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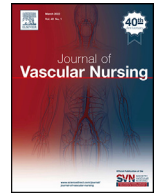
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Implementation and evaluation of a supervised exercise programme for people with claudication in York, England

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Background: Supervised exercise therapy (SET) has been shown to improve claudication symptoms in patients with peripheral artery disease (PAD), and it is recommended as a first-line treatment in national and international guidelines. Despite this, supervised exercise programmes have not been widely implemented in many countries. This quality improvement project aimed to implement and evaluate an exercise service for people with claudication in York, England.

Methods: The York Claudication Exercise Service was launched in October 2023. Eligible patients were referred from vascular clinics at York Hospital. The service provided each participant with two, 1-hour exercise sessions per week over a 12-week programme. Standardised assessments were performed before and after the programme. Routinely assessed outcomes (e.g., recruitment, attendance, satisfaction, and treadmill walking distances) were used to evaluate the service over the first 12 months. Descriptive statistics were used to explore feasibility, acceptability, fidelity, and preliminary effects. A cost-comparison analysis was also conducted before and after the exercise service was implemented.

Results: By May 2024, 65 eligible patients had been referred, with 29 patients (44.6 %) commencing the exercise sessions. The exercise programme was delivered as intended and the median number of sessions attended was 19 (out of 24). At service exit, 13 (59.1 %) out of 22 participants reported an improvement in their claudication symptoms and were discharged to primary care. The mean (95 % CI) increase in pain-free walking distance was 110 m (39 to 182). All but one participant rated the service as 'good' or 'excellent'. Economic modelling estimated that the programme would result in an annual cost-saving of £223.21 per person, or £366.40 per person using estimated costs for a future delivery model.

Conclusions: The service was successfully implemented within the existing care pathway. The evaluation indicated a high level of patient satisfaction, improvement in claudication symptoms and prevention of unnecessary referrals for vascular imaging and revascularisation. Agreements have been obtained to continue the service for at least 2 more years. During this period, sustainability funding will be sought, and the service will be adapted to improve access and uptake.

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Abbreviations: EQ-5D-5L, EuroQol-5 Dimensions, 5-level version; EQ-VAS, EuroQol Visual Analogue Scale; IMD, Index of Multiple Deprivation; MWD, maximum walking distance; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; PFWD, pain-free walking distance; SEP, supervised exercise programme; SET, supervised exercise therapy; UK, United Kingdom; VascuQoL-6, Vascular Quality of Life Questionnaire-6; YSTHFT, York and Scarborough Teaching Hospitals NHS Foundation Trust.

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Introduction

PAD is a progressive atherosclerotic disease that is prevalent worldwide, affecting 113 million people aged 40 and older.¹ Claudication, which is cramping, aching, or pain in the calves, thighs, or buttocks, is the classic symptom of PAD. For people with claudication, the goals of treatment are twofold: (i) secondary prevention of cardiovascular disease through management of risk factors (e.g., tobacco use, dyslipidaemia, diabetes, hypertension and physical inactivity); (ii) improving functional status, with treatment options including exercise training, revascularisation and vasodilator therapy.²

In 2012, the United Kingdom (UK)'s National Institute for Health and Care Excellence (NICE) published a clinical guideline on the diagnosis and management of PAD.² This guideline recommended that a 3-month supervised exercise programme should be offered as a first-line therapy for claudication. Despite this recommendation, the availability and use of SET for this population has remained low.^{3–5} For example, the findings of two recent nationwide surveys showed that fewer than half of UK vascular units offered SET.^{4,6} The York and North Yorkshire Vascular Unit within York and Scarborough Teaching Hospitals NHS Foundation Trust (YSTHFT) was one such unit that had never had a dedicated exercise service. To address this gap in local service provision, National Health Service (NHS) and university staff collaborated to design, implement and evaluate a supervised exercise programme for people with claudication who attended vascular clinics at York Hospital. Here, we describe the new service and present the outcomes of the first 12 months.

Methods

Context

YSTHFT provides a comprehensive range of acute hospital and specialist healthcare services, including vascular services for approximately 800,000 people living in and around York, North Yorkshire, North East Yorkshire and Ryedale – an area covering 3400 square miles.⁷ York Hospital is designated by NHS England as the arterial centre (Hub Hospital) and offers a range of inpatient and outpatient services including complex open and endovascular arterial procedures. In addition, the York and North Yorkshire Vascular Unit provides direct outpatient and day surgery services in five spoke hospitals and a health centre. To date, patients diagnosed with claudication in the community have been provided exercise advice and best medical therapy as per NICE guidance.² Referral to secondary care has been supported by the commissioners when there is diagnostic uncertainty, significant impairment to quality of life or lack of symptom improvement following six months of exercise advice. Patients are seen in one of 12 consultant-led general vascular clinics run weekly over seven sites. Following confirmation of diagnosis, patients are either discharged with exercise advice and best medical therapy, or referred for cross-sectional imaging with magnetic resonance angiography or computed tomography angiography. These patients are discussed in the vascular multidisciplinary team with vascular surgeons and interventional radiologists present before being reviewed in clinic and counselled about endovascular or open surgical procedures.

