1 **Title:** PREFERred Exercise Modalities in Patients with Intermittent Claudication.

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Abstract

Objectives

Conventional supervised exercise programmes (SEP) for claudicants are traditionally based on time-constrained, group-based structured programmes usually at a hospital site. Uptake of SEP is poor, despite the high level evidence demonstrating its clinical effectiveness, therefore alternative forms of exercise programmes are needed which are more acceptable to patients. This study aimed to explore a range of exercise modalities to determine patient preferences for exercise delivery on a national level.

Methods

This was a questionnaire survey to identify and incorporate patient preferences when designing a multi-centre nationwide health-service evaluation of patient preference to exercise in the UK NHS (the PREFER study). Patients with documented stable intermittent claudication (IC) who were suitable for an SEP were given a questionnaire to fill out at their clinic visit. Data was recorded using the Bristol Online Survey tool (http://www.survey.bris.ac.uk/) and analysed descriptively.

Results

Thirty complete questionnaires were analysed. Participants were generally unilateral claudicants (80 %) with symptoms for over 1 year (64 %). Only 6 of the 30 patients had engaged in a lifelong routine of exercise. 87% patients indicated that they had not taken part in an exercise programme but 73% of those indicated that they would be willing to participate to improve their walking. Most patients expressed a preference for a home exercise programme (50%) followed by a hospital SEP. The majority of patients (43%) were happy to

exercise three days per week using a walking based programme (53%). There was however no consensus on the duration or intensity of the exercise programme.

Conclusions

SEP is the recommended first line treatment for IC patients, however the vast majority of patients fail to engage with or complete an exercise programme. This study demonstrates that exercise therapy should be individualised and take a patient-centred approach. Commissioning groups should incentivise hospitals and clinicians to engage with their patient populations to understand their needs and deliver an appropriate service.

Keywords: intermittent claudication (IC), structured exercise programme (SEP), questionnaire survey

Introduction

It is estimated that 5% of the population over the age of 50 will suffer with ischaemic muscle pain during exercise due to intermittent claudication (IC), a symptom of peripheral arterial disease (PAD) (1). IC has a significant effect on physical activity levels, walking ability and ultimately quality of life (2). In 2012 the National Institute of Clinical Excellence (NICE) published guidance that every patient with IC should be treated initially with best medical therapy and a supervised exercise programme (SEP) (3). However a systematic review and survey demonstrated that service provision, patient uptake and patient adherence within the United Kingdom's National Health Service (UK NHS) is still relatively poor (4, 5).

In the UK the NHS provides free and accessible healthcare to all. The UK NHS offers SEP as a group-based structured exercise programme 2 – 3 times per week for a minimum of 12 weeks (4, 5). However there is wide variation across the UK in the duration and frequency of SEPs (5). Commonly cited reasons for non-attendance include time constraints, travel and transport difficulties and family commitments(6). Dropout rates are variable but can be as high as 50%, which is similar to other rehabilitation programmes (7). Alternative exercise provisions are needed which are more acceptable and appealing to patients. However, patient exercise preference has not been investigated in this specific patient population (8). Data from other populations have suggested that online and home interventions are both popular and successful (7, 9).

The aim of this study was to assess the gap between patient preference and modes of current exercise prescription in the UK NHS for patients with intermittent claudication.

Methods

Design

This was a questionnaire survey to identify and incorporate patient preferences in designing and implementing a multi-centre nationwide health-service evaluation in the UK NHS (the PREFER study). A questionnaire was developed to assess key points regarding exercise programmes for IC patients. To ensure clarity and content validity the questionnaire it was reviewed by a group of vascular specialists (8 vascular consultants, 3 research nurses and 7 vascular fellows) and tested on 5 IC patients in a SEP at a tertiary vascular unit in the UK NHS. Questions focused on the likelihood of participation, previous experience and preference of service delivery format.

