Dissertation

A feasibility study for the implementation of a disease-management program for patients with peripheral arterial disease

submitted by

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Declaration

This dissertation is entirely my own original work, and I have acknowledged by name all those individuals and organisations that have contributed to the research upon which it is based. I have also made appropriate references to all other material used. In preparing this thesis, and all related publications, I have complied with the “Guidelines of the Medical University of Graz on Good Scientific Practice.”

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Disclosures

The current doctoral thesis was the basis for the preparation of a manuscript, which has been published in the journal "Vasa European Journal of Vascular Medicine". The published manuscript was drafted by the doctoral candidate, Andreas Prenner. Therefore, significant parts of the doctoral thesis are similar to the published manuscript. The publisher's permission for use can be found in the appendix.

"Usability of a telehealth-nurse supported home-based walking training for peripheral arterial disease – The Keep Pace! pilot study"(1)

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Abbreviations and Definitions

6 MWT ..... *Six-minute walk test*
ABI ..... *Ankle-brachial index*
AHA ..... *American Heart Association*
CKD ..... *Chronic Kidney Disease*
CLI ..... *Critical limb ischemia*
CTA ..... *Computed tomography angiography*
CVD ..... *Cardiovascular diseases*
DSA ..... *Digital subtraction angiography*
DUS ..... *Duplex ultrasound*
ESC ..... *European Society of Cardiology*
ESVM ..... *European Society of Vascular Medicine*
HDL ..... *High-density lipoprotein*
KIT ..... *Keep in Touch*
LDL ..... *low-density lipoprotein*
MRA ..... *Magnetic resonance angiography*
PAD ..... *Peripheral Arterial Disease*
PAOD ..... *Peripheral arterial occlusive disease*
PFWD ..... *Pain-free walking distance*
TUG ..... *Time Up and Go*

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Abstract in German

Die periphere arterielle Verschlusskrankheit (PAVK) ist eine Erkrankung, die durch unzureichende Sauerstoffversorgung aufgrund von Veränderungen der arteriellen Gefäße der Extremitäten gekennzeichnet ist. Ab einem bestimmten Stadium führt dies zu Schmerzen beim Gehen, was die Patient:innen zwingt, stehen zu bleiben und die Mobilität und Lebensqualität massiv beeinträchtigt. Evidenzbasierte Leitlinien empfehlen unter anderem Lebensstiländerungen und strukturiertes Gehtraining.

Im Rahmen dieser Studie wurde der Telegesundheitsdienst „Keep pace!“ für PAVK Patientinnen im Stadium IIa und IIb entwickelt und die Gehstrecke, die Lebensqualität, das Wissen der Patient:innen über PAVK sowie die Patientenzufriedenheit evaluiert. Das 12-wöchige Programm „Keep pace!“ beinhaltete neben Wissensvermittlung, ein strukturiertes ambulantes Gehtraining, das mittels eigens konzipierter App angeleitet und überwacht wurde. Ein „Geolokation-Tracking“ ermöglichte App-basierte 6-Minuten-Gehtests. Die Betreuung durch Pflegepersonal erfolgte zunächst über einen Zeitraum von 8 Wochen telefonisch, gefolgt von 4 Wochen eigenständigem Training. App-basierte Erinnerungen und Wissensupdates erfolgten regelmäßig.

Ergebnisse von 19 nicht-randomisierten Teilnehmer:innen zeigten eine hohe Zufriedenheit mit dem Programm (95,4%) in verschiedenen Dimensionen, einschließlich Systemqualität, Informationsqualität, Servicequalität, Nutzungsabsicht, Zufriedenheit und gesundheitlichen Vorteilen. Im 6-Minuten-Gehtest verbesserten sich die schmerzfreie (76,3±36,8m auf 188,4±81,2m, +112,2m, $p<0,001$) sowie totale (308,8±82,6m auf 425,9±10,1m; +117,2m, $p<0,001$) Gehstrecke signifikant. Letztlich konnten 42,1% der Teilnehmer:innen mehr als 200 Meter schmerzfrei gehen, wurden somit vom PAVK Stadium IIb in IIa reklassifiziert. Neben der Verbesserung der körperlichen Funktion reduzierte das Programm signifikant Schmerzen (+15,5%, $p=0,008$) und verbesserte die soziale Teilhabe (+10,5%, $p=0,042$). Weiters verbesserten die Teilnehmer:innen ihre richtigen Antworten im Wissenstest signifikant von 65,8% bei Einschluss auf 89,8% nach 12 Wochen ($p<0,001$).

Zusammenfassend zeigte das neu etablierte Telemedizin-Programm „Keep pace!“ eine hohe Patientenzufriedenheit, signifikant verbessertes Erkrankungsverständnis und eine signifikante Verbesserung der Gehstrecke sowie des körperlichen Wohlbefindens bei PAVK-Patient:innen.

Abstract in English

Peripheral Arterial Disease (PAD) is a condition characterized by insufficient oxygen supply due to arterial vessel alterations in the extremities. From a certain stage, this leads to pain when walking, forcing patients to stop walking and thus affecting mobility and quality of life. Evidence-based guidelines recommend lifestyle changes, exercise therapy, and angioplasty for PAD management.

Therefore, this study introduces a telehealth service, "Keep pace!", developed to address the needs of PAD patients in stage IIa and IIb, and evaluates the walking distances, patient knowledge about PAD and patient satisfaction. The 12-week telehealth program imparts their knowledge and enables participants to engage in structured ambulatory walking training using a new specially designed mobile app by instruction and monitoring progress. The geolocation tracking function of the mobile app allowed for self-paced 6-minute walk tests. Initially, nurses provided supervision via telephone calls for a period of eight weeks, after which participants were encouraged to exercise independently. App-based reminder and knowledge updates happened regularly over the whole study.

The results from 19 non-randomized participants revealed high satisfaction with the telehealth service (95.4%) across various dimensions, including system quality, information quality, service quality, intention to use, satisfaction, and health benefits. There was a significant improvement in pain-free walking distance (76.3±36.8m to 188.4±81.2m, +112.2m, $p<0.001$), with 42.1% (8 participants) reaching 200 meters and more (reclassifying from PAD stage IIb to IIa). Furthermore, participants demonstrated also enhanced mobility in the total distance covered in 6-minute-walking test (308.8±82.6m to 425.9±107.1m, +117.2m, $p<0,001$). In addition to enhancing physical function, the program significantly reduced discomfort (+15.5%, $p=0.008$) and improved social participation (+10.5%, $p=0.042$). Participants exhibited a significant increase in correct answers in the knowledge test, rising from 65.8% at baseline to 89.8% after 12 weeks ($p<0.001$).

In conclusion, the new designed telehealth program “Keep pace!” exhibited high patient satisfaction, a significant improvement about PAD-Knowledge and significantly improved walking distance and physical well-being in PAD patients.

1 Introduction

Cardiovascular diseases (CVDs) represent the leading cause of death worldwide, accounting for 32% of global mortality (2) [1]. Among the various types of CVDs, atherosclerosis-related diseases are particularly prominent. Atheriosclerosis is characterized by the accumulation of cholesterol esters and fats in arterial walls. This chronic inflammatory disease affects arteries such as the coronary, carotid, and major leg arteries, leading to the formation of atherosclerotic plaques. The formation of these plaques can result in a significant narrowing of the vessels, which in turn can lead to a reduction in the oxygen supply to the organs. This can manifest as symptoms such as angina or intermittent claudication. Moreover, ruptured plaques can trigger blood clot formation, resulting in acute medical emergencies like heart attacks and strokes, contributing significantly to global CVD-related deaths. Addressing the underlying risk factors, including smoking, unhealthy diet, physical inactivity, and alcohol consumption, is crucial in preventing CVDs. Additionally, early detection through medical counselling and medication plays a pivotal role in effective disease management. However, in low- and middle-income countries, limited access to healthcare exasperates the burden of CVDs, leading to delayed detection and poorer health outcomes. Efforts to reduce this burden necessitate comprehensive strategies, including integrating CVD management into universal health coverage and ensuring access to essential medicines and technologies. (3) [1]

Peripheral Arterial Disease (PAD), a specific form of CVD, due to narrowed or blocked arteries in the extremities, particularly the lower limbs, limit patients' radius of mobility. This quality of life limiting condition emphasizes the importance of holistic approaches to prevention, early detection, and treatment to intervene disease development and progression as recommended in actual guidelines.

Through concerted efforts at both national and global levels, focusing on equitable access to healthcare and preventive measures, the burden of CVDs can be alleviated, leading to improved public health outcomes worldwide (4).

[1] https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds) (22.06.2024)

1.1 Peripheral Arterial Disease (PAD)

Peripheral arterial occlusive disease (PAOD), also known as peripheral arterial disease (PAD), occurs when the blood vessels that supply oxygen to the legs and arms become narrowed. This narrowing is typically due to the endothelial dysfunction and build-up of fatty deposits. Various factors, such as smoking, can contribute to this condition. Initially, there may be no symptoms. PAD begins asymptomatic. As the blood vessels become more narrowed, pain may initially occur during exertion, which is described as muscle discomfort. This pain may be relieved within minutes of rest (intermittent claudication). However, as the disease progresses, pain may occur even at rest. Furthermore, the healing of wounds is slowed down, and PAD may ultimately lead to necrosis, which necessitates amputation. The disease is classified into distinct grades, as indicated by the Rutherford and Fontaine classifications. These are illustrated in Table 1, according to the clinical symptoms (5).

Table 1: Classification of PAD according to Rutherford grades and categories, and Fontaine stages

Rutherford			Fontaine	
Grade	Category	Clinical symptoms	Stage	Clinical symptoms
0	0	Asymptomatic	I	Asymptomatic
I	1	Mild claudication	IIa	Pain-free walking distance > 200m
I	2	Moderate claudication	IIb	Pain-free walking distance < 200m
I	3	Severe claudication		
II	4	Rest pain	III	Rest pain
III	5	Limited Ischemic ulceration not exceeding ulcer of the digits of the foot	IV	Ischemic ulcers or gangrene
III	6	Severe ischemic ulcers or gangrene		

Source: Author's construction (adapted from ESVM and ESC (4, 5))

Scientific societies, such as the European Society of Cardiology (ESC), the European Society of Vascular Medicine (ESVM) and the American Heart Association (AHA), publish evidence based guidelines for the management of PAD (4-6).

1.1.1 Risk factors for PAD

Tobacco consume stands out as one of the most significant modifiable risk factors for PAD. The myriad harmful chemicals in tobacco smoke initiate a cascade of events, damaging the endothelial lining of arteries and promoting the formation of atherosclerotic plaques. Moreover, exposure to passive smoke can also elevate the risk of PAD. (4)

Diabetes mellitus, especially when poorly controlled, substantially elevates the risk of PAD. The persistent elevation of blood glucose levels in diabetes damages blood vessels and nerves, accelerating the progression of atherosclerosis, the primary pathological process underlying PAD. (4)

Hypertension exerts detrimental effects on arterial walls, leading to endothelial dysfunction and arterial stiffness. This predisposes individuals to accelerated atherosclerosis and reduced blood flow to the peripheral arteries, thereby increasing the risk of PAD. (4)

Dyslipidaemia is characterized by abnormal levels of cholesterol and triglycerides in the blood, is closely linked to the development and progression of PAD. Elevated levels of low-density lipoprotein (LDL) cholesterol and decreased levels of high-density lipoprotein (HDL) cholesterol contribute to the formation of atherosclerotic plaques, further narrowing the arterial lumen. (4)

The presence depression in PAD patients is increasingly significant. Depression development notably impacts both quality of life and walking performance. Reduced walking performance may, in turn, contribute to reactive depressive conditions. However, data from interventions using antidepressants or psychiatric treatment for PAD patients are currently lacking. (7)

Advancing age is an immutable risk factor for PAD, with its prevalence increasing significantly from the age of 50 years, while men generally exhibit a higher risk of PAD compared to women (8).

Chronic Kidney Disease (CKD) exacerbates the risk of PAD through multifaceted mechanisms, including endothelial dysfunction, dyslipidaemia, and systemic inflammation. The relationship between CKD and PAD underscores the importance of comprehensive cardiovascular risk management in individuals with renal impairment. PAD guidelines from ESVM and AHA PAD guidelines recommend that in patients with renal failure, attention should be paid to the concomitant presence of arteriosclerosis in the lower limb, as such disease in this patient population has a poorer prognosis. (4)

Chronic inflammatory disorders such as rheumatoid arthritis and systemic lupus erythematosus augment the risk of PAD through heightened systemic inflammation and immune dysregulation. The pro-inflammatory milieu potentiates endothelial dysfunction and accelerates atherosclerotic plaque formation. (5)

In conclusion, understanding of PAD risk factors is essential for tailored risk stratification, early intervention, and preventive strategies. Multifaceted approaches targeting modifiable risk factors, such as smoking cessation, glycaemic control, dyslipidaemia treatment, blood pressure management, lifestyle modifications, and regular physical activity and comprehensive cardiovascular risk assessment, are imperative for mitigating the burden of PAD and improving long-term clinical outcomes.

1.1.2 Epidemiology

The estimated prevalence of PAD in Austria is 3-10%, rising to 15-20% by the age of 70 years. Nevertheless, precise data are unavailable, as there is a dearth of substantial registry data and the capacity to derive prevalence from routine data. (3)

Across the European continent, a prevalence of 5.3% was detected (9).

To date, there has been a notable scarcity of gender-specific analyses regarding PAD. While earlier reports focused on male patients with PAD, recent studies indicate a shifting trend towards more female patients. However, data are showing that women are more likely to be asymptomatic or to report symptoms less frequently, resulting in a lower likelihood of screening and treatment. (3, 4, 8)

An internal analysis of patient admissions at the Department of Angiology, University Hospital, was conducted as part of project planning. Based on clinical documentation system data between January 1st and December 31st, 2018, a total of 1,761 patients with PAD were admitted. Of these, 982 patients (55.8%) received inpatient treatment, while 1.261 patients (71.6%) received outpatient care at least once. The patient cohort comprised 653 women (37.1%) and 1.108 men (62.9%), with a median age of 73±11.2 years (range 27-98 years). Women had a median age of 77±11 years, seven years older than men with a median age of 70±11 years.

1.1.3 Diagnostic for PAD

For the diagnosis of PAD, various procedures are available, ranging from anamnesis and clinical examination to angiographic visualization of the vessels, depending on the stage of care and complexity (4, 5).

1.1.3.1 Anamnesis

In order to make an accurate diagnosis of PAD, it is essential to obtain a detailed history from the patient regarding their leg symptoms. Symptoms that are particularly indicative of PAD include pain, cramps, or a sensation of heaviness in the legs, which tend to occur during physical exertion and improve at rest. In addition, it should inquire about unilateral or bilateral complaints, skin changes and poorly healing wounds. In addition, all PAD relevant risk factors should be recorded. (6, 10)

1.1.3.2 Clinical examination

The clinical examination of PAD is essential for its diagnosis and management. The examination for PAD begins with inspecting the limb for changes in skin colour and wounds. A clinical test, the Ratschow test plays a minor role, because there are no recommendation guidelines. The pulse palpation method is a logical choice due to the low threshold involved. While the presence of palpable foot pulses does not definitively exclude the possibility of PAD, the absence of palpation can be an indicative factor. Palpating the pulses alone has a low sensitivity of only 20% for recognising PAD. (4-6)

Assessing the condition of the skin is crucial, especially for diabetics with PAD. It is important to evaluate integrity, turgor, sweating, colour, muscle atrophy, deformity, and temperature, as it helps distinguish between primary neuropathic or ischemic lesions. Regular foot examinations by trained personnel can significantly increase patient awareness and prevent potential issues. (5)

1.1.3.3 Ankle-brachial index (ABI)

Additionally, Doppler ultrasonographic measurement of arterial occlusion pressures in the dorsalis pedis artery, posterior tibial artery, and, if necessary, the fibular artery should be performed on a supine patient at rest. This examination concludes with the calculation of the ankle-brachial index (ABI) by dividing these ancle pressures by the systolic blood pressure

measured ‘brachial’ in the upper limbs. The ankle-brachial index (ABI) is a diagnostic tool for PAD with a normal range of 0.9-1.3 (4). An ABI value of less than 0.9 indicates significant PAD with high sensitivity (>90%) and specificity (>99%). Table 2 outlines ABI categories for assessing PAD severity. The ABI is an objective marker for cardiovascular morbidity and mortality. An ABI of less than 0.9 is associated with an increased risk of cardiovascular events. However, potential measurement errors should be considered. ABI values close to the threshold of 0.9 should be confirmed through repeated measurements. Furthermore, an ABI > 1.3 is defined as ‘false elevated’ and occurs in patients with non-occlusive arteries of the lower limbs indicating high calcification, therefore other diagnostic tools are needed in such patients. In conclusion, ABI measurement is crucial in diagnosing and assessing the severity of PAD, aiding in risk stratification and prognostication. Its integration into clinical practice improves the management of PAD patients and reduces the risk of adverse cardiovascular outcomes. (5)

The following Table illustrates ABI values according to the severity of PAD:

Table 2: ABI Range and PAD Severity Grades

ABI Range	PAD Severity
> 1.3	Falsely elevated values (calcification)
> 0.9	Normal
0.75-0.9	Mild PAD
0.5-0.75	Moderate PAD
< 0.5	Severe PAD (critical ischemia)

Source: Author’s construction (adapted from ESVM and ESC (4, 5))

1.1.3.4 Treadmill walking test

To assess clinical symptoms, walking distance, and efficacy of treatment, stress tests as Treadmill walking tests are recommended. It is necessary to measure the ABI at rest, followed by determining walking capacity (e.g. on a treadmill at 3.2 km/h with a 10-12% incline). The documented parameters comprise pain-free walking distance (PFWD) and absolute walking distance, walking time, and ankle pressure with ABI after exercise. A decrease in ABI by 20%

is diagnostic for PAD. In cases where a treadmill is unavailable, supervised 6-minute walk test in a corridor over a defined distance can substitute for treadmill test. Patients who are unable to undergo treadmill testing or are not able to walk on a level surface can be assessed through active repetitive plantar flexion. It can be postulated that stress tests serve as an indicator of the efficacy of claudication treatment, as they permit an objective assessment of the patient's walking ability (pain-free, absolute walking distance) in comparison with baseline values. (11, 12)

1.1.3.5 Six-minute walk test (6 MWT)

The six-minute walk test (6 MWT) is a well-established and validated method for assessing walking endurance in individuals with PAD (13). Unlike more complex assessments like treadmill stress tests, the 6 MWT offers a practical and cost-effective means of evaluating functional capacity without requiring sophisticated equipment or highly specialized personnel. This test has demonstrated its utility across various clinical contexts, showing responsiveness to therapeutic interventions, prognostic value for predicting rates of mobility loss and mortality. To assess the walking performance, a standardised 6 MWT can be done. In this test, the patient has to walk for 6 minutes along an incline-free corridor of at least 30 meters in length. The patient walks directly back and forth between two boundary cones. The aim for the patient is to cover as much distance as possible within the specified time frame. During the 6 MWT, the patient is asked to tell the examiner when the first claudication occurs and which leg is affected in order to determine the pain-free walking distance (PFWD). If the patient has to stop due to claudication, this is noted as the absolute walking distance. At the end of the 6-minute walk period, the total walking distance covered is measured. (14)

The 6 MWT represents a valuable tool in the assessment of walking endurance in individuals with PAD, offering a practical and reliable means of gauging functional capacity and monitoring treatment outcomes. Its simplicity, coupled with its robust psychometric properties, underscores its utility in both clinical and research settings. (15)

1.1.3.6 Duplex ultrasound (DUS)

Duplex ultrasound (DUS) has emerged as the preferred diagnostic modality for the assessment of the aorta, its branches, and the pelvic and leg arteries. DUS, a non-invasive imaging modality, has been shown to be effective in all stages and serves as the basic diagnostic modality for PAD management (4). In Austria it can be provided in outpatient clinics, but not in primary care (16).