Service design

The principal investigator met with the consultant vascular surgeon in September 2022 to discuss the possibility of establishing a supervised exercise programme for claudication in York. At this

time, there was no specific funding available to support this initiative, but there was an opportunity to deliver an exercise service by collaborating with YSJ Active; a team of exercise professionals at York St John University.⁸ The YSJ Active team, which was already involved in running several exercise-based prehabilitation and rehabilitation programmes, agreed to help pilot a new service.

The launch of the 'York Claudication Exercise Service' was preceded by a 6-month design and preparation phase. Activities of this phase included: formation of the service team; establishing protocols and processes for participant recruitment, data collection and intervention delivery; obtaining relevant management, ethical and governance approvals; development of service materials, including information leaflets and assessment forms; training of service delivery staff and referring clinicians; purchasing of equipment and consumables; and development of a participant database.

The service team consisted of staff from York Hospital (consultant vascular surgeon, vascular specialist nurse, junior doctor, cardiac physiotherapist, service manager) and York St John University (Professor of Clinical Exercise Science, Senior Lecturer in Sport and Exercise Science, exercise instructor). The following team roles were assigned: clinical lead – a consultant vascular surgeon; academic lead – a Professor of Clinical Exercise Science; service coordinator – a vascular specialist nurse; exercise delivery lead – an exercise instructor for YSJ Active; database coordinator – a medical doctor.

The team explored the possibility of incorporating the exercise programme into the existing local cardiac rehabilitation service, as has been done successfully elsewhere.⁹ However, this was not possible because the cardiac rehabilitation service had insufficient capacity to start enrolling patients with claudication. The team therefore decided to pursue a standalone programme delivered by YSJ Active at the University.

The structure and content of the exercise service was determined during several meetings between service team members and informed by Quality Statement 3 of NICE Quality Standard 52,¹⁰ NICE Clinical Guideline 147,² and published guidelines on how to implement supervised exercise programmes for people with claudication.^{11,12} Key features of the service included: (i) early identification and referral of eligible patients, (ii) assessment of participants at service entry, (iii) delivery of a structured exercise programme, and (iv) the re-assessment of participants on completion of the exercise programme.

Participant recruitment

Potentially eligible patients were identified from consultant-led outpatient vascular clinics at York Hospital. At these clinics, individual management plans are agreed, with optional 'next steps' including referral to the new exercise service, vascular imaging, discharge to primary care with verbal advice, or a combination of options such as exercise therapy with pending imaging. Inclusion criteria for the supervised exercise programme were age ≥ 18 years old, a clinical diagnosis of claudication, self-reported functional limitations due to claudication symptoms, and ability to walk without walking aids (with the exception of using a walking stick for reassurance). Exclusion criteria were being unwilling or unable to participate, unable to provide informed consent, or the presence of any of the following: functional impairment that was unrelated to PAD, chronic limb-threatening ischaemia, a history of major surgery within the previous 3 months, unstable cardiac disease, or any other health conditions that may prevent safe participation. Eligible patients who were offered SET were given a participant information leaflet (Supplementary Material 1) and ad-

ditional verbal information about the programme by the service coordinator prior to their enrolment.

Entry and exit assessments

Service entry and exit assessments were conducted by the service coordinator at a clinical room at York St John University. Each assessment visit lasted approximately 1 hour and involved the measurement of stature, body mass, ankle-brachial pressure indices, health status (EQ-5D-5 L¹³), disease-specific quality of life (VascuQoL-6¹⁴), and pain-free and maximum walking distances. Walking distances were assessed using the graded treadmill walking protocol previously described by Treat-Jacobsen et al.¹⁵ The distance walked prior to initial onset of pain was defined as pain-free walking distance and the distance at which the participant stopped due to claudication pain was defined as the maximum walking distance. The entry assessments also included the collection of demographic information and screening for comorbid conditions. The exit assessments also included the completion of a short participant feedback questionnaire, which asked questions about if/whether their claudication symptoms have changed ('improved', 'same', or 'worse')⁹, what parts of the service were most and least useful, if they would recommend the service to other people in a similar situation, and their rating of specific aspects of the service (5-point scale from 'Very poor' to 'Excellent').

Supervised exercise programme

The exercise programme was designed to be consistent with the recommendations of NICE Clinical Guideline 147², i.e., 2 h of supervised exercise a week over a 3-month period. This was operationalised as two, 1-hour, group-based exercise sessions per week on non-consecutive days over 12 consecutive weeks.

