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Marie Guidon
Royal College of Surgeons in Ireland

Hannah McGee
Royal College of Surgeons in Ireland

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Exercise-based Interventions and Health-related Quality of Life in Intermittent Claudication: a 20-year (1989-2008) review

Marie Guidon[a] and Hannah McGee[b]

[a]School of Physiotherapy, Royal College of Surgeons in Ireland, Dublin 2, Ireland

[b]Division of Population Health Sciences (Psychology), Royal College of Surgeons in Ireland, Dublin 2, Ireland

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Corresponding author/requests for reprints:

Professor Marie Guidon

School of Physiotherapy, Royal College of Surgeons in Ireland, Dublin 2, Ireland

Tel: 00 353 1 402 2396

Fax: 00 353 1 402 2471

E-mail: mguidon@rcsi.ie

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Abstract

Background: Peripheral arterial disease (PAD) is a chronic, progressive disease with significant cardiovascular risk. Symptoms include pain in leg muscles on walking, relieved by rest (intermittent claudication). Treatment aims to maintain or improve quality of life (QoL) by minimising ischaemic symptoms and preventing progression to vascular occlusion. Management strategies include exercise-based interventions.

Methods: Research from 1989-2008 was systematically reviewed to identify the QoL impact of exercise-based interventions in patients with intermittent claudication.

Results: Twenty-three studies were identified. Five were randomised controlled trials. Studies were summarised in terms of exercise interventions, QoL measures used and QoL findings. The majority used a generic QoL instrument; most commonly the Short Form Health Survey (SF-36). Eleven studies reported beneficial effects on the SF-36 Physical Functioning scale. Some also reported positive effects on the scales of Bodily Pain, Role-Physical, Vitality, General Health and the Physical Component Score. In seven studies, a disease-specific measure was used. In six of these, both generic and disease-specific questionnaires were used. Disease-specific measures demonstrated greater improvements across a range of QoL domains.

Conclusions: Greater use of disease-specific measures and an extended follow-up period may enable a more definitive picture to emerge regarding effects of exercise on QoL in intermittent claudication.

Word Count: 200

Keywords: intermittent claudication; peripheral arterial disease, exercise; quality of life

Introduction

Peripheral arterial disease (PAD) results in reduced blood flow to the extremities causing pain on exercise (intermittent claudication [IC]) which is relieved by rest. As IC is a chronic, progressive disease with significant cardiovascular risk, it has a considerable impact on both functional status and quality of life (QoL) [1]. Factors impacting on the QoL of patients with PAD including fatigue, inactivity, social role limitations and depression, result in lower QoL for PAD patients than anticipated based on clinical status and disease severity [2].

PAD exercise programmes have demonstrated significant increases in walking distances [3]. The effect of this increase on QoL is unclear [4-6]. A 2006 Cochrane review of supervised versus non-supervised exercise therapy [4] concluded that although supervised exercise resulted in significantly increased walking distance, the relevance of this for QoL required additional research. A subsequent Cochrane review of exercise and IC concluded that the QoL results reported in six studies were variable and depended on the comparisons made [3].

The purpose of this paper was to review all exercise-based interventions which assessed QoL of patients with IC as either a primary or secondary end-point. This included a broader range of studies than in the previous Cochrane reviews i.e. all exercise (not just walking) studies, non-exercise control groups and non-randomised studies.

Methods

The review involved systematic searches in the 20-year period 1989 to 2008 of the following databases: PubMed, PsycINFO, CINAHL and Cochrane Database of Systematic Reviews. The search terms used were 'intermittent claudication', 'peripheral arterial disease', 'peripheral vascular disease', 'quality of life', 'exercise', 'walking', 'physical activity' and 'rehabilitation'. All terms were used as text words (i.e. words appearing in the title, abstract, key words and as subject headings). Searches were limited to studies published in English. Reference lists of retrieved articles were hand-searched for additional references. Papers were included if the study was designed as a clinical trial of an exercise-based intervention and QoL was specifically stated to be a primary or secondary outcome measure.

Results

Following elimination of duplicates, searches yielded 356 results. Of these, 24 journal articles met defined selection criteria. Authors confirmed that two publications reported on the same group of patients [7, 8]. Therefore the final number of studies was 23, of which five were randomised controlled trials [7-12] (see Table 1).