1.1.3.7 Computed tomography angiography (CTA)

In cases where DUS assessment of vascular flow is inconclusive, additional imaging modalities such as computed tomography angiography (CTA) are required. CTA has emerged as an investigator-independent and reliable method with high sensitivity and specificity for vascular diseases, due the widespread availability of modern multi-row CT in countries with a high level of resources. It allows for high-quality multi-planar and three-dimensional visualization of the aortoiliac, femoropopliteal and lower vascular systems and their surrounding anatomical structures. Middle-line reconstructions facilitate precise pre-calculation of interventional or reconstructive surgical measures and are indispensable for measuring endografts in aortoiliac vessels. CTA offers advantages such as very short examination times, detection of coexisting diseases that may mimic PAD symptoms, submillimeter spatial resolution, and anatomically-topographic vascular representation crucial for vascular surgeons. (4, 6)

However, limitations of CTA include radiation exposure, the necessity of iodine-containing contrast media administration, overestimation of stenosis degree in thin vessels with calcified stenoses, and, depending on the device generation, the need for extensive post-processing (17).

1.1.3.8 Magnetic resonance angiography (MRA)

Magnetic resonance angiography (MRA) is a non-invasive imaging method that provides investigator-independent, high-quality three-dimensional vascular reconstructions using standard magnetic resonance imaging (MRI) scanners with surface coils and three-dimensional gradient echo sequences, achieving high sensitivity and specificity. A major advantage of this examination is that the patient is not exposed to radiation during the MRA. However, access to CTA is easier in Austria than to MRA, as there are more CT scanners than MRI scanners available to the population. (4, 16)

1.1.3.9 Digital subtraction angiography (DSA)

Intra-arterial digital subtraction angiography (DSA) is regarded as the gold standard for vascular imaging due to its exceptional accuracy and clarity. DSA is the visualization of the vessels (usually the arteries). During DSA, a catheter with a diameter of 1 to 1.5 mm is inserted into the arteries under local anaesthetic, usually via the groin or the crook of the arm. Each procedure is monitored under X-ray fluoroscopy to avoid injury to the vessels. Contrast agent can be injected through the catheter to visualize the vessels on the X-ray image. However, its

role as a purely diagnostic procedure is diminishing, with non-invasive methods such as DUS, MRA, and CTA becoming increasingly preferred for their high sensitivity and specificity. The advantages of intra-arterial DSA include comprehensive documentation, extensive experience as a well-established procedure, and the ability to integrate diagnostics and interventions in a single session. It is particularly precise, especially in assessing in-stent stenoses.

However, the invasiveness of intra-arterial DSA presents risks for patients. Potential complications include hematoma, false aneurysm, bleeding, arteriovenous fistula, and contrast-related issues like contrast-induced nephropathy, allergic reactions, and contrast-induced hyperthyroidism. These complications affect subsequent patient management in approximately 0.7% of cases and are associated with a mortality rate of 0.16%. The incidence of complications in intra-arterial angiography varies depending on comorbidities such as heart and renal failure, as well as other risk factors like advanced age and diabetes. In case of severe renal failure, it is advisable to avoid the use of contracts agents with the potential for nephrotoxicity, and to consider alternative procedures such as CO2 angiography. (4)

1.1.3.10 Diagnostic algorithm for PAD

The following Figure 1 shows the diagnostic process for PAD in 4 steps. This graduated approach is recommended in the care guidelines PAD Guidelines ESC 2017 and ESVM 2019 (4, 5). This guarantees an adequate risk-benefit ratio for the diagnostic approach of the individual patient.

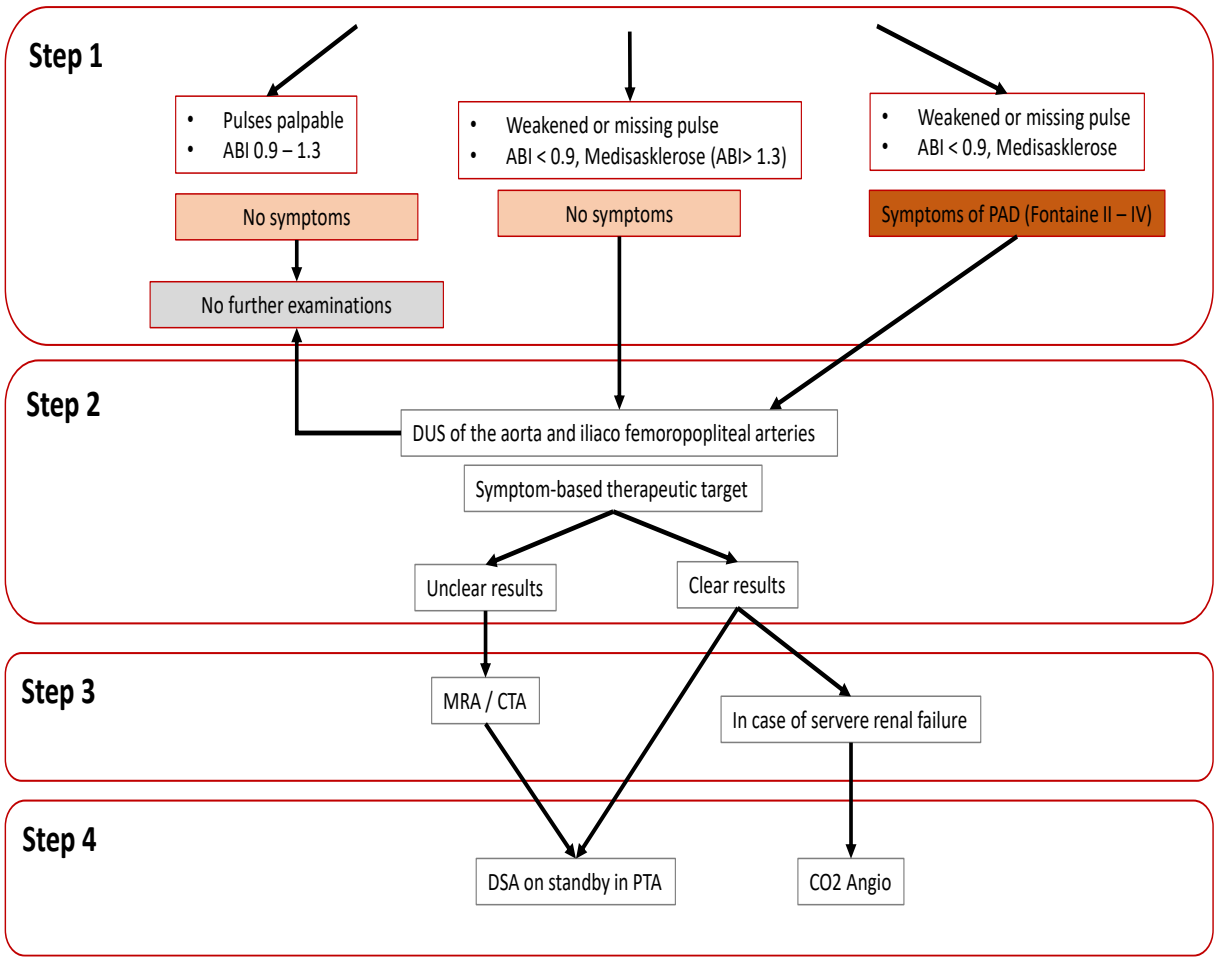

Figure 1: Diagnostic process for PAD patients.

Source: Author's construction (adapted from ESVM and ESC (4, 5))

1.1.4 Therapy for PAD

The objectives of PAD management are threefold: firstly, to reduce the risk of future cardiovascular events across all Fontaine stages; secondly, to enhance walking performance and mobility, thereby improving quality of life specifically in Fontaine Stage II; and thirdly, in Fontaine Stages III and IV, to preserve limbs, alleviate pain, and sustain or enhance overall quality of life. The evidence-based care for such patients consists of several components and should be offered according to the patient's needs. (4, 5)

1.1.4.1 Lifestyle changes

A first line recommendation for patients with diagnosed PAD is to implement lifestyle modification (5, 6).

Smoking cessation is paramount in reducing the risk of PAD and its associated complications. Interventions to aid smoking cessation encompass a combination of behavioural counselling, pharmacotherapy, and support programs tailored to individual needs. Behavioural interventions often include cognitive-behavioural therapy techniques aimed at modifying smoking behaviours and addressing triggers for tobacco use. Additionally, pharmacotherapy options such as nicotine replacement therapy or prescription medications may be prescribed to alleviate withdrawal symptoms and cravings. Moreover, the implementation of comprehensive tobacco control policies, public awareness campaigns, and smoking cessation programs at community and population levels can further support individuals in their efforts to quit smoking and reduce PAD risk. (4, 5)

For individuals with diabetes mellitus, meticulous glycaemic control is essential to mitigate the risk of PAD and its complications. Management strategies for diabetes encompass a multifaceted approach, including adherence to dietary recommendations, regular physical activity, and appropriate use of antidiabetic medications. Patients are encouraged to adopt a balanced diet rich in vegetables, fruits, whole grains, and lean proteins while limiting intake of refined carbohydrates and saturated fats. Regular monitoring of blood glucose levels, adherence to medication regimens, and proactive management of diabetic complications such as peripheral neuropathy are integral components of diabetes care aimed at reducing PAD risk. (4, 5)

The management of hypertension plays a pivotal role in reducing the risk of PAD and its adverse outcomes. Chronic hypertension exerts detrimental effects on arterial walls, leading to

endothelial dysfunction and arterial stiffness, which predispose individuals to accelerated atherosclerosis and reduced blood flow to the peripheral arteries. Treatment strategies for hypertension encompass lifestyle modifications and pharmacotherapy aimed at achieving and maintaining target blood pressure goals. Lifestyle modifications include adopting a heart-healthy diet low in sodium, maintaining a healthy weight, engaging in regular physical activity, limiting alcohol intake, and implementing stress reduction techniques such as meditation or yoga. Pharmacotherapy options for hypertension management may include angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARB), diuretics, beta-blockers, calcium channel blockers, or combination therapies tailored to individual patient needs. Dyslipidaemia, characterized by abnormal levels of cholesterol and triglycerides in the blood, is closely linked to the development and progression of PAD. Elevated levels of low-density lipoprotein (LDL) cholesterol and decreased levels of high-density lipoprotein (HDL) cholesterol contribute to the formation of atherosclerotic plaques, further narrowing the arterial lumen. Management of dyslipidaemia in PAD patients typically involves the use of statins as the cornerstone pharmacotherapy. Statins effectively lower LDL cholesterol levels and stabilize atherosclerotic plaques, thereby reducing the risk of cardiovascular events. Lifestyle modifications, including adherence to a heart-healthy diet, regular exercise, smoking cessation, and weight management, complement the pharmacotherapy in managing dyslipidaemia and mitigating PAD risk. Additionally, lipid-lowering agents such as ezetimibe or PCSK9 inhibitors may be considered as adjunctive therapy in patients with persistent dyslipidaemia despite statin treatment or those at high cardiovascular risk. Regular lipid monitoring and adjustment of medication regimens based on treatment response and individual risk profiles are essential components of dyslipidaemia management in PAD patients. (4-6)

1.1.4.2 Walking exercise therapy

Another aspect for patients with intermittent claudication, Fontaine stage IIa and IIb, is walking exercise therapy. Supervised walking exercise therapy (SET) has shown to improve walking distance, reduce symptoms, and improve quality of life in patients with PAD. The mechanism behind this improvement, is a hypoxia induced collateral vessel development. This neovascularisation is a natural compensation mechanism of the body, by which cells under repeated or chronic hypoxia get a hormone-stimulated newly-build bypassing arterial system, to maintain arterial perfusion and therefore maintain oxygen supply and cell survival. By intentionally repeated transient simulated hypoxia of affected cells downstream of an arterial

stenosis, PAD exercise training enhances collateral vessel development, which is radiographically visualisable. (18-20)

Studies have shown that structured walking training can increase the pain free walking distance of patients with claudication by 200% in 12 weeks. Individual daily interval training of 60 minutes with 5- to 15-minute intervals has also been shown to be effective in increasing walking distance. The aim of this walking training is to encourage patients to push themselves further when walking, despite the onset of pain, until they are unable to continue walking. After a short recovery at rest, patients should continue walking training. Furthermore, the evidence showed that walking training can be equivalent to endovascular interventions in terms of long-term outcomes. (4, 21, 22)

The ESC, AHA and ESVM guidelines recommend supervised exercise programs for patients with PAD, with the strongest level of recommendation and high grade of evidence in Fontaine stages II. Both guidelines also recommend unsupervised walking exercise (ESC: I C, ESVM: IIa B) with a duration, intensity, and type of exercise are similar in both guidelines, giving 30-60 minutes per session, at least 3 times per week, and at least moderate intensity. (4, 6, 23, 24)

However, there is an underutilization of supervised walking training despite its recommendation as first-line therapy for PAD. A survey across 17 European countries reveals significant variability in its availability and characteristics, emphasizing the urgent need for detailed guidance to ensure optimal care for PAD patients (25).

Therefore, the integration of walking training should be a cornerstone in managing PAD providing varied protocols and emphasizing the need for comprehensive programs while addressing existing disparities in supervised walking training access across Europe (10). Data focusing on walking training have shown, that supervised walking training is more effective than unsupervised home-based approaches, unless the amount of home-based training was monitored and actually done (19, 21, 26). This indicates the crucial role of intrinsic motivation and satisfying observation or rather extrinsic motivation of home-based trainings. Integrating resource-optimized telemedical solutions with patients' preferences for convenient care close to home, a supported home-based walking training fulfils these requirements. Objectified burden in terms of walking time and distance as well as patient-based validated disorder-specific questionnaires (e.g. Medical Outcome Short Form SF-36, Walking Impairment Questionnaire) can be applied to evaluate treatment (20, 27).

1.1.4.3 Overview of recommendations for walking training for patients with PAD

The following recommendations for walking training from the ESVM, the ESC and the AHA are presented in tabular form.

Table 3: Overview of walking training recommendations in current guidelines

European Society of Vascular Medicine (ESVM) – 2019 (4)	COR	LOE	European Society of Cardiology (ESC) /European Society for Vascular Surgery (ESVS) – 2017 (5)	COR	LOE	American College of Cardiology/American Heart Association – 2024 (6)	COR	LOE
It is recommended that structured walking training is offered to all PAD patients with intermittent claudication as an inherent part of basic treatment.	I	B	In patients with intermittent claudication, supervised exercise training is recommended.	I	A	In patients with chronic symptomatic PAD, Structured exercise training is recommended to improve walking performance, functional status, and quality of life (QOL).	1	A
It is recommended that supervised training programs under regular instruction be offered as they are more effective than unstructured vascular training.	I	B	In patients with intermittent claudication, unsupervised exercise training is recommended when supervised exercise training is not feasible or available.	I	C	In patients with chronic symptomatic PAD, a structured community-based exercise program with behavioural change techniques is effective to improve walking performance, functional status, and QOL.	1	A
It is recommended that a supervised Vascular Workout for in patients with intermittent claudication should take place at least 3 times a week for at least 30-minutes. over at least 3 months.	I	B	When daily life activities are compromised despite exercise therapy, revascularization should be considered.	IIa	C	In patients who have undergone revascularization for chronic symptomatic PAD, after revascularization is effective to improve walking performance, functional status, and QOL.	1	A

European Society of Vascular Medicine (ESVM) – 2019 (4)	COR	LOE	European Society of Cardiology (ESC) /European Society for Vascular Surgery (ESVS) – 2017 (5)	COR	LOE	American College of Cardiology/American Heart Association – 2024 (6)	COR	LOE
Daily individual vascular training should be considered in the conservative treatment of patients with intermittent claudication if no supervised training programs are available. It is less effective than supervised programmes.	IIa	B	When daily life activities are severely compromised, revascularization should be considered in association with exercise therapy.	IIa	B	In patients with functionally limiting claudication, SET or a structured community-based exercise program should be offered as an initial treatment option.	1	B-R
			On top of general prevention, statins are indicated to improve walking distance.	I	A	In patients with chronic symptomatic PAD, alternative programs of non-walking structured exercise therapy (e.g., arm ergometry, recumbent stepping) can be beneficial to improve walking performance, functional status, and QOL.	2a	A
						In patients with chronic symptomatic PAD, the usefulness of structured walking exercise therapy that avoids moderate to severe ischemic symptoms is uncertain.	2b	B-R
(COR = Class of Recommendation, LOE = Level of Evidence) *(B-R= Moderate Quality of evidence of 1 or more RCTs; Metanalyses of moderate-quality RCTs)*						In patients with chronic symptomatic PAD, the usefulness of unstructured exercise to improve walking performance, functional status, and QOL is uncertain.	2b	B-R

1.1.4.4 Interventional treatment

Revascularizing treatment of PAD through open surgical procedures or endovascular methods serves as symptomatic treatment for progressive chronic atherosclerosis in PAD. However, these methods do not address the underlying atherosclerotic process, necessitating further consideration. Indications for interventional PAD treatment include PAD stage according to Fontaine or Rutherford classification, site, morphology, and complexity of vascular lesions, concomitant disorders and procedural risk, and patient preferences. Patient-specific treatment preferences are particularly crucial, considering the feasibility of various treatments across different PAD stages. Treatment decisions, such as conservative versus invasive approaches, especially in earlier stages of claudication, and in critical limb ischemia (CLI), should be made in consultation with patients, weighing the pros and cons of each approach. Accessibility of therapeutic methods and the expertise of local interventionists and surgeons also influence treatment recommendations (4). The following Table provides an overview of the therapeutic strategies corresponding to the Fontaine stages (4).