Each session comprised a 10-minute warm-up (based on cardiac rehabilitation guidelines¹⁶ and involving a variety of standing pulse-raising and mobility exercises), 40 min of interval-based overground walking (as five, 6-minute exercise bouts over a 30 m course with 2 min passive recovery), and 5–10 min of bodyweight resistance exercise, static stretching and passive recovery. For each 6-minute walking bout, participants were encouraged to walk as far as they could and at a speed that elicited claudication pain. The exercise programme was free of charge however participants had to cover their own travel expenses.

The exercise programme was conducted in a sports hall at York St John University, approximately 1 mile away from York Hospital. The facility had ample free parking and was on a main bus route from York city centre. The closest bus stop was less than 100 m away. The sports hall was big enough for the 30 m walking course, and the University provided all the basic equipment that was required: chairs, hand counters (for counting the number of lengths walked), and a large television with internet access (for playing music and displaying an exercise interval timer).

All exercise sessions were supervised by a qualified exercise instructor and the maximum class size was 10 participants. The instructor's primary responsibilities were to ensure that the participants exercised safely and according to the standardised protocol. However, they also collected data on walking distances and claudication pain and provided advice about additional self-managed exercise to complete away from the supervised sessions. An ideal weekly target was to complete both supervised sessions, 1–3 purposeful outdoor walks of at least 30 minutes' duration each, and a home-based strength and balance exercise routine at least two times per week. To support this, a home exercise leaflet and log (Supplementary Materials 2 and 3) was given to each participant at

the start of their 12-week programme. Towards the end of the 12-week programme, the exercise instructor sign-posted participants to other relevant physical activity opportunities.

Pathway post structured exercise programme

During the exit assessment, the option of re-referral to a consultant vascular surgeon was discussed with those participants whose symptoms were not improved by the programme and were having a significant impact on their day-to-day activities. Participants who reported an improvement in their symptoms were discharged with a letter to their general practitioner.

Service implementation and evaluation

The service was launched on 12th October 2023. We evaluated the service over the first 12 months. The routinely collected data allowed for a detailed exploration of feasibility, acceptability, fidelity, and preliminary effects; factors which have been proposed to influence the sustainability and scalability of healthcare interventions.¹⁷ The following were determined:

- Rates of referral, eligibility, recruitment and retention
- Reasons for ineligibility, non-recruitment, and early withdrawal
- Participant characteristics
- Rates of attendance
- Reasons for non-attendance
- The extent to which intervention components were delivered as planned
- Number and type of adverse events
- Participant feedback, including satisfaction ratings and ideas for improvement
- Change from entry to exit in health-related outcomes (i.e., symptoms, walking distances, health status, and disease-specific quality of life)
- Rates of missing data
- Reasons for missing data
- Barriers and facilitators of implementation

Analyses were based on data collected up to 12th October 2024. Data for participants who had not completed the supervised exercise programme by this date were excluded. Analyses were conducted using Microsoft Excel and JASP (version 0.16.3). Descriptive statistics (e.g., frequency, percentage, mean, SD, 95 % CI) were used for all indicators of feasibility, acceptability and fidelity. Exercise progression was assessed by comparing walking distance from the first session with those from the midpoint session (typically session 12) and final session (typically session 24) using Analysis of Variance with Repeated Measures. Post-hoc analysis was undertaken using Bonferroni-corrected t-tests.

Economic modelling

The service team commissioned York Health Economics Consortium to undertake some early economic modelling in the form of a cost-comparison analysis, which was conducted prior to commencement of the exercise service and updated following the end of the study. The model compared the costs associated with the supervised exercise programme with the current standard of care. A decision tree method was used for a one-year time horizon. An annual patient cohort of 65 was used in the analysis as this was the number of patients who were offered the supervised exercise programme. The proportion of the cohort going through each node of the decision tree was taken from the results of the service evaluation.

