high INtensity Interval Training In pATiEnts with intermittent claudication (INITIATE): a qualitative acceptability study

Short title: Acceptability of high-intensity interval training in intermittent claudication

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Category: Original article

Declarations of interest: none'

Data availability statement: The data underlying this article will be shared on reasonable request to the corresponding author.

Introduction: A novel high-intensity interval training (HIIT) programme has demonstrated feasibility for patients with intermittent claudication (IC). The aim of this study was to explore patient perspectives of the HIIT programme to inform refinement and future research.

Methods: All patients screened and eligible for the 'high intensity interval training in patients with intermittent claudication (INITIATE)' study, were eligible to take part in a semi-structured interview. A convenience subsample of patients was selected from three distinct groups: 1) those who completed the HIIT programme, 2) those who prematurely discontinued the HIIT programme and 3) those who declined the HIIT programme. Interviews considered patients views of the programme and experiences of undertaking and/or being invited to undertake it. Interviews were audio recorded, transcribed verbatim and analysed via thematic analysis.

Results: Eleven out of 31 participants who completed the programme and twelve out of 38 decliners were interviewed. No participants who withdrew from the programme agreed to interview. The three key themes were; personal reflections of the programme; programme facilitators and barriers; and perceived benefits. Completers enjoyed taking part, reported symptomatic improvement and would complete it again. Practical and psychological barriers exist, such as transport and motivation. Changes to the programme were suggested.

Conclusion: Findings support the acceptability of this novel HIIT programme, which in combination with the feasibility findings, suggest that a fully powered randomised controlled trial, comparing HIIT to usual-care supervised exercise programmes is warranted.

Study registration: NCT04042311

Study funding: This study is funded by the NIHR [Research for Patient Benefit programme (PB-PG-0418-20014)]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care

Introduction

Uptake and adherence to supervised exercise programmes (SEP), the first-line treatment for intermittent claudication (IC)[1,2], is suboptimal[3]. Time is a key patient barrier[4-6]. This had led us to develop an alternative, more time-efficient exercise programme, in the form of high-intensity interval training (HIIT)[7,8], which has completed the feasibility phase[9]. The Medical Research Council guidance notes that intervention acceptability is a key element to be considered within the feasibility phase[10]. Additionally, when complex intervention research transitions from one phase to another, refinements may be required and involving intervention users in this refinement process can improve the feasibility and acceptability of the future, refined intervention[10]. Qualitative research provides an opportunity to understand patient acceptability of the intervention by exploring their experiences, whilst also giving them the opportunity to inform potential refinements.

The evidence base for HIIT in patients with IC is limited[7], and although this intervention has been considered in patients with coronary artery disease[11], it is novel in the IC population, so acceptability testing, and patient led refinement are important development steps. Additionally, although this intervention is designed to be more time-efficient, it may mean that other barriers become more pertinent and these need to be understood and addressed in future iterations. Finally, other patient-level factors such as motivation or enjoyment[3] may lead to disengagement with the intervention which could impact on adherence. Therefore, the aim of this qualitative study was to investigate patient perceptions, and therefore acceptability, of our HIIT programme to inform intervention refinement and future research.

Methods

Study design

This qualitative study, reported in accordance with the COREQ checklist (Appendix 1), was embedded within the 'high INtensity Interval Training In pATiEnts with intermittent claudication' (INITIATE) study[9]. This was a single-arm, proof-of-concept study, performed at two UK NHS Trusts, recruiting patients with IC, referred to a usual-care SEP. The study was registered prospectively on clinicaltrials.gov (NCT04042311) and all study procedures were approved by a UK NHS Research Ethics Committee (reference: Bradford Leeds – 18/YH/0112). Full details of the patient identification and recruitment processes and the inclusion / exclusion criteria for INITIATE are provided in the study protocol, as is a description of the intervention[12].

Briefly, the intervention was a six-week, supervised HIIT programme performed three times per week, using a stationary cycle ergometer. Intensity was set using a baseline cardiopulmonary exercise test.

In-depth, semi-structured interviews were conducted with a convenience subsample from three distinct groups:

Group one: participants who successfully completed the HIIT programme.

Group two: Those who agreed to participate in the HIIT programme but discontinued after ≥1 session.

Group three: Participants who were eligible for recruitment to INITIATE but declined to participate.