Table 4: Therapeutic strategies corresponding to the Fontaine stages

Therapeutic Strategy	Fontaine-Stage			
	I	**II**	**III**	**IV**
Risk Factor Management	+	+	+	+
Antiplatelet Agents		+	+	+
(Supervised) Exercise Therapy		+	+	
Wound Care				+
Endovascular Therapy		+*	+	+
Surgical Therapy		+*	+	+

(The application of certain therapies may depend on appropriate individual morphology and patient preference)*
Source: Author's construction (adapted from ESVM and ESC (4, 5)

1.1.5 Situation in Austria

In Austria, the care for patients with PAD is a collaborative effort involving various healthcare professionals and organizations. At the forefront of PAD care are vascular specialists, typically found within hospital departments of angiology or vascular surgery. These specialists are responsible for diagnosing PAD, assessing its severity, and developing personalized treatment plans. Primary Care also play a crucial role in PAD care, as they often serve as the first point of contact for patients experiencing symptoms such as leg pain or cramping during physical activity. General practitioners can perform initial assessments, order diagnostic tests, and refer patients to specialists for further evaluation and treatment. In addition to physicians, PAD care in Austria may involve interdisciplinary teams comprising nurses, physiotherapists, dietitians, and other allied health professionals. Nurses provide ongoing support to PAD patients, assisting with medication management, wound care, and lifestyle counselling. Dietitians may provide guidance on nutrition and weight management, addressing lifestyle factors that contribute to PAD progression. In Austria, there are only structured walking programs in the field of outpatient and inpatient rehabilitation. Currently, there is no telehealth service for PAD. The Austrian health system invested 82 million euros in the treatment of this chronic disease in 2012 (3, 16).

Overall, PAD care in Austria is a coordinated effort involving multiple stakeholders, with a focus on early detection, comprehensive treatment, and ongoing support to improve patient outcomes and quality of life (16).

Creating a telehealth service for PAD based on the health goals in Austria is imperative for several reasons, aligning closely with the nation's health objectives:[2] One goal of Austria's health objectives is to ensure equitable access to healthcare services for all citizens. By establishing a telehealth service for PAD, individuals living in remote or underserved areas can receive timely medical attention and advice without the need for physical travel to healthcare facilities. This enhances accessibility and reduces disparities in healthcare access across regions. Prevention and early detection and intervention are crucial in managing PAD effectively and preventing severe complications such as limb amputation. Through a telehealth platform, individuals can undergo remote screenings, receive education on risk factors, and

[2] https://gesundheitsziele-oesterreich.at/english-summary/ (15.05.2024)

access preventive measures tailored to their needs. This aligns with Austria's goal of promoting preventive healthcare measures to reduce the burden of chronic diseases. [2]

PAD is a chronic condition that requires long-term management and monitoring program. A telehealth service can facilitate regular follow-ups, medication management, and lifestyle counselling for patients with PAD, promoting better disease management and quality of life. This corresponds to Austria's objective of improving the management of chronic diseases to enhance overall health outcomes (28).

Empowering patients with knowledge about their condition is essential for self-management and adherence to treatment plans. Through such consultations, patients can engage in educational sessions, receive personalized advice, and actively participate in decision-making regarding their health (18). This fosters patient empowerment and contributes to Austria's aim of promoting health literacy and patient-centred care.[2]

Telehealth services have the potential to optimize healthcare resource utilization, reduce unnecessary hospital visits, and lower healthcare costs associated with PAD management. By leveraging technology for remote consultations, virtual monitoring, and electronic health records, healthcare providers can deliver efficient and cost-effective care while achieving Austria's goal of ensuring sustainable healthcare systems (29-31).

In conclusion, establishing a disease management program in form of a telehealth service for PAD aligns with Austria's health goals by improving accessibility, promoting prevention and early detection, enhancing chronic disease management, empowering patients, and optimizing healthcare efficiency.[2]

2 Aims of the study

The aim of this study was to investigate the feasibility and usability of a telehealth service for patients suffering from PAD in stage IIa and IIb.

2.1 Research object: Telehealth service for PAD "Keep pace!"

The telehealth service "Keep Pace!" was developed by a team of scientists from the Medical University of Graz in Austria and the AIT Austrian Institute of Technology. It provided patients with remote medical care and monitoring via telephone nurse calls and digital medical equipment. The aim of the program was to support patients in performing regular walking exercises over a 12-week period to increase their walking distance, physical function and to improve their health literacy in relation to the disease.

The program was specifically designed for patients with PAD Fontaine stage IIa and IIb who were able to perform supervised, structured ambulatory exercise training and use a monitoring app on their smartphone.

Patients were able to take part wherever they lived and were supervised by a nurse by telephone for eight weeks. In the subsequent four weeks, patients performed their structured exercise therapy independently without phone support.

Current studies, data and guidelines give a clear indication that structured walking training can improve symptoms and walking distance. There are currently several telehealth services for the care of chronic diseases, but not for PAD and walking training. We investigated whether walking training could be successfully supported by telehealth services. (1, 4, 5, 27)

2.2 Hypothesis

Based on literature, the following central hypotheses were developed for this research project:

- The telehealth service achieves a satisfaction rate of at least 80% in each dimension, thus indicating overall user satisfaction.
- The telehealth service can increase pain-free walking distance in a 6 MWT after 12 weeks.
- The telehealth service can increase the total walking distance in a 6 MWT after 12 weeks.
- The telehealth service can improve the quality of life as measured by the SF-36 after 12 weeks.
- The telehealth service improves knowledge about PAD in patients after 12 weeks.
- Performing the 6-minute walk test with the app is equivalent to performing the walk test by healthcare personnel.
- The telehealth service can reduce the time in the Time Up and Go test (TUG) after 12 weeks.

3 Material and Methods

Based on the literature, the following study design was developed for the pilot study.

3.1 Study design

The trail was an investigator-initiated, single-center prospective trial conducted at the University Hospital Graz, Austria. This pilot study on intermittent claudication treatment in patients with PAD spanned 12 weeks, from November 2022 to August 2023. It was planned to include 20 non-randomised participants.

The protocol specified that each participant was to be observed over a period of 90 (±14) days, with two observation phases: phase 1 lasting 60 (±14) days, followed by phase 2 lasting 30 (±14) days. Phases vary due to nursing calls in phase 1, while phase 2 was without phone calls. Three visits were scheduled as part of the study: an initial visit at the outpatient clinic (visit 1), followed by a telephone consultation after 60 (±14) days (visit 2), and a final visit at the outpatient clinic after further 30 (±14) days (visit 3).

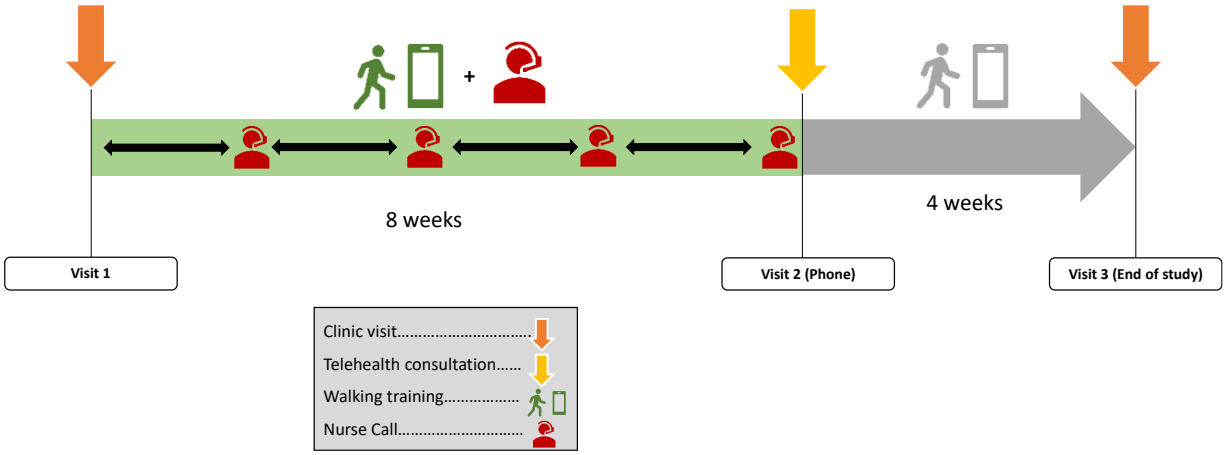

Figure 2: Study process of the participants.

Source: Author's construction, published (1), reprinted by permission.

3.2 Inclusion criteria

Per protocol the study involved patients aged between 18 and 80 years. The study's inclusion criteria required patients aged between 18 and 80 years, with PAD in stages IIa and IIb (as per the Fontaine classification), written consent, ownership of an Android mobile device, and an understanding to use the telehealth services.

3.3 Exclusion criteria

Exclusion criteria prohibited patients with PAD stages I, III and IV, non-compliance to perform walking training and incompatible smartphone software.

3.4 Recruitment process

The participants were recruited from the Angiology Outpatient Department at the University Hospital Graz, Austria. PAD patients with Fontaine stage IIa and IIb were contacted by telephone to ask whether they would like to participate in the study in principle, after which an appointment was made for screening examination.

As this study was a pilot study, no case number planning was carried out. The number of participants was set at 20 based on comparable projects already carried out with the same study objective for another disease as the clinical project ‘Telbiomed 5000’ of Herzmobil Tirol (30).

During the execution and planning of the study, the Declaration of Helsinki (in its current version) and the guidelines of "Good Clinical Practice" were considered. Additionally, the framework directive for "IT infrastructure in the application of telemonitoring" was consulted for the study planning.

3.5 Reference projects

The following reference programs, which use the same IT application (app), are currently being conducted. The data-management-system mobile application (DMS app) system is also used in the "Herzmobil" project in Styria and Tyrol as part of routine care, where patients with chronic heart failure are managed. Currently, the DMS app is also being used in two other studies. These are observational studies not subject to the Medical Devices Act. Both projects have received ethical approval and are conducted under the following titles:

- Telemedical follow-up of patients hospitalized with Coronavirus Disease 2019 (COVID-19) DRKS study ID: DRKS00022244
- Establishment of a training database of voice recordings and body weight trends in haemodialysis patients for the development of an algorithm for early detection of hydrostatic volume overload: DRKS study ID: DRKS00020763

3.6 Ethical approval

Ethical approval for the study was obtained from the Ethics Committee of the Medical University of Graz (34-127 ex 21/22 1566-2021). This can be found in the appendix.

The trial has also been registered on clinicaltrails.gov under the number: NCT05619835

3.7 Risk-benefit assessment and precautions

The enrolled patients directly benefit from participating in the study, as it constitutes a complementary measure to standard care according to the guidelines of the ESVM and ESC.

The steps are recorded using a Beurer pedometer AS 99. According to the instruction manual, this is not a medical device. The app is solely for communication and step detection. The app is currently also used in two other observational studies. Like the present study, these are also not subject to examination under the Medical Devices Act.

Since it is neither a medical product nor any other measure not already established in standard care, there is no expected risk. The only potential risk, the disclosure of sensitive patient data, is minimized through pseudonymization and access restriction. The results of this study can serve as a basis for broader implementation of the app to optimize prevention.

3.8 Used Technologies

The studies used the following resources, provided by the AIT Austrian Institute of Technology. Technical support was also provided by the AIT Austrian Institute of Technology. The application was carried out by clinical specialists in angiology, who were reported to the ethics department as part of the study.

3.8.1 DMS app "Keep in Touch" (KIT) for patients

The participating patients had access to a data-management-system mobile application (DMS app) "Keep in Touch" (KIT) which represented their entry point to the "Keep Pace!" telehealth service, See Figure 3. The DMS app "Keep in Touch" was installed on the smartphones of the participants at visit 1. The participants were trained on how to use the app and its functions.

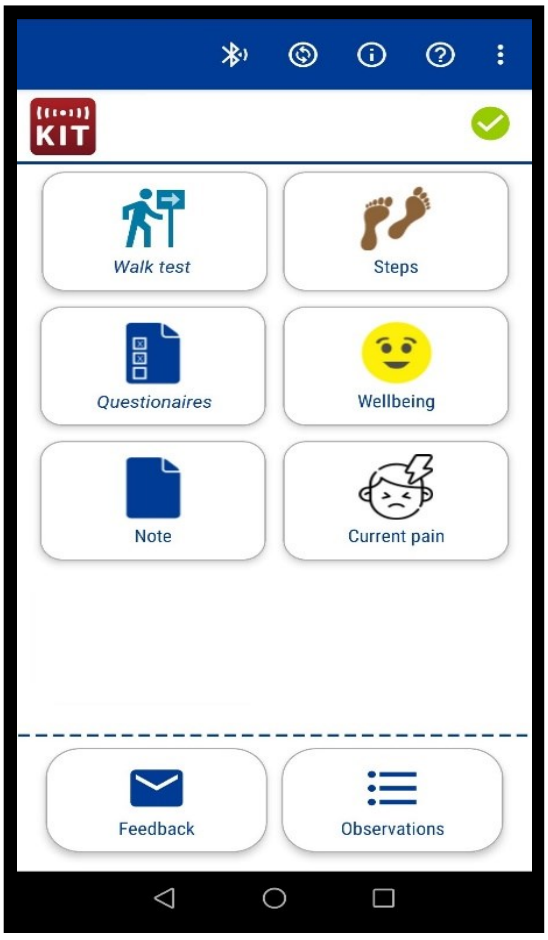

Figure 3: Screenshot of the mobile app (Menu) as used by the patient

Source: Author's construction, published (1), reprinted by permission.

This app was tailored to the needs of PAD patients in regards of the available data tracking options. These tracked data included well-being and pain sensation which were supposed to be recorded on a daily basis. Additionally, the step count was tracked automatically by the application using the connected external pedometer, see Figure 6. This app was connected to the backend and automatically uploaded the tracked data which was then visible to the nurse via the frontend, see Figure 7. To improve adherence to the walking training, the telehealth service was able to send notifications to the DMS app, reminding the patients of their exercises.

3.8.2 App based 6 MWT

Another function of the app was a 6 MWT test. The DMS app documents the distance walked in meters during this time. The 6 MWTs of the DMS app are performed by patients alone during the study, and also concurrently with the 6 MWTs by nursing staff during in-person visits. The 6 MWTs serve to objectify walking performance. The subsequent two images (Figure 4 and 5) illustrate the app view for patients. Initially, comprehensive instructions are provided on how to perform the procedure. Upon confirmation, the 6 MWT can commence. A stopwatch is integrated into the app, and the user is alerted when the test has been completed.

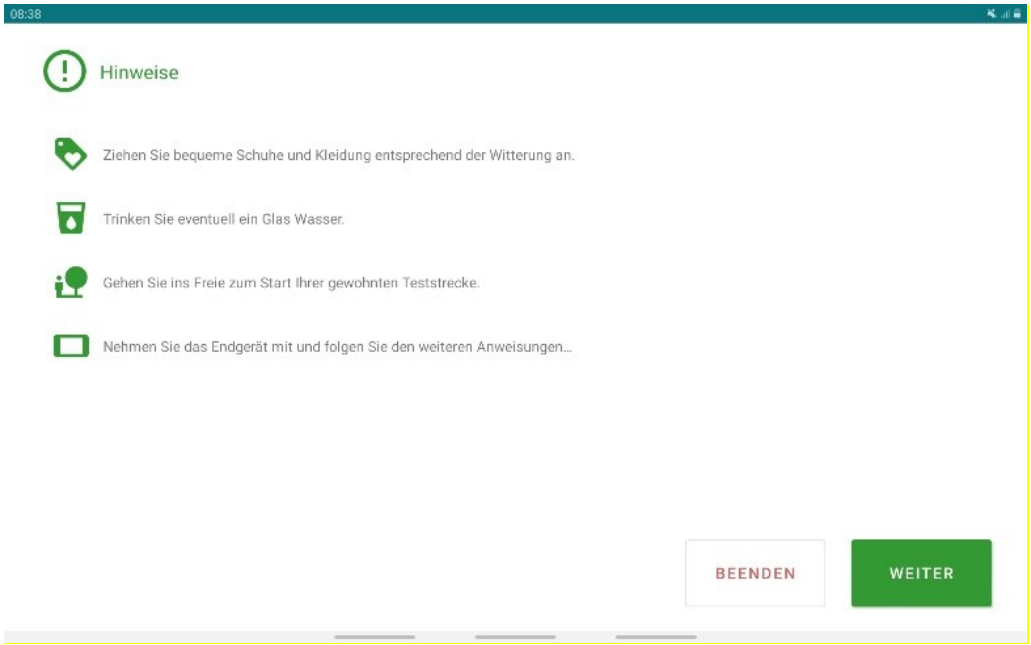

Figure 4: Screenshot of the mobile app as used by the patient for the 6 MWT with introductions

Source: Author's construction

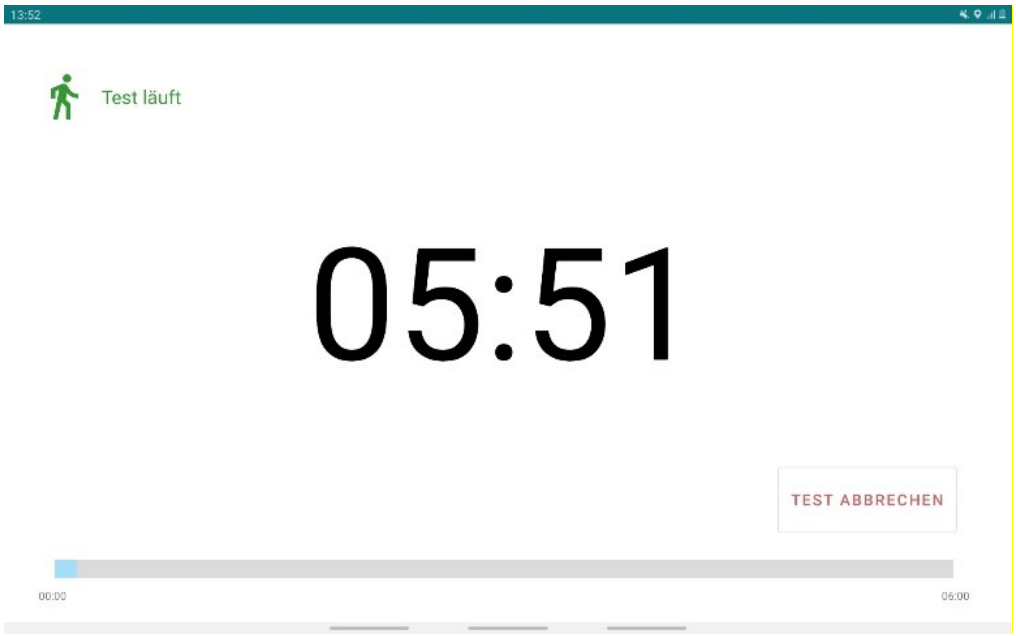

Figure 5: Screenshot of the mobile app as used by the patient with the stopwatch for the 6 MWT

Source: Author's construction

3.8.3 Step counter

Additionally, the participants received a step counter that recorded their daily steps. This device, worn on the wrist by the participants, could automatically transmit the step data to the DMS app. The step counters AS99 from Beurer were not considered medical devices according to the manufacturer's manuals.