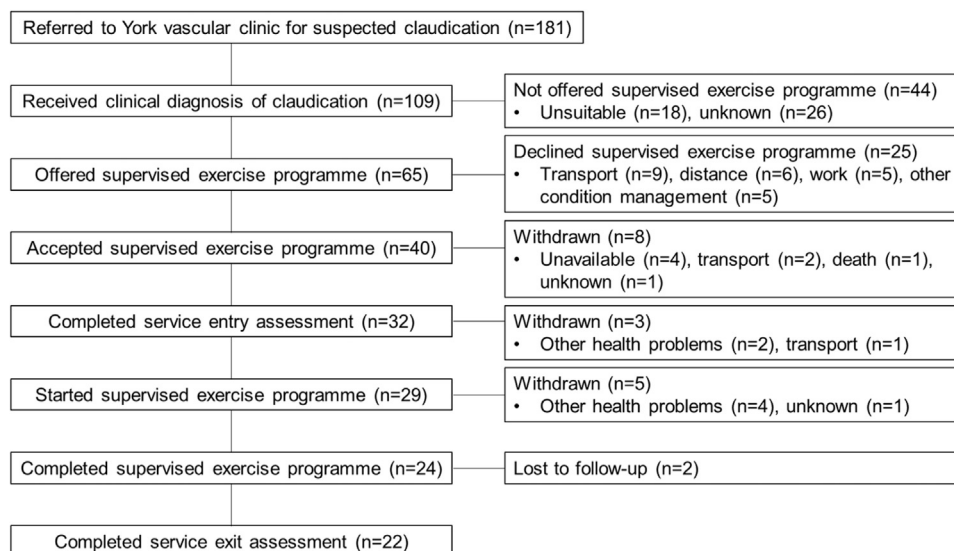


Fig. 1. Flow of patients into and through the service.

Costs associated with the exercise programme were calculated in two ways, both considering staff time and room/equipment hire. The first programme cost used the costs from the 12-month pilot period, including the costs of the exercise instructor, service coordinator, and room hire. The second programme cost considered what costs may look like in the future, using a potential new model of delivery whereby the exercise sessions would be delivered by a community-based physical activity referral scheme. Procedure costs were taken from NHS cost collection data, using weighted average where several currency codes were included. Supplementary Table 1 provides the list of inputs used and where they were sourced.

The modelling estimated the incremental cost per cohort and per person. It also calculated the incremental resource use associated with this change in cost. Following initial model construction, one-way deterministic sensitivity analysis was conducted for all base-case parameters by varying them by 15 % (with a lower limit of zero to ensure values remained feasible). This was to measure the impact of any uncertainty in the model parameter values.

Ethical considerations

This project was registered as a service evaluation with the Hospital Trust's Surgical Care Group on 19th June 2023. Therefore, the project was deemed exempt from review by an NHS Research Ethics Committee. Governance approval was also granted by York St John University on 30th June 2023. All participants provided written informed consent on enrolment to the exercise programme. This consent covered both their involvement in the exercise programme and the use of their routinely collect data for service evaluation.

Results

Patient recruitment and flow through the service

Fig. 1 summarises the flow of patients into and through the service. By May 2024, 65 patients were offered the supervised exercise programme, of which 29 (44.6 %) accepted and commenced the exercise sessions. Twenty-four participants (82.8 %) completed the programme and 22 (75.9 %) completed the exit assessment.

Participant characteristics

Participant characteristics at service entry are shown in Table 1. The large majority of participants were male (90.1 %), white British (84.4 %), over the age of 65 years (84.4 %), retired (90.6 %), and hypertensive (78.1 %). A majority were also ex-smokers (68.8 %), bilateral claudicants (56.3 %), and with a self-reported pain-free walking distance of 50–200 yards (62.5 %). Participants lived on average 8.4 miles (range 1.5–42) away from the exercise facility. Most (78.1 %) participants were able to drive themselves to the exercise classes, with a few needing to travel by public transport ($n = 5$, 15.6 %), their mobility scooter ($n = 1$), or receive a lift from someone else ($n = 1$).

Intervention delivery

Among the 29 participants who attended at least one exercise session, 478 exercise sessions were attended out of a maximum of 696 sessions, giving an overall attendance rate of 68.7 % for the 12-week (24-session) programme. The mean number of sessions attended was 16.5 (SD 7.4, median 19). Four (13.8 %) participants attended all 24 sessions, 18 (62.1 %) attended at least 18 (i.e., 75 %) sessions, and 8 (27.6 %) attended 12 (i.e., 50 %) or fewer sessions. Among the 218 missed sessions, the most common reasons for non-attendance were health problems ($n = 60$), withdrawn from programme ($n = 49$), holiday ($n = 29$), other commitments ($n = 28$), and unknown ($n = 24$).

Overall, the supervised exercise sessions were delivered as originally planned in terms of both structure and content and there were no exercise-related adverse events. Of the 478 attended sessions, there were only 10 sessions (2.1 %; among 7 participants) in which fewer than five full walking bouts were completed. Reasons for incomplete walking bouts included needing a toilet break ($n = 7$ bouts among 7 sessions), being late to the session ($n = 4$ bouts among 2 sessions), and breathing difficulties due to comorbid respiratory disease ($n = 2$ bouts among 1 session).

A total of 2377 walking bouts (each of 6 minutes' duration) were completed within the 478 attended sessions. The most frequently reported pain score at the end of walking bouts was 4 ('unbearable, cannot continue'): 1254 (53 %) of all walking bouts. Almost all ($n = 2329$, 98 %) of the walking bouts were completed with a claudication pain score of 2 ('moderate') or more, whereas

Table 1

Participant characteristics at service entry.