Consent and Data collection

All patients approached for the INITIATE study were eligible for interview, and study consenters were able to opt in or out of the interview whilst consenting to the study. Patients were approached via mail with a follow-up telephone call. Patients who declined to take part

in the INITIATE study were asked if they would agree to be interviewed and interview-specific consent was obtained. Participants interviewed via telephone provided verbal consent, which was audio recorded.

One-off, semi-structured interviews were undertaken. All interviews were informed by a topic guide, adapted from similar studies previously undertaken by the authors (SP and AEH; Appendix 2). Interviews were flexible to allow exploration of participant responses. Participants were informed that they did not have to answer questions that they felt unable to and that all responses were confidential. All interviews were audio recorded, transcribed verbatim and pseudonymised. Field notes were not made. All interviews were conducted by the lead researcher (SP), a male post-graduate exercise physiologist, who had attended a National Centre for Social Research training course, and was supervised by MT, an experienced qualitative researcher. A PhD student was present for five interviews; all other interviews were conducted with only the researcher and participant present.

Interviews were conducted face-to-face in a private clinic room or via telephone to accommodate COVID-19 restrictions. Telephone interviews result in a loss of visual cues but there is no evidence that they produce lower quality data[13], and this option allowed participants to take part without attending the research site.

Outcomes of interest

The outcomes of interest were related to patients views of the structure of the HIIT programme and experiences of undertaking and/or being invited to undertake it.

Sample size and data analysis

A specific, pre-specified sample size was not set but using informational power as a guide[14], a target of 10 interviews per group was set as the minimum sample size given the focussed topic.

NVivo (Lumivero, 2022, release 1.7.1) was used to manage the data and line by line coding was performed by the lead researcher (SP) using an inductive thematic analysis approach, whereby concepts were identified from within the data[15]. This involved reading and re-reading the transcripts and creating initial codes for any statements that were related to the research questions. Similar codes and patterns of responses were then merged together into final codes which were grouped and placed into themes, using a coding matrix (Table 1). To ensure that the analysis was robust, the coding matrix and raw data were reviewed by the supervisor (MT). The analysis was further refined through discussion of the initial and final themes. Transcripts were not returned to participants for clarification prior to analysis nor was feedback provided on the findings.

Results

Quantitative data regarding screening, eligibility, recruitment, completion, adherence and measures of walking distance and quality of life are available elsewhere[9]. All 31 participants that completed the exercise programme opted into taking part in an interview during the consent process. Eleven were selected for interview, four from one site and seven from the other. Thirteen patients who declined the HIIT programme were interviewed. The first 12 decliners contacted from site one agreed to be interviewed. All 26 decliners from site two were contacted for interview; one consented. Four participants commenced the intervention and chose to withdraw but none agreed to an interview. In total, 73 patients were approached for interview, 44 agreed and 24 were selected (11 completers and 13 decliners).

Of the 24 interviewees, the mean age was 71 ± 8 years, ranging from 59 to 89 years and 68% were male. For completers, the mean age was 72 ± 4 years and 82% were male. For decliners, the mean age was 70 ± 9 years and 54% were male. The age range of those completing the intervention and participating in an interview was slightly narrower than the overall cohort of participants completing the intervention (66 to 81 years compared to 51 to 88 years). Eight interviews were conducted face-to-face and 16 over the telephone. Interviews lasted between six and 33 minutes.

Three major themes were identified with several sub-themes (Table 1). These themes are explored below, and quotes are provided with key participant characteristics to aid interpretation.

Personal Reflections of the programme

Gruelling but beneficial

Generally, the programme was well received, with the majority of those who participated in the exercise intervention providing positive feedback such as "*I thought it was really good*" *(Completer, female, 66)* and "*I thoroughly enjoyed it*" *(Completer, male, 72)*. Despite this positive feedback, some found the programme very hard, "*quite hard really, yes*" (Completer, male, 81), but this was not sufficient to prompt them to drop out. Even when they described the programme as good this did not mean participants necessarily enjoyed it, with most finding it hard work, and one person describing it as "*gruelling*" *(Completer, male, 69).* A minority even described it as painful… "*it was extremely painful*" *(Completer, male, 67)*. However, completers talked about how that the programme got easier over time. In addition, they felt that the difficulty of the programme was necessary to provide a benefit…

"*…sometimes you have got to go that bit further haven't you and just push yourself a bit*

more to get a result" *(Completer, female, 66)* and some reported enjoying the challenge of it. It is also likely that the difficulty/challenge of the programme contributed to the sense of achievement reported upon completion of each session "*oh yeah, from start to finish there is a sense of achievement*" *(Completer, male, 69).* Finally, most completers stated that they would be willing to complete the programme again and would also encourage others.

