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A plantar flexion device exercise programme for patients with peripheral arterial disease: A randomised prospective feasibility study

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Abstract

Objectives To determine if the use of a plantar flexion device (Step It pedal) in a newly developed exercise programme is of benefit to patients with peripheral arterial disease.
Design Prospective feasibility trial with patients randomised to either standard care or the Step It exercise programme plus standard care.
Setting Physiotherapy Department at Cumberland Infirmary, Carlisle, UK.
Participants Patients were identified from the vascular team's referral list. In total, 42 patients agreed to take part; 18 in the control group and 24 in the intervention group.
Interventions Eligible participants were randomised and received either standard care or took part in a plantar flexion resistance exercise programme, involving the Step It pedal, for a period of 12 weeks.
Main outcome measures Maximum walking distance, claudication distance and ankle brachial pressure index.
Results Eighty-three percent of patients completed the study. Improvements in median distance to claudication symptoms and maximum walking distance were observed in the intervention group but not in the control group. Nine out of 15 (60%) participants in the control group and 14 out of 20 (70%) participants in the intervention group improved their walking distance. Ankle brachial pressure index remained virtually unchanged in both groups.
Conclusions Due to the variability of patients' fitness in the sample, it cannot be concluded whether use of the Step It pedal has additional benefits to patients over standard care. However, the study completion rate implies that patients with peripheral arterial disease are receptive to undertaking exercise programmes.

Keywords: Peripheral arterial disease; Plantar flexion; Exercise; Claudication

Introduction

Peripheral arterial disease is a common progressive disorder of the vasculature. The underlying aetiology of peripheral arterial disease is atherosclerosis, and therefore patients are at high risk of associated cardiovascular diseases such as myocardial infarction and stroke [1,2]. Narrowing of the arteries leads to reduced oxygen supply, thereby resulting in intermittent claudication symptoms (i.e. exercise-induced pain in the calves, thighs or buttocks), limited capacity to exercise and increased risk of tissue loss [3]. Peripheral arterial disease can be categorised using the Fontaine classification according to the absence or presence of intermittent claudication symptoms. In the USA alone, approximately 6% of the population are affected by this disease [4]. A UK study involving adults aged 55–74 years found that 4.5% experienced intermittent claudication symptoms [5].

Patients who receive support, training and education about exercise improve their walking distance by, on average, 150% [6,7]. Most previous research studies applied programmes involving weight-bearing or aerobic exercise (e.g. walking, rowing and cycling) to try and improve the maximum walking distance that patients can reach. Due to the increased risk of cardiovascular accidents in patients with peripheral arterial disease, the underlying atherosclerosis and the aversion to strenuous exercise by most patients, an alternative exer-

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cise programme that does not involve high-impact aerobic exercise regimes may be more appropriate than the aforementioned cycling and rowing programmes.

Supervised exercise programmes have been shown to benefit patients [8,9]. One recent study by McDermott *et al.* showed that supervised lower extremity resistance training has significant benefits over normal management involving education and advice on diet and exercise [10]. A 6-month programme resulted in improved maximum treadmill walking time, although 6-min walking distance did not improve over that of the control group. The lower extremity exercises included repetitions of knee extensions, leg presses and leg curls.

This pilot clinical research study applied the Step It rocker pedal (Step It System AB, Saltsjöbaden, Sweden) for the first time in patients with peripheral arterial disease. This is a small device, very similar to the pedal used to operate a bass drum on a drum kit, which is easy to use from a seated position and was first devised to help alleviate the risk of 'economy syndrome' (i.e. deep vein thrombosis) for travellers on long haul flights. Patients may be receptive to this form of exercise in addition to walking, especially if they are elderly, frail, have a fear of falling or have an aversion to the idea of 'exercise'. The aim of this initial randomised, controlled, prospective feasibility study was to determine the efficacy of the Step It pedal by measuring patients' maximum walking distance as well as ankle brachial pressure index. Both the control group and the intervention group received advice on diet and exercise, and were monitored for physical parameters.

