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

S. Pymer, A.E. Harwood, S. Ibeggazene, G. McGregor, C. Huang, A.R. Nicholls, L. Ingle, J. Long, M. Rooms, I.C. Chetter, M. Twiddy

PII: S0890-5096(24)00027-X

DOI: https://doi.org/10.1016/j.avsg.2023.11.043

Reference: AVSG 7029

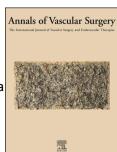
To appear in: Annals of Vascular Surgery

Received Date: 25 September 2023 Revised Date: 15 November 2023 Accepted Date: 22 November 2023

Please cite this article as: Pymer S, Harwood A, Ibeggazene S, McGregor G, Huang C, Nicholls A, Ingle L, Long J, Rooms M, Chetter IC, Twiddy M, high INtensity Interval Training In pATiEnts with intermittent claudication (INITIATE): a qualitative acceptability study, *Annals of Vascular Surgery* (2024), doi: https://doi.org/10.1016/j.avsg.2023.11.043.

This is a PDF file of an article that has undergone enhancements after acceptance, such as the addition of a cover page and metadata, and formatting for readability, but it is not yet the definitive version of record. This version will undergo additional copyediting, typesetting and review before it is published in its final form, but we are providing this version to give early visibility of the article. Please note that, during the production process, errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

© 2024 The Author(s). Published by Elsevier Inc.



- 1 high INtensity Interval Training In pATiEnts with intermittent claudication
- 2 (INITIATE): a qualitative acceptability study
- 3 Short title: Acceptability of high-intensity interval training in intermittent claudication
- 4 Pymer, S¹
- 5 Harwood, AE^{2,6}
- 6 Ibeggazene, S¹
- 7 McGregor, G^{2,3,4}
- 8 Huang, C⁵
- 9 Nicholls, AR⁶
- 10 Ingle, L⁶
- 11 Long, J^1
- 12 Rooms, M
- 13 Chetter, I.C¹
- 14 Twiddy, M⁵
- 15 Institutions:
- ¹Academic Vascular Surgical Unit, Hull York Medical School, Hull, UK.
- ²Department of Cardiac Rehabilitation, Centre for Exercise & Health, University Hospital,
- 18 Coventry, UK
- ³Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry,
- 20 UK
- ⁴Centre for Sport Exercise & Life Sciences, Coventry University, Coventry, UK
- ⁵Institute of Clinical and Applied Health Research, Hull York Medical School, University of
- 23 Hull, Hull, UK.
- ⁶Department of Sport, Health & Exercise Science, University of Hull, Hull, UK.
- ⁷Department of Cardiology, University Hospitals Coventry & Warwickshire NHS Trust,
- 26 Coventry, UK
- ⁸Division of Health Sciences, Warwick Medical School, University of Warwick, Coventry,
- 28 UK

29	Corresponding Author: Sean Pymer, Academic Vascular Surgical Unit, Hull York Medical
30	School, Hull, UK. <u>S.Pymer@nhs.net</u>
31	Category: Original article
32	
33	Declarations of interest: none'
34	
35	Data availability statement: The data underlying this article will be shared on reasonable
36	request to the corresponding author.
37	
38	

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 suboptimal³. Time is a key patient barrier⁴⁻⁶. 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 phase⁹. The Medical Research Council guidance notes that intervention acceptability is a key element to be considered within the feasibility phase¹⁰. 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 intervention¹⁰. 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 limited⁷, and although this intervention has been considered in patients with coronary artery disease¹¹, 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 enjoyment³ 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.

93	Methods	
94	Study design	
95	This qualitative study, reported in accordance with the COREQ checklist (Appendix 1), was	
96	embedded within the 'high INtensity Interval Training In pATiEnts with intermittent	
97	claudication' (INITIATE) study ⁹ . This was a single-arm, proof-of-concept study, performed	
98	at two UK NHS Trusts, recruiting patients with IC, referred to a usual-care SEP. The study	
99	was registered prospectively on clinicaltrials.gov (NCT04042311) and all study procedures	
100	were approved by a UK NHS Research Ethics Committee (reference: Bradford Leeds –	
101	18/YH/0112). Full details of the patient identification and recruitment processes and the	
102	2 inclusion / exclusion criteria for INITIATE are provided in the study protocol, as is a	
103	description of the intervention ¹² .	
104	Briefly, the intervention was a six-week, supervised HIIT programme performed three times	
105	per week, using a stationary cycle ergometer. Intensity was set using a baseline	
106	5 cardiopulmonary exercise test.	
107	In-depth, semi-structured interviews were conducted with a convenience subsample from	
108	three distinct groups:	
109	Group one: participants who successfully completed the HIIT programme.	
110	Group two: Those who agreed to participate in the HIIT programme but discontinued after	
111	$1 \ge 1$ session.	
112	Group three: Participants who were eligible for recruitment to INITIATE but declined to	
113	participate.	
114	Consent and Data collection	
115	All patients approached for the INITIATE study were eligible for interview, and study	
116	consenters were able to opt in or out of the interview whilst consenting to the study. Patient	
117	were approached via mail with a follow-up telephone call. Patients who declined to take par-	