Figure 6: Step Counter AS 99 from Beurer

Source: Author's construction

3.8.4 Interface of the telehealth platform for healthcare personnel

The telehealth service “Keep Pace!” included a web-based front end, which could be accessed by the nurse in charge and displayed the uploaded data on a patient level, as shown in Figure 7.

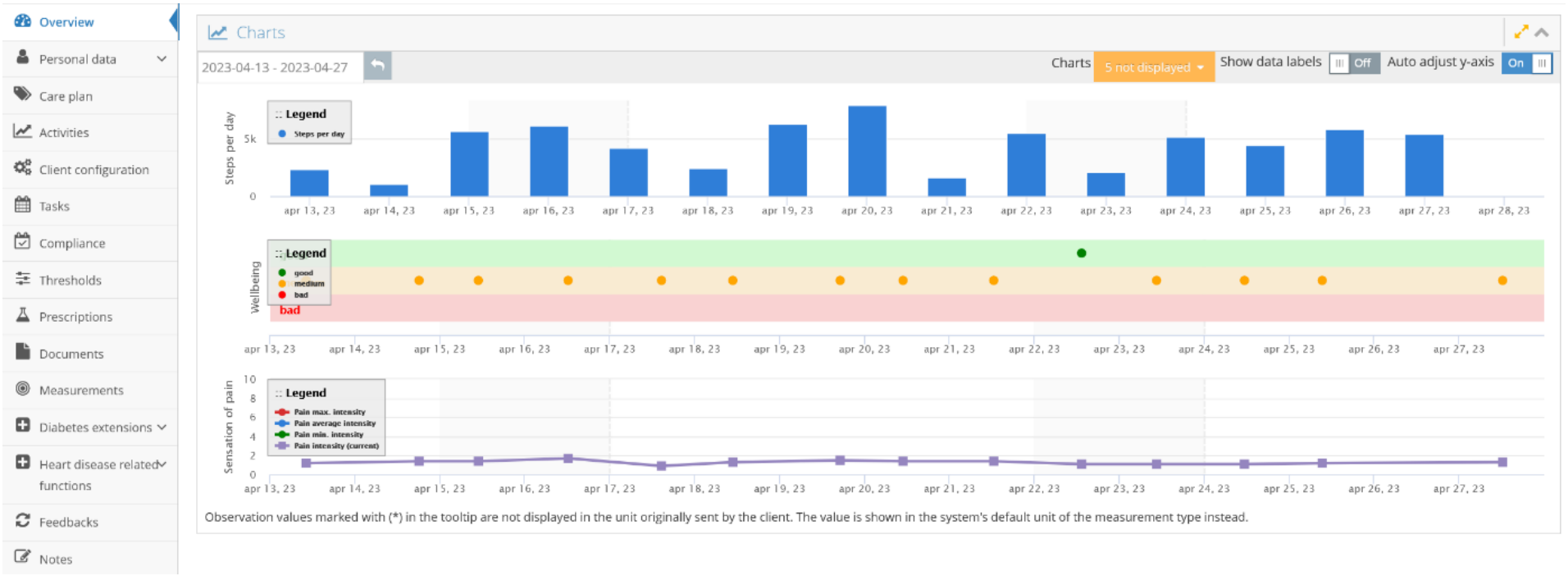

Figure 7: User interface of the telehealth platform as seen by healthcare personnel

Source: Author’s construction, published (1), reprinted by permission.

3.8.5 Time up and Go Test

For the assessment of functional health status, a specialized Time Up and Go (TUG) test device was used as a measure of physical fitness independent of walking capacity. This allows standardized and qualified measurement parameters to be captured by individuals without additional assistance, simplifying the execution of the TUG test. The results serve as aids for the individual assessment of functional health status, but not for diagnosis or therapy. Thus, the TUG device is not a medical product.

The patented measurement method automatically evaluates the test execution, thereby achieving high validity of the test results. The device is fixed on a conventional chair with armrests. Upon starting the measurement, participants receive short and clear instructions (audible beep sound).

The sequence corresponds to the classic TUG test: The person sits on a chair with armrests, arms resting on the chair's backrest, and the back against the chair's backrest. Upon command, the person rises and walks to a wall (or cabinet or shelf) located three meters away. There, the person turns around and returns to the chair, where they sit back in the starting position.

The device, with optical and acoustic signals for positioning the chair (3m distance from the wall), measures the time taken and also records the person's movement pattern. This allows for the control of correct measurement execution and, if necessary, prompts the person to repeat the measurement.

3.9 Outcome Measures

The following outcome measures were defined for the project.

Table 5: Tabular overview of examinations per visit

	Visit 1 *Baseline*	60 days *(±14)*	**Visit 2**	30 days *(±14)*	**Visit 3** *End of Study*
	Phase 1			**Phase 2**	
Outpatient clinic visit	X				X
Phone visit			X		
Inclusion and exclusion criteria Control	X				
Declaration of consent	X				
Anamnesis, medical history	X				
Questionnaire SF-36	X				X
Knowledge test	X				X
PAD Knowledge training	X		X		
Download the app, ID, app training	X				
6-min walk test (nurse)	X				X
6-min walk test (DMS app)	X	X		X	X
DMS app Reminder		X		X	
Phone Contact Reminder		X			
Guide-based interview (Satisfation)			X		X
Time up and Go Test	X				X

3.9.1 Demographic and clinical characteristics of participants

The medical history and anamnesis of the participants was collected. The following parameters were included:

- Height
- Weight
- Age
- Sex
- Diagnosis and stage of PAD
- Other cardiovascular diagnoses
- Cardiovascular risk factors (smoking status, depression, dyslipidaemia, diabetes mellitus, hypertension)
- Subjective pain-free walking distance
- Subjective absolute walking distance

3.9.2 Patient satisfaction with the telehealth service

At the junctures of visits 2 (conducted via telephone) and 3 (clinic), guided interviews incorporating a questionnaire regarding the satisfaction of patients PAD regarding the telehealth service were administered. The survey was structured based on the six evaluation criteria outlined by DeLone and McLean (32).

The guidance for the interviews was adapted to the needs of the study. Respondents were asked to rate the following 23 statements, which were suitable sorted into 'the six evluation criteria' categories, on a scale of 1 to 10, with 1 being ‘do not agree’ and 10 being ‘total agree'.

The following statements were developed for the satisfaction survey:

System Quality (Ease of Use):

- The processes of the telehealth service, consisting of providing knowledge about PAD, the walking training, and the mobile phone app, were easy for me to integrate into my daily life.
- The information I received regarding PAD was easy for me to understand.
- Using the mobile phone app, including the walking training, was easy for me.

Information Quality (Personal Benefit):

- The information I received regarding PAD was personally valuable to me and I benefited from it.
- The information I received through the pedometer was personally valuable to me and I benefited from it.
- The information I received through the phone contacts was personally valuable to me and I benefited from it.

Service Quality (Support):

- I felt well cared for by the telehealth service, consisting of providing knowledge about PAD, the walking training, and the mobile phone app.
- The phone contacts were important to me.
- The mobile phone app, including the walking training, was important to me.

Usage Intention (Interest in Use):

- I would like to continue using the telehealth service in the future.
- I would like to continue using the mobile phone app in the future.
- I would like to be regularly cared for through phone contacts regarding my PAD in the future.

Satisfaction of Use (Suitability):

- The telehealth service, consisting of providing knowledge about PAD, the walking training, and the mobile phone app, is suitable for managing PAD in this form and I would recommend it.
- The mobile phone app is suitable for managing PAD in this form and I would recommend it.
- The phone contacts are suitable for managing PAD in this form and I would recommend them.
- The knowledge dissemination is suitable for managing PAD in this form and I would recommend it.

Health Benefits (Behaviour Change):

- Through the telehealth service, consisting of providing knowledge about PAD, the walking training, and the mobile phone app, I have positively changed my behaviour (e.g., physical activity, risk behaviour, smoking).
- Through the mobile phone app, I have positively changed my behaviour (e.g., walking distance, lifestyle, risk behaviour, smoking).
- Through the phone contacts, I have positively changed my behaviour (e.g., walking distance, lifestyle, risk behaviour, smoking).
- Through the knowledge dissemination, I have positively changed my behaviour (e.g., walking distance, lifestyle, risk behaviour, smoking).

Overall Satisfaction

- I was satisfied with the telehealth service for PAD, consisting of providing knowledge about PAD, the walking training, and the mobile phone app.
- I was satisfied with the mobile phone app.

Furthermore, an evaluation was conducted to determine the proportion of patients who would be satisfied with the telehealth service if telephone calls were not provided by a nurse during the program.

3.9.3 Walking distance in the 6 MWT

A standardized and evidence-based 6 MWT was conducted with the participants by a certified nursing professional at the Department of Angiology and also by an app at the same time at visits 1 and 3. The distance covered during this time was documented as total walking distance by the nurse and the app. Furthermore the nurse documentated the pain-free and absolute walking distance.

During the study period, between visit 1 and visit 3, participants are required to perform an app-based 6 MWT at home once a week, which measured only the total walking distance. This was documented using the DMS app.

3.9.4 Steps per day

The telehealth service was designed to enable participants to continuously monitor their steps and visualize them over time, thereby providing a basis for motivation for structured walking training. The external pedometer (e.g. Beurer wrist pedometer) was used to count the steps and transfer the step count data to the app. Manual entry of steps taken was possible as an additional function, but this was visible as such a manual entry.

3.9.5 Limitations in the activities of daily living (Quality of life, SF-36)

The SF-36, or Short Form Health Survey, is a widely used questionnaire designed to assess health-related quality of life across various populations and health conditions, including PAD patients (27). It consists of 36 questions that cover eight different health domains:

1. Physical Functioning: Assesses the ability to perform activities of daily living, such as walking, lifting, and self-care tasks.
2. Role Limitations due to Physical Health: Measures the extent to which physical health issues interfere with work or other daily activities.
3. Bodily Pain: Evaluates the intensity and impact of pain experienced by the individual.
4. General Health Perceptions: Gauges overall perceptions of health, including feelings of vitality and wellness.
5. Vitality: Assesses energy levels, fatigue, and enthusiasm for life.
6. Social Functioning: Measures the ability to engage in social activities and maintain relationships with others.
7. Role Limitations due to Emotional Problems: Examines the extent to which emotional problems, such as depression or anxiety, interfere with work or daily activities.
8. Mental Health: Assesses psychological well-being, including mood, stress levels, and emotional stability.

For PAD patients, the SF-36 can provide valuable insights into their overall health status, functional limitations, pain levels, and emotional well-being. By completing the questionnaire, patients and healthcare providers can better understand the impact of PAD on various aspects of the patient's life and tailor treatment plans accordingly. Additionally, the SF-36 can be used to monitor changes in health status over time and evaluate the effectiveness of interventions

aimed at improving PAD symptoms and overall quality of life (27). The SF-36 is provided in the attachment.

3.9.6 Time up and Go Test

The Time up and Go (TUG) test result Interpretation is given according to "Performance-oriented mobility assessment (33).

1. Individuals requiring less than 10 seconds are fully independent in their daily mobility.
2. Individuals taking 11-19 seconds have mobility limitations, but typically without functional consequences.
3. Individuals requiring between 20-29 seconds have mobility limitations that can have functional consequences. The walking speed of these participants is approximately 0.5 meters per second. Further assessment is necessary in this case.

3.9.7 Education Sessions on walking training, PAD Knowledge and Tests

At visit 1 a brief knowledge training session on general information about PAD and the walking training was provided. The contents of the training session included the correct execution of walking training, the self-paced app-based 6 MWT at home, as well as personnel intervention for reduction of personal risk factors related to PAD. The training session were conducted on a one-to-one basis. The content of the training session was based on the current guideline of the European Society for Vascular Medicine for PAD (4). The participants had the opportunity to ask questions. This session was conducted by a certified nurse in accordance with the Health and Nursing Care Act (GuKG) [3]. The knowledge tests were administered during visit 1, before the training session about risk factors took place and visit 3. It encompasses a range of topics including identifying risk factors associated with heart and vascular diseases, understanding of optimal target values for LDL-cholesterol and blood pressure, recognizing the benefits of specific interventions such as structured walking exercises, and comprehending the role of medications like statins and anticoagulants in managing PAD.

[3] §16 Bundesgesetz über Gesundheits- und Krankenpflegeberufe (Gesundheits- und Krankenpflegegesetz – GuKG) idgF (23.05.2024)

3.10 Statistical methods

The data analysis was conducted using SPSS version 29. Demographic data were analysed with descriptive analyses. User satisfaction was analysed based on a Likert-scale questionnaire with descriptive statistical analysis due to conversation of numeric ranges 1–10 of the questionnaires to logical common grading of 0% – 100% and given in spider charts and bar diagrams. Results of the total and pain-free walking distance in the 6 MWT were analysed at visit 1 and 3 with parametric tests, compared with Wilcoxon-test and distribution shown boxplots. The authors of the SF-36 provide a specified analysis of the data, weighting the responses to derive a percentage score for each quality-of-life aspect under consideration.[4] Results of the SF-36 Questionnaire, TUG tests and knowledge tests were also analysed using the Wilcoxon-test for inferential statistics.

[4] https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form/survey-instrument.html (22.06.2024)

4 Results

4.1 Baseline demographic and clinical characteristics of participants

In total, 46 patients were evaluated for eligibility from the waiting list for an endovascular procedure. A further two patients were referred to the study directly from the outpatient clinic and were not on the waiting list.

A total of 28 patients was excluded from the study. Of these, 17 did not fulfil at least one of the inclusion criteria. Additionally, 10 patients declined participation in the study for personal reasons, and one patient was not included for another reason.

Following this, 20 patients were enrolled in the study and be further called participants.

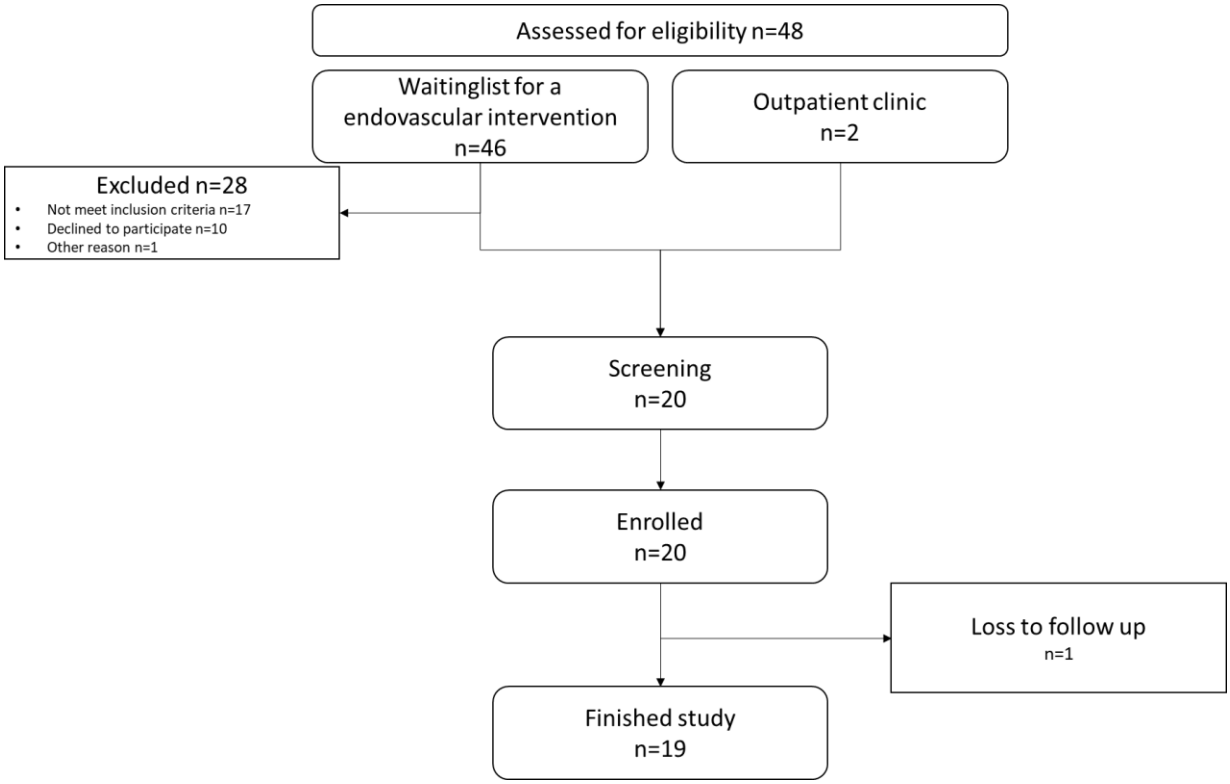

Figure 8: Flowchart of study (Screening, enrolment, finishing)

Source: Author's construction, published (1), reprinted by permission.

Of these participants, 13 were male (65%). Following enrolment, one participant withdrew from the study and subsequently died at home after seven days. No relation of the participant's death to the clinical trial could be identified. A total of 19 participants successfully completed the

study after an average of 90 days. Consequently, only 19 participants were included in all comparative analyses based on data from the entire duration of the study.

The mean age of the participants upon inclusion was 63.1±6.6 years. Male participants were not significantly younger (p=0.643). Twelve out of the 20 participants (60%) were active tobacco users. The further demographic and clinical characteristics are presented in Table 6.