Methods

Study design and subjects

This was a prospective, single-centre, controlled, randomised research study with 1:1 allocation to the control group and the intervention group. Patients were identified from referrals to the vascular clinic at Cumberland Infirmary, Carlisle. Symptomatic peripheral arterial disease, Fontaine IIa or higher, was diagnosed in patients by consultant vascular surgeons when first consulted on symptoms alone: exertional calf pain upon walking and an ankle brachial pressure index <0.90 [3,11]. Adult patients with symptomatic intermittent claudication due to peripheral arterial disease who were capable of giving informed consent were invited to participate in the study; there were no age restrictions. Patients were excluded according to the following criteria: unstable cardio/respiratory condition, such as uncontrolled hypertension, cardiovascular accident or myocardial infarction within the last 2 months; surgery within 6 weeks of enrolment; major amputation of one or more lower limbs; and blood glucose level >13 mmol/l (i.e. uncontrolled diabetes) [10,12]. Following consent, the patients were allocated at random to either the control group or the intervention group. The study was performed unblinded, and a non-restricted randomised sequence was obtained – and visible to researchers beforehand – for the whole sample using a freeware randomisation program (http://www.randomizer.org). The corresponding author (LJ) generated the randomisation sequence, LR and JT enrolled patients, and NT measured the study outcomes.

Interventions

Participants were randomised to either the control group (standard care) or the intervention group (standard care plus use of the Step It pedal) for a period of 12 weeks. Neither participants nor researchers were blinded regarding the allocated intervention. All participants initially attended one exercise class in the hospital for baseline measurements, and then continued their exercises (i.e. plantar flexion using the Step It pedal) and care programme unsupervised at home thereafter. Patients in both groups were advised to walk to their maximum walking distance each day and to attempt to increase this distance as they were able. The second study appointment in the hospital took place 12 weeks after patient enrolment. In addition to the standard care received by the control group, the subjects in the intervention group were also asked to undertake exercises at home using the Step It rocking pedal. These exercises consist of lower limb exercise training (resisted plantar flexion) whilst seated. The resistance of the pedal is equivalent to approximately 6 kg. The exercise sessions were performed three times per week for 12 weeks with the following pattern: 2 minutes exercise/2 minutes rest, 10 times, to equal 20 minutes of exercise in total. The patients were shown how to use the Step It pedal at the baseline appointment, and were asked to try it out to demonstrate they could use the instrument. Throughout the study programme, the participants were asked to record an exercise diary.

Primary and secondary outcomes

Outcome measures were recorded at baseline and at 12 weeks, with distance walked as the primary outcome measure. The data for claudication distance (i.e. the distance at which there is onset of claudication pain) and maximum walking distance were obtained using a treadmill set at 3.2 km/hour (as reported by Hiatt *et al.* [14]) and a 10° gradient. If no claudication pain developed, the maximum walking distance was recorded as the claudication distance. The secondary outcome measure was the ankle brachial pressure index, which was measured with a handheld Doppler machine. This tool is commonly used for diagnosis and monitoring of peripheral arterial disease [14]. In healthy persons, the ankle brachial pressure index is at least 1, with the systolic blood pressure equal in all limbs or higher in the ankle [3]. The highest measure of the dorsalis pedis and posterior tibial pressure was divided by the brachial pressure in the right arm of the patient. Since the recruited participants had claudication symptoms in either the right leg, left leg or both legs, the ankle brachial pressure index score for either the affected leg (unilateral disease) or the average of the ankle

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Table 1
Demographic overview of and completion rate in the two study groups

	Control group ($n = 18$)	Intervention group ($n = 24$)	P-Value
Mean age (range)	71 (47 to 86)	66 (45 to 77)	0.13
Gender (male/female)	13/5	15/9	0.52
Smoker	5 (28%)	7 (29%)	0.92
Bilateral/unilateral peripheral arterial disease	5 (28%)/13 (72%)	7 (29%)/17 (71%)	0.91
Diabetes	0 (0%)	2 (8%)	0.22
Beta-blockers	1 (6%)	2 (8%)	0.74
Statins	17 (94%)	19 (79%)	0.16
Completion rate	15/18 (83%)	20/24 (83%)	1

[a]Comparison of two study groups by one-way analysis of variance.

brachial pressure index scores for both legs (bilateral disease) is presented to account for this.

Data analysis and sample size

In order to determine the required sample size, the assumption was made that distribution of data would be normal, and it was estimated – based on previous studies – that the mean baseline maximum walking distance for all participants would be 300 m with a standard deviation of 100 m [9,10]. It was estimated, for the purpose of an *a-priori* sample size calculation, that the intervention group would improve by 20% after 12 weeks, with the control group remaining static. Applying a two-tailed unpaired *t*-test to compare the means of the control and intervention groups, and taking into account 80% power, 5% significance plus a 10% participant dropout rate, the total number of participants required was 90 (45 in each group). The changes in claudication distance, maximum walking distance and ankle brachial pressure index between baseline and 12 weeks in the control and intervention groups were determined. Statistical analyses were performed using Statistical Package for the Social Sciences Version 17 (SPSS Inc., Chicago, IL, USA).