Table 1 here

There was wide variety in the exercise intervention employed. Most studies used treadmill walking as the primary mode of exercise training [9, 11-22]. The most commonly reported duration of supervised exercise was twelve weeks [9, 12, 15, 17-21, 23-25] (Table 1). A range of follow-up measurement times were reported: two studies recording findings at six weeks [14, 26], eleven at twelve weeks [9, 12, 18-21, 23, 25, 27-29], twelve at six months [7, 8, 11-14, 16, 18, 19, 21, 22, 24, 28] and five at one year [10, 13, 14, 28, 30] (Table 1).

Generic QoL Measures

The SF-36 questionnaire (36 items in eight scales and two summary measures) is the recommended generic QoL measurement instrument in PAD [31]. It was the most frequently used generic QoL measure (16 studies) [7-9, 11, 13, 14, 16-19, 21, 22, 24, 26-28, 30], with two studies using the SF- 20 [12, 20] and two assessing general health status and global QoL using a numeric rating scale [15, 23]. One study used the EQ-5D [13], a 3-level, 5-dimensional instrument and one used the Profil der Lebensqualitat Chronisch Kranker (PLC) questionnaire [25] (Table 1). The 40-item PLC, validated in

German, measures six dimensions of health. One study used several generic QoL questionnaires (Hospital Anxiety and Depression Scale, Mood Adjective Check List, General Health Rating Index- Current Health, Global indices: Quality of Life and Physical Condition, Life Satisfaction Scale, Sickness Impact Profile) [10]. Six studies used both a generic and a disease-specific questionnaire [10, 14, 15, 21, 23, 28] with one study using only a disease-specific questionnaire [29].

Disease-Specific QoL Measures

Of the seven studies that used disease-specific measures [10, 14, 15, 21, 23, 28, 29] (Table 1), the Peripheral Arterial Occlusive Disease 86 (PAVK-86) questionnaire was used in three [15, 21, 23] . The PAVK-86, an 86-item questionnaire validated in German, covers seven QoL dimensions [32]. The Intermittent Claudication questionnaire, a 16-item measure with a single health dimension score [33], was used in 2 studies [14, 28]. One study [29] used the VascuQoL- a five domain, 25-item questionnaire developed for patients with a wide range of chronic lower limb ischaemia [34]. One study [10] used the Sickness Impact Profile - Intermittent Claudication scale (a twelve-item IC-specific scale [35]) and a study-specific Symptoms and Complaints Scale .

Generic Assessment of QoL following Participation in Supervised Exercise Programmes

SF-36: Eleven of 16 studies [8, 9, 13, 16, 17, 19, 21, 22, 24, 26, 28] reported an improvement in SF-36 Physical Functioning following participation in supervised exercise. Improvements in Bodily Pain (6 studies) [9, 16, 17, 19, 21, 22], Role-

Physical (5 studies) [9, 17, 21, 24, 26], Physical Component Score (3 studies) [7, 17, 19] and Vitality and General Health (one study) [9] were also reported.

SF- 20: In the 2 studies using the SF-20 , there were improvements in the Physical Functioning domain following supervised treadmill exercise [12, 20] with an increase in the Well-being domain in the strength training group study only [12].

Profil der Lebensqualitat Chronisch Kranker (PLC): Four dimensions (Physical Capacity, Psychological Functioning, Positive Mood, Social Functioning) improved and Negative Mood decreased after completion of a twelve-week exercise programme [25] .

All SF-36, SF-20 and PLC changes were associated with increases in walking ability.

Sickness Impact Profile (SIP): A significant improvement was noted only in the Recreation and Pastimes category (of eleven categories assessed) at one-year follow-up assessment [10].

Disease-specific Assessment of QoL following Participation in Supervised Exercise Programmes

Disease-specific questionnaires demonstrated improvements across a range of domains. However, the diversity of questionnaires used, the variation in exercise regimes and inclusion criteria limit robust interpretation of study findings. Three studies used both the PAVK-86 and a generic QoL measure [15, 21, 23]. In one, both the SF-36 and

PAVK-86 detected improvements in pain and functional status but the PAVK-86 also detected improvement in the anxiety domain [21]. In the second study, improvements in all PAVK-86 domains (except general complaints) were reported. However, no changes were noted with the global generic measure [23]. In the third study, the Pain and Functional Status domains of the PAVK- 86 significantly correlated with walking distance but the global generic measure showed no correlation.