Table 6: Participants' characteristics

			Female (n=7)	**Male** (n=13)	**Total** (n=20)
Age	years	mean (SD)	64.14 (8.68)	62.46 (5.39)	63.05 (6.55)
Weight	kilograms	mean (SD)	70.14 (9.5)	81.67 (11.95)	77.64 (12.27)
Hight	meters	mean (SD)	1.65 (0.03)	1.76 (0.05)	1.72 (0.07)
BMI	kg/m²	mean (SD)	25.79 (3.44)	26.33 (4.51)	26.15 (4.08)
Subjective pain free walking distance	meters	Mean (SD)	73.57 (50.22)	81.54 (37.16)	78.75 (41.04)
Fontaine stage IIa*	participants	n	0	0	0
Fontaine stage IIb*		n	7	13	20
Diabetics		n (%)	1 (14%)	2 (15%)	3 (15%)
Hypercholesterolaemia		n (%)	7 (100%)	13 (100%)	20 (100%)
Smokers		n (%)	2 (28%)	10 (77%)	12 (60%)
Coronary artery disease		n (%)	3 (43%)	4 (31%)	7 (35%)

*(Participants characteristics at visit 1 separated by gender and in total;BMI= Body Mass Index; SD = standard deviation; * = diagnosed before screening for the study) Source: Author's construction, published (1), reprinted by permission.*

4.2 Patient satisfaction with the telehealth service

The program received high satisfaction ratings from the participants, with an average score of 93.3±0.05% at visit 2 after 60 days of enrolment and 95,4±0.03% at visit 3 from 19 participants across all dimensions. In Figure 9 participants satisfaction is shown including system quality, information quality, service quality, intention to use, satisfaction and health benefits.

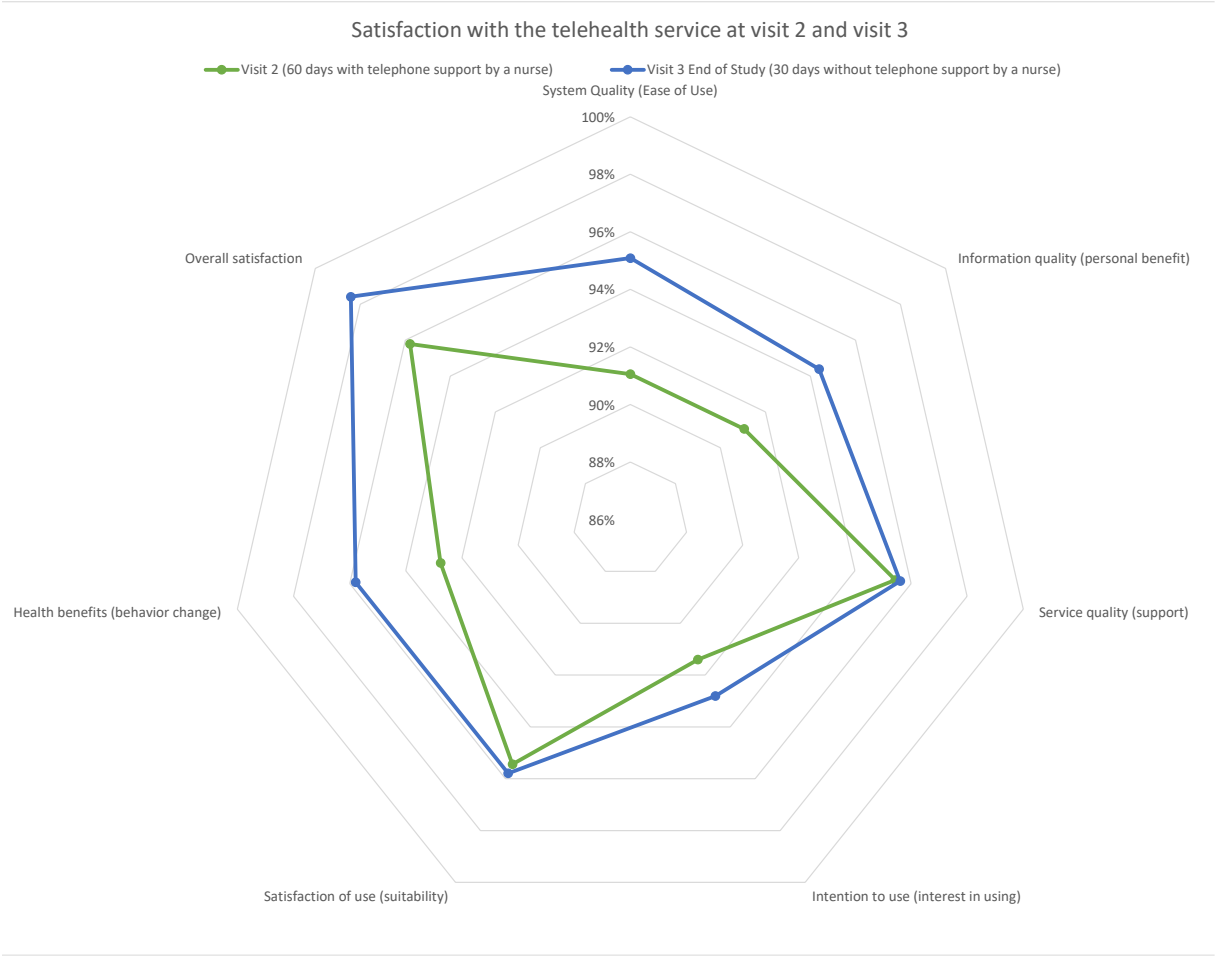

Figure 9: Spider chart of the satisfaction survey

Source: Author's construction, published (1), reprinted by permission.

At visit 2 and visit 3 six dimensions of the telehealth service were assessed:

System Quality (Ease of Use): Participants rated the ease of use at 91.1±0.73%. This positive trend continued into visit 3, with a rating of 95.1 ±0.16%, as reported by 19 participants.

Information Quality (Personal Benefit): Users rated information quality at 91.1±0.34%. This trend continued in visit 3 with a rating of 94.4±0.17%.

Service Quality (Support): Service quality, measured by the level of support, received a rating of 95.4±0.09% during visit 2. This level of satisfaction continued into visit 3, where it was graded at 95.6±3.22%.

Intention to Use (Interest in Using): Users expressed strong interest in using the system, with a rating of 91.4±0.07% during visit 2. This intention to use remained consistent with 92.8±4.07% in visit 3.

Satisfaction of Use (Suitability): Moreover, satisfaction with system usage was reported at 95.4±0.13% during visit 2. This high level of satisfaction continued into visit 3, where it was reported at 95.8±4.36%.

Health Benefits (Behaviour Change): A mean of 92.8±0.08%. of participants agreed in experiencing behaviour changes resulting from their interactions with the healthcare information system during visit 2. This positive trend continued in visit 3, with health benefits rated at 95.8±4.13%.

Overall Satisfaction: The study concluded with an overall satisfaction rating of 95.8±0.20%. during visit 2 and 98.4±3.31% during visit 3, encompassing users' satisfaction with all aspects of the healthcare information system.

In Figure 10 the ratings of the questionnaire regarding the satisfaction of patients PAD at visits 2 and 3 are shown with bar diagrams. The survey was structured based on the six evaluation criteria outlined by DeLone and McLean (26), whereby the detailed affiliation of the respective question is listed in the Materials and Methods. Respondents were asked to rate each of the statements on a scale of 1 to 10, with 1 being ‘do not agree’ and 10 being “total agree”.

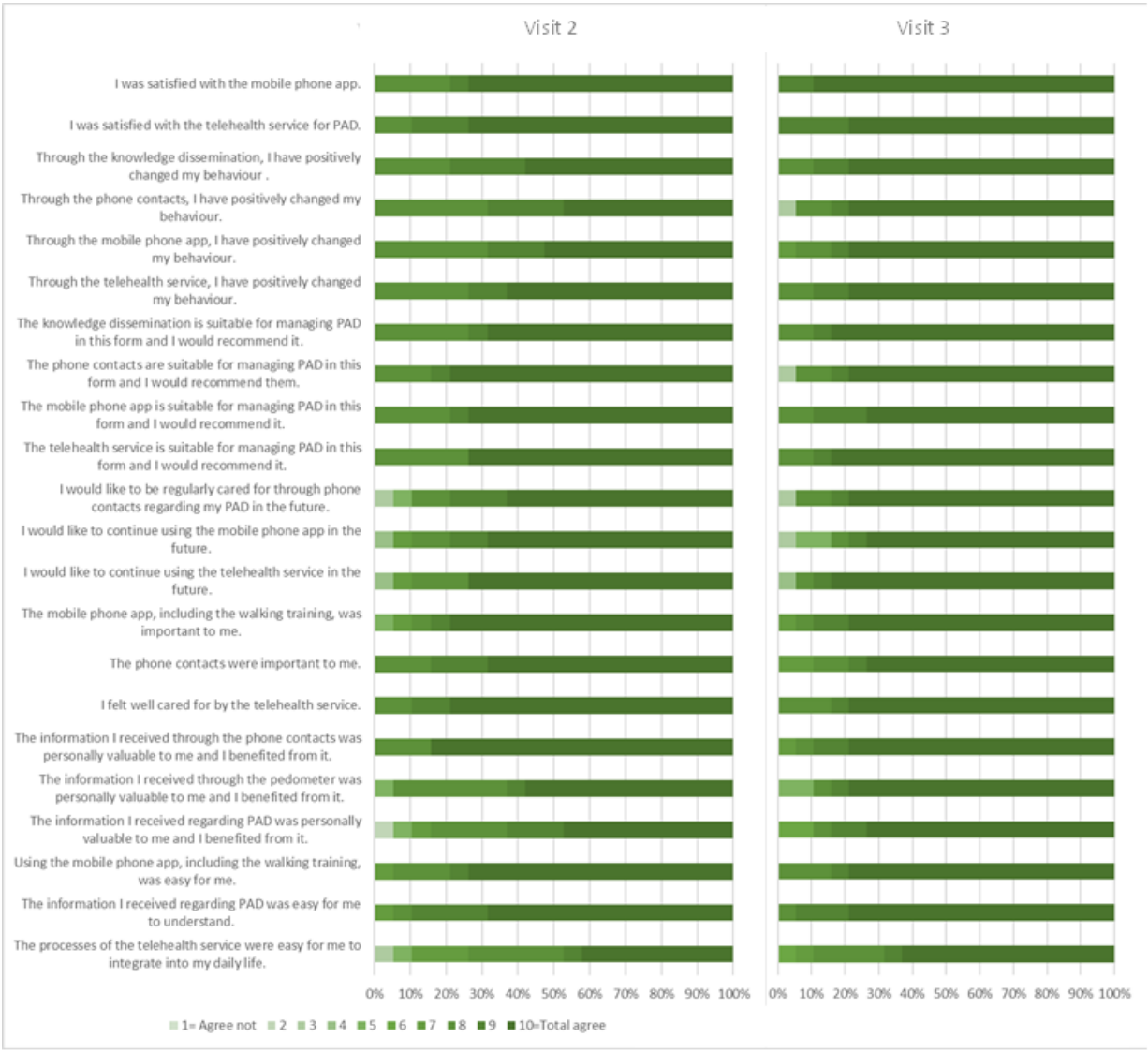

Figure 10: Bar diagram of the satisfaction survey

Source: Author's construction

4.2.1 Satisfaction of walking training without nurse support

At visit 2, after the phase with phone calls, 14 participants (73.7%) expected the telehealth service not to be as helpful without regularly telephone calls. At visit 3, after having passed this phase without nurse calls, even 15 participants (78.9%) rated so.

4.3 Walking distance in the 6 MWT

During visit 1 and 3, the walking distances were assessed, including the pain-free, absolute and total walking distance in the 6 MWT, by a certified nursing professional. Simultaneously, the total walking distance was synchronized and recorded using the app.

Table 7: Pain-free and the total walking distance in 6 MWT conducted by the nurse

	Visit 1 *Baseline*	**Visit 3** *End of study*	**Difference**		
	mean (SD), meters	*mean (SD), meters*	mean, *meters*	*(%)*	*p-value*
Pain-free walking distance	76.26 *(36.82)*	188.42 *(81.17)*	+112.15	+147.1%	***<0.001****
Total walking distance (6 MWT)	308.79 *(82.62)*	425.94 *(107.09)*	+117.16	+37.9%	***<0.001****

*(n = 19; * = p-value below 0.05 was defined as significant difference using Wilcoxon-test) Source: Author's construction, published (1), reprinted by permission.*

The pain-free walking distance has even more than doubled as it improved significantly by 147.1%. The distribution of the pain-free walking distance among the participants is shown in Figure 11, with 42.1% (8 participants) reaching 200 meters and more at the end of study.

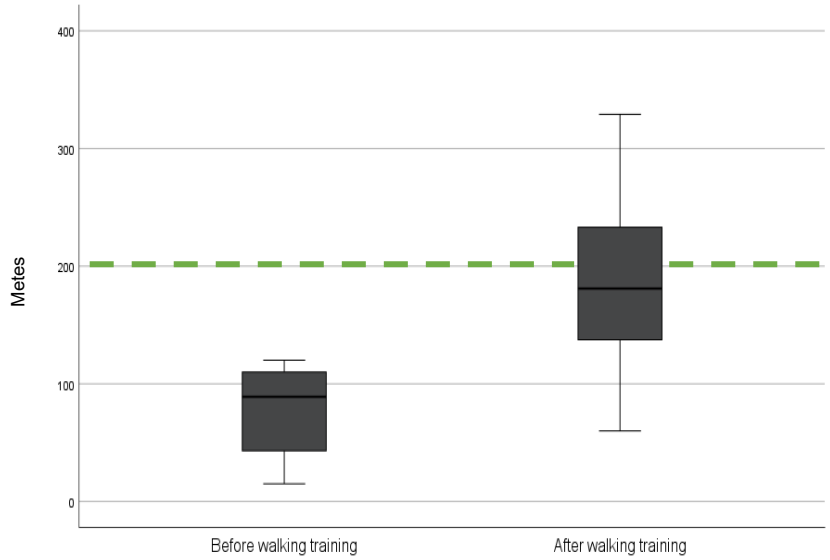

Figure 11: Distribution of the pain-free walking distance in 6 MWT conducted by the nurse (visit 1 and 3)

Source: Author's construction, published (1), reprinted by permission.

The results of the total walking distance in the 6 MWT conducted by a nurse showed a significant improvement from baseline with 308.79 (±82.62) meters to 425.94 (±107.09) meters at the end of the study. The mean distance increased significantly by 117.2 meters (+ 37.9%, p<0.001). The distribution of the total walking distance in the 6 MWT among the participants is shown in Figure 12.

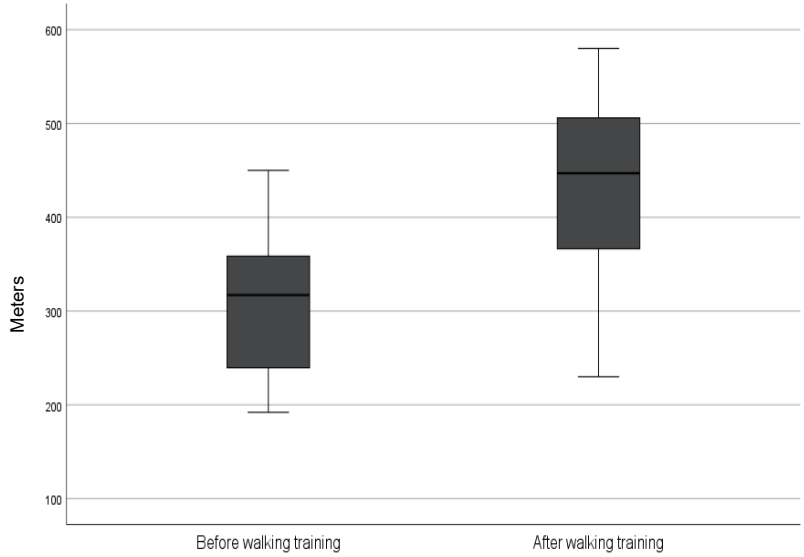

Figure 12: Distribution of total walking distance in 6 MWT conducted by the nurse (visit 1 and 3)

Source: Author's construction, published (1), reprinted by permission.

The number of participants, who had to stop at least once during the 6 MWT, due to claudication therefore reaching their absolute walking distance, decreased from 15 participants (78.9%) at visit 1 to only 4 participants (21.1%) at visit 3, see Figure 13.

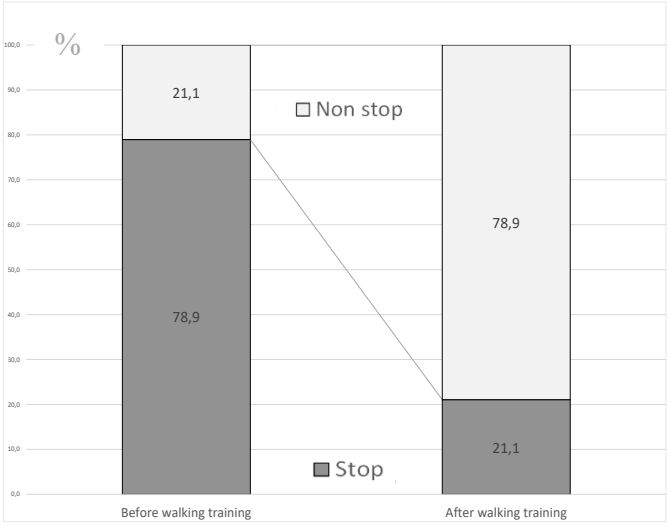

Figure 13: Proportion of participants reaching absolute walking distance in 6 MWT conducted by the nurse (visit 1 and 3)

Source: Author's construction

The remaining 4 participants (21.1%), who still reached their absolute walking distance in the 6 MWT at the end of study (visit 3), demonstrated a 130.6% increase in absolute walking distance from 90.0±21.2 meters (visit 1) to 207.5±52.6 meters (visit 3), although this was not statistically significant (p=0.109).

4.3.1 Walking distance by app-based 6 MWT

Furthermore, the participants were required to perform at least one 6 MWT per week at home. The first and the last 6 MWT via the app were conducted during clinic visits 1 and 3. A total of 283 walking tests were conducted by the 20 participants, with an average of 14.9 tests per participant per study period of 12 weeks. On mean, the participants covered 395.04 (±115.41) meters per 6 MWT.

4.3.2 Walking distance in 6 MWT determined by the nurse compared to the app

At visit 1, a 6 MWT determining a total walking distance was conducted on 20 participants by a nurse as well as by the app. The difference of the total walking distance obtained by the nursing staff (312.40±82.02m) and the app (320.37±86.21m) was 7.94±32.06 meters, this was not statistically significant (p=0.313).