Patients

Patients with stable IC on best medical therapy were identified and selected at their clinic visit. The responsible clinician (vascular surgeon/registrar or vascular nurse specialist) completed the demographic and medical questions in section one. Patients were then requested to complete section two which contained an initial explanatory section followed by questions assessing patients exercise history, perceptions and preferences. Patients were excluded if they could not understand written English or did not have capacity to understand the health-service evaluation. All questionnaires were given a unique and confidential participant identifier.

Data Extraction

Data was recorded using the Bristol Online Survey (BOS) tool (http://www.survey.bris.ac.uk/) and analysed descriptively. The BOS tool is a web-based programme that allows users to create surveys, record data and analyse results.

Results

A total of 30 completed questionnaires were collected and included in the analysis. Sixteen patients were male and 14 patients were female. The mean age of patients was 69.5±7 years.

Patients mainly reported unilateral symptoms (80 %) and had symptoms for over 1 year (64 %). All patients reported symptom duration > 3 months. Ten patients were active smokers, 15 had recently quit smoking, while 5 had never smoked. Common co-morbidities included hypertension (19 patients) and diabetes (7 patients). Less common co-morbidities included chronic obstructive pulmonary disease, asthma, chronic kidney disease, atrial fibrillation, ischemic heart disease and dyslipidaemia.

Previous Physical Activity

Only 6 patients had engaged in a lifelong routine of exercise. 14 patients stated that they had participated in some form of exercise during adulthood but this was not maintained. The remainder of patients had done no formal physical activity since leaving secondary school.

Barriers to Participation

Time was the most commonly reported barrier to SEP attendance (28%) followed by travel (23%). Patients reported musculoskeletal issues e.g. back or joint pain (25%) or cardio-respiratory complaints (13%) e.g. asthma or breathlessness which precluded exercise. The expense associated with exercise class attendance was reported by 2 patients as a barrier to SEP. One patient stated that they would be embarrassed to attend the SEP but did not give a reason why and another patient highlighted work as a barrier. The remaining two patients indicated that they had no restrictions to attending an SEP.

Perception to Exercise

Twenty-six (86.7%) patients had never previously participated in a SEP. Only four patients had taken part in some form of an exercise programme, which included cardiac rehabilitation and "physical therapy". Twenty-two (73%) patients stated that they would like to take part in an exercise programme to improve their walking. Comments from patients who preferred not to participate in a SEP included: full time working, no spare time and legs too painful to walk.

Preference to Exercise (Table 1)

33% of patients preferred group exercise, 36.7% preferred to exercise alone while the remainder were happy to consider either option. 50% of patients preferred home exercise, 36.6% preferred a hospital-based programme, 10% preferred a community (gym) based programme and 3.3% indicated they would like an online web based system. Of the 63.3% preferring a non-hospital based programme, only 26.3% indicated no support was required. The remainder expressed a preference for ongoing support in the form of a monthly face-to-face meeting (26.3%), email (10.5%) or phone call (21%), or weekly emails (10.5%) or phone calls (5.3%).

When asked how many days per week they would prefer to exercise 43.3% of patients were happy to exercise 3 days per week, 36.6% patients preferred 2 days per week, 10% patients preferred once per week and 10% patients indicated they were happy to exercise more often. With regard to preferred exercise duration the most popular option was 30 minutes (26.7%) followed by 60 minutes (23.3%), 20 minutes (16.7%), 40 minutes (16.7%) and the remaining selected another option. In response to preferred exercise modality 53.3% of patients were happy with a walking based exercise programme, 36.7% preferred swimming and the rest selected dancing, strength sessions, circuit training and cycling. Finally, preference for

exercise intensity was equally divided between short duration/high intensity and long duration/moderate intensity.

Discussion

Within the UK NHS the guidelines for exercise in patients with IC indicate that they should take part in a SEP at least twice per week for a period of 12 weeks, however the provision of SEP is widely variable across the country (5). In addition not all patients are able to attend the exercise programmes on offer. Clearly this suggests that alternative forms of exercise provisions are needed and this has been investigated in other clinical populations (8).

