

1-3-2013

One-year effect of a supervised exercise programme on functional capacity and quality of life in peripheral arterial disease.

Marie Guidon

Royal College of Surgeons in Ireland

Hannah McGee

Royal College of Surgeons in Ireland

Citation

Guidon M, McGee H. One-year effect of a supervised exercise programme on functional capacity and quality of life in peripheral arterial disease. *Disability and Rehabilitation*. 2013;35(5):397-404

This Article is brought to you for free and open access by the School of Physiotherapy at e-publications@RCSI. It has been accepted for inclusion in School of Physiotherapy Articles by an authorized administrator of e-publications@RCSI. For more information, please contact epubs@rcsi.ie.

— Use Licence —

Attribution-Non-Commercial-ShareAlike 1.0

You are free:

- to copy, distribute, display, and perform the work.
- to make derivative works.

Under the following conditions:

- Attribution — You must give the original author credit.
- Non-Commercial — You may not use this work for commercial purposes.
- Share Alike — If you alter, transform, or build upon this work, you may distribute the resulting work only under a licence identical to this one.

For any reuse or distribution, you must make clear to others the licence terms of this work. Any of these conditions can be waived if you get permission from the author.

Your fair use and other rights are in no way affected by the above.

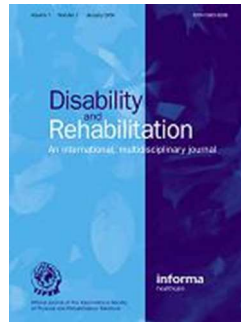
This work is licenced under the Creative Commons Attribution-Non-Commercial-ShareAlike License. To view a copy of this licence, visit:

URL (human-readable summary):

- <http://creativecommons.org/licenses/by-nc-sa/1.0/>

URL (legal code):

- <http://creativecommons.org/worldwide/uk/translated-license>
-



One-year effects on functional capacity and quality of life in a peripheral arterial disease population following a supervised exercise programme

Journal:	<i>Disability and Rehabilitation</i>
Manuscript ID:	TIDS-11-2011-003
Manuscript Type:	Research Paper
Keywords:	peripheral arterial disease, exercise, functional capacity, quality of life, intermittent claudication

SCHOLARONE™
Manuscripts

Implications for Rehabilitation

- Peripheral arterial disease has a considerable impact on functional capacity and quality of life
- Functional capacity and quality of life are improved in patients with peripheral arterial disease up to one year post-participation in supervised exercise
- Improvements at one year are reduced from those noted immediately following an exercise programme

Abstract

Purpose Peripheral arterial disease (PAD) is a chronic, progressive disease with a significant cardiovascular and cerebrovascular risk burden and a considerable impact on functional capacity and quality of life (QoL). Exercise programmes result in significant improvements in walking distances but long-term effects are uncertain. The aim of this study was to assess the one-year effects of participation in a 12-week supervised exercise programme for PAD patients.

Methods Patients were randomly allocated to a control (n=16) or an exercise (n=28) group. Data regarding functional capacity (Walking Impairment Questionnaire WIQ), disease-specific QoL (Intermittent Claudication Questionnaire ICQ) and generic QoL (SF-36) were collected at baseline, 12 weeks and one year.

Results At 12 weeks, there was a trend towards improved QoL in both groups, greater in the exercise group ($p=.066$) and a trend towards improved functional capacity (WIQ Stair-climbing $p=.093$) in the exercise group. At one year, improvements in the exercise group (although reduced from those recorded immediately following the exercise programme) were maintained from baseline. Scores in the control group reflected a continuing deterioration in functional capacity and QoL.

Conclusions Participation in a supervised exercise programme results in improvements in functional capacity and QoL at one year post-participation.

Introduction

Peripheral arterial disease (PAD) is a manifestation of generalised atherosclerotic disease in which the arterial lumen becomes progressively narrowed by atherosclerotic plaques. This gradual narrowing of the lumen results in reduced blood flow to the tissues causing pain on exercise, relieved by rest (intermittent claudication [IC]). PAD has two significant consequences - a reduction in quality of life (QoL) and functional capacity due to peripheral symptoms and a significantly increased cardiovascular morbidity and mortality risk. While local disease in the leg follows a relatively benign course, the major morbidity and mortality risk is from associated coronary and cerebrovascular disease [1].

Although the risk factors for PAD are the same as those for coronary artery disease, individuals with PAD face considerable challenges to exercise due to their symptomatology [2]. Walking is associated with the onset of leg pain and frequent rest periods during walking are required to relieve the pain.

Management of PAD aims to improve cardiovascular risk factors and to maintain or improve QoL by eliminating ischaemic symptoms and preventing progression to vascular occlusion. Exercise interventions have resulted in significant increases in treadmill walking distances [3] but the effects of these increases on quality of life and functional capacity in the community setting are unclear [4]. In addition the long-term benefits in this patient population are also uncertain [3]. The aim of this study was to evaluate the one-year effects of participation in a 12-week supervised exercise programme for patients with IC.