118	in the INITIATE study were asked if they would agree to be interviewed and interview-	
119	specific consent was obtained. Participants interviewed via telephone provided verbal	
120	consent, which was audio recorded.	
121	One-off, semi-structured interviews were undertaken. All interviews were informed by a	
122	topic guide, adapted from similar studies previously undertaken by the authors (SP and AEH;	
123	Appendix 2). Interviews were flexible to allow exploration of participant responses.	
124	Participants were informed that they did not have to answer questions that they felt unable to	
125	and that all responses were confidential. All interviews were audio recorded, transcribed	
126	verbatim and pseudonymised. Field notes were not made. All interviews were conducted by	
127	the lead researcher (SP), a male post-graduate exercise physiologist, who had attended a	
128	National Centre for Social Research training course, and was supervised by MT, an	
129	experienced qualitative researcher. A PhD student was present for five interviews; all other	
130	interviews were conducted with only the researcher and participant present.	
131		
132	Interviews were conducted face-to-face in a private clinic room or via telephone to	
133	accommodate COVID-19 restrictions. Telephone interviews result in a loss of visual cues but	
134	there is no evidence that they produce lower quality data ¹³ , and this option allowed	
135	participants to take part without attending the research site.	
136		
137	Outcomes of interest	
138	The outcomes of interest were related to patients views of the structure of the HIIT	
139	programme and experiences of undertaking and/or being invited to undertake it.	
140		
141	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 data¹⁵. This involved reading and rereading 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 elsewhere⁹. 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).

166 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, 167 168 the mean age was 70 ± 9 years and 54% were male. The age range of those completing the 169 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). 170 Eight interviews were conducted face-to-face and 16 over the telephone. Interviews lasted 171 172 between six and 33 minutes. 173 174 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 175 176 interpretation. 177 Personal Reflections of the programme 178 Gruelling but beneficial 179 180 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" 181 (Completer, female, 66) and "I thoroughly enjoyed it" (Completer, male, 72). Despite this 182 positive feedback, some found the programme very hard, "quite hard really, yes" (Completer, 183 184 male, 81), but this was not sufficient to prompt them to drop out. Even when they described 185 the programme as good this did not mean participants necessarily enjoyed it, with most 186 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). 187 188 However, completers talked about how that the programme got easier over time. In addition, 189 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 190

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 cooldown. 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

216	variety of exercise formats may have improved the programme "perhaps you could do a	
217	mixture, one session on the bike and one session on the treadmill" (Completer, male. 68).	
218		
219	Some sessions were delivered one-to-one, whilst others were delivered in a group-based	
220	setting. A large proportion of participants were willing to engage in a group-based	
221	programme, and felt that it would add a social or competitive element, which could	
222	encourage people to continue "I think that would be good because you could communicate	
223	and say, well how are you getting on?" (Completer, male. 68). There was some suggestion	
224	that a group-based programme may put some people off participating due to the potential for	
225	embarrassment or an adverse response to competition, but overall, a group-based programme	
226	was viewed as acceptable going forwards.	
227		
228	Programme facilitators and barriers	
229	Recognising the benefits	
230	Study accepters took part because they recognised the potential benefits of exercise, either for	
231	themselves, or for future patients "If it gives you some guidance to the programme that you	
232	are doing I was pleased to take part for that reason" (Completer, male. 75) and "I thought	
233	well I will go if it does somebody else any good" (Completer, male. 81).	
234		
235	Most participants perceived there to be a personal benefit to their symptoms, health or both.	
236	"I wanted to improve my walking actually and perhaps improve my health as well"	
237	(Completer, male. 68). The benefits of exercising with little perceived risk was also important	
238	"It is not hurting you in any way is it and I mean exercise, even if it didn't make your legs	
239	any better, it's got to be good for other parts of your body" (Completer, female. 66). This	
240	was echoed by others who stated that participation was a 'no lose' situation.	

7	1	1	

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

Barriers

participation.