Results

In total, 42 patients were recruited into the study; 18 in the control group and 24 in the intervention group. The CONSORT guidelines require a statement on the number of patients assessed for eligibility [15]. This was not recorded in this study, therefore no data are available on the number of patients who did not meet the inclusion criteria or who declined to participate. Of the 42 patients recruited, three patients in the control group and four patients in the intervention group discontinued during the 12-week study programme. The reasons were surgical intervention (one case in control group and one case in intervention group – both had angioplasty) or no reason given (two cases in control group and three cases in intervention group). The control group and the intervention group did not differ significantly in the demographic and clinical make-up of the participants (see Table 1). More diabetic patients were allocated to the intervention group but this difference was not statistically significant.

The claudication distance and maximum walking distance were measured for all 35 participants who completed the study (15 in the control group and 20 in the intervention group); however, the ankle brachial pressure index was not available for one control participant at baseline and was therefore excluded from this outcome measurement. The trial was discontinued when an interim analysis was performed of the data. The primary reason was the variance in the values of the primary outcome measures (claudication distance and maximum walking distance, see results below). No unintended effects were observed in any of the participants. The data for the 42 participants enrolled, rather than the 90 participants originally planned, are given below.

Claudication distance and maximum walking distance

Both the claudication distance and the maximum walking distance measured in all patients showed a wide range (Figs. 1 and 2, respectively). The claudication distance achieved by patients varied enormously; for example, from 10 m to 520 m in the control group at baseline. The median distance walked before the development of claudication symptoms was 100 m [interquartile range (IQR) 40 to 137 m] for the control group at baseline and remained at 100 m (IQR 60 to 180 m) at 12 weeks. For the intervention group, the median distance walked before the development of claudication symptoms changed from 65 m (IQR 50 to 110 m) to 85 m (IQR 53 to 138 m) over the 12-week period. It should be noted that participants did not always stop walking due to claudication pain. One control participant and three intervention participants did not experience any claudication pain before finishing their walking test; shortness of breath and tiredness were the reasons on these occasions. Where no claudication pain was experienced, the claudication distance was considered to be equal to the maximum walking distance. The maximum distance walked by participants ranged from 40 m for one patient in the control group at baseline to 770 m for another patient. Over the 12-week trial programme, the maximum distance walked by participants in the control group worsened; the median distance reduced from 260 m (IQR 100 to 325 m) to 210 m (IQR 140 to 430 m). However, for

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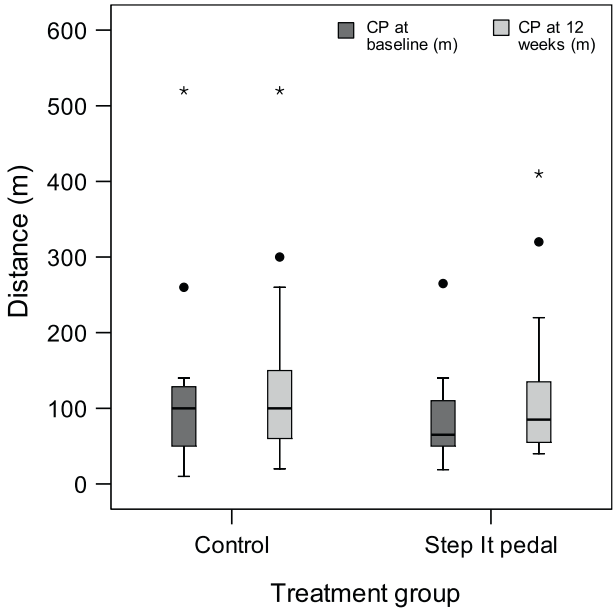

Fig. 1. Distance to claudication pain (CP) for the control and intervention groups. Outliers not included in box and whisker plot are denoted with an asterisk or dot.

participants in the intervention group, the median maximum distance walked improved from 160 m (IQR 103 to 274 m) to 200 m (IQR 110 to 308 m) at the 12-week endpoint.

Maximum walking distance and claudication distance were further analysed to determine how many participants actually showed an improvement in distance walked for these two parameters. Table 2 shows that more participants who used the Step It pedal improved their claudication distance compared with those in the control group. The number of participants who improved their maximum walking distance was similar in both study groups, although more participants in the intervention group improved their claudication distance.