Methods

Study design

This was a randomised controlled trial. Data was collected at baseline, 12 weeks and one year. Ethical approval for the study was obtained from the Hospital Ethics Committee.

Participants

Participants with an ankle:brachial index (ABI) < 0.9 were identified from the Non-Invasive Vascular Laboratory logbook and medical charts subsequently reviewed for inclusion/exclusion criteria. Inclusion criteria were: Fontaine Stage II (intermittent claudication) diagnosed by history of leg pain on exercise relieved by rest, classified by presence /absence of pulse/s, site of pain, ABI < 0.9 at rest and/or decrease in ankle pressure by 15mmHg or more after exercise, stable disease for 3 months and residing within the geographical catchment area of the hospital. Exclusion criteria were: Fontaine Stages I, III and IV; coexisting clinical condition which precluded participation in exercise programme including unstable cardiorespiratory disease, neurological/orthopaedic limitation to exercise, poorly controlled hypertension, active major medical problem including but not limited to cancer, renal/liver disease, dementia, poorly controlled diabetes mellitus; abdominal aortic aneurysm; myocardial infarction within the previous 6 months; acute onset or within the first months of onset of claudication and revascularisation procedure/surgery within the previous 6 months.

Procedure

Participants who met the inclusion criteria were contacted by phone or letter to invite them to participate in the study. Following written informed consent, participants were referred for a symptom-limited cardiopulmonary exercise test. The test was conducted to determine the participant's cardiac status, possible underlying coronary

1
2
3 artery disease and to outrule any contraindications to participation in an exercise
4 programme. Results of the treadmill test were also used to set the initial training
5 workload. The exercise test was conducted under cardiology supervision. On
6
7 successful completion of the exercise test, participants were randomly allocated to a
8 control or an exercise group. Randomisation was conducted by computer-generated
9 random sealed envelope method.
10
11
12
13
14
15
16
17

18 The control group continued with usual care, i.e. ABI measurement, advice regarding
19 exercise and smoking cessation and review at scheduled out-patient clinic
20 appointments. The exercise group participated in a twice-weekly supervised
21 exercise programme for 12 weeks. A 12-week exercise programme has been
22 recommended as initial treatment for PAD patients [5, 6]. The exercise programme
23 was based on the hospital cardiac rehabilitation programme. The total duration of the
24 programme was one hour, including warm-up and cool down periods. Participants
25 underwent a 10 minute warm-up consisting of gentle walking, stepping and stretching
26 exercises (upper limb, lower limb and trunk). Participants then exercised for 30-40
27 minutes using a range of exercise equipment - treadmill, stepper, elliptical trainer,
28 recumbent cycle ergometer and upper/lower limb cycle ergometer. Individualised
29 exercise programmes were designed. Participants were encouraged to exercise at
30 an intensity of 70-80% of their exercise test maximum or 70-80% predicted heart rate
31 maximum if the exercise test was terminated due to the onset of ischaemic leg pain
32 before predicted heart rate maximum was achieved. On the treadmill participants
33 were encouraged to continue exercising until they were unable to continue due to leg
34 pain (generally a maximum of 10 minutes). Participants were then permitted to rest
35 until the pain subsided and then were encouraged to recommence exercising. The
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 exercise level was set at an intensity that produced moderate claudication pain within
4
5 5 minutes. Exercise was progressed by increasing resistance and/or time.
6
7

8 9 **Measurements**

10
11 Baseline data obtained for all participants included demographic information,
12
13 cardiovascular risk factors, current medications, claudication history and blood
14
15 samples.
16
17

18 19 *Functional Capacity*

20
21 The Walking Impairment Questionnaire (WIQ) has been specifically developed and
22
23 validated for participants with IC to measure community-based walking ability [7, 8]
24
25 and to monitor the effectiveness of therapeutic interventions. It has been validated
26
27 against treadmill testing for objective assessment of functional walking ability and
28
29 recommended as an alternative to treadmill testing for use in daily practice [9]. The
30
31 questionnaire assesses participant-reported walking speed, distance, stair-climbing
32
33 ability and limitations in walking ability. The participant ranks his/her degree of
34
35 difficulty walking specific distances on a 0-4 Likert scale where 0 represents inability
36
37 to walk the distance and 4 represents no difficulty. For walking speed the subject
38
39 ranks the degree of difficulty walking slowly, at average speed, quickly or running or
40
41 jogging. In the stair-climbing component, participants rank their ability to walk up and
42
43 down one, two or three flights of stairs respectively. Scores are divided by the
44
45 maximum possible score to obtain the percentage score with higher scores indicating
46
47 greater functional walking ability.
48
49
50
51
52
53
54
55
56
57
58
59
60

Disease- specific quality of life

The Intermittent Claudication Questionnaire (ICQ) has been validated for use in an IC population to identify small but important changes in quality of life [10]. It consists of 16 items providing a single health dimension score and has a brief completion time (average 3.7 minutes). Each question has a 5 or 6 point adjectival response scale. It is scored from 0-100 where 0 is the best possible and 100 the worst possible health state. Total score is calculated using the coding and transformation scheme developed by the authors. Higher scores indicate poorer QOL.