Psychological barriers to taking part

266	Motivation to exercise acted both as an important barrier, but also facilitator to participation.	
267	Some participants acknowledged their own lack of motivation to exercise. For these	
268	participants, the structured, centre-based, supervised nature of the intervention was the reason	
269	they enrolled on the programme, as these participants were aware that they would not pro-	
270	actively exercise at home, due to their lack of motivation "because it is as I told you before,	
271	exercise is not something that is at the top of my list, never has been" (completer, female, 66).	
272	However, a lack of motivation was also put forward as a reason why 'other people' may not	
273	take part "people have to put the effort in".	
274	Another mental barrier was a lack of awareness. It was identified that some patients may lack	
275	awareness of their condition, the treatments including exercise, and the benefits of it. One	
276	participant described how the symptoms of IC can be misinterpreted, resulting in a delay in	
277	diagnosis "about 12 or 18 months before I tore my Achilles and that took about 10 months	
278	to recover and it was not long after that this started and I did not know whether it was	
279	associated" (Completer, male. 72). Even with a diagnosis, some participants were unaware	
280	of the benefits of exercise as a treatment for IC, and did not understand the need to induce	
281	pain to improve symptoms via the growth of collateral circulation "I am just trying to think,	
282	how could exercises do anything to your artery, if it is furred up, how does exercise clear it?'	
283	(Decliner, male. 78). Finally, study decliners in particular found it difficult to distinguish	
284	between structured exercise (i.e., SEP) and everyday physical activity. This meant the	
285	benefits of SEP were not understood and so they rejected the programme as they believed	
286	that the general physical activity they did at home was enough "I am moving about on it, I	
287	just don't think there's gonna be any more benefits from what I'm actually doing" (Decliner,	
288	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 intensity¹⁹. 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 guidelines²⁰ and further reduces the time barrier.

Several barriers were identified, most of which have been noted previously²¹. 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 PAD²³ 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 implementation²⁴, 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 nationwide²⁵. The same HIIT programme has recently been considered and recommended as an adjunct in UK CR services¹¹, 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 required²⁵, 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 previously²⁸, and may be due to the poor health literacy reported by the majority of patients with IC²⁹. There is a need to improve patient education and a group-based education programme has been piloted with promising results³⁰. 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 used²⁸. 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 scale³³. It is postulated that this is due to a continuous rebound effect that is felt during recovery intervals³⁴⁻³⁶, 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.

415	Conclusion	
416	The aim of this study was to consider the acceptability of a novel HIIT programme for	
417	patients with IC, designed to maximise patient benefit and reduce the time commitment.	
418	Overall, most patients enjoyed the programme and despite finding it difficult would complete	
419	it again. In addition, some changes were suggested for the programme structure that will be	
420	incorporated in its future development. These findings support the acceptability of this novel	
421	HIIT programme, as well as strengthening the need for a fully powered RCT, with embedded	
422	recruitment SWATs.	
423		
424	Author contributions	
425	Concept and design: SP, AEH, SI, GM, CH, MT, ARN, LI, JL, MR, ICC,	
426	Acquisition of data, analysis and interpretation: SP, MT	
427	Drafting or critically revising the article: SP, AEH, SI, GM, CH, MT, ARN, LI, JL, MR, ICC.	
428	Final approval: SP, AEH, SI, GM, CH, MT, ARN, LI, JL, MR, ICC.	
429	Accountability: SP, AEH, SI, GM, CH, MT, ARN, LI, JL, MR, ICC.	
430		

