Intervention element	**Negative Comments**	**Positive Comments**	**Possible change**
1	Front page	Nil	All patients (6/6) liked the photo and the colours (orange/blue). Encouraging, makes people want to walk.	N/A
2	Overall booklet	2/6 patients found the text a bit small.	Very positive, simple & effective language, non jargon, feels friendly and encouraging. A friendly guide, useful resource, that will cover the current gap of info resources.	Make the text bigger.
3	PAD- Page 3	P11: Words “lifelong” and “amputation” are alarming – this wasn’t discussed at his clinical appointment. However, he agrees that it’s important	Very informative, all like the figure.	N/A

		information and does not wish for these to be removed.		
4	PAD – Page 3	One patient found the colours in the diagram a bit “muted” and asked if we can make them more professional and vibrant.	Great representation of PAD, clear, easy to understand.	N/A
5	Meds – page 4&5	-	Right info, easy to follow. Nice photo. No need to change anything.	N/A
6	Smoking & PAD – pages 6&7	The text in the image is a bit small and it needs to be more polished.	Overall wording is good and relatively encouraging. Doesn’t feel patronising. Smokers like the fact that it talks about cutting down. Patients who haven’t smoked also found this section clear and informative. Although it’s not applicable to them, it could help other patients. All patients prefer the current photo, timeline of smoking, instead of the previous (R1) photo.	Make the text in the figure bigger.
7	Exercise – page 8-10	P8: Could potentially add treadmill in page 11	Happy with all info, encouraging to keep walking, not harmful,	Correct minor typo

		Minor typo in page 10: wa-ter	simple language, like practical tips.	
8	Goals – pages 11-13	-	Really useful & like examples. P11 said that this doesn't really apply to him because he is very organised but it's good to know he is doing the right things and it will also be useful for people who don't have a routine.	N/A
9	CLTI Page - 14	-	Great but can be alarming as some people didn't know about it.	N/A
10	Support resources	-	Like all resources, especially mental health. Was not previously aware of CF or Legs Matter.	N/A

Appendix 8. Final PAD&Me booklet (following designer input)



Figure 8.1 Front and content page



Figure 8.2 Pages 3 and 4

Could taking statins make my leg pain worse?
Statins don't cause PAD symptoms, so can't make your claudication pain worse. Research in people taking statins has found that over 90% of the muscle pain or discomfort patients reported was not caused by the statin itself.

Statins help protect your arteries and lower your risk of heart attack, stroke, and amputation. They are an important part of keeping you healthy for life and are not the cause of your pain. Like any other medication, some people may have an allergy and/or intolerance to specific statins. If you have any concerns or questions, speak to your doctor, nurse or pharmacist. Most patients can switch to a type of statin that may work better for them. You don't have to figure it out alone.

How can I make it easier to take my medications every day?
1. Keep a medication tracker so you stay on top of your doses.
2. Try setting reminders on your phone or use sticky notes.
3. Try to link your medication to other daily habits, like brushing your teeth or having breakfast.
4. Ask your pharmacist about packaging that might help to make it easier to take your medication, like a Dosett box.
5. If you pay for your prescription ask your pharmacist about a prescription prepayment certificate, which might save you money on your medications.
6. Prescriptions are free to people with diabetes and some other chronic conditions as well as those over 60 and/or living in Scotland, Wales or Northern Ireland. Check with your pharmacy about whether this applies to you.



3. Smoking & PAD

The decision to quit smoking is your choice, however, quitting will really improve your PAD and your health in general, and is strongly advised. This section is about the benefits of quitting smoking for your PAD and where to find help if you are thinking about quitting or cutting down.

I've smoked for years, would quitting now even make a difference?
Quitting smoking, even after being diagnosed with PAD, slows artery damage, lowers your risk of needing surgery, and your risk of having a heart attack, stroke and amputation. Within two weeks, your circulation will begin to improve, making exercise and walking feel easier. By quitting now, you can take more control over your future.