Exercise programme components

Most participants, including completers and decliners, were happy with the structure of the programme. The HIIT intervention involved 20-minute sessions, plus a warm-up and cool-down. Most participants were happy with the length of each session, although, three participants suggested reducing the warm-up and cool-down to five minutes each, which would reduce the session length to 30 minutes. Additionally, the frequency of three times per week was too burdensome for some, "*I think three times a week would be too much*" *(Decliner, male. 78)*. For others, the challenging time commitment was not insurmountable… "*It was it was tricky at the beginning to start managing it, but it was OK – I could do it, yes*" *(Completer, male. 67)*. In contrast, everyone thought the programme duration of six weeks was acceptable and the minimum programme length thought to be worthwhile. For some, as expected, six weeks was more attractive than the 12-week SEP.

Cycling was the exercise modality used. Some found the saddle uncomfortable, and one interviewee declined the programme as they had been advised not to cycle following orthopaedic surgery. For the majority, cycling was acceptable and several completers stated that they preferred using the bike over the treadmill, although others felt that being offered a

variety of exercise formats may have improved the programme… "*perhaps you could do a mixture, one session on the bike and one session on the treadmill*" (*Completer, male. 68)*.

Some sessions were delivered one-to-one, whilst others were delivered in a group-based setting. A large proportion of participants were willing to engage in a group-based programme, and felt that it would add a social or competitive element, which could encourage people to continue… "*I think that would be good because you could communicate and say, well how are you getting on?*" (*Completer, male. 68)*. There was some suggestion that a group-based programme may put some people off participating due to the potential for embarrassment or an adverse response to competition, but overall, a group-based programme was viewed as acceptable going forwards.

Programme facilitators and barriers

Recognising the benefits

Study accepters took part because they recognised the potential benefits of exercise, either for themselves, or for future patients "*If it gives you some guidance… to the programme that you are doing… I was pleased to take part for that reason"* (Completer, male. 75) and *"I thought well I will go if it does somebody else any good…"* (Completer, male. 81).

Most participants perceived there to be a personal benefit to their symptoms, health or both. "*I wanted to improve my walking actually… and perhaps improve my health as well"* (Completer, male. 68). The benefits of exercising with little perceived risk was also important *"It is not hurting you in any way is it and I mean exercise, even if it didn't make your legs any better, it's got to be good for other parts of your body…"* (Completer, female. 66). This was echoed by others who stated that participation was a 'no lose' situation.

Practical barriers to taking part

Three key physical barriers were identified, namely: time, location and transport difficulties and cost. These impacted some participants more than others and worked in isolation or in combination. As mentioned above, the time commitment of the programme was still perceived as a barrier for some, despite a reduction in the programme length from 12 to six weeks. Additionally, the programme ran during working hours, and so did not always fit in with participants daily lives… "*it's just with me working, that's the problem*" *(Decliner, female. 62)*. For retirees, the absence of work was given as a reason why they could attend the programme "*not really, no, because, I am retired now, so don't have to take time off work*" *(Completer, male. 68),* highlighting time, and time of day, as a key challenge for the intervention.

At one site, exercise sessions were held at a hospital and the distance people had to travel combined with poor transport links were barriers to participation "*well it were too far really, to come*" *(Decliner, male. 77)*. For those relying on public transport, attending could mean taking multiple buses, adding time and increasing costs. Only one participant mentioned cost as a personal barrier, though others alluded to it, noting the importance of things like free parking or bus travel, often available to those of pension age. This suggests that like time, cost may be a more influential barrier for those of working age.

Other physical barriers included severe co-morbidities that were worse than IC and precluded participation.

Barriers

Psychological barriers to taking part

Motivation to exercise acted both as an important barrier, but also facilitator to participation. Some participants acknowledged their own lack of motivation to exercise. For these participants, the structured, centre-based, supervised nature of the intervention was the reason they enrolled on the programme, as these participants were aware that they would not pro-actively exercise at home, due to their lack of motivation "*because it is as I told you before, exercise is not something that is at the top of my list, never has been*" *(completer, female, 66).* However, a lack of motivation was also put forward as a reason why 'other people' may not take part… "*people have to put the effort in".*