References

- 432 1. Aboyans V, Ricco J-B, Bartelink M-LE, et al. 2017 ESC Guidelines on the Diagnosis and
- 433 Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for
- 434 Vascular Surgery (ESVS) Document covering atherosclerotic disease of extracranial carotid
- and vertebral, mesenteric, renal, upper and lower extremity arteries Endorsed by: the
- 436 European Stroke Organization (ESO) The Task Force for the Diagnosis and Treatment of
- 437 Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the
- 438 European Society for Vascular Surgery (ESVS). European heart journal. 2017;39(9):763-816.
- 439 2. NICE. Peripheral arterial disease: diagnosis and management. Clinical guidance 147.
- 440 2012. https://www.nice.org.uk/guidance/CG147
- 441 3. Harwood A-E, Smith GE, Cayton T, Broadbent E, Chetter IC. A systematic review of
- the uptake and adherence rates to supervised exercise programs in patients with
- intermittent claudication. *Annals of vascular surgery*. 2016;34:280-289.
- 444 4. Harwood AE, Hitchman LH, Ingle L, Doherty P, Chetter IC. Preferred exercise
- 445 modalities in patients with intermittent claudication. Journal of Vascular Nursing. 2018;
- 446 5. Harwood AE, Pymer S, Ibeggazene S, Ingle L, Caldow E, Birkett ST. Provision of
- exercise services in patients with peripheral artery disease in the United Kingdom. Vascular.
- 448 Aug 4 2021:17085381211035259. doi:10.1177/17085381211035259
- 449 6. Cetlin MD, Polonsky T, Ho K, et al. Barriers to participation in supervised exercise
- 450 therapy reported by people with peripheral artery disease. *Journal of Vascular Surgery*.
- 451 2023/02/01/2023;77(2):506-514. doi:https://doi.org/10.1016/j.jvs.2022.09.014
- 452 7. Pymer S, Palmer J, Harwood AE, Ingle L, Smith GE, Chetter IC. A systematic review of
- 453 high-intensity interval training as an exercise intervention for intermittent claudication.
- 454 Journal of Vascular Surgery. 2019/06/27/
- 455 2019;doi:https://doi.org/10.1016/j.jvs.2019.03.050
- 456 8. Pymer S, Ibeggazene S, Palmer J, et al. Considering the Feasibility, Tolerability, and
- 457 Safety of High-Intensity Interval Training as a Novel Treatment for Patients With
- 458 Intermittent Claudication. *Journal of Cardiopulmonary Rehabilitation and Prevention*.
- 459 2020; Publish Ahead of Print
- 460 9. Pymer S, Harwood AE, Rhavindhran B, et al. High-intensity interval training in
- patients with intermittent claudication. *Journal of Vascular Surgery*. 2023;
- 462 10. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and
- evaluating complex interventions: update of Medical Research Council guidance. bmj.
- 464 2021;374
- 465 11. McGregor G, Powell R, Begg B, et al. High-intensity interval training in cardiac
- 466 rehabilitation: a multi-centre randomized controlled trial. European Journal of Preventive
- 467 *Cardiology*. 2023:zwad039.
- 468 12. Pymer S, Harwood A, Ibeggazene S, et al. High INtensity Interval Training In pATiEnts
- with intermittent claudication (INITIATE): protocol for a multicentre, proof-of-concept,
- 470 prospective interventional study. BMJ Open. 2020;10(7):e038825. doi:10.1136/bmjopen-
- 471 2020-038825
- 472 13. Novick G. Is there a bias against telephone interviews in qualitative research?
- 473 Research in nursing & health. 2008;31(4):391-398.
- 474 14. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies:
- guided by information power. *Qualitative health research*. 2016;26(13):1753-1760.

- 476 15. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in
- 477 *psychology*. 2006;3(2):77-101.
- 478 16. Gardner AW, Poehlman ET. Exercise rehabilitation programs for the treatment of
- 479 claudication pain: a meta-analysis. *Jama*. 1995;274(12):975-980.
- 480 17. Bulmer AC, Coombes JS. Optimising exercise training in peripheral arterial disease.
- 481 Sports Medicine. 2004;34(14):983-1003.
- 482 18. Treat-Jacobson D, McDermott MM, Bronas UG, et al. Optimal exercise programs for
- 483 patients with peripheral artery disease: a scientific statement from the American Heart
- 484 Association. *Circulation*. 2019;139(4):e10-e33.
- 485 19. Tuner SL, Easton C, Wilson J, et al. Cardiopulmonary responses to treadmill and cycle
- 486 ergometry exercise in patients with peripheral vascular disease. J Vasc Surg. Jan
- 487 2008;47(1):123-30. doi:10.1016/j.jvs.2007.09.001
- 488 20. ACSM. ACSM's guidelines for exercise testing and prescription. 10th ed. ed.
- 489 Lippincott, Williams, & Wilkins; 2018.
- 490 21. Harwood A-E, Broadbent E, Totty JP, Smith GE, Chetter IC. "Intermittent claudication
- 491 a real pain in the calf"—Patient experience of diagnosis and treatment with a supervised
- 492 exercise program. *Journal of Vascular Nursing*. 2017;35(3):131-135.
- 493 22. Barbosa JP, Farah BQ, Chehuen M, et al. Barriers to physical activity in patients with
- intermittent claudication. *International journal of behavioral medicine*. 2015;22(1):70-76.
- 495 23. Pande RL, Creager MA. Socioeconomic inequality and peripheral artery disease
- 496 prevalence in US adults. Circulation Cardiovascular quality and outcomes. 2014;7(4):532-
- 497 539. doi:10.1161/CIRCOUTCOMES.113.000618
- 498 24. Harwood A, Smith G, Broadbent E, Cayton T, Carradice D, Chetter I. Access to
- 499 supervised exercise services for peripheral vascular disease patients. The Bulletin of the
- 500 Royal College of Surgeons of England. 2017;99(6):207-211.
- 501 25. Doherty P, Harrison A, Petre C, et al. *The National Audit of Cardiac*
- 502 Rehabilitation Quality and Outcomes Report 2019. 2019.
- 503 26. Galea MN, Bray SR, Ginis KAM. Barriers and facilitators for walking in individuals with
- intermittent claudication. *Journal of aging and physical activity*. 2008;16(1):69-84.
- 505 27. Abaraogu U, Ezenwankwo E, Dall P, et al. Barriers and enablers to walking in
- 506 individuals with intermittent claudication: A systematic review to conceptualize a relevant
- and patient-centered program. *PloS one*. 2018;13(7)
- 508 28. Bridgwood BM, Nickinson ATO, Houghton JSM, Pepper CJ, Sayers RD. Knowledge of
- 509 peripheral artery disease: What do the public, healthcare practitioners, and trainees know?
- 510 *Vascular Medicine*. 2020/06/01 2020;25(3):263-273. doi:10.1177/1358863X19893003
- 511 29. Striberger R, Axelsson M, Kumlien C, Zarrouk M. Health literacy in patients with
- 512 intermittent claudication in relation to clinical characteristics, demographics, self-efficacy
- and quality of life A cross-sectional study. Journal of Vascular Nursing. 2022/09/01/
- 514 2022;40(3):121-127. doi:https://doi.org/10.1016/j.jvn.2022.09.001
- 515 30. Gorely T, Crank H, Humphreys L, Nawaz S, Tew GA. "Standing still in the street":
- 516 experiences, knowledge and beliefs of patients with intermittent claudication—a qualitative
- 517 study. *Journal of Vascular Nursing*. 2015;33(1):4-9.
- 518 31. Madurasinghe VW, Bower P, Eldridge S, et al. Can we achieve better recruitment by
- 519 providing better information? Meta-analysis of 'studies within a trial' (SWATs) of optimised
- participant information sheets. BMC Medicine. 2021/09/23 2021;19(1):218.
- 521 doi:10.1186/s12916-021-02086-2