It is not surprising that the majority of patients with IC in this study had not engaged or were not engaging in regular physical activity. It is acknowledged that PAD is frequently associated with unhealthy lifestyle choices (e.g. high prevalence of smokers) and these patients are perhaps the least likely to engage or commit to improved lifestyle behaviours (10). Indeed only 6 patients (20%) were engaged in a lifelong routine of exercise. A previous study has demonstrated that patients with claudication report that leg symptoms significantly impair their day to day ability to function which may lead to a negative cycle of disability with reduced activity leading to symptom deterioration (6). This could perhaps explain why PAD patients are less committed to engage with exercise compared to their age matched healthy peers. An overwhelming 87% of patients had never taken part in an exercise programme (gym/rehabilitation etc.), but 73% said that they would take part in exercise if offered to improve their walking. This is substantially different to findings reported in clinical practice where only 1 in 3 patients with IC actually attend and complete an exercise programme (5). At initial review with a vascular consultant, patients often agree to participate in an SEP but then decline or do not commit to a programme when given a firm offer. This

may reflect the fact that current SEPs do not match patient's specific expectations, requirements or preferences.

As we have previously documented, time (both inconvenient time of SEP and time to travel) is one of the biggest barriers to physical exercise (6) and was the most commonly cited reason for non SEP attendance by patients in this study. Additionally, leg pain was also mentioned as one of the biggest reasons or possibly "fears" for attending an exercise programme. Previous evidence supports our findings that pain or fear of pain may discourage patients from exercising (11). However, systematic reviews suggest that clinically relevant improvements in walking distance can be attained at a lower threshold, without inducing pain, which may increase participation rates (8, 12). A meta-analysis demonstrated that an adjunctive exercise, such as arm ergometer, produced superior results for cardio-respiratory fitness (13). A pilot randomised control trial demonstrated arm ergometer could also improve pain free walking distance and maximal walking distance, offering an alternative to treadmill based exercise (14). Despite this high level of evidence, walking up to and past the point of pain is encouraged in SEPs. Perhaps if this advice were revised it may improve uptake and adherence to exercise programmes (8).

A systematic review demonstrated that SEPs are superior in terms of outcome compared to home exercise (15, 16). However home exercise programmes which come with patient support may be as beneficial as a SEP and could facilitate greater uptake and adherence to programmes (17). In this study almost half the patients indicated that they would prefer to exercise at home, with only 37% preferring exercise in the hospital setting. Perhaps hospital trusts and commissioning groups (who strategise, plan and buy healthcare services for local NHS providers) should consider providing alternative exercise options for patients. Patients who preferred a home based programme generally expressed a preference for regular support

but the frequency and method of support varied considerably. This validates individual patient specific management based on patient preferences, however this may be difficult for the service providers to deliver.

Most UK vascular centres with SEPs aim to deliver 2-3 supervised sessions per week. NICE and TASC-II guidelines recommend patients should commit to two hours exercise per week (1, 3, 5). World Health Organisation and the American College of Sports Medicine guidelines recommend patients participate in moderate to vigorous exercise three days per week (18). The majority of patients in this study were happy to exercise between 2 and 3 days per week. However many vascular centres are limited to providing exercise programmes on only 1 or 2 days a week frequently restricted by funding, staffing and resource issues (4, 5, 19). Home-based programmes may help alleviate some of these restrictions as observed with cardiac rehabilitation programmes (20).

SEPs are commonly walking based often on a treadmill to maintain walking speeds and distances (12). This was the preferred mode of exercise for over 50% of patients in this study. Swimming was the next most popular exercise modality but this mode of exercise in this specific group of patients has not been investigated and perhaps merits further research. Perhaps alternative exercise programmes (e.g. including swimming, arm ergometer etc.) may be more appealing and suitable for claudicants who fear or struggle with walking based programmes.

Conclusions

SEP is the recommended first line treatment for all patients with IC, however the majority of patients with IC fail to engage with or complete an exercise programme. Evidence from this study supports the provision of exercise therapy which is individualised and patient-centred.

Commissioning groups should incentivise hospitals and clinicians to engage with their patient populations to understand their needs and deliver an appropriate service.