Another mental barrier was a lack of awareness. It was identified that some patients may lack awareness of their condition, the treatments including exercise, and the benefits of it. One participant described how the symptoms of IC can be misinterpreted, resulting in a delay in diagnosis *"about 12 or 18 months before I tore my Achilles… and that took about 10 months to recover and it was not long after that this started and I did not know whether it was associated" (Completer, male. 72)*. Even with a diagnosis, some participants were unaware of the benefits of exercise as a treatment for IC, and did not understand the need to induce pain to improve symptoms via the growth of collateral circulation *"I am just trying to think, how could exercises do anything to your artery, if it is furred up, how does exercise clear it?" (Decliner, male. 78)*. Finally, study decliners in particular found it difficult to distinguish between structured exercise (i.e., SEP) and everyday physical activity. This meant the benefits of SEP were not understood and so they rejected the programme as they believed that the general physical activity they did at home was enough "*I am moving about on it, I just don't think there's gonna be any more benefits from what I'm actually doing*" *(Decliner, female. 64)*.

It was common for patients to be anxious about taking part and a fear of the unknown, a fear of failure and a belief that they would not be able to complete the programme put some off even attempting it… "*because I think it did like scare me off a little bit thinking it would be a bit too much and I wouldn't be able to do it*" *(Decliner, female. 69)*.

Reducing barriers or encouraging engagement

Participants identified strategies that could encourage participation. Offering reimbursement to those unable to access free transport and parking *"but if it was covered for them, they would be naff not to take it up" (Completer, male. 69)*, reducing the frequency of exercise sessions to twice per week *"I think if I had to go somewhere it is too much… I could do twice [a week]" (Decliner, female, 59)* and having multiple exercise locations were viewed as key to addressing the practical barriers faced by patients.

Education to improve understanding was viewed as useful, especially to reduce anxiety related to a fear of the unknown and failure. Some patients who completed the programme highlighted that their apprehension to exercise had been reduced and they had the confidence to continue exercising... *"I almost had a bit of a phobia about going in the gym. I think that has gone now" (Completer, female. 66)*. Patients also mentioned an increased understanding of their condition, exercise and its benefits in terms of symptoms and the development of collateral circulation.

Information and education materials about HIIT could be written by patients that have participated in the programme, with quotes to show how they benefitted, as this is more likely to resonate with the reader…*"I think perhaps you could give examples… of other people who have done the course and how it has improved them, could maybe give them examples…*

improvements that could happen" (Completer, male, 68). However, it was acknowledged that each person has their own learning style and a range of formats should be available, with leaflets, videos and taster sessions, all suggested.

Perceived benefits of HIIT

Most patients that completed the programme reporting an improvement in their symptoms in terms of their walking ability "*oh yes yeah, before I used to have regular stops to where I was going, but now I can walk further and when I do have to stop, I don't have to stop for as long to recuperate*" *(Completer, male, 68)*. Some patients also reported improvements in other aspects of their health… *"I lost a bit of weight which is always good" (Completer, male. 72).* Others reported a lack of improvement… "*not a lot, no, not a lot…[of improvement], I would say about the same*" *(Completer, female, 76)*, or felt that they had not improved, but an improvement had been noted by family members "*my wife said I did walk a bit better, yes*" *(Completer, male, 81)*. One patient who did not report an improvement in their symptoms, was able to realise the benefit of exercise for their general health… "*I knew it was doing me good, that's the main thing*" *(Completer, male, 81)*, which may have contributed to them continuing the programme.

Discussion

The aim of this study was to gain an understanding of patient perceptions and therefore acceptability of a novel HIIT programme for patients with IC. Most participants (including decliners) were positive about the programme and its structure, with some minor changes, whilst completers reported symptomatic benefits and would complete it again. Overall, this supports its acceptability.

Three key changes to the programme were suggested. First, some felt that the frequency could be reduced to once or twice per week. Although current evidence suggests that the optimal SEP frequency for improving walking distance is three times per week, RCT evidence is lacking[16-18]. In addition, NICE guidance recommends two hours (i.e. two sessions) per week and existing SEPs in the UK are predominantly delivered over 1-2 sessions per week[2,5]. Therefore, reducing HIIT frequency to twice per week appears reasonable and may further improve acceptability.

Next, some participants felt that offering a variety of exercises would aid acceptability. However, this would involve a circuit-based approach, which would come at the detriment of intensity (due to the need for changing equipment) and time-efficiency. Therefore, keeping a cycle-based approach appears most appropriate, as this was largely acceptable to patients and will allow them to reach the required intensity[19]. The final suggested change was to reduce the length of the warm-up and cool-down to five minutes each, which is supported by international guidelines[20] and further reduces the time barrier.