Generic quality of life

The Medical Outcomes Study Short- Form 36 (MOS-SF36) questionnaire with 36 items in eight scales and two summary measures is the recommended health status or generic QoL measurement instrument in PAD [5] and is the most widely used [11]. The 36-item questionnaire assesses eight health dimensions - physical functioning (PF), social functioning (SF), role limitations due to physical problems (RP), role limitations due to emotional problems (RE), bodily pain (BP), mental health (MH), vitality (VT) and general health (GH). Each dimension has a scoring scale from 0 (worst quality of life) to 100 (best quality of life). Scores representing overall physical functioning and mental functioning are calculated from the individual scales and are presented as the physical component scale (PCS) and the mental component scale (MCS). Higher scores indicate better health states. The standard (4-week) recall version was used.

Statistical Analysis

All variables were examined for accuracy of data entry, missing values and presence of outliers. All variables were tested for normality using the Kolmogorov-Smirnov goodness-of-fit test. Group differences at baseline for demographic and clinical characteristics were assessed by Chi square tests for categorical variables and independent t-tests for numeric variables. Group differences at baseline for functional capacity and disease-specific quality of life scores were assessed by non-parametric methods, i.e. the Mann-Whitney test. SF-36 scores were examined using parametric tests (independent t-tests). Differences between groups at 12 weeks were examined with ANCOVA analysis using the general linear model to control for baseline scores. The post-trial variable was the predicted variable and the baseline values and study group were entered as co-variables.

For analysis of variables at baseline, 12 weeks and one year, each primary and secondary outcome was independently analysed with repeated measures analysis of variance. The analysis was conducted to examine the effects of participation in the exercise intervention at one year post-participation in relation to both baseline scores and those observed at 12 weeks. Within each outcome a Bonferroni adjustment was used to protect for a Type I error rate. Simple (main) effects for time and study group and the interaction effect of time and study group were the factors of interest. Where a significant result was found, means were further examined by pairwise comparisons using repeated measures ANOVA to examine the main effects of time, group and identify any differences in changes over time between the groups.

Statistical significance was set at $p < 0.05$. Data were analysed using the Statistical Package for the Social Sciences (SPSS) for Windows Version 17.0 (SPSS Inc., Chicago, Ill. USA).

Results

During the period November 2006 - June 2009, 548 patients with an ankle:brachial index (ABI) < 0.9 at rest and residing within the geographical catchment area of the Hospital were identified from the Non-Invasive Vascular Laboratory logbook. Following review of medical charts one hundred and fifty-six patients met the inclusion criteria. Of these, one hundred and three patients agreed to participate and were scheduled for exercise testing. Results of exercise testing are indicated in figure 1. Forty-four patients were subsequently randomised to a control and an exercise group.

Insert figure 1 about here

Both groups had similar baseline demographic and clinical profiles and none of the profile characteristics were found to differ statistically significantly between the two groups (table 1) with the exception of systolic blood pressure which was significantly higher ($p=.027$) in the control group. There were no differences in medication use between the groups.

Insert table 1 about here

Patients were deemed to have completed the exercise programme if they had 80% or greater attendance at scheduled exercise sessions ($n=24$). Twelve participants (exercise $n=11$; control $n=1$) withdrew prior to 12-week data collection (figure 1) and one participant was unavailable due to stent insertion. Regarding patients who withdrew from the exercise programme ($n=11$), all had withdrawn by week 4, i.e. commencing participants either withdrew early or completed the overall programme. There were no significant differences in any demographic or clinical variables

1
2
3 between those who withdrew and those who completed the programme The final
4 numbers available for analysis at twelve weeks were 31 (exercise n=17 and control
5 n=14). Partial data only was available for one participant in the control group as the
6 self-administered questionnaires were not returned. This participant subsequently
7 withdrew from the one-year assessment. The final numbers available for analysis at
8 one year were 30 (exercise n=17 and control n=13). Data from 12 participants in the
9 control group were available for analysis across all three time points.

10
11
12 Outcome measures are presented in table 2.

13
14
15
16
17
18
19
20
21
22 *Insert table 2 about here*
23
24
25

26 The exercise group had lower average WIQ scores, i.e. poorer functional capacity,
27 than the control group at baseline. At twelve weeks, increases were observed in all
28 WIQ scores in the exercise group with the largest mean difference over time in the
29 WIQ Distance score (increase of 14.29 points) and a trend towards improvement
30 observed for the WIQ Stair-climbing ($p=.093$) score. At one year there was a
31 significant interaction effect between Time and Study Group for the WIQ Stair-
32 climbing score [$F(2, 54) = 3.654, p=.032$] and average WIQ scores remained higher
33 than at baseline. In the control group average WIQ scores at one year were lower
34 than at baseline for all WIQ categories.