Figure 8.3 Pages 5 and 6

But quitting is hard, how can I do it?
Quitting is hard but many people with PAD have done it, and so can you. You don't have to quit smoking all at once. Start by cutting down, delay your first cigarette, smoke fewer each day, or set a quit date and work towards it.

Many people smoke when they feel stressed, tired, bored or believe it helps them relax. Recognising these common triggers is the first step. Once you know what sets off the urge, you can plan how to respond. You might want to smoke when stressed, but we know that when nicotine wears off, stress levels actually get higher than before. When the urge hits, swap the cigarette for something healthier: have a glass of water, a walk, or a light snack. Cravings might come, especially in social situations or when someone offers you a cigarette. Practise what you'll say in advance. Having a plan makes it easier to stay confident and in control. Replacing the habit helps build long-term change. Every cigarette that you don't smoke helps your body get better!

What should I do if I am thinking abbut cutting down or quitting smoking?
Everyone is different, so the best way to quit is the way that fits you and your lifestyle. But you don't have to do this alone! It's okay to need extra encouragement; don't beat yourself up if you don't do it right away.

The NHS Stop Smoking Service is free, supportive, and designed to help you find what works best for you, not force you to follow one set plan. Support might include one-to-one or group sessions, medicines to reduce cravings and/or nicotine replacement therapy (like patches or gum).

Using NHS support and stop-smoking treatments together can make you up to 4 times more likely to quit for good! To get started, call 0300 123 1044, search "NHS Stop Smoking Service", or visit the NHS website, which also offers a stop-smoking app and help to create your own quit plan.

4. Physical Activity & PAD

It hurts when I walk, won't that damage my legs?
It's normal to worry, but walking with claudication is safe and one of the best things you can do for your legs even if it hurts. If you avoid walking because of pain, your muscles get weaker, your blood flow slows down even more, and it becomes harder to walk as far.



Although walking through the pain may feel uncomfortable or frustrating at first, it is not harmful and it will help in the longer term. Walking to the point of discomfort, and continuing a little before resting, encourages your body to build new blood pathways around the blocked areas. Over time, this improves circulation, strengthens your legs, and helps reduce the pain over time. With regular walking, you'll likely find it easier to go further without stopping and stay more active and independent in daily life.

Figure 8.4 Pages 7 and 8

What activities should I be doing?

The goal is to work up to 30 minutes of walking each day. It might feel challenging at first, but every step counts toward building strength and stamina.
Try to make this extra walking just for exercise, beyond what you normally do, over time. It will become a healthy daily habit.

You can use a timer to keep track:

1. Start the timer when you begin your walk.
2. Walk at your usual pace until you feel pain – keep going for as long as you can manage.
3. When you need to stop and rest, pause the timer.
4. Start the timer again when you start walking.
5. Repeat this until you've walked for a total of 30 minutes (rest time doesn't count).

It may take longer than 30 minutes overall, because you'll need to stop and rest along the way, and that's okay. Over time, as you practice walking through some discomfort, you will find you can walk longer before needing to rest. To feel confident, try to walk in a safe, familiar place and keep a water bottle with you.

How can I fit exercise into my day when I don't have time?

Walking and staying active every day can make a real difference. Look at your daily routine and pick a time that works best for you to exercise. For example, get off the bus a stop earlier, take the stairs instead of the lift, or go for a short walk after meals. Making it part of your routine helps it become a habit that's easier to keep up. Small changes to your daily routine can help you form a habit of being more active and healthy.

What can I do to stay active during adverse weather?

If the weather is bad or too hot to go outside, there are still plenty of ways to keep moving indoors! While these suggestions won't directly improve your claudication, as you need to walk for 30 minutes every day to do that, staying active in general is really important for your health.