However, at visit 3, a significant difference (p<0.001) was found between the two measurement methods carried out by 19 participants (nurse 425.95±107.09m) versus app (392.99±106.01m). The mean difference was 32.95±32.69 meters, whereby the app measured shorter distance.

To examine the hypothesis that the elevated speed and the high number of laps completed by participants during the 6 MWT at the clinic at visit 3 were the cause of the observed difference, further analyses were conducted.

Based on the mean distance participants completed in the 6 MWT, as measured by the nurse with 312.40 meters at visit 1, all participants with a distance greater than this value were excluded for the analysis of walking distance at visit 3. Only three participants had a distance of 312.40 meters or below at visit 3 and where therefore included in this further analysis. A comparison of the distances measured by the nurse (240.00±17.32m) versus app (199.46±12.81m) for these three participants revealed no significant difference (p=0.109).

4.4 Steps per day

The following Table presents an overview of participants' mean daily step counts, capturing both the central tendencies and the spread of values. In this study involving 20 participants, the mean was recorded at 4,972.5±556.5 steps per day.

Table 8: Mean steps per day per participant

	ID_1	ID_2	ID_3	ID_4	ID_5	ID_6	ID_7	ID_8	ID_9	ID_10
Mean	**7911.77**	**1874.01**	**5889.19**	**5560.16**	**2419.71**	**4416.00**	**3955.86**	**3713.60**	**1724.43**	**5938.11**
± ***SD***	*2792.97*	*957.72*	*2667.80*	*1072.34*	*1192.29*	*1898.23*	*1883.17*	*1873.41*	*1018.83*	*1884.84*
Minimum	1976	473	195	1987	171	1077	575	1185	32	2253
Maximum	14790	6000	13036	8318	5667	10035	8288	13805	4920	11649

	ID_11	ID_12	ID_13	ID_14	ID_15	ID_16	Klo ID_17	ID_18	ID_19 *	ID_20
Mean	**6533.55**	**5842.36**	**3450.61**	**3351.21**	**5529.00**	**5029.69**	**4876.80**	**1240.49**	**3824.33**	**2781.13**
± ***SD***	*2884.07*	*2256.68*	*1781.67*	*1684.79*	*3197.70*	*1899.07*	*3060.31*	*708.68*	*2211.48*	*1557.42*
Minimum	31	652	222	170	1002	447	922	98	580	121
Maximum	13149	15256	8859	7218	16513	10151	15834	3387	6242	7565

*SD = Standard Deviation; * loss to follow up. Source: Author's construction*

Furthermore, the undulating daily walking activity with the number of steps per participant per day over a period of 90 days as well as the mean steps per day of all participants is shown in Figure 14.

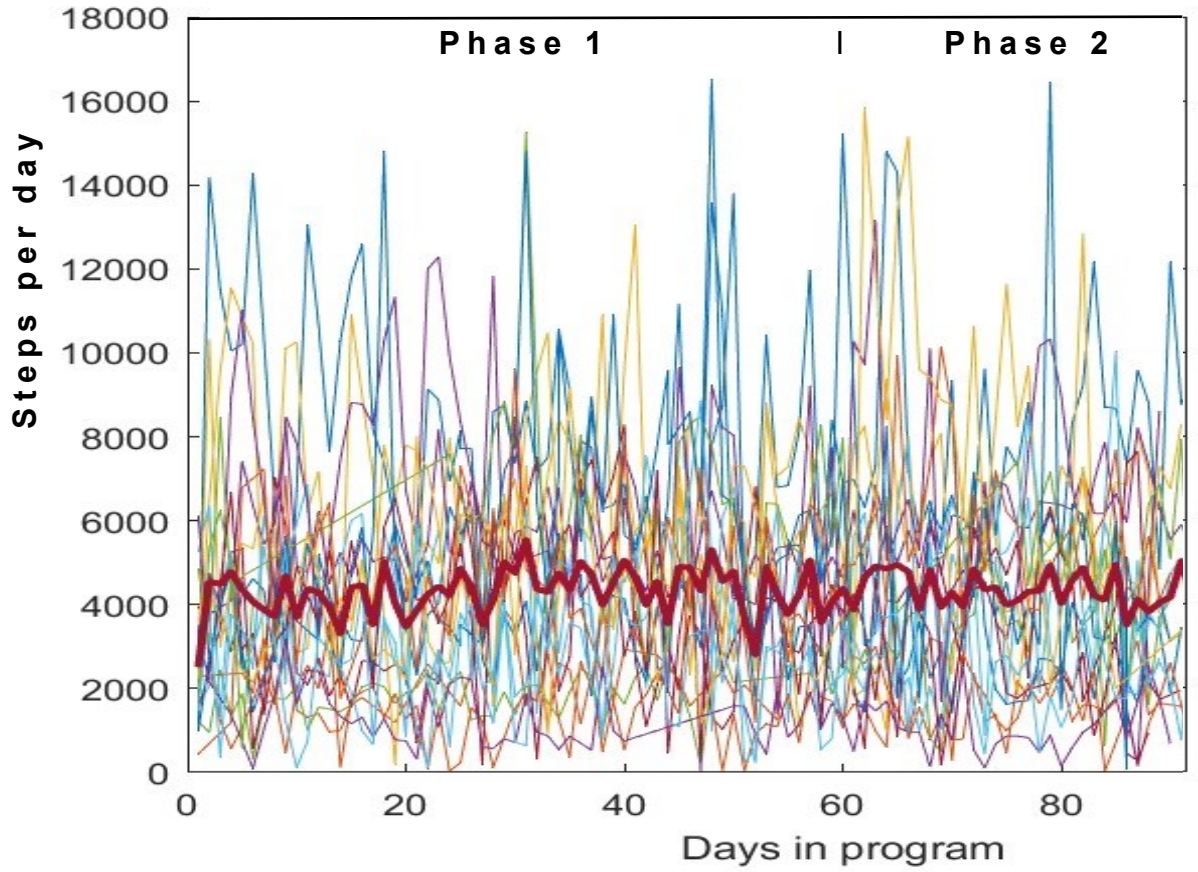

Figure 14: Mean steps per day per participant over the whole study duration

Source: Author's construction

4.5 Limitation of daily life (Quality of Life, SF-36)

The questionnaire SF-36 was carried out on 19 participants at visit 1 and visit 3. All detailed results are presented in Table 9. As the authors of the SF-36 provide a specified analysis of the data, thus the given data are all labelled with the unit %. Consequently, the changes are also presented in the text as absolute or relative change. Results in the dimensions physical function (absolute change +13.15%, $p<0.05$), bodily pain control (absolute change +15.53%, $p<0.01$) and social roles (absolute change +10.53%, $p<0.05$) improved significantly from visit 1 to visit 3.

Table 9: Results of the SF-36 Health Survey Dimensions and Scores (visit 1 and 3)

	Visit 1 *Baseline*	**Visit 3** End of study	**Changes**		
	mean (SD), %	*mean (SD), %*	*absolute, %*	*relative, %*	*p-value*
Physical Function	44.74 *(17.75)*	57.89 *(22.13)*	+13.15	+29.39	***0.018****
Role Physical	35.52 *(29.83)*	42.10 *(29.82)*	+6.58	+18.52	*0.302*
Bodily Pain	42.89 *(14.77)*	58.42 *(18.38)*	+15.53	+36.21	***0.015****
Mental Health	65.05 *(19.12)*	69.89 *(18.15)*	+4.84	+7.44	*0.308*
Role Emotional	61.40 *(29.83)*	73.68 *(29.81)*	+12.28	+20.00	*0.297*
General Health	63.16 *(11.69)*	60.53 *(12.57)*	-2.63	-4.16	*0.204*
Role Social	72.37 *(23.78)*	82.89 *(19.19)*	+10.53	+14.54	***0.042****
Vitality	44.74 *(15.41)*	52.11 *(14.56)*	+7.37	+16.47	*0.167*

*(n = 19; * = p-value below 0.05 was defined as significant difference using Wilcoxon-test) Source: Author's construction, published (1), reprinted by permission.*

4.6 Time up and Go test

The TUG test was conducted twice per participant at visit 1, resulting in a total of 40 tests at visit 1. At visit 3, the remaining 19 participants were able to perform the TUG test twice each.

A significant reduction in the time required to complete the test was observed between visit 1 and 3 comparing first pass at visit 1 with first pass at visit 3 (-1.5s, $p < 0.002$) as well as second passes (-1.6s, $p < 0.001$), showing for faster movements in the performed TUG test.

The results are presented in the following Table.

Table 10: TUG tests with first pass and second pass (visit 1 and 3)

	Visit 1 *Baseline*	**Visit 3** *End of study*	**Changes**	
	mean, seconds (SD)	*mean, seconds (SD)*	*seconds*	*p-value*
TUG test (first pass)	11.95 *(2.7)*	10.49 *(2.6)*	*- 1.46*	***< 0.002****
TUG test (second pass)	11.60 *(2.7)*	9.95 *(2.8)*	*- 1.65*	***< 0.001****
seconds	*- 0.35*	*- 0.54*		
p-value	*0.296*	***0.031****		

*(n = 19; * = p-value below 0.05 was defined as significant difference using Wilcoxon-test)*
Source: Author's construction

When evaluating the repeatability of the TUG test, which needs adequate explanation and adherence, the two consecutive passes are compared with each other. While participants seemed to perform better in the second passes, at visit 1 there was no significant difference between first pass and second pass (0.35s, p=0.296), while at visit 3 there was a significant difference (0.54s, p=0.031).

Distribution of the TUG test performance is shown in Figures 15 and 16.

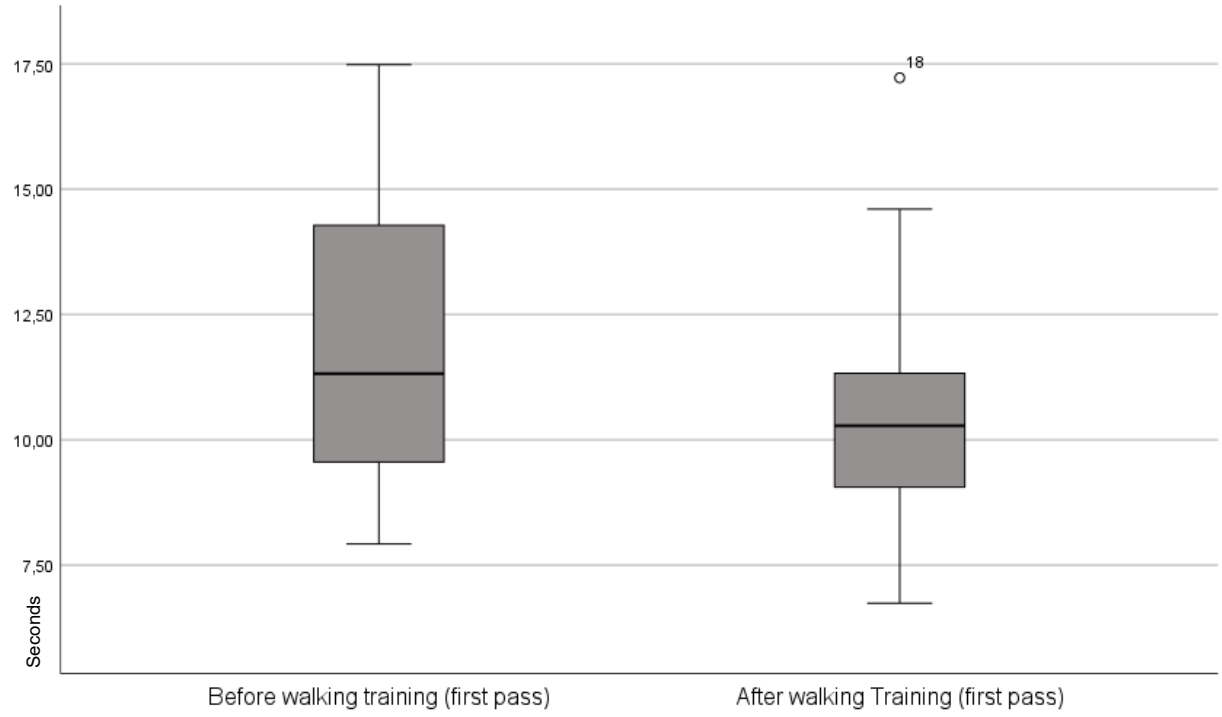

Figure 15: TUG test first pass (visit 1 vs. visit 3)

Source: Author's construction

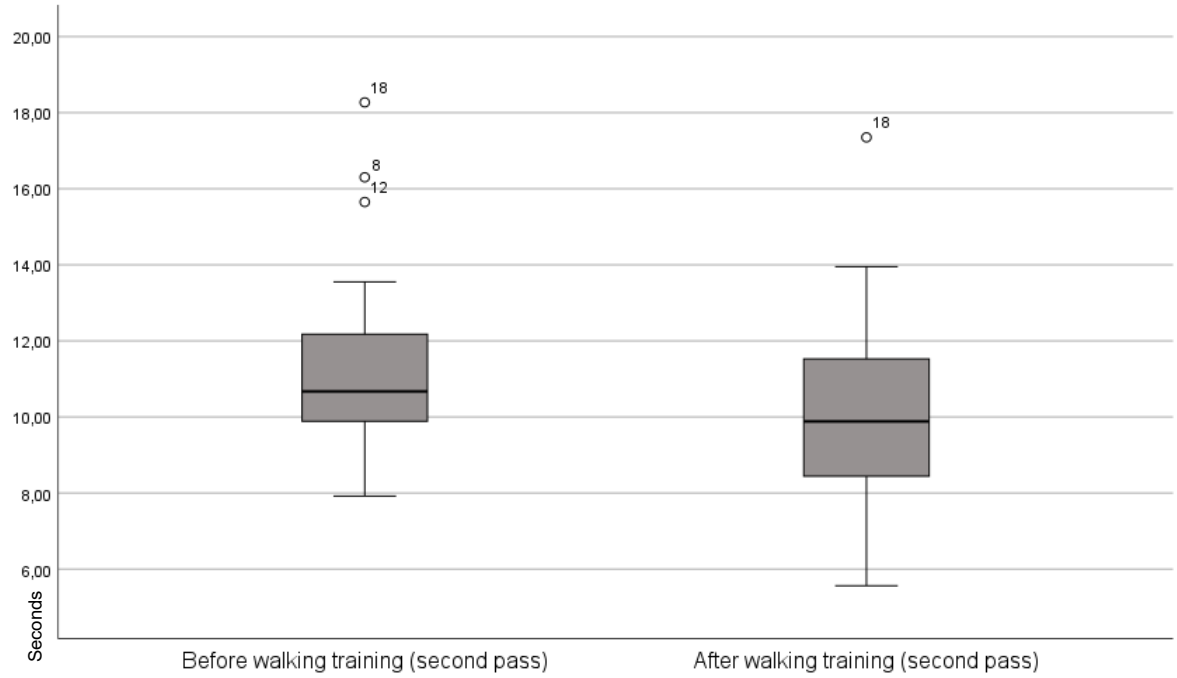

Figure 16: TUG test second pass (visit 1 vs. visit 3)

Source: Author's construction

4.7 Knowledge about PAD

A total of 19 knowledge tests about PAD were analysed between visit 1 and visit 3. The participants achieved 65.8% correct answers at visit 1 and 89.8% correct answers at visit 3, representing a significant increase of 24.1% in correct answers.

Table 11: Participants' level of knowledge about PAD (visit 1 and 3)

	Visit 1 *Baseline*	**Visit 3** *End of study*	**Changes**	
	mean, Percentage of correct answers (SD)		*Percentage of correct answers (%), (SD)*	*p-value*
Correct answers in PAD knowledge test	65.8% *(17.8)*	89.8% *(8.4)*	+24.1% (15.8%)	***< 0.001****

*(n = 19; * = p-value below 0.05 was defined as significant difference using Wilcoxon-test) Source: Author's construction*

The boxplots in Figure 17 also show a decrease in the spread from correct answers (%) at the end of study (visit 3) compared to baseline (visit 1).

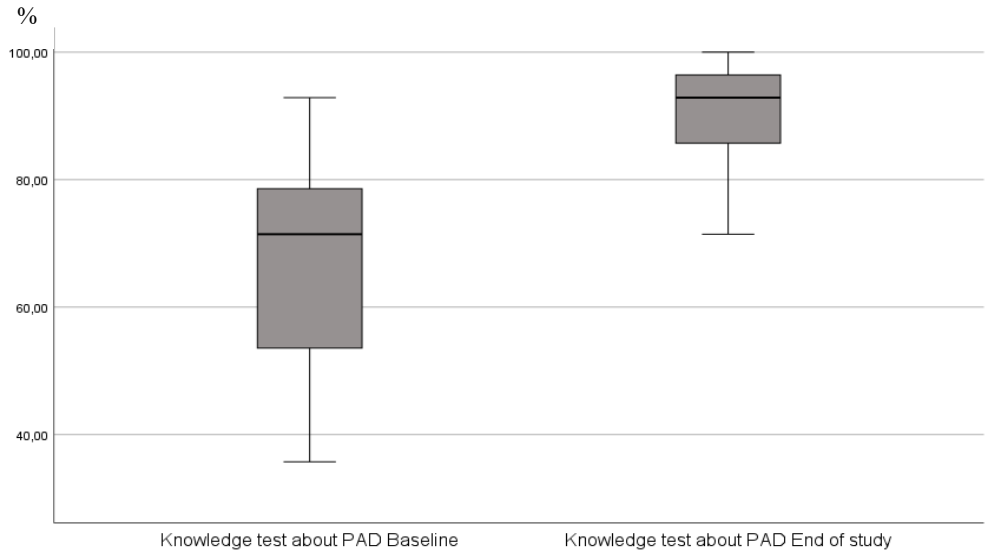

Figure 17: Distribution of corrected answers in the knowledge test (visit 1 and 3)

Source: Author's construction

5 Discussion

Supervised walking exercise therapy and lifestyle modification have been demonstrated to improve walking distance, reduce symptoms, and improve quality of life in patients with PAD and is also recommended in all current clinical guidelines (4-6).

The aim of this study was to investigate the feasibility of a disease management program in form of a telehealth service with nurse support, implementing a structured ambulatory walking training for patients suffering from PAD in stage IIa and IIb. PAD is a disease that mainly affects older people, so it was important to tailor the program to their needs. (34)

Patient satisfaction was identified as the primary endpoint, as it is a key factor in ensuring real patient engagement with the program.