References

1. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Journal of vascular surgery. 2007;45 Suppl S:S5-67.
2. Lane R, Ellis B, Watson L, et al. Exercise for intermittent claudication. The Cochrane database of systematic reviews. 2014;7:CD000990.
3. NICE. Lower limb peripheral arterial disease: diagnosis and management. London: National Institure for Health and Care Excellence. 2012;CG147.
4. Harwood A, Smith G, Broadbent E, et al. Access to supervised exercise services for peripheral vascular disease patients. The Bulletin of the Royal College of Surgeons of England. 2017;99(6):207-11.
5. Harwood AE, Smith GE, Cayton T, et al. A Systematic Review of the Uptake and Adherence Rates to Supervised Exercise Programs in Patients with Intermittent Claudication. Annals of vascular surgery. 2016;34:280-9.
6. Harwood AE, Broadbent E, Totty JP, et al. "Intermittent claudication a real pain in the calf"-Patient experience of diagnosis and treatment with a supervised exercise program. Journal of vascular nursing : official publication of the Society for Peripheral Vascular Nursing. 2017;35(3):131-5.
7. Chaplin E, Hewitt S, Apps L, et al. The evaluation of an interactive web-based Pulmonary Rehabilitation programme: protocol for the WEB SPACE for COPD feasibility study. BMJ open. 2015;5(8):e008055.
8. Al-Jundi W, Madbak K, Beard JD, et al. Systematic review of home-based exercise programmes for individuals with intermittent claudication. European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery. 2013;46(6):690-706.
9. Devi R, Singh SJ, Powell J, et al. Cochrane Corner: are there benefits of using web-based interventions in the secondary prevention of coronary heart disease? Heart. 2016;102(23):1860-1.
10. Popplewell MA, Bradbury AW. Why do health systems not fund supervised exercise programmes for intermittent claudication? European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery. 2014;48(6):608-10.
11. Sharath SE, Kougias P, Barshes NR. The influence of pain-related beliefs on physical activity and health attitudes in patients with claudication: A pilot study. Vascular medicine. 2017:1358863X17709944.
12. Parmenter BJ, Raymond J, Dinnen P, et al. A systematic review of randomized controlled trials: Walking versus alternative exercise prescription as treatment for intermittent claudication. Atherosclerosis. 2011;218(1):1-12.
13. Parmenter BJ, Dieberg G, Smart NA. Exercise training for management of peripheral arterial disease: a systematic review and meta-analysis. Sports medicine. 2015;45(2):231-44.
14. Treat-Jacobson D, Bronas UG, Leon AS. Efficacy of arm-ergometry versus treadmill exercise training to improve walking distance in patients with claudication. Vasc Med. 2009;14(3):203-13.
15. Fokkenrood HJ, Bendermacher BL, Lauret GJ, et al. Supervised exercise therapy versus non-supervised exercise therapy for intermittent claudication. The Cochrane database of systematic reviews. 2013(8):CD005263.
16. McDermott MM, Polonsky TS. Home-Based Exercise: A Therapeutic Option for Peripheral Artery Disease. Circulation. 2016;134(16):1127-9.
17. Gardner AW, Parker DE, Montgomery PS, et al. Efficacy of quantified home-based exercise and supervised exercise in patients with intermittent claudication: a randomized controlled trial. Circulation. 2011;123(5):491-8.
18. American College of Sports Medicine. Guidelines to Exercise Testing and Prescription 9th Edition: Wolters Kluwer; 2017.

19. Muller-Buhl U, Engeser P, Leutgeb R, et al. Low attendance of patients with intermittent claudication in a German community-based walking exercise program. Int Angiol. 2012;31(3):271-5.
20. Dalal HM, Evans PH, Campbell JL, et al. Home-based versus hospital-based rehabilitation after myocardial infarction: A randomized trial with preference arms--Cornwall Heart Attack Rehabilitation Management Study (CHARMS). International journal of cardiology. 2007;119(2):202-11.