	Participants who completed the entry assessment (n = 32)	Participants who completed the entry and exit assessments (n = 22)
Age, years	70.9 (7.5)	71.5 (7.1)
Range	54–82	54–82
Male sex, n (%)	27 (84.4)	20 (90.1)
Ankle-brachial pressure index	0.68 (0.15)	0.67 (0.13)
Duration of claudication symptoms, n (%)		
<6 months	1 (3.1)	1 (4.5)
6–12 months	8 (25)	5 (22.7)
1–2 years	6 (18.8)	4 (18.2)
2 or more years	17 (53.1)	12 (54.5)
Unilateral or bilateral claudication, n (%)		
Unilateral	14 (43.8)	7 (31.8)
Bilateral	18 (56.3)	15 (68.2)
Self-reported pain-free walking distance, n (%)		
<50 yards	3 (9.4)	2 (9.1)
50–200 yards	20 (62.5)	15 (68.2)
>200 yards	9 (28.1)	5 (22.7)
Body mass index, kg/m ²	27.5 (4.8)	28.9 (3.8)
Ethnicity, n (%)		
White British	27 (84.4)	18 (82.8)
Other	5 (15.6)	4 (18.2)
Employment status, n (%)		
Employed	2 (6.3)	2 (9.1)
Unemployed	1 (3.1)	0 (0)
Retired	29 (90.6)	20 (90.9)
IMD decile	7.8 (2.6)	8.0 (2.4)
Range	3–10	3–10
Smoking status, n (%)		
Yes	4 (12.5)	1 (4.5)
No, never smoked	6 (18.8)	5 (22.7)
No, used to smoke	22 (68.8)	16 (72.7)
Previous myocardial infarction, n (%)	7 (21.9)	4 (18.2)
Previous stroke, n (%)	2 (6.3)	1 (4.5)
Diabetes, n (%)	8 (25)	6 (27.3)
Hypertension, n (%)	25 (78.1)	17 (77.3)
Distance to exercise facility (miles)	8.4 (8.4)	10.0 (10.3)
Range	1.5–42	1.5–42
Mode of travel to exercise facility, n (%)		
Car (self-drives)	25 (78.1)	21 (95.5)
Car (lift)	1 (3.1)	0 (0)
Public transport	5 (15.6)	1 (4.5)
Mobility scooter	1 (3.1)	0 (0)

IMD, Index of Multiple Deprivation (1 = most deprived to 10 = least deprived; calculated using postcode data).

87 % ($n = 2070$) were completed with a claudication pain score of 3 ('intense') or more. Within-session averaging of pain scores revealed that 461 (96 %) of the 478 attended sessions had an average reported pain score of 2 or more, whereas 370 (77 %) sessions had an average reported pain score of 3 or more. At the participant level, session pain scores progressed from a mean of 2.8 arbitrary units (SD 1.2) in the first session to 3.4 (SD 0.5) at midpoint and 3.4 (SD 0.6) in the final session (data from $n = 22$ complete cases).

The total distance walked per session progressed from a mean of 1992 m (SD 589) in the first session to 2231 m (SD 569) at midpoint and 2246 m (SD 649) in the final session ($n = 22$ complete cases). Individual walking distance trajectories are shown in Fig. 2. Mean total walking distance differed statistically significantly between time points ($F[1.721, 36.133] = 23.396, p < 0.001$). Total walking distance was statistically significantly increased from the first session to the midpoint session (239 m [95 % confidence interval, CI, 135 to 342], $p < 0.001$), and from the first session to the final session (254 m [95 % CI, 150 to 357], $p < 0.001$), but not from the midpoint session to the final session (15 m [95 % CI, -89 to 119], $p = 1.000$).

All participants received verbal encouragement and advice to complete additional self-managed walking and resistance exercises away from the supervised sessions. However, only seven participants received the exercise leaflet for supporting self-managed ex-

ercise because of a delay in obtaining approval to use it from the Hospital's review panel.

Health-related outcomes

Table 2 summarises service outcome data for the 22 participants who completed both the entry and exit assessments. At service exit, 13 (59.1 %) out of 22 respondents reported an improvement in their claudication symptoms, 7 (31.8 %) reported no change, and 2 (9.1 %) felt their symptoms had deteriorated. The median (95 % CI) increase in pain-free and maximum walking distances at service exit was 92 m (30 to 187) and 77 m (-17 to 226), respectively. Average values for the health status and disease-specific quality of life outcomes increased slightly from entry to exit, but the 95 % CIs spanned zero.