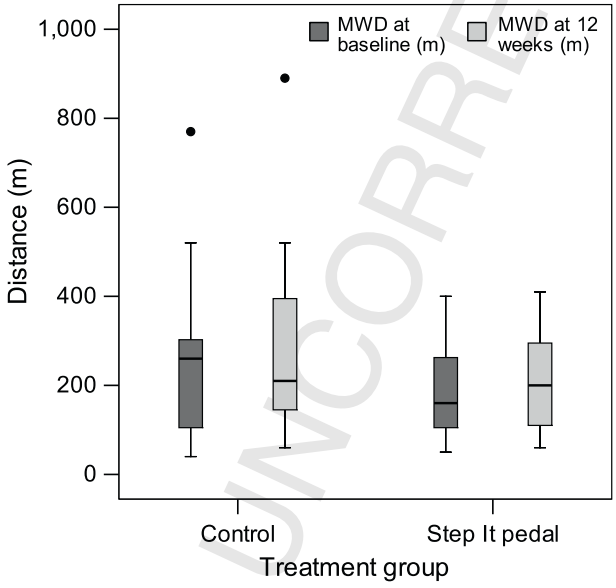

Fig. 2. Maximum walking distance (MWD) in the control and intervention groups. Outliers not included in box and whisker plot are denoted with a dot.

Table 2
Comparison of participants' response rates at 12 weeks

	No. of participants with improved distance	
	Control group	Intervention group
Claudication distance	7/15 (47%)	13/20 (65%)
Maximum walking distance	9/15 (60%)	14/20 (70%)

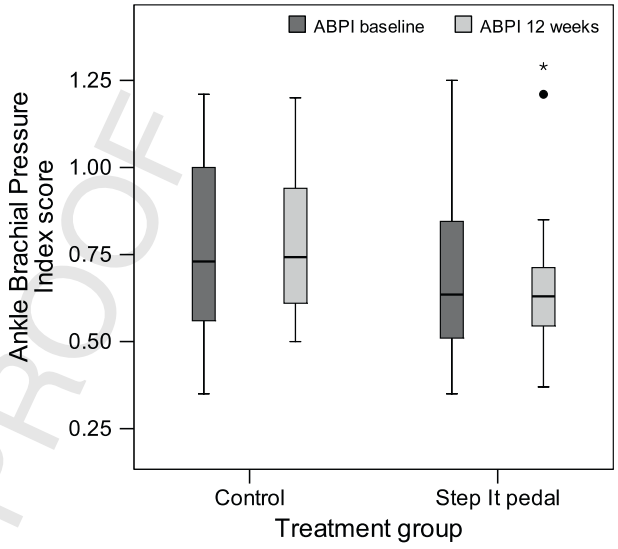

Fig. 3. Ankle brachial pressure index (ABPI) score in the control and intervention groups. Outliers not included in box and whisker plot are denoted with an asterisk or dot.

Ankle brachial pressure index

A secondary objective of this study was to conduct ankle brachial pressure index measurements to determine whether the plantar flexion exercise pedal could possibly have a positive effect. As shown in Fig. 3, the median ankle brachial pressure index remained virtually unchanged over the 12-week study period. A marginal improvement was seen in the control group (baseline: 0.73, IQR 0.56 to 1.00; 12 weeks: 0.74, IQR 0.61 to 0.97), and the median ankle brachial pressure index decreased by a fraction in the intervention group (baseline: 0.64, IQR 0.51 to 0.87; 12 weeks: 0.63, IQR 0.54 to 0.73). Four control participants and three intervention participants had an ankle brachial pressure index >0.9 at baseline, despite the fact that patients had originally been diagnosed with peripheral arterial disease by the vascular team using ankle brachial pressure measurements as a diagnostic tool.

Discussion

The first clinical study involving the Step It pedal, conducted on healthy volunteers, was published recently [16]. The hypothesis that increased calf muscle exercise may alle-

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viate the claudication symptoms experienced in peripheral arterial disease and thereby reduce the pain experienced in the lower extremities was therefore followed up using the Step It pedal in this pilot study. The primary objective of this study was to determine whether an unsupervised exercise programme involving a plantar flexion pedal that stimulates calf muscle exercise can potentially reduce claudication symptoms in patients with peripheral arterial disease. There was little difference in the percentage of patients in the control group and the intervention group who improved their walking distance over the 12-week programme, as measured by claudication distance and maximum walking distance, and the effect size seen in either group is not likely to be clinically relevant. The average percentage improvement in the median maximum walking distance for the intervention group was 25%, whereas an improvement of 30% is considered clinically significant [17,18]. As mentioned above, the considerable variance in distance walked by patients led to the discontinuation of the study. Bearing in mind that peripheral arterial disease is a progressive disorder that worsens over time, a positive note is that neither the control nor the intervention group deteriorated very much over the measured 12-week period in terms of measurement outcomes (Figs. 2 and 3). Other studies have shown that exercise programmes increase the fitness of patients with peripheral arterial disease by 50–200% [5,9]. The completed diaries provided by the participants did not indicate a high degree of non-compliance with the Step It exercise programme.