35
36
37
38
39
40
41
42
43
44
45
46
47
48 At baseline the exercise group had higher scores for the Intermittent Claudication
49 Questionnaire (ICQ), reflecting a poorer level of disease-specific quality of life. At
50 twelve weeks, there was a trend towards improved quality of life in both groups,
51 greater in the exercise group ($p=.066$). At one year, there was a significant
52
53
54
55
56
57
58
59
60

1
2
3 difference in ICQ over Time [F (2, 54) =5.268, p=.008] with a substantial interaction
4
5 effect between Time and Study Group [F (2, 54) = 3.003, p=.058] (figure 2).
6
7

8 *Insert figure 2 about here*
9

10
11 No significant differences between groups were demonstrated for any of the SF-36
12
13 scores over the three time points.
14
15

18 Discussion

20 The aim of this study was to evaluate the one-year effects of participation in a 12-
21
22 week supervised exercise programme on functional capacity and quality of life for
23
24 patients with intermittent claudication (IC). Intermittent claudication has a
25
26 considerable impact on functional capacity [12] with a reluctance to walk due to leg
27
28 pain. Quality of life in PAD patients is influenced by functional capacity [13] and the
29
30 Walking Impairment Questionnaire (WIQ) is the most accurate qualitative measure of
31
32 functional capacity [14]. It has been reported that the Distance score is the most
33
34 sensitive to change following supervised exercise [15]. The results of the current
35
36 study substantiate this. Statin use has been shown to improve walking distance and
37
38 speed in patients with PAD [16, 17]. However, as there was only one change (one
39
40 participant commenced on statin medication during the 12-week exercise period) to
41
42 medications during the 12-week study period in either group, this was not thought to
43
44 be a contributing factor in this study. At one year increases in all Walking Impairment
45
46 Questionnaire (WIQ) categories in the exercise group were demonstrated, indicating
47
48 maintenance of benefits although there was a decrease in scores from those
49
50 recorded immediately following completion of the exercise programme. Decreases
51
52 in all WIQ scores in the control group from baseline to one year were found,
53
54 reflecting a continuing deterioration in functional capacity. To the researchers'
55
56
57
58
59
60

1
2
3 knowledge, WIQ data at one year following a 12-week supervised exercise
4 programme is not available for comparison although improvements in Distance and
5 Speed scores have recently been reported following a one-year supervised exercise
6 intervention in the community [18].
7
8
9

10
11
12 At twelve weeks improvements were noted in the Intermittent Claudication
13 Questionnaire (ICQ) scores in both groups with differences across groups bordering
14 on significance. Similar changes have been reported in other studies [19, 20].
15 Improvements in ICQ scores following supervised exercise were reported with no
16 changes in SF-36 scores [20] or borderline significant increase in the Physical
17 Functioning domain only [19] reflecting the increased sensitivity of the disease-
18 specific measure. However, neither of these studies were randomised controlled
19 trials. In the current study, although there was some increase in ICQ scores (i.e. QoL
20 deterioration) in the exercise group at one year, scores remained at a lower level
21 than baseline (reflecting improved QoL) and maintenance of benefits. In the control
22 group ICQ scores were higher than baseline scores indicating a deterioration in QoL
23 at one year.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38

39 The absence of research on long-term outcomes (i.e. one year or more) of exercise
40 training has been highlighted [21]. Although maintenance of improvements in
41 exercise capacity and activity patterns at two years following discharge from cardiac
42 rehabilitation (CR) have been reported [22], the demographic profile of CR
43 participants is quite dissimilar to the PAD population, i.e. younger, fewer
44 comorbidities and this may influence on-going exercise participation following a
45 formal exercise programme. Additional support may be required in the PAD patient
46 population to promote longer-term exercise benefits. Of note in the current study is
47 that participants were primarily concerned about the presence of leg pain rather than
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 more serious cardiovascular complications with an under-appreciation of the link with
4
5 coronary artery and cerebrovascular disease. However, 50% of participants were
6
7 current smokers with increased mean body mass index and waist circumference
8
9 values evident in both groups suggesting that participation in a multidisciplinary
10
11 rehabilitation programme, targeting these increased cardiovascular risk factors would
12
13 be beneficial.
14

15
16 This study had a number of limitations. As it was not feasible to monitor the level of
17
18 unsupervised exercise that may have been undertaken by either group outside the
19
20 formal programme, it is possible that this may have been a confounding factor.
21