In the two studies using both the ICQ and SF-36 measures, improvements in ICQ scores were reported with no change in SF-36 domains in one study [14] and a borderline increase in physical functioning domain in the other [28]. In a study administering a battery of tests, only a change in the SIP Recreation and Pastimes category and a global rating for physical condition were noted [10], with no change in the SIP_{IC} scale.

QoL improvements were associated with increases in walking distances in all studies except one [10].

QoL Assessment following Participation in Unsupervised Exercise Programmes

Varying definitions of unsupervised home exercise programmes confounded the interpretation of QoL findings. Unsupervised exercise programmes comprised differing levels of support, use of specific patient instructions, diaries and logbooks, follow-up phone calls and weekly lectures. None of the seven studies [18-21, 27-29] of unsupervised exercise had a control group. Unsupervised exercise had a minimal effect on QoL as measured by SF-36. Walking distances were unchanged or demonstrated smaller improvements than with supervised exercise. However some QoL improvement was noted with disease-specific measures. In the two studies using the SF-36 and a disease-specific questionnaire, improvement in ICQ score with no change in any SF-36

domains was noted [28] and an increase in Pain and Anxiety in the PAVK–86 but no change in the SF-36 Bodily Pain domain [21]. Changes in all VascuQol domains (except social functioning) were also noted [29].

Discussion

The majority of changes were reported from scores obtained immediately following completion of an exercise programme. However, the time between initial and subsequent assessment is an important factor. It has been postulated that improvements in QoL and mental health may lag behind improvements in ambulatory function [9, 11] and this may explain the limited change in SF-36 Role- Emotional and Mental Health domains. Patients in exercise programmes may also underestimate QoL because improvement occurs slowly and less noticeably than with interventions, such as revascularisation [13]. The prevalence of concomitant chronic illnesses such as diabetes, hypertension and coronary artery disease is very common in PAD and can impact on QoL [36, 37]. Of the 23 studies reviewed, only seven [7-12, 24, 26] included a non-exercise control group. Two of these were non-randomised [24, 26]. This also confounds the interpretation of QoL assessment findings.

In five of the six studies reporting generic and disease-specific QoL findings, generic measures did detect additional QoL changes. Disease-specific measures were however more responsive to QoL improvements and detected changes across a range of domains following both supervised and home-based exercise. However a variety of instruments was used. Although the VascuQoL instrument has been recommended [38], it has not been evaluated against the ICQ for QoL effects of exercise interventions. The PAVK-

86 takes 20 minutes to complete and may prove too time-consuming for many practical applications.

The findings of studies included in this review support the positive impact of exercise on physically-related components of QoL for IC. QoL improvements were associated with gains in exercise performance evidenced by increases in claudication times and distances which were greater following supervised than unsupervised exercise. These improvements were maintained in those patients who continued to exercise on a regular basis following discontinuation of the formal exercise programme [17, 28]. Greater improvements in exercise performance and QOL following unsupervised exercise programmes correlated with self-reported exercise adherence [29].

Social support may be a significant contributor to QoL in patients with IC. The peer support of supervised exercise participation may prevent deterioration in QoL associated with conservative therapy [24].

A more ambivalent picture emerged regarding effects on the more psychological dimensions assessed. Impairment in these aspects has been established in IC patients [23, 39]. Overall however, the capacity to draw firm conclusions was severely hampered by the plethora of instruments used, and timeframes assessed. PAD and IC are increasing in prevalence and will need intensive interventions – both pharmacological and exercise based – to minimise their personal and societal impact. The role of exercise in the prevention and progression of vascular disease has been emphasised [40]. Better use of QOL instruments is needed to document differential benefits of particular programmes; evidence is increasingly needed to justify programme funding. As in other areas of cardiovascular assessment, a programme of psychometric evaluation of instruments is needed to inform the international clinical

and research community about the best instruments to use [41, 42]. Thus standardised evaluation and use of disease-specific QoL measures, with longer and more comparable follow-up periods may enable a more definitive picture to emerge regarding the effects of exercise on QoL and the disease-specific instrument of choice.