Participant feedback

Service feedback responses were recorded for 21 participants. The responses to the Likert scale questions are summarised in Table 3. All but one respondent said that they would recommend the programme to other people in a similar situation to themselves. The remaining participant who said they would not recommend it cited reasons of the sports hall being too cold and one of the exercise sessions being scheduled too early in the day. A

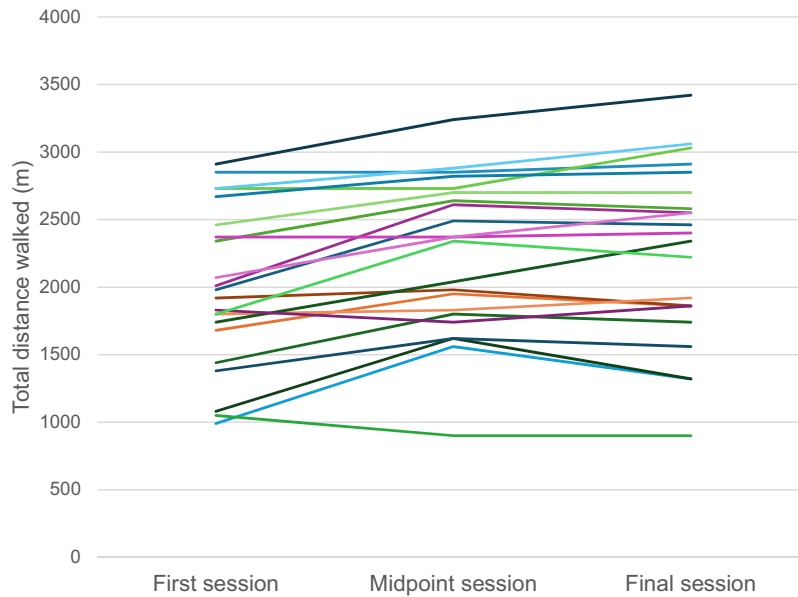


Fig. 2. Total distance walked in the first, midpoint and final exercise sessions for each participant ($n = 22$ complete cases).

Table 2

Outcome data for participants who completed entry and exit assessments.

	N	Service entry	Service exit	Difference (95 % CI)
PFWD, m	20			
Median (IQR)		179 (65–318)	257 (135–530)	92 (30 to 187)
MWD, m	18			
Median (IQR)		355 (186–775)	513 (223–872)	77 (–17 to 226)
VascuQOL-6*	20			
Mean (SD)		14.8 (3.2)	15.4 (2.9)	0.6 (–1.2 to 2.4)
EQ-5D utility index†	22			
Median (IQR)		0.748 (0.653–0.831)	0.744 (0.663–0.833)	0.008 (–0.052 to 0.090)
EQ-VAS‡	21			
Median (IQR)		50 (48–75)	70 (50–75)	5 (–5 to 15)

Median differences and 95 % CI were calculated using the Hodges-Lehmann estimator.

MWD, maximum walking distance; PFWD, pain-free walking distance.

* VascuQOL-6 scores range from 6 to 24, with higher scores indicating a better health status.

† EQ-5D utility scores range from –0.594 to 1, with higher scores indicating a better health status.

‡ EuroQol Visual Analogue Scale (EQ-VAS) scores range from 0 to 100, with higher scores indicating a better health status.

Table 3

Frequency of responses to Likert scale questions on the exit evaluation form.

Question	Very poor	Poor	Fair	Good	Excellent
How would you rate your experience with...					
... the recruitment process?	0 (0 %)	0 (0 %)	2 (10 %)	11 (52 %)	8 (38 %)
... the assessment sessions?	0 (0 %)	0 (0 %)	1 (5 %)	7 (33 %)	13 (62 %)
... the exercise sessions?	0 (0 %)	1 (5 %)	1 (5 %)	11 (52 %)	8 (38 %)
... the home exercise advice?	1 (5 %)	2 (10 %)	10 (48 %)	5 (24 %)	3 (14 %)
... the programme overall?	0 (0 %)	1 (5 %)	0 (0 %)	12 (57 %)	8 (38 %)

similar, largely positive pattern of responses was observed for the questions about the recruitment process, the assessment sessions and the exercise sessions. Feedback about the home exercise advice was, however, more varied. The reasons behind the negative and fair responses all related to insufficient advice being given which is explained, in part, by the delay in the home exercise leaflet and log being approved for use.

A variety of responses were given to the open-ended feedback questions. Positive responses included that the programme provided multiple health benefits and impetus for lifestyle behaviour change, that the exercise facility had good accessibility, and that the group format provided community and support. Suggestions for improvements included having a warmer exercise facility dur-

ing the winter months, moving the early morning session to later in the day, having alternative locations to reduce travel distances, and offering more individualisation of the exercise programme and support for lifestyle behaviour change.