22
23 Inclusion in the study may have raised awareness of the benefit of exercise and
24
25 patients in the control group may have increased their level of independent exercise
26
27 and physical activity. Increased monitoring of blood pressure, weight and blood test
28
29 results may have influenced lifestyle behavioural changes and this may have
30
31 resulted in a more optimal outcome for the control group than for a “usual care” group
32
33 under normal circumstances. It is also possible that the presence of comorbid
34
35 conditions was a confounding factor, impacting on functional capacity and quality of
36
37 life.
38
39
40
41
42

43 **Conclusion**

44
45
46 Although small, study numbers were similar to other studies. Reviews of exercise
47
48 therapy for intermittent claudication have concluded that average study numbers in
49
50 this patient population range from 20-59 participants as most patients are elderly and
51
52 co-morbidities are common [3, 4]. Results demonstrated that participation in a
53
54 supervised exercise programme resulted in improvements in functional capacity and
55
56 quality of life at one year. These benefits, while decreased from those recorded
57
58
59
60

1
2
3 immediately following completion of the exercise programme, were maintained at
4
5 one year post-participation. Referral to an on-going maintenance programme may
6
7 be required to effect longer-term exercise benefits.
8
9

10 11 **Acknowledgements**

12
13 The assistance of the Non-Invasive Laboratory and Cardiology Departments with
14
15 patient testing is gratefully acknowledged. This research was supported by a grant
16
17 from the Institutional Research Committee.
18
19

20 21 **Declaration of Interest**

22
23 The authors report no declarations of interest.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

References

1. Criqui MH, Langer RD, Fronek A, Feigelson HS, Klauber MR, McCann TJ, et al. Mortality over a period of 10 years in patients with peripheral arterial disease. *N Engl J Med.* 1992; 326:381-6.
2. Galea M, Bray S. Predicting walking intentions and exercise in individuals with intermittent claudication: An application of the theory of planned behavior. *Rehabilitation Psychology.* 2006; 51:29-305.
3. Watson L, Ellis B, Leng GC. Exercise for intermittent claudication. *Cochrane Database Syst Rev.* 2008:CD000990.
4. Bendermacher BL, Willigendael EM, Teijink JA, Prins MH. Supervised exercise therapy versus non-supervised exercise therapy for intermittent claudication. *Cochrane Database Syst Rev.* 2006:CD005263.
5. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *Eur J Vasc Endovasc Surg.* 2007; 33 Suppl 1:S1-75.
6. Hirsch AT, Haskal ZJ, Hertzner NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): executive summary a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease) endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular

1
2
3 Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation.

4
5 Journal of the American College of Cardiology. 2006; 47:1239-312.

6
7 7. Regensteiner JG, Steiner JF, Panzer RJ, Hiatt WR. Evaluation of walking
8
9 impairment by questionnaire in patients with peripheral arterial disease. *J Vasc Med*
10
11 *Biol.* 1990; 2:142-52.

12
13 8. McDermott MM, Liu K, Guralnik JM, Martin GJ, Criqui MH, Greenland P.
14
15 Measurement of walking endurance and walking velocity with questionnaire:
16
17 validation of the walking impairment questionnaire in men and women with peripheral
18
19 arterial disease. *J Vasc Surg.* 1998; 28:1072-81.

20
21 9. Nicolai SP, Kruidenier LM, Rouwet EV, Graffius K, Prins MH, Teijink JA. The
22
23 walking impairment questionnaire: an effective tool to assess the effect of treatment
24
25 in patients with intermittent claudication. *J Vasc Surg.* 2009; 50:89-94.

26
27 10. Chong PF, Garratt AM, Golledge J, Greenhalgh RM, Davies AH. The
28
29 intermittent claudication questionnaire: a patient-assessed condition-specific health
30
31 outcome measure. *J Vasc Surg.* 2002; 36:764-71; discussion 863-4.

32
33 11. Guidon M, McGee H. Exercise-based interventions and health-related quality
34
35 of life in intermittent claudication: a 20-year (1989-2008) review. *Eur J Cardiovasc*
36
37 *Prev Rehabil.* 2010; 17:140-54.

38
39 12. Regensteiner JG. Exercise rehabilitation for the patient with intermittent
40
41 claudication: a highly effective yet underutilized treatment. *Curr Drug Targets*
42
43 *Cardiovasc Haematol Disord.* 2004; 4:233-9.

44
45 13. Muller-Buhl U, Engeser P, Klimm HD, Wiesemann A. Quality of life and
46
47 objective disease criteria in patients with intermittent claudication in general practice.
48
49 *Fam Pract.* 2003; 20:36-40.

50
51 14. Myers SA, Johanning JM, Stergiou N, Lynch TG, Longo GM, Pipinos, II.
52
53 Claudication distances and the Walking Impairment Questionnaire best describe the
54
55

1
2
3 ambulatory limitations in patients with symptomatic peripheral arterial disease. J
4 Vasc Surg. 2008; 47:550-5.