Several barriers were identified, most of which have been noted previously[21]. A reliance on public transport, and the associated prohibitive factors in terms of time and money, has been demonstrated previously[21,22]. This may be due to the relationship between low socioeconomic status and PAD[23] and can increase health inequalities amongst patients. It is therefore important to address these barriers. In the short-term, as more research will be required prior to implementation of this HIIT programme, it is important that all patients are reimbursed for any expenses that are incurred, this will also help to ensure that the sample is representative and the intervention is acceptable and appropriate for the target population.

In the longer term, to aid engagement in SEPs, including HIIT, one possible solution would be to make more exercise centres available so that patients could choose to attend the one closest to them. However, this may not be possible given the current funding, staffing and facility constraints that preclude widespread SEP implementation[24], though HIIT may reduce these barriers, potentially increasing provision opportunities. An alternative solution would be to allow patients with IC to be referred into established cardiac rehabilitation (CR) programmes, which are more readily available nationwide[25]. The same HIIT programme has recently been considered and recommended as an adjunct in UK CR services[11], suggesting that in future, HIIT could also be provided to patients with IC in this setting. However, uptake rates for CR programmes, despite their wider availability, are also poor at 50%, so addressing other barriers would be required[25], though by combing SEP with CR, this service could become more cost-effective.

A lack of motivation to exercise is a key barrier for patients, but our data suggest that for some patients at least, a recognition of this, may also act as a facilitator, especially if they have access to a structured SEP, as noted previously in previous studies[26,27]. Importantly, our study demonstrated a clear lack of awareness or understanding about IC. This has been highlighted previously[28], and may be due to the poor health literacy reported by the majority of patients with IC[29]. There is a need to improve patient education and a group-based education programme has been piloted with promising results[30]. However, it is important that education is individually tailored and other methods developed with patients such as patient feedback in invitation materials, YouTube videos and taster sessions could be used[28]. The ability of such methods to improve recruitment and retention into SEP/HIIT programmes could be tested via studies embedded within trials[31,32], and if found to be beneficial to recruitment, these could be embedded into routine practice.

Finally, participants found HIIT sessions difficult, though this led to a feeling of satisfaction upon completion. This notion that HIIT is considered less enjoyable during exercise, but more enjoyable after exercise has been demonstrated previously via the quantitative measures of the feeling scale and the physical activity enjoyment scale[33]. It is postulated that this is due to a continuous rebound effect that is felt during recovery intervals[34-36], which amalgamate in conjunction with a final rebound effect upon completion of the session, to create this feeling of post-exercise enjoyment. However, there is limited data to support this, as enjoyment is usually measured during HIIT intervals rather than recovery intervals. In addition, affect has not been considered in patients with IC. Therefore, future work should consider measuring affect over the course of the programme, both during work and recovery intervals.

Strengths and limitations

The relatively large sample included in this qualitative analysis is a key strength. No withdrawers agreed to be interviewed, meaning that this group is not represented, but we did gain a rich understanding about the reasons for declining participation, which helps us understand the barriers faced. Next, due to the COVID-19 pandemic, several interviews had to be performed over the telephone, which may have impacted upon the data collected[13,37]. There is only limited evidence to suggest that telephone interviews produce lower-quality data than face-to-face interviews, but some of our interviews were very short, and the use of telephone interviews may have played a role in that as the population were older adults. Finally, the transcripts were not shared with participants prior to analysis for clarification nor was feedback provided on the findings, so we do not know if our interpretations resonate with patients.

Conclusion

The aim of this study was to consider the acceptability of a novel HIIT programme for patients with IC, designed to maximise patient benefit and reduce the time commitment. Overall, most patients enjoyed the programme and despite finding it difficult would complete it again. In addition, some changes were suggested for the programme structure that will be incorporated in its future development. These findings support the acceptability of this novel HIIT programme, as well as strengthening the need for a fully powered RCT, with embedded recruitment SWATs.

Author contributions

Concept and design: SP, AEH, SI, GM, CH, MT, ARN, LI, JL, MR, ICC,

Acquisition of data, analysis and interpretation: SP, MT

Drafting or critically revising the article: SP, AEH, SI, GM, CH, MT, ARN, LI, JL, MR, ICC.

Final approval: SP, AEH, SI, GM, CH, MT, ARN, LI, JL, MR, ICC.

Accountability: SP, AEH, SI, GM, CH, MT, ARN, LI, JL, MR, ICC.

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