Another crucial aspect was to assess the efficacy of the treatment. The pain-free walking distance is a pivotal indicator of the efficacy of effective PAD treatment, but the assessment of quality of life is also a central aspect of the treatment. Furthermore, strengthening health literacy is an important aspect for people with PAD so that they can cope with their disease in a self-determined way. The applicability of novel test procedures such as the TUG, which are not yet used in the treatment of PAD, was also examined.

This multimodal evaluation aimed to ascertain the feasibility of the telehealth service, examining whether this concept can be implemented in its current form.

5.1 Patient satisfaction

Satisfaction with the telehealth service was high. After the study period the participants rated the system's ease of use at an impressive 95%, highlighting the intuitive and user-friendly interface. Information quality received a high rating of 94%, indicating that the system's information was considered accurate, relevant, and beneficial to users' healthcare needs. Service quality, measured at 96%, indicated that the system effectively addressed user inquiries and concerns. Users expressed a strong interest in using the system (93%), and satisfaction with its use was rated at 96%. Importantly, 96% of users reported health behaviour changes due to their interactions with the system. These high satisfaction rates are at a comparable level with the findings from telehealth service in chronic heart failure patients as previously found by Ammenwerth et al. (30).

Another important finding of this pilot study is that most participants stressed the importance of healthcare professional contact during the program, as 78.9% of participants who completed both phases of the study with and without telephone interaction, agreed that the telehealth service would be less effective without regular telephone calls. This finding is supported by the study by Li et al., which highlights the need for improved health professional-patient communication and efforts to increase the uptake and implementation of structured exercise programs for patients with PAD (35).

The regular telephone consultation was part of the telehealth service thought as an important extrinsic motivator for the patients to keep adherent to the 12-week training program. In contrast to the Bearne et al. (36) where physical therapists supported the walking training, in our project care was provided by a qualified nurse. It is evident that healthcare professionals remain crucial for patient motivation and care. As demonstrated by Galea Holmes and colleagues, an understanding of the disease, including its risk factors and pathophysiology, and an appreciation of the treatment approaches in PAD, had been associated with improved walking distance in 6 MWT (37).

In studies evaluating telehealth systems in people aged 50 and above, participants emphasised the ease of use. Furthermore, it was discovered that it is of paramount importance to differentiate between self-efficacy with technology and self-efficacy in patients' health when prescribing a telehealth service. In particular, older individuals may exhibit high levels of health self-efficacy, yet simultaneously demonstrate lower levels of technology self-efficacy. It is

therefore of the utmost importance to consider the provision of support in the form of advice and assistance with medical queries, as well as technical difficulties at a low-treshold, when implementing a telehealth service. (38)

In this study, a specifically educated PAD nurse was identified as the optimal point of service, who should provide the requisite holistic care, integrating walking training advice based on knowledge training and supervisor functions, i.e. re-evaluating the current status of risk factor management, at a low threshold. (37)

Given that all healthcare professionals, particularly those nurses with specialised training in PAD, are a limited and valuable resource, it is important to ensure that they are used efficiently. Upcoming technologies may facilitate the delivery of telehealth services, reducing barriers and stress for participants. This is achieved through the provision of reduced need for personal consultations, fast responses to individual needs and questions, support and motivation impulses.

The telehealth service could be stressed further by reducing the duration of the initial nurse-supported phase or by incorporating new technologies, such as chat-bots, which have already demonstrated effectivness in tobacco cessation support (39). As the belief of healthcare professional in the patients' capabilities plays a significant role in realizing lifestyle modification (40), the combination of intial helathcare professional conatct and relationship building, followed by telehealth care may be indispensable.

The intention to use a digital health application was found to be dependent on the perceived burden of the disease, as well as the presence of noticeable symptoms or a perceived threat, according to Schröder et al. (38). This underscores the fact, that only patients with PAD IIb were willing to participate in this study. This finding should be considered when telehealth services with walking training are planned to be implemented in standard care for symptomatic PAD patients.

It is vital that healthcare professionals should understand themselves as unintentional gatekeepers providing access to specific telehealth programs (41). This entails being aware of potential biases in assumptions of patients' technical competencies, especially in older age groups. Ball et al. (42) highlight the opening gap, whereby older people experience exclusion in the use of technology and consequently lose contact with others. Further studies indicate that ageism is pervasive within the healthcare system (43). Consequently, it is recommended that

all patients receive empathic and illustrative information, as well as appropriate training. Following this, a joint assessment should be conducted to determine the usability of the technical aspects of the telehealth service. Rather than excluding patients a priori due to ageism, it is preferable to assess their suitability for the service on an individual basis.

5.2 Walking distance

This training program led to significant improvements in both, pain-free walking distance and total walking distance in the 6 MWT. The mean total walking distance covered in the 6 MWT increased by +117.2 meters, reflecting a remarkable improvement in participants' mobility (+ 37.9%), even higher than the ones reported in other studies. Bearne et al. reported a lower increase in the intervention group from 352.9 meters to 380.6 meters in the 6 MWT in the same 3-month period (36). However, the present project used a multi-modal approach, including a nurse who provided supervision, as well as self-paced walking training by the patient. A major aspect of our project is the independence of walking training in terms of place and time. Patients were motivated to carry out walking trainings anywhere and at any time and therefore able to incorporate it into their everyday lifes.

Moreover, the pain-free walking distance increased (from 76.26 to 188.42 meters, i.e. factor 2.47) during this telehealth program, but was slightly lower than the improvement by a factor of 3, which is demanded from a structured walking training in outpatient clinics as mentioned in the ESC and ESVM guidelines (4, 5). Nevertheless focusing on the high burden of individual daily movement radius disability with symptomatic PAD, the pain-free walking distance increased by 147.1% in this study, representing a more than doubling. This was a satisfying outcome for the participants, as i.e. evidenced by the significant improvement in social participation.

Moreover, at the beginning of the study, none of the participants were able to walk more than 200 meters without pain. However, by the end of the study, 42.1% of participants were able to walk 200 meters or more without experiencing pain, which resulted in them being reclassified from PAD stage IIb to stage IIa.

The novel integration of these technologies enabled structured walking training at home, with progress monitored via an app as well as by the participants themselves. External motivation could be provided by healthcare professionals based on the app data during phase 1. The impact of unblinded recording of steps and total walking distance in the 6-minute walk test with geolocation tracking on patient motivation is currently being investigated in an interesting study. It is hypothesised that unblinded counted steps per day will promote physical activity in patients with PAD (44).

5.3 Quality of Life

Nevertheless, the improvement achieved during the program represents an increase in mobility and a positive influence on the patients' daily lives. This could be demonstrated by surveying (SF-36) the following aspects of health-related quality of life, including improvements in pain control (absolute change +15.53%, p=0.015), physical function (absolute change +13.15%, p=0.018) and role of social participation (absolute change +10.53%, p=0.042). While previous studies have been unable to demonstrate improvements in quality of life aspects following walking training (45), others have employed the Vascular Quality of Life Questionnaire (VascuQoL) (46) or Walking Impairment Questionnaire (WIQ) (21).

Lanzi et al. demonstrated that walking training led to significant improvements in all dimensions of the SF-36. However, this was achieved with greater use of resources, as the training involved three sessions per week over three months, delivered each time face-to-face by an exercise physiologist (25).

Comparable findings to those reported here, with significant improvements in regard to bodily pain (absolute change +13.4%) and physical function (absolute change +12.3%) were obtained by Nicolaï et al. after 12 months in the SF-36 questionnaire, again with the need for greater resources being evident in the supervised exercise training group (21).

An important aspect in the implementation of supervised walking training is the accompanying assessment of the effectiveness of the treatment. In addition to measuring PFWD, studies always recommend the assessment of quality of life using standardised and validated questionnaires such as the SF-36, which is one of the most widely used tools for this purpose. These should always be surveyed before the start of walking training and after its completion. (20, 27)

5.4 Applicability of the app-based 6 MWT

The integration of a home-based 6 MWT regimen represents a pivotal advancement in the field of patient monitoring and functional assessment. By enabling participants to engage in periodic tests from the comfort of their residences, this approach avoids the logistical challenges associated with clinic-based assessments. The noteworthy volume of tests conducted during this study (14.9 tests per participant over 12 weeks) underscores the feasibility and acceptance of such a regimen. Furthermore, the mean total distance covered per 6 MWT provides a quantifiable indicator of participants' functional progression and the efficacy of interventions administered over the study period.

The comparison of measurements derived from traditional clinical evaluations conducted by nursing staff with those obtained via the app offers intriguing insights into the reliability and validity of app-based assessments. The initial observation (visit 1) indicated a congruence between the two modalities, suggesting that the app has the capacity to accurately capture and quantify participants' walking distances in a manner comparable to conventional methodologies. However, at visit 3, a significant discrepancy was identified between the measurements, suggesting potential discrepancies between the app's output and clinically derived metrics by the nurse. Given the substantial increase in the distance between visits 1 and 3 and the emergence of a discrepancy, a hypothesis was formulated, that the elevated speed and the high number of laps completed by participants during the 6 MWT at the clinic at visit 3 were the cause of the observed difference. Therefore, further analyses were conducted. Upon the exclusion of all participants with a distance greater than the mean distance observed during visit 1, the discrepancy was no longer evident.

As geolocation tracking is the mechanism behind the measurement of the app, the sort of route taken by the 6 MWT may influence in the accuracy of app-based distance measuring. During visits 1 and 3, the nurse conducted the tests on a straight test track with a minimum length of 30 meters, as recommended by the guidelines. However, a straight track with repetitive laps may have negatively impacted the accuracy of the results of the geolocation tracking. It is possible that the precision of the geolocation tracking may have been less accurate when participants were turning at the end of the straight. This may have resulted in a reduction in the distance recorded at the end of the straight than that which they had actually done. Obviously this assumed imprecision in geolocation at the laps end is more pronounced as the number of

laps completed during the 6 MWT increases. This may explain why the discrepancy between the nurse and app-measurement results was only apparent at visit 3. Previous data show that the accuracy of geolocation tracking is influenced by several factors, as the localisation and proximity of the device to the body (47). Consequently, further research is needed to address the current limitations of knowledge. Based on the findings, it is recommended that short, repetitive test tracks with ends and the need to turn at one point should be avoided.

5.5 Applicability of the TUG test

The administration of the TUG test at visits 1 and 3 provides valuable insights into the temporal evolution of participants' functional mobility. A notable observation emerged from the analysis, indicating a significant reduction in the time required to complete the TUG test between visits 1 and 3. This noteworthy accelerated performance witnessed at visit 3, suggests a sustained trajectory of enhancement in functional capacity among patients undergoing walking training.

During both clinical visits, participants were instructed to follow the test protocol and then underwent a first pass of testing, with a second pass following. While participants seemed to perform better in the second passes, at visit 1 there was no significant difference between the first pass and the second pass, while at visit 3 there was a significant difference. This inconsistency underscores the potential harms in reproducibility and reliability of TUG test outcomes, as previously demonstrated (48).

In order to reaffirm the utility of the TUG test as a robust metric for assessing functional mobility in PAD patients, it may be beneficial to consider conducting multiple repetitions. Previous studies have only investigated the TUG test in a single administration, which may not be optimal for the stability of this complex performance. Multiple test administrations lend credibility to the validity of TUG test results and bolster confidence in its clinical applicability (49).

As previous studies also investigated, the observed improvements in TUG test performance bear significant implications for PAD management strategies (49). The demonstrated efficacy of the intervention in enhancing functional mobility underscores the importance of targeted interventions aimed at optimising patients' physical capabilities. However, the inconsistency in test outcomes underscores the dependence of the reliability of the TUG test on repetition, as it is known as a sensitive tool for monitoring changes in functional status over time.

5.6 Knowledge transfer for PAD patients

The substantial and significant increase in correct answers from 65.8% to 89.8% from visit 1 to visit 3 underscores the efficacy of educational interventions in augmenting participants' understanding of PAD-related concepts. This improvement is indicative of enhanced knowledge retention and comprehension over time, which is paramount for empowering patients to make informed decisions regarding their health management, as participants were trained about PAD knowledge and risk factor management at visit 1 after the knowledge test, updated at visit 2 and via regular app-reminders, but retested at visit 3.

The notable rise in correct responses suggests a positive impact on participants' awareness and understanding of PAD. Such improvements are instrumental in fostering patient engagement and adherence to treatment regimens. Effective patient education serves as a cornerstone in chronic disease management, empowering individuals to actively participate in their care and adopt healthier lifestyles (21).

The observed increase in correct answers and decrease of standard deviation, which can be nicely seen in the boxplot in Figure 17 highlights the importance of integrating comprehensive patient education initiatives into clinical practice. Healthcare providers should prioritize the dissemination of accurate and accessible information tailored to patients' needs and preferences. Emphasizing the importance of ongoing education and reinforcement can further enhance patients' knowledge retention and self-management skills, as previous studies have shown. (50, 51)

6 Limitations

The study's sample size was relatively small with only 20 participants and did not contain a control group. Therefore, further studies are needed to quantify the specific impact of the telehealth program on patient outcomes and to differentiate between the effects of the intervention and potential natural disease progression or other factors. As both approaches to enhance motivation, intrinsic motivation (the loop effect of positive reinforcement of the self-paced 6 MWT by the app using geolocation tracking) and extrinsic motivation (nurse calls), were used simultaneously in phase 1, it was not possible to differentiate between their respective influences.

This study could also have been influenced by potential confounders, which may have affected the performance of patients in 6 MWT due to other comorbidities, e.g. heart failure or COPD.

Another limitation of this study was, that no patients with Fontaine stage IIa were enrolled. This may be due to a lack of motivation to participate in a study, as they felt little restriction in their daily lives. When utilising the 6 MWT in patients with stage IIa, the pain-free walking distance may also extend beyond the 6 minutes and may not be captured.

The study had a relatively short follow-up period of 90 days, which may not capture the long-term effects of the telehealth program on patients' well-being and health outcomes. Longer-term follow-up could provide valuable insights into the program's sustainability and lasting benefits.

Patients who chose to participate in the telehealth program may have had inherent motivations or characteristics that differed from those who did not enrol. This potential selection bias may influence the observed outcomes and limit the applicability of the program to a broader patient population.

7 Conclusion

In accordance with the clinical guidelines of the ESC, ESVM and AHA, the initial intervention for claudication in patients with PAD should be a modification of lifestyle and walking training (4-6).

The pilot study demonstrated that such a service is feasible and usable for patients with PAD of different ages and was able to improve their walking distances with telemedical supported walking trainings, performed independently of time and location, including rural settings.

The study's findings indicate high usability of the telehealth service “Keep pace” with high patient satisfaction and with significant positive effects on physical well-being, social engagement along with enhanced walking distance.

The telehealth-nurse supported service has the potential to adress an important gap in the care landscape for patients with PAD and provides low-threshold and efficient care to people, especially in the area of resource-efficient motivation support for home-based walking training. The obtained results justify further studies to test the effectiveness of this type of care in a larger population, including a control group and a longer follow-up period.

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10 Attachment

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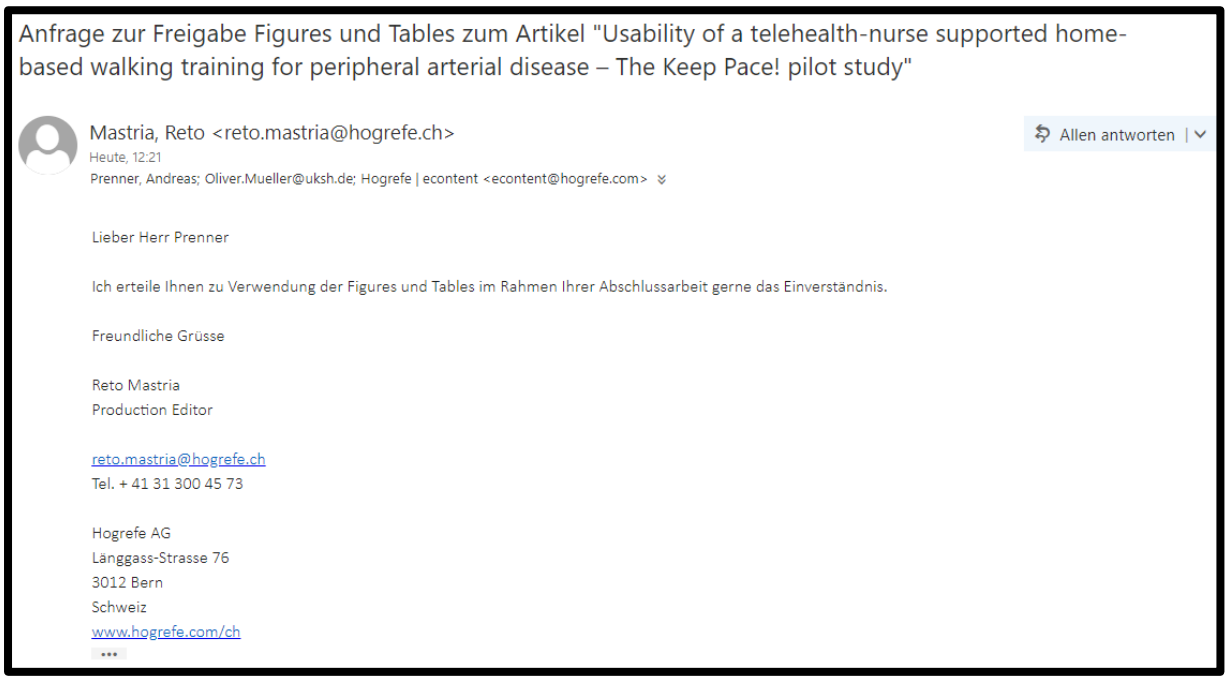

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Allen antworten

Lieber Herr Prenner

Ich erteile Ihnen zu Verwendung der Figures und Tables im Rahmen Ihrer Abschlussarbeit gerne das Einverständnis.