5
6
7 15. Regensteiner JG, Hiatt WR, Coll JR, Criqui MH, Treat-Jacobson D,
8 McDermott MM, et al. The impact of peripheral arterial disease on health-related
9 quality of life in the Peripheral Arterial Disease Awareness, Risk, and Treatment:
10 New Resources for Survival (PARTNERS) Program. Vasc Med. 2008; 13:15-24.

11
12
13
14
15 16. McDermott MM, Guralnik JM, Greenland P, Pearce WH, Criqui MH, Liu K, et
16 al. Statin use and leg functioning in patients with and without lower-extremity
17 peripheral arterial disease. Circulation. 2003; 107:757-61.

18
19
20
21
22 17. Mohler ER, 3rd, Hiatt WR, Creager MA. Cholesterol reduction with
23 atorvastatin improves walking distance in patients with peripheral arterial disease.
24 Circulation. 2003; 108:1481-6.

25
26
27
28
29 18. Nicolai SP, Teijink JA, Prins MH. Multicenter randomized clinical trial of
30 supervised exercise therapy with or without feedback versus walking advice for
31 intermittent claudication. J Vasc Surg. 2010; 52:348-55.

32
33
34
35
36 19. Cheetham DR, Burgess L, Ellis M, Williams A, Greenhalgh RM, Davies AH.
37 Does supervised exercise offer adjuvant benefit over exercise advice alone for the
38 treatment of intermittent claudication? A randomised trial. Eur J Vasc Endovasc
39 Surg. 2004; 27:17-23.

40
41
42
43
44 20. Kakkos SK, Geroulakos G, Nicolaidis AN. Improvement of the walking ability
45 in intermittent claudication due to superficial femoral artery occlusion with supervised
46 exercise and pneumatic foot and calf compression: a randomised controlled trial. Eur
47 J Vasc Endovasc Surg. 2005; 30:164-75.

48
49
50
51
52 21. Spronk S, Bosch JL, Veen HF, den Hoed PT, Hunink MG. Intermittent
53 claudication: functional capacity and quality of life after exercise training or
54
55
56
57
58
59
60

1
2
3 percutaneous transluminal angioplasty--systematic review. Radiology. 2005;
4
5 235:833-42.

6
7 22. Boesch C, Myers J, Habersaat A, Ilarraza H, Kottman W, Dubach P.

8
9 Maintenance of exercise capacity and physical activity patterns 2 years after cardiac
10
11 rehabilitation. J Cardiopulm Rehabil. 2005; 25:14-21; quiz 2-3.
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For Peer Review