In order to gain an understanding of why the patients in this study did not improve dramatically, the baseline performance of participants in other studies was assessed. In studies by Zwierska *et al.* and McDermott *et al.*, the mean maximum distance that participants could walk was approximately 300 m (standard deviation approximately 90 m) [8,10]. A Cochrane report also reported a baseline maximum distance walked by patients of 300 m [9]. In the present study, the median maximum walking distance at baseline ranged from 160 m for the intervention group to 260 m for the control group. This implies that a proportion of the patients in the sample were less fit than those in the two abovementioned studies which demonstrated a positive effect of an exercise programme.

In the study by Zwierska *et al.*, mean ankle brachial pressure index at baseline was 0.65 (improving to 0.68 after a 24-week exercise programme), which is similar to the median of 0.64 for the intervention group in the present study [8]. In their study, the index increased to 0.68 after a 24-week exercise programme, whereas the median ankle brachial pressure index in the intervention group in the present study decreased to 0.63. These results are in line with other evidence which shows that the ankle brachial pressure index does not change significantly with exercise in patients with peripheral arterial disease [6]. The present data are also concordant with one other study that evaluated a year-long exercise programme in patients with peripheral arterial disease [17]. The study by Crowther *et al.* had a similar drawback to the present study in terms of sample size (total $n = 21$), raising the possibility for obtaining a false-negative result. Another complication of using the ankle brachial pressure index as an outcome measure is that the measurements may differ depending on the experience of the person performing the measurements and the method applied [19,20].

In another pilot study, involving a total of 25 patients with peripheral arterial disease, Wang *et al.* randomised participants to either a control group or a plantar flexion exercise group and showed a 20% increase in time to exhaustion for the plantar flexion group [21]. The plantar flexion device used on that occasion was an ergometer (a pedal attached to a exercise bike), and the supervised training involved 4 × 4-minute exercise intervals three times per week. Together with the data obtained in the present study, it may be that localised exercise of the calf muscles alone is insufficient to resolve claudication symptoms due to the limited resistance of the pedal itself, limited exercise time or lack of whole-body aerobic exercise. It may, however, be of use to prepare patients before they embark on a more strenuous aerobic exercise programme, although more research on a larger scale is needed [21].

Part of the reason for using the Step It pedal in the present study was due to the notion that even very unfit people can use it. Originally, the Step It pedal was designed for use in aeroplanes for long haul flights, so that the lower leg could be exercised with the aim of reducing 'economy syndrome'. The data obtained with the present sample show a considerable degree of variance, and therefore it was not possible to determine if a significant benefit is associated with use of the Step It pedal. However, this could potentially be achieved with a larger sample, provided that the study is better controlled in terms of patients' Fontaine classification, and the maximum and minimum distance that subjects are able to walk at baseline.

This study has a number of limitations. Firstly, the sample size was small. As this was a single-centre study, only patients from a certain area were recruited, which together with the limited sample size means that the results may not be representative of a wider population. Cumbria is a county in the UK with a high prevalence of cardiovascular disease in its population. The two study groups were, however, well balanced in terms of demographics and comorbidities, and this study does add to the recent literature about the application of specific lower limb exercise programmes in patients with peripheral arterial disease [7,8,10,14,21]. One other drawback may be that the exercise programme may not have been sufficiently intensive to improve fitness levels. Nevertheless, a 20-minute exercise session was likely to represent an increase compared with the patients' usual level and frequency of exercise, and is in alignment with other plantar flexion exercise programmes used [21]. With unsupervised exercise, there is always a risk that participants do not comply with the programme. It has been shown that those in supervised exercise programmes fare better than patients who are asked to exercise unsupervised [9].

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In conclusion, although exercise has been shown to be beneficial in general in patients with peripheral arterial disease, further larger scale research is needed to determine whether intermittent claudication symptoms can be solved by applying exercise programmes that concentrate on the calf muscles. The pilot data obtained in this study could inform researchers when devising a research protocol and determining the required sample size.

Ethical approval: National Health Service National Research Ethics Service, West Midlands Committee (Ref. No. 09/H1014/38).

Funding: The Step It pedals were provided by the Step It company.

Conflict of interest: None declared.

Uncited references

Q1 [13,22].

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