Here are some simple things you can at home or indoors:

- Going up and down the stairs, or around your house
- Doing seated exercises, like heel raises and knee extensions
- Try standing up to work, by putting your laptop on a box or shelf, or even getting a standing desk
- Get up and walk when adverts are on the TV
- Use a stepper or an exercise bike
- Walk around a covered shopping centre



Figure 8.5 Pages 9 and 10

5. Goal Setting

Making manageable changes

This booklet covers different ways you can look after your health. Setting goals, such as taking your medications daily, exercising, and looking after your health, will help you make healthy changes. It's normal to feel unsure about where to start.

Remember:

- Start with what feels easiest or most important to you right now.
- You don't have to change everything all at once.
- Things like reminders, diaries, tracking apps, having a routine and getting support can really help.
- One step at a time! Even small changes can make a difference.

Your personal goal planner

Use the planner below to set weekly goals, track your progress, and think about what might help you next week.

Tips for filling this in:

- You can focus on one goal each week.
- Start with something small and manageable, don't overwhelm yourself.
- At the end of each week, take a moment to reflect: What helped? What was hard? What could help next week?
- Keep your planner somewhere you'll see it daily, like on the fridge or bedside table.
- You can set your goals independently, with family and friends or your healthcare professional.
- Celebrate your progress, every small change matters!

Example PAD Goals

Date	Weekly Goal	Where & When Action Planning	Tick If Goal Achieved	Challenges & Solutions
1st August 2025	Walk for 10 minutes every day after my meals	I will walk right after breakfast, lunch and dinner. If it's raining, I will walk around the house for 10 minutes after breakfast, lunch and dinner.	○ Monday ● Tuesday ○ Wednesday ● Thursday ● Friday ● Saturday ● Sunday	**Challenge:** Don't like walking alone. **Solution:** Listen to music when I walk, or walk with a friend, or phone a friend when I am walking.
15th August 2025	Take my cholesterol-lowering tablet daily.	When I brush my teeth at night, I will immediately take my statin.	● Monday ○ Tuesday ● Wednesday ● Thursday ● Friday ○ Saturday ● Sunday	**Challenge:** Going to bed late and forgetting to take my medications. **Solution:** Keep my statins next to my toothbrush.
30th August 2025	Cut down from 20 to 15 cigarettes per day.	If I feel the urge to smoke outside of my 15 planned cigarettes, then I'll delay for 5 minutes and drink a glass of water or chew gum instead.	● Monday ● Tuesday ● Wednesday ● Thursday ● Friday ○ Saturday ● Sunday	**Challenge:** Strong cravings when stressed or with coffee/alcohol. **Solution:** Keep water and gum nearby, and avoid smoking triggers (e.g., limit coffee/alcohol).