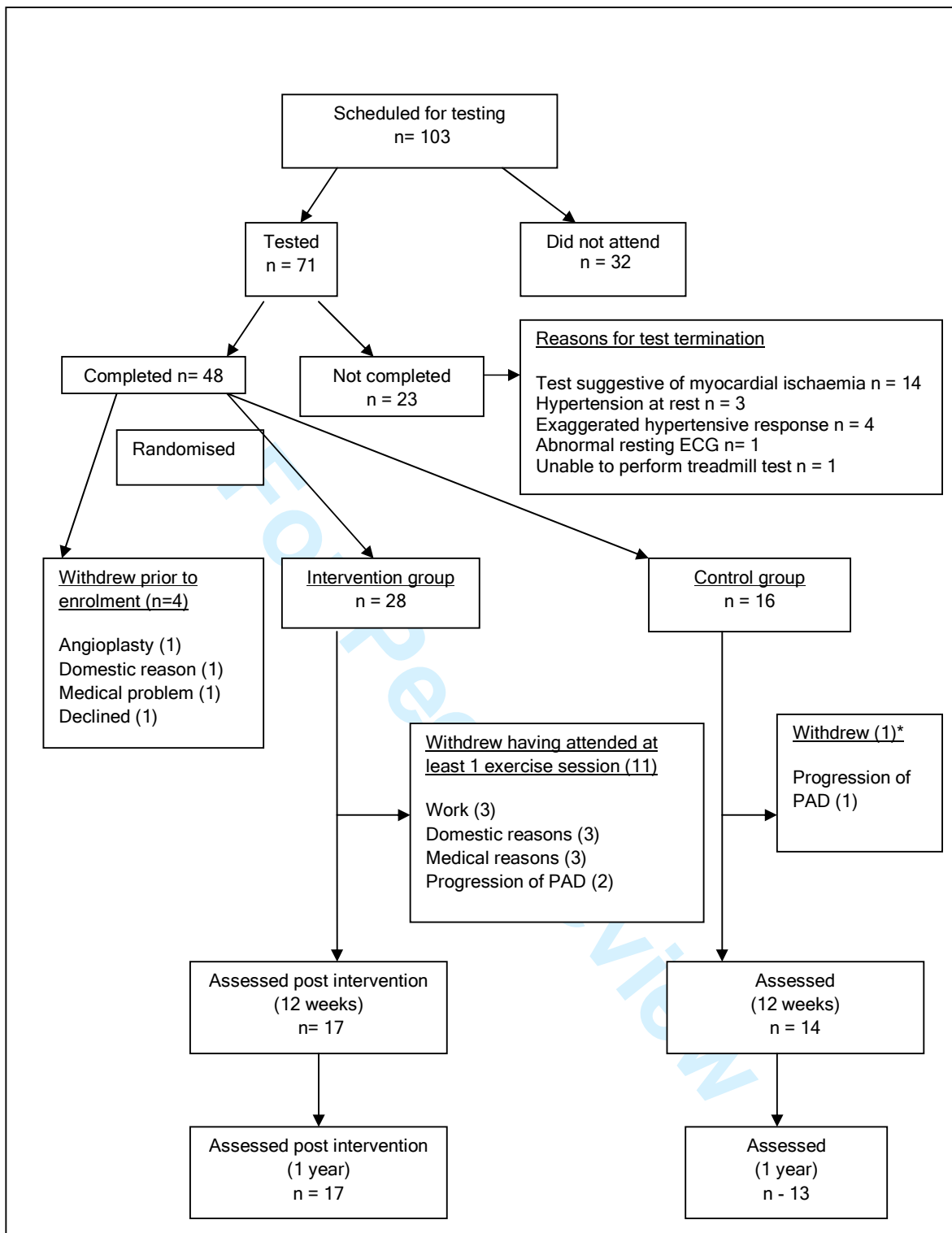


Figure 1. Exercise testing outcomes and participant flow through the study

Table 1. Baseline demographic and clinical characteristics

	Control Group (n = 16) mean (SD)	Exercise Group (n = 28) mean (SD)	p value
Demographic			
Age (yrs)	67.1(7.5)	67.0 (8.6)	.970
Male (%)	75	67.9	.617
Current smoker (%)	43.5	55.5	.632
Diabetes (%)	81.25	67.85	.325
PAD Duration (%)			
3-12 months	18.8	14.8	.947
13-36 months	31.3	25.9	
> 36 months	50	59.3	
Ankle/brachial index (ABI)			
ABI resting (R)	.76 (.20)	.78 (.23)	.769
ABI resting (L)	.70 (.20)	.74 (.19)	.564
ABI exercise (R)	.68 (.31)	.58 (.34)	.408
ABI exercise (L)	.52 (.23)	.60 (.60)	.418
Cardiovascular Risk Factors			
Triglycerides (mmol/L)	2.06 (2.48)	1.63 (.73)	.396
Total cholesterol (mmol/L)	4.25 (1.03)	4.37 (1.05)	.730
LDL cholesterol (mmol/L)	2.17 (.78)	2.33 (.77)	.520
HDL cholesterol (mmol/L)	1.22 (.20)	1.29 (.45)	.563
HbA1C (mmol/L)	6.01 (.92)	5.93 (.72)	.760
Hs CRP(mg/L) ^a	11.63 (23.93)	9.23 (19.09)	.722
Fasting blood glucose (mmol/L)	6.05 (1.30)	6.02 (2.21)	.964
Plasma Fibrinogen (g/L)	4.02 (.81)	3.88 (.79)	.590
Waist circumference (cms)	102 (7.03)	102.56 (12.17)	.869
BMI (kg/m ²)	29.74 (2.76)	29.59 (4.73)	.896
Systolic blood pressure (mmHg)	150.3 (21.6)	136.6 (17.2)	.027
Diastolic blood pressure (mmHg)	75.2 (7.0)	72.6 (7.5)	.276

^a Exercise n=26

LDL cholesterol, Low-density lipoprotein cholesterol; HDL cholesterol, High-density lipoprotein cholesterol; HbA1C, Glycosylated haemoglobin; HsCRP, High-sensitivity C-reactive protein; BMI, Body Mass Index