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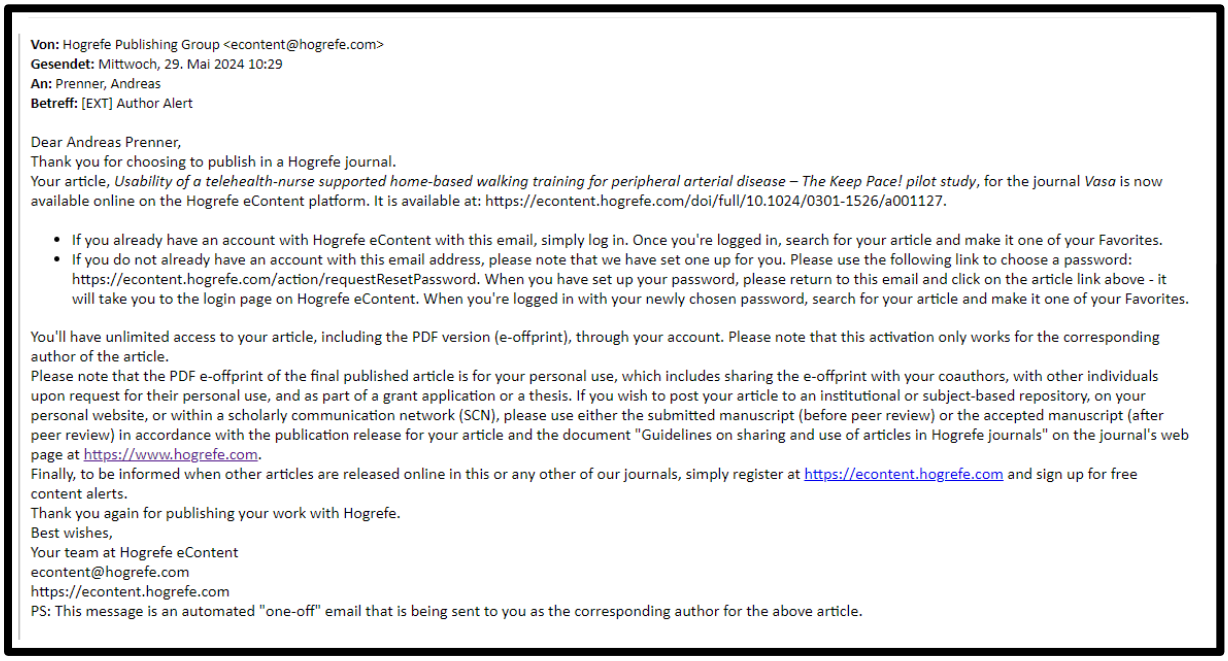

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Wissenstest über pAVK (=Richtige Antwort =Falsche Antwort)

1. Nennen Sie die Risikofaktoren für Herz- und Gefäßerkrankungen?	
Tabakkonsum	Bluthochdruck
Übergewicht	Erhöhte Blutfette
2. Womit kann die Neubildung der kollateralen Gefäße (Umgehungskreisläufe) direkt gefördert?	
Regelmäßiges Gehtraining	Lokale Gefäßaufdehnung
3. Der Zielwert bei meinem Cholesterinwert, namens LDL, liegt laut Experten bei…	
Zumindest unter 55mg/dl	Zumindest unter 100mg/dl
Zumindest unter 110mg/dl	Zumindest unter 120mg/dl
4. Regelmäßige Blutdruckkontrollen sind bei Gefäßerkrankungen wichtig. Der Zielbereich liegt …	
Zumindest unter 140/90 mmHg.	Jedenfalls unter 90/60 mmHg
Über 160/90 mmHG	Zwischen 150/80 bis 180/100 mmHg
5. Der Der Body-Mass-Index – auch Körpermasseindex sollte in welchem Bereich liegen?	
20-25 kg/m^2	25-30 kg/m^2
12- 18 kg/m^2	27-35 kg/m^2
6. Passivrauchen ist kein Risikofaktor für Gefäßerkrankungen.	
Richtig	Falsch
7. Was ist im Hinblick auf die Einnahme von Statinen (Cholesterinsenker) richtig?	
Können bei Erreichen der Cholesterin-Zielwerte (LDL) abgesetzt werden	Hemmen die Cholesterinentstehung in der Leber, bringen Cholesterin aus dem Blut in die Zellen und stabilisieren bereits vorhandene Einlagerungen in Gefäßwänden
Dürfen nicht mit Aspirin gemeinsam eigenommen werden	Regelmäßige Kontrolle des Laborwertes (LDL) als Marker der Blutfette
8. Zur medikamentösen Therapie der Gefäßerkrankungen stehen gerinnungshemmende und cholesterinsenkende Medikamente zur Verfügung, die auch kombiniert werden können.	
Richtig	Falsch
9. Welche Therapie ist für die frühen Stadien einer Gefäßerkrankungen am besten?	
Strukturiertes Gehtraining	Operationen
10. Wie oft soll ein strukturiertes Gehtraining zur Vorbeugung von Gefäßkomplikationen durchgeführt werden?	
3-mal wöchentlich zirka 30 bis 60 Minuten	2-mal monatlich zirka 5 bis 10 Minuten
1-mal wöchentlich zirka 30 bis 60 Minuten	1-mal monatlich zirka 5 bis 10 Minuten
11. Ein strukturiertes Gehtraining kann laut Studienergebnissen die Gehstrecke…	
Innerhalb von 12 Wochen verdreifachen	Reduzieren
Innerhalb von 2 Wochen verdoppeln	Erst nach einem 1 Jahr erhöhen
12. Durch das Überwinden der Schmerzgrenze beim Gehen kann ich einen Beitrag zur Gefäßneubildungen leisten.	
Richtig	Falsch
13. Wie lange soll mein Training zur Steigerung der Gehstrecke laut Empfehlungen bei täglicher Anwendung sein?	
Täglich eine Stunde Intervalltraining mit 5 bis 15 Minuten Intervallen (Einheiten) und Pausen dazwischen	Täglich mindestens drei Stunden Intervalltraining mit 45 Minuten Intervallen (Einheiten) und Pausen dazwischen
Täglich eine Stunde Intervalltraining mit 1 Minuten Intervallen (Einheiten) und dazwischen 20 Minuten Pausen	Täglich mindestens 6 Stunden Intervalltraining mit 5 bis 15 Minuten Intervallen (Einheiten) und Pausen dazwischen
14. Worauf kann sich das strukturiertes Gehtraining positiv auswirken?	
Psychisches Befinden	Schmerzfreie Gehstrecke
Blutzucker-Verwertung	Gesamter Fettstoffwechsel

Fragebogen SF-36

In diesem Fragebogen geht es um Ihre Beurteilung Ihres Gesundheitszustandes. Der Bogen ermöglicht es, im Zeitverlauf nachzuvollziehen, wie Sie sich fühlen und wie Sie im Alltag zurechtkommen.

Bitte beantworten Sie jede der folgenden Fragen, indem Sie bei den Antwortmöglichkeiten die Zahl ankreuzen, die am besten auf Sie zutrifft.

1. Wie würden Sie Ihren Gesundheitszustand im Allgemeinen beschreiben?
(Bitte kreuzen Sie nur eine Zahl an)
Ausgezeichnet..... 1
Sehr gut..... 2
Gut..... 3
Weniger gut..... 4
Schlecht..... 5

2. Im Vergleich zum vergangenen Jahr, wie würden Sie Ihren derzeitigen Gesundheitszustand beschreiben?
(Bitte kreuzen Sie nur eine Zahl an)
Derzeit viel besser als vor einem Jahr..... 1
Derzeit etwas besser als vor einem Jahr..... 2
Etwa so wie vor einem Jahr..... 3
Derzeit etwas schlechter als vor einem Jahr..... 4
Derzeit viel schlechter als vor einem Jahr..... 5

3. Im folgenden sind einige Tätigkeiten beschrieben, die Sie vielleicht an einem normalen Tag ausüben. Sind Sie durch Ihren derzeitigen Gesundheitszustand bei diesen Tätigkeiten eingeschränkt? Wenn ja, wie stark?
(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

TÄTIGKEITEN	Ja, stark eingeschränkt	Ja, etwas eingeschränkt	Nein, überhaupt nicht eingeschränkt
a. anstrengende Tätigkeiten, z.B. schnell laufen, schwere Gegenstände heben, anstrengenden Sport treiben	1	2	3
b. mittelschwere Tätigkeiten, z.B. einen Tisch verschieben, staubsaugen, kegeln, Golf spielen	1	2	3
c. Einkaufstaschen heben oder tragen	1	2	3
d. mehrere Treppenabsätze steigen	1	2	3
e. einen Treppenabsatz steigen	1	2	3
f. sich beugen, knien, bücken	1	2	3
g. mehr als 1 Kilometer zu Fuß gehen	1	2	3
h. mehrere Straßenkreuzungen weit zu Fuß gehen	1	2	3
i. eine Straßenkreuzung weit zu Fuß gehen	1	2	3
j. sich baden oder anziehen	1	2	3

4. Hatten Sie in den vergangenen 4 Wochen aufgrund Ihrer körperlichen Gesundheit irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause ?
(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

SCHWIERIGKEITEN	JA	NEIN
a. Ich konnte nicht so lange wie üblich tätig sein	1	2
b. Ich habe weniger geschafft als ich wollte	1	2
c. Ich konnte nur bestimmte Dinge tun	1	2
d. Ich hatte Schwierigkeiten bei der Ausführung (z.B. ich musste mich besonders anstrengen)	1	2

5. Hatten Sie in den vergangenen 4 Wochen aufgrund seelischer Probleme irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause (z.B. weil Sie sich niedergeschlagen oder ängstlich fühlten)?
(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

SCHWIERIGKEITEN	JA	NEIN
a. Ich konnte nicht so lange wie üblich tätig sein	1	2
b. Ich habe weniger geschafft als ich wollte	1	2
c. Ich konnte nicht so sorgfältig wie üblich arbeiten	1	2

6. Wie sehr haben Ihre körperliche Gesundheit oder seelischen Probleme in den vergangenen 4 Wochen Ihre normalen Kontakte zu Familienangehörigen, Freunden, Nachbarn oder zum Bekanntenkreis beeinträchtigt?
(Bitte kreuzen Sie nur eine Zahl an)
Überhaupt nicht..... 1
Etwas..... 2
Mäßig..... 3
Ziemlich..... 4
Sehr..... 5

7. Wie stark waren Ihre Schmerzen in den vergangenen 4 Wochen?
(Bitte kreuzen Sie nur eine Zahl an)
Ich hatte keine Schmerzen..... 1
Sehr leicht 2
Leicht..... 3
Mäßig..... 4
Stark..... 5
Sehr stark..... 6

8. Inwieweit haben die Schmerzen Sie in den vergangenen 4 Wochen bei der Ausübung Ihrer Alltagstätigkeiten zu Hause und im Beruf behindert?
(Bitte kreuzen Sie nur eine Zahl an)
Überhaupt nicht..... 1
Ein bißchen..... 2
Mäßig..... 3
Ziemlich..... 4
Sehr..... 5

9. In diesen Fragen geht es darum, wie Sie sich fühlen und wie es Ihnen in den vergangenen 4 Wochen gegangen ist. (Bitte kreuzen Sie in jeder Zeile die Zahl an, die Ihrem Befinden am ehesten entspricht). Wie oft waren Sie in den vergangenen 4 Wochen...

(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

BEFINDEN	Immer	Meistens	Ziemlich oft	Manchmal	Selten	Nie
a. ...voller Schwung	1	2	3	4	5	6
b. ...sehr nervös	1	2	3	4	5	6
c. ...so niedergeschlagen, dass Sie nichts aufheitern konnte	1	2	3	4	5	6
d. ...ruhig und gelassen	1	2	3	4	5	6
e. ...voller Energie	1	2	3	4	5	6
f. ...entmutigt und traurig	1	2	3	4	5	6
g. ...erschöpft	1	2	3	4	5	6
h. ... glücklich	1	2	3	4	5	6
i. ...müde	1	2	3	4	5	6

10. Wie häufig haben Ihre körperliche Gesundheit oder seelischen Probleme in den vergangenen 4 Wochen Ihre Kontakte zu anderen Menschen (Besuche bei Freunden, Verwandten usw.) beeinträchtigt?

(Bitte kreuzen Sie nur eine Zahl an)

Immer..... 1
Meistens..... 2
Manchmal..... 3
Selten..... 4
Nie..... 5

11. Inwieweit trifft jede der folgenden Aussagen auf Sie zu?

(Bitte kreuzen Sie in jeder Zeile nur eine Zahl an)

AUSSAGEN	Trifft ganz zu	Trifft weitgehend zu	Weiß nicht	Trifft Weitgehend nicht zu	Trifft überhaupt nicht zu
a. Ich scheine etwas leichter als andere krank zu werden	1	2	3	4	5
b. Ich bin genauso gesund wie alle anderen, die ich kenne	1	2	3	4	5
c. Ich erwarte, dass meine Gesundheit nachlässt	1	2	3	4	5
d. Ich erfreue mich ausgezeichneter Gesundheit	1	2	3	4	5

Votum

Medizinische Universität Graz
Ethikkommission

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Tel.: +43 / 316 / 385-13928

FOLGEVOTUM

gültig bis 16.02.2024

EK-Nummer:	34-127 ex 21/22 1566-2021
Studientitel:	A Usability Study of a tele-health service for patients with peripheral arterial disease
Prüfer:	Assoc.-Prof. Priv.-Doz. Dr.med Günther Silbernagel Medizinische Universität Graz, Univ. Klinik für Innere Medizin
Sponsor:	Medizinische Universität Graz, Univ. Klinik für Innere Medizin
Ansprechpartner:	Ass.-Prof. PD Dr. Günther Silbernagel, 8036 Graz, Auenbruggerplatz 15
CRO:	-
Antragsteller:	Medizinische Universität Graz
Ansprechpartner:	Mag. Andreas Prenner

Die o.a. Studie wurde von der Ethikkommission erstmals in der Sitzung 03-21/22 am 13.12.2021 behandelt.
Die Ethikkommission ist zu folgendem Schluss gekommen:

Es besteht kein Einwand gegen die Durchführung der Studie in der vorliegenden Form.

Stimmberechtigte bzw. anwesende Mitglieder bei der Behandlung waren: Siehe beiliegende Liste vom 13.12.2021.

Kommissionsmitglieder, die für diesen Tagesordnungspunkt als befangen anzusehen waren und daher gemäß Geschäftsordnung an der Entscheidungsfindung und Abstimmung nicht teilgenommen haben: keine

Zur Beurteilung vorliegende Dokumente:

Dokumente eingegangen am 22.11.2021, begutachtet in der Sitzung 03-21/22 am 13.12.2021	
✓ Cover Letter Anschreiben Version 1.0	17.11.2021
✓ Antragsformular ECS	22.11.2021
Originalprotokoll Studienprotokoll_Usabilitystudy_V1.3 Version:1.3	20.10.2021
Informed Consent Form Einverstaendniserklaerung_Usabilitystudy_V1.1 Version:1.1	16.11.2021
✓ Case Report Form Case Report Form_Usabilitystudy_V1.0 Version:1.0	20.10.2021
✓ CV CV_Andreas Prenner Version:1.0	17.11.2021
✓ CV CV_Günther Silbernagel Version:1.0	30.03.2021
✓ Sonstiges: Benutzhandbuch_V3.0 Version:3.0	20.10.2021
✓ Sonstiges: Antrag auf Erlassung des Beitrages Version: 1.0	17.11.2021
Dokumente eingegangen am 03.12.2021, begutachtet in der Sitzung 03-21/22 am 13.12.2021	
✓ Antragsformular ECS Unterschriftenseiten	29.11.2021
✓ Protocol Signature Page 1.3	20.10.2021
Dokumente eingegangen am 02.02.2022, begutachtet im 'expedited Review' am 16.02.2022	
✓ Originalprotokoll 1.4	20.01.2022
✓ Informed Consent Form tc 1.2	19.01.2022
✓ Sonstiges: Antwortschreiben 1.0	31.01.2022
✓ Letter of Authorization Med.Uni Graz, mit Auflage	13.01.2022

Dokumente eingegangen am 05.04.2022, begutachtet im 'expedited Review' am 25.04.2022	
✓ CV Mitarbeiter Seinost	16.03.2022
Dokumente eingegangen am 29.07.2022, begutachtet im 'expedited Review' am 12.09.2022	
✓ Originalprotokoll 1.5	28.07.2022
✓ Informed Consent Form 1.3	28.07.2022
✓ Sonstiges: EK-Meldeformular	29.07.2022
Dokumente eingegangen am 19.10.2022, begutachtet im 'expedited Review' am 06.12.2022	
✓ Originalprotokoll 1.7	17.10.2022
✓ Sonstiges: EK-Meldeformular	19.10.2022
Dokumente eingegangen am 15.02.2023, begutachtet im 'expedited Review' am 24.02.2023	
✓ Zwischenbericht	15.02.2023

Datum Erstvotum: 16.02.2022

Die Ethikkommission geht - rechtlich unverbindlich - davon aus, dass es sich um keine klinische Prüfung nach AMG bzw. MPG handelt.

Es handelt sich um eine Studie im Rahmen einer Dissertation.

Das Votum der Ethikkommission berührt in keiner Weise die alleinige Verantwortung der Prüferin / des Prüfers / der Prüfer für die ordnungsgemäße Durchführung der Studie unter Einhaltung aller einschlägiger gesetzlicher Bestimmungen und Richtlinien.

Weiters machen wir darauf aufmerksam, dass der Kommission unverzüglich zu melden sind:

- Abweichungen vom Protokoll aus Sicherheitsgründen oder Protokolländerungen

- Änderungen, die das Risiko der Teilnehmer/-innen erhöhen oder die Durchführung der Studie wesentlich beeinflussen

- Mutmaßliche unerwartete schwerwiegende Nebenwirkungen - SUSARs (AMG-Studien ab 1.5.2004; Directive 2001/20 EC), SADEs (Verordnung 74/2017 und 746/2107) oder schwerwiegende unerwünschte Ereignisse - SAEs (andere Studien)

- Jegliche Information über sonstige Umstände, die die Sicherheit der Teilnehmer/-innen oder die Durchführung der Studie beeinträchtigen können

zusätzliche Auflagen: Die behördlich vorgeschriebenen Maßnahmen hinsichtlich der COVID-19 Pandemie müssen beachtet werden. Der Prüfer und der Sponsor müssen in ihrem jeweiligen Wirkungskreis unter allfälliger Beachtung von Leitlinien gewährleisten, dass keine zur Bekämpfung der Pandemie benötigten Ressourcen gebunden werden bzw. ausreichend Personal vorhanden ist und die TeilnehmerInnen durch ihre Studienteilnahme keiner zusätzlichen Infektionsgefahr ausgesetzt werden.

Graz, 24. Februar 2023

Univ.Prof.DI Dr.Josef Haas
Vorsitzender

Univ.Prof.Dr.Hans Peter Dimai
Stv. Vorsitzender

Achtung: Bitte bei allen das Projekt betreffende Schreiben oder telefonischen Anfragen die EK-Nummer angeben!

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Rechtsform: Juristische Person öffentlichen Rechts gem. UG 2002. Information: Mitteilungsblatt der Universität. UID: ATU 575 111 79. Bankverbindung: Raiffeisen Landesbank Steiermark IBAN: AT443800000000049610, BIC: RZSTAT2G