Barriers and facilitators of implementation

The service team identified several factors that they perceived influenced the 'implementability' of the service. Key enabling factors included: securing senior management 'buy-in' to establish the service; achieving good patient engagement through effective supervision and peer support; effective multidisciplinary team work-

Table 4

Estimated difference in costs and resource use between the new and standard pathways.

	Exercise Pathway	Standard Pathway	Incremental
Annual total cost per cohort	£83,698	£98,207	-£14,508
Total cost per person	£1288	£1511	-£223
Number of angiograms	14	30	-16
Number of endovascular procedures	9	15	-6
Number of follow-up appointments	52	65	-13

ing with clear roles and responsibilities; and locating the service in a central, easily accessible venue. Two key barrier themes were identified: (i) resources and (ii) beliefs about the initiative. Regarding resources there was no specific funding to establish the service. It therefore had to be delivered with existing staff, facilities and equipment, which constrained several aspects, for example, the number and timing of sessions that were offered each week, the number of venues, and the availability of staff to cover sessions when the service coordinator and exercise instructor were away. Regarding beliefs, the varied referral behaviour of the consultants gave the impression that they had varied levels of 'buy-in' to this new condition management option. The service coordinator also indicated that some other hospital staff seemed to hold the perception that this was research rather than a quality improvement initiative, which resulted in some resistance to them supporting patient recruitment activities.

Economic modelling

The economic analysis estimated that implementing a supervised exercise programme for people with claudication would result in a cost-saving of £223.21 per person, or a saving of £14,508 for a cohort of 65 people. This was due to the reduction in the number of angiograms, endovascular procedures, and follow-up appointments in the intervention cohort. The difference in costs and resource use for the cohort is reported in Table 4.

Deterministic sensitivity analysis showed that the parameters where uncertainty had the largest impact were the proportion of the standard care cohort receiving an angiogram, the proportion of the standard care cohort receiving angioplasty following an angiogram, and the cost of angioplasty (with and without stenting). The full results of the sensitivity analysis can be found in Supplementary Table 2. The tornado diagram in Supplementary Figure 1 ranks the input parameters by how much impact any uncertainty in their values has on the model results. It should be noted that some variables are one-sided because they were limited to a maximum plausible range of 100 %. Varying all parameters by 15 % still resulted in a cost-saving in all scenarios.

Setting the cost of the exercise intervention per person to £193, which was the cost quoted for exercise delivery by a community-based physical activity referral scheme plus the cost of a service coordinator, resulted in a per-person cost-saving of £366.40 (and a saving of £23,816 for a cohort of 65). The costs of each arm are reported in Supplementary Table 3 (resource use remaining the same as the base case). Deterministic sensitivity analysis showed that the parameters where uncertainty had the largest impact on the model results were the standard care cohort receiving an angiogram, the standard care cohort receiving angioplasty/stenting, and the cost of angioplasty/stenting. Once again, varying all the parameters by 15 % (within a clinically plausible range) still resulted in a cost saving. This is shown in the tornado diagram in Supplementary Figure 2.

Discussion

The main aim of this project was to implement and evaluate an exercise service for people with claudication, with a key focus on providing a vascular unit in Northern England with a sustainable solution for offering guideline-recommended SET. To achieve this, a university-hospital partnership was formed and a new service designed that would fit seamlessly into the existing care pathway. Our evaluation of the first 12 months showed favourable outcomes across the domains of feasibility, fidelity, acceptability, and health effects, which support the usefulness and sustainability of the service.

Only three other UK-based evaluations of SET for claudication have been published to date^{9,18,19} and these studies vary in design, delivery model and comprehensiveness of evaluation. Leslie et al.¹⁸ evaluated a service in Wolverhampton offering SET or basic advice and found greater walking improvements in the supervised group, though no information was reported on feasibility or acceptability. Matthews et al.⁹ described the integration of claudication patients into a cardiac rehabilitation programme in Salford, with 72 % of completers reporting symptom improvement; however, standardised outcomes and data on fidelity and acceptability were lacking. Murgitroyd et al.¹⁹ reported on a collaboration in Edinburgh where leisure centres delivered SET, noting modest improvements in 6-minute walk distances and low completion rates (24 %). Our findings align with these studies in that most participants completing the programme experienced improved symptoms and walking ability. However, the York service uniquely reported in-depth data across feasibility, fidelity, and acceptability domains. This comprehensive approach enables a fuller understanding of the service's potential for sustainability and scalability and supports recent calls for more consistent reporting of implementation outcomes of healthcare interventions.¹⁷

The York Claudication Exercise Service ran at full or near-full capacity for most of the 12-month pilot period, which suggests that it was feasible to recruit and retain participants. However, over half of patients who were offered the exercise programme declined to participate, often for reasons associated with accessibility (e.g., distance, transport). We are therefore exploring opportunities to improve accessibility, such as expanding the range of venues and session times and developing a home-based alternative whereby exercise sessions will be delivered remotely through an online platform. Other changes we are exploring to maintain good levels of retention include having a warmer exercise facility during the winter months and offering more support for lifestyle behaviour change.