Figure 8.6 Pages 11 and 12

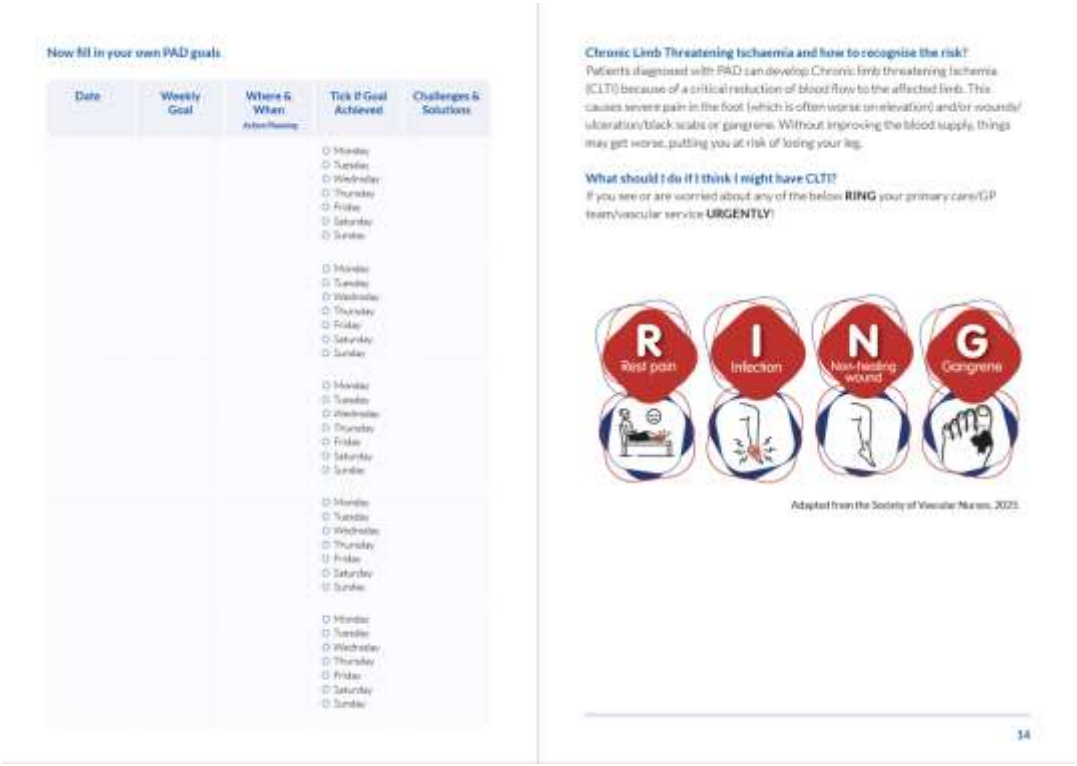


Figure 8.7 Pages 13 and 14

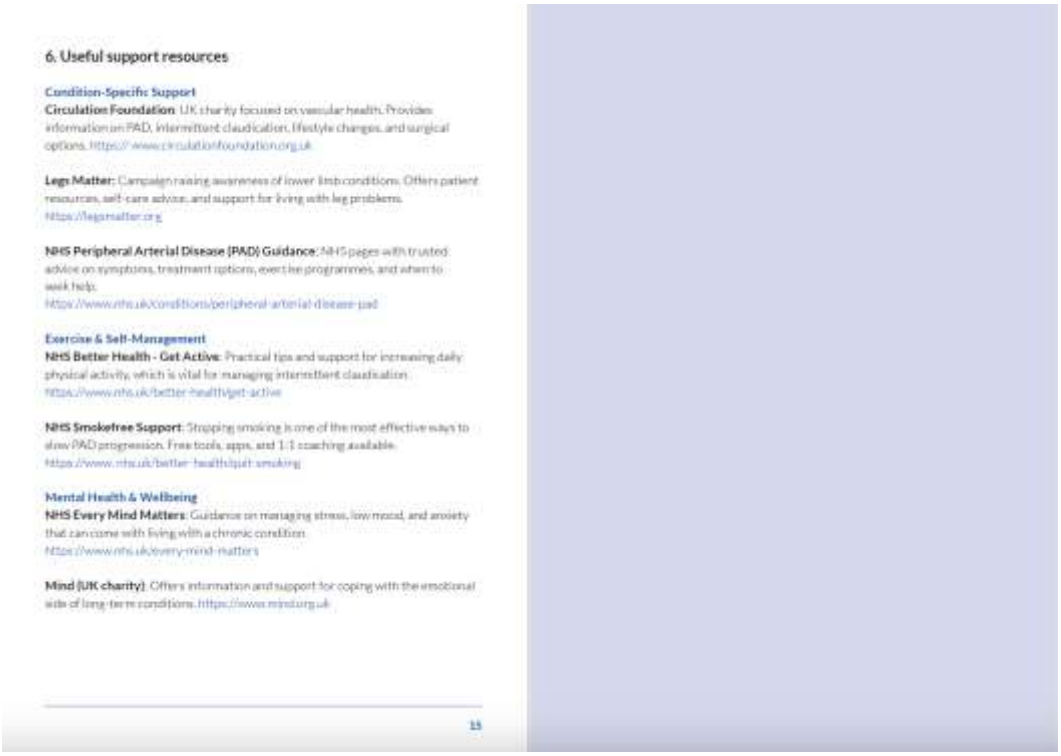


Figure 8.8 Page 15 and back page