Table 2. Quality of Life and Functional Capacity Measures

Outcome Measures	Control Group (n=12)			Exercise Group (n= 17)		
	Mean (SD)			Mean (SD)		
	Baseline	12 weeks	One year	Baseline	12 weeks	One year
ICQ	33.83 (18.04)	30.36 (14.98)	38.54 (24.26)	34.11 (19.81)	24.37 (17.94)	27.94 (19.83)
WIQ						
Stair- climbing	64.24 (38.62)	48.61 (33.35)	54.86 (36.23)	45.88 (32.59)	54.43 (33.72)	51.22 (31.52)
Distance	44.23 (29.59)	40.17 (32.77)	38.47 (27.70)	31.25 (22.12)	45.54 (28.92)	38.85 (30.69)
Speed	39.04 (24.39)	41.49 (28.63)	33.42 (18.99)	37.33 (26.96)	45.01 (24.87)	40.15 (22.14)
SF-36						
Physical Functioning (PF)	37.74 (9.70)	38.46 (9.04)	36.51 (10.04)	36.11 (7.68)	39.88 (9.16)	39.33 (10.73)
Role Physical (RP)	38.28 (11.83)	40.12 (10.84)	39.92 (11.46)	43.17 (10.99)	44.32 (9.71)	43.17 (10.54)
Bodily Pain (BP)	43.76 (11.66)	41.52 (9.75)	39.97 (9.15)	44.94 (9.65)	45.24 (9.76)	46.06 (9.28)
General Health (GH)	43.64 (10.58)	44.16 (8.64)	42.76 (10.93)	44.92 (9.81)	44.10 (9.58)	41.63 (7.52)
PCS	38.81 (11.06)	38.19 (9.84)	37.53 (10.30)	38.79 (9.14)	40.77 (8.45)	40.75 (9.61)
Vitality (VT)	46.60 (12.00)	46.89 (9.72)	45.85 (10.40)	48.97 (9.50)	51.17 (8.74)	48.60 (8.96)
Social Functioning (SF)	46.85 (13.92)	49.12 (9.14)	43.67 (13.45)	47.85 (11.24)	49.79 (10.87)	43.38 (14.83)
Role Emotional (RE)	42.27 (12.79)	49.16 (14.40)	41.95 (14.87)	48.56 (11.32)	49.02 (9.67)	45.13 (13.50)
Mental Health (MH)	48.84 (9.49)	49.78 (8.86)	48.60 (7.35)	50.34 (9.44)	51.50 (8.97)	50.84 (8.20)
MCS	49.40 (8.65)	52.05 (9.22)	48.58 (10.25)	53.35 (9.79)	54.10 (9.10)	49.99 (10.95)

ICQ, Intermittent Claudication Questionnaire; WIQ, Walking Impairment Questionnaire; SF-36, Medical Outcomes Survey Short-Form 36; PCS, Physical Component Summary; MCS, Mental Component Summary

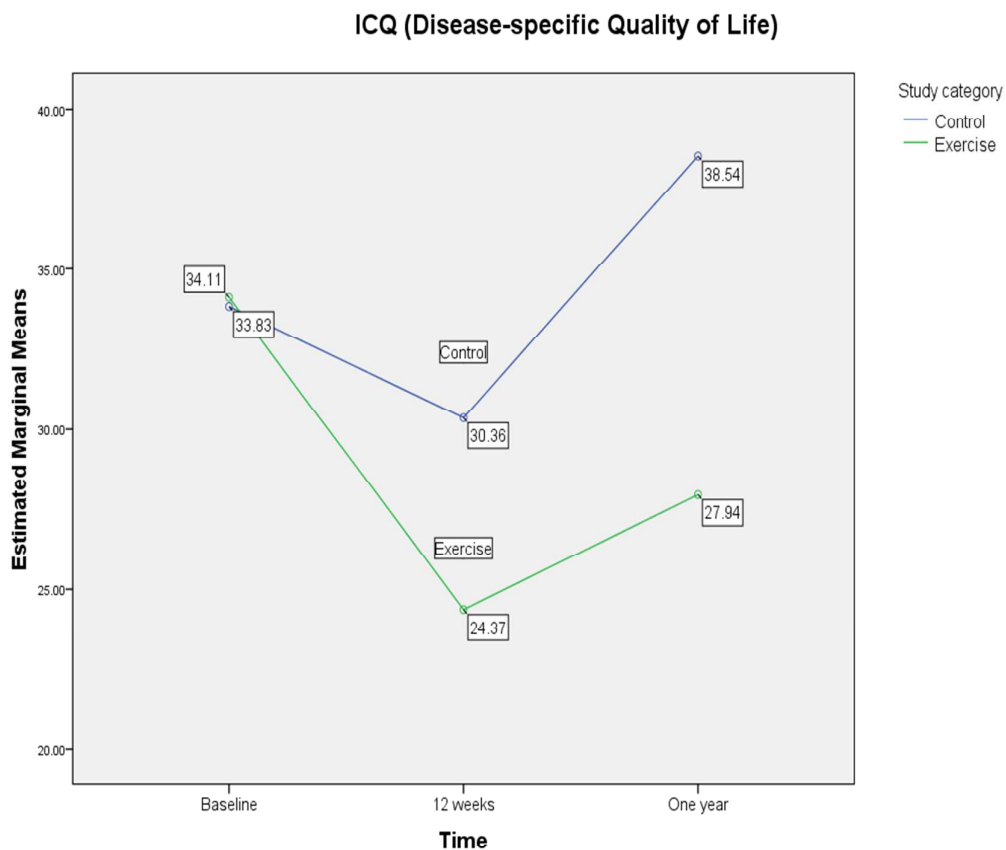


Figure 2. Intermittent Claudication Questionnaire mean scores at Baseline, 12 weeks and One year