The service was largely delivered as planned on a consistent basis and there were low rates of missing data, which suggests that intervention delivery and data collection were both feasible. We have however identified the need to build in additional support and cover for the service team, particularly for the service coordinator and exercise instructor, who were responsible for most of the day-to-day activity. No major changes are planned regarding data collection however we have agreed an alternative treadmill protocol for patients who cannot perform the walking assessment at the standard speed. We are also looking to create placement opportunities within the service for undergraduate physiotherapy students, which will provide some extra support for service delivery.

The economic model estimated the exercise programme to be cost saving compared with standard care in the base case, by £223 per person per year. Cost savings may not necessarily be cash releasing but rather represent efficiency gains through released capacity which would be of benefit to the Trust should the programme be implemented permanently. Deterministic sensitivity analysis showed that both scenarios would still be cost saving,

suggesting that the results are generally robust to uncertainty in the parameters. Given that health-related utility values have now been collected, we would recommend using them to perform a cost-effectiveness analysis in a future economic evaluation, to establish the relationship between incremental health and incremental costs.

Limitations

Although quality improvement initiatives do not aim to provide generalisable knowledge,²⁰ we do acknowledge some limitations to the generalisability of the work. The assessment and exercise training protocols were relatively simple and therefore should be implementable in other settings, but the generalisability of the university-hospital collaboration model is questionable. This model worked well in York because of the close proximity of the university and hospital and the willingness and ability of both parties to collaborate, but this model might not be possible for other vascular units. An alternative approach might be to integrate patients with claudication into existing cardiac rehabilitation services^{9,21} or similar exercise rehabilitation schemes managed by local leisure centres.¹⁹

Our data collection protocol was comprehensive, conformed to relevant quality standards¹⁰, and was acceptable to patients and assessors. However, the current service evaluation is limited in that longer-term outcomes were not assessed, nor were outcomes at organisational and healthcare provider levels.

The economic analysis also had limitations. Due to the small size of the study, there may be a lot of uncertainty with the results. Some of this was measured by conducting deterministic sensitivity analysis to assess some of the impact that parameter uncertainty could have had on the results. However, it was not possible to understand the full extent of potential difference of these parameters from the true input values, because the input values may vary by more than 15 % of those used in the analysis. Using a larger sample size in the future will allow for standard errors to be estimated which can be used as a more realistic reflection of variation rather than an arbitrary 15 % in the sensitivity analysis. Additionally, it is recommended that a further economic evaluation be conducted to patient outcomes through a cost-effectiveness analysis, using the collected health-related utility data.

A final limitation was that the planned support for home- and community-based exercise was only fully implemented partway through the pilot period due to the delay in obtaining approval to use it from the Hospital's review panel.

Conclusions

The findings indicate that it was possible to successfully implement a supervised exercise programme that complied with NICE guidance for the management of PAD within the existing care pathway of a vascular unit in Northern England. Participants were satisfied with the service and experienced improved claudication symptoms, reducing the need for onward referral to hospital-based vascular services. Economic modelling demonstrated potential cost savings to the NHS. Key enablers of success included: securing senior management 'buy-in' to establish the service; achieving good patient engagement through effective supervision and peer support; effective multidisciplinary team working; and locating the service in a central, easily accessible venue. Agreements have been obtained to continue the service in its current format for at least 2 more years. Refinements will be made to improve access and uptake and funding will be sought to sustain and expand the service.

Declaration of competing interest

The authors have no competing interests to declare.

CRediT authorship contribution statement

Garry A. Tew: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Resources, Supervision, Visualization, Writing – original draft. **Lisa Sharpe:** Writing – review & editing, Resources, Project administration, Investigation, Data curation. **Asim Abbas:** Writing – review & editing, Software, Project administration, Investigation, Data curation. **Martin Bond:** Writing – review & editing, Supervision, Project administration, Investigation, Data curation. **Alastair Jordan:** Writing – review & editing, Supervision, Methodology, Investigation. **Hannah Ross:** Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Formal analysis, Data curation. **Nick Hex:** Writing – review & editing, Validation, Supervision, Software, Resources, Methodology. **Rachael MacDonald:** Writing – review & editing, Validation, Supervision, Software, Resources, Methodology, Formal analysis. **Andrew Thompson:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Conceptualization.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.jvn.2025.07.002](https://doi.org/10.1016/j.jvn.2025.07.002).

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