- 522 32. Knapp P, Mandall N, Hulse W, et al. Evaluating the use of multimedia information
- when recruiting adolescents to orthodontics research: a randomised controlled trial. *Journal*
- 524 *of Orthodontics*. 2021;48(4):343-351.
- 525 33. Niven A, Laird Y, Saunders DH, Phillips SM. A systematic review and meta-analysis of
- affective responses to acute high intensity interval exercise compared with continuous
- 527 moderate- and high-Intensity exercise. *Health Psychology Review*. 2020:1-34.
- 528 doi:10.1080/17437199.2020.1728564
- 529 34. Thum JS, Parsons G, Whittle T, Astorino TA. High-intensity interval training elicits
- higher enjoyment than moderate intensity continuous exercise. *PloS one*.
- 531 2017;12(1):e0166299.
- 35. Jung ME, Bourne JE, Little JP. Where does HIT fit? An examination of the affective
- response to high-intensity intervals in comparison to continuous moderate-and continuous
- vigorous-intensity exercise in the exercise intensity-affect continuum. *PloS one*.
- 535 2014;9(12):e114541.
- 536 36. Malik AA, Williams CA, Weston KL, Barker AR. Perceptual and cardiorespiratory
- responses to high-intensity interval exercise in adolescents: Does work intensity matter?
- 538 Journal of sports science & medicine. 2019;18(1):1.
- 539 37. Irvine A. Duration, dominance and depth in telephone and face-to-face interviews: A
- comparative exploration. *International Journal of Qualitative Methods*. 2011;10(3):202-220.

Table 1 - Coding table

Initial Code	Merged code	Theme
Enjoyment / Difficulty	Gruelling but	Personal
Got easier / needs to be	beneficial	reflections
difficult		of the
Willingness to do again and		programme
encourage others		
Programme structure	Exercise	
Type of exercise	programme	
Group based vs. 1 to 1	components	
Took part to help us and	Recognising the	Programme
others	benefits	facilitators
Took part for own health or		and barriers
symptoms		
Time	Practical barriers	
Location / transport		
Cost		
Health or lifestyle		
Motivation to exercise	Psychological	
Lack of awareness /	barriers	
understanding		
Apprehension / anxiety		
Reimbursement	Encouraging	
Reducing frequency	engagement	
More local centres		
Education to increase		
understanding – supported		
by patients		
Alternatives – leaflets,		
videos, taster sessions.		
Improvement in symptoms	Improvement in	Perceived
/ walking	symptoms, walking	benefits
Improvement in health	and health	
Lack of improvement	Lack of	
	improvement	