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Table 1: Exercise intervention studies for patients with intermittent claudication (1989-2008): summary of studies assessing quality of life

Study	No of participants[a]	Exercise Intervention	Time of Outcome Measurement	ICD/ACD changes following exercise (metres)	QoL measure	QoL findings	Additional Comments
Spronk 2008 [16]	Exercise (75) Endovascular revascularisation (76)	Supervised treadmill walking 30 minutes x 2/week x 24 weeks	Baseline, 6 months, 1 year	ICD Post exercise mean score improvement (6 months): 899 (743, 1054) (1 year): 943 (786, 1099) ACD Post exercise mean score improvement (6 months): 1138 (1006, 1270) (1 year): 1034 (896, 1170)	EQ-5D *Rating scale* SF-36 *Physical Functioning* domain only	Mean score improvement in 6 months (0.09) and 12 months (0.07) EQ5D, *rating scale* and SF-36 *Physical Functioning* in both groups. Difference between groups not statistically significant. Increase in EQ-5D *rating scale* and SF-36 *Physical Functioning* in exercise group from 6 to 12 months. Non-significant decrease in all QoL measures from 6 to 12 months in revascularisaton group	Prospective randomised clinical trial Postulated that exercise group may have underestimated QoL initially as improvements occur slowly with exercise No control group 11 patients in exercise group underwent surgical intervention or revascularisation. Study designed to demonstrate clinically relevant differences rather than QOL Patients excluded on anatomical basis who may have been good candidates for exercise Compliance: N/A
Roberts *et al* 2008 [31]	Exercise (47)	Unsupervised home-based walking exercise programme supported by weekly telephone advice/exercise diaries 1 hour walking/day x 12 weeks	Baseline and 12 weeks	ICD N/A ACD Pre: 126 Post 222 (p<0.001) 76% increase	VascuQoL (disease-specific, 5 domains) (A*ctivities, Symptoms, Pain, Emotional Effects and Social Functioning*)	Scores increased significantly (p<0.0001) in all domains except *Social Functioning* % increase Total score 22.4% A*ctivities* 26.3% *Symptoms* 23% *Pain* 41.6% *Emotional Effects* 20%	No control group and remote type of supervision VascuQoL is not entirely specific to claudicant patients. It can be used across a range of chronic lower limb ischaemia Median compliance 5 hours/week Exercise compliance correlated with % change in max walk distance and total VascuQol score
Jeger *et al* 2008 [27]	Exercise (99) Fontaine Stage 1 (27)	Supervised cardiac rehabilitation programme- aerobic, strength	Baseline and 12 weeks	ICD/ACD N/A % target workload on cycle ergometer	PLC (generic, 6 dimensions) (*Physical Capacity,*	Four dimensions (*Physical Capacity, Psychological Functioning, Positive Mood, Social Functioning)* improved. *Negative Mood* decreased. Tendency towards decrease in *Social Well-being*	Population of coronary artery disease patients with PAD participating in a formal cardiac rehabilitation programme.

ICD, Initial claudication distance; ACD, Absolute claudication distance; EQ-5D,EuroQoL-5D; SF-36,Medical Outcomes Study 36-Item Short Form Health Survey; Fontaine Stage I (asymptomatic): Fontaine Stage II (intermittent claudication): Fontaine Stage III (rest pain); PLC, Profil der Lebensqualitat Chronisch Kranker questionnaire; PAVK-86, Peripheral Arterial Occlusive Disease 86;VascuQoL, Vascular Quality of Life Survey; ICQ, Intermittent Claudication Questionnaire; CCQ, Charing Cross Claudication Questionnaire; Sickness Impact Profile$_{IC,}$ Sickness Impact Profile Intermittent Claudication Scale

[a] Reported as presented in paper (in some cases this is the number recruited, in some the number completing the study)

Table 1: Exercise intervention studies for patients with intermittent claudication (1989-2008): summary of studies assessing quality of life

Study	No of participants[a]	Exercise Intervention	Time of Outcome Measurement	ICD/ACD changes following exercise (metres)	QoL measure	QoL findings	Additional Comments
	Fontaine Stage II (69) Fontaine Stage III (3) Total 1508 patients	and coordination training 12 weeks Weeks 1-4: Mixed physical activities 1-2 hours daily Weeks 5-12: Mixed physical activities 1-2 hours x 2 days/week		stress test Pre: 69% +/-17 Post: 82% +/-25	*Psychological Functioning, Positive Mood, Negative Mood, Social Functioning, Social Well-being*). Validated for German speaking population	% increase *Physical Capacity* 25% *Psychological Functioning* 15% *Positive Mood* 12.5% *Negative Mood* 17% decrease *Social Functioning* 15%	Patients with PAD had higher dropout rate (18% discontinuation of exercise, 18 out of 99 pts). No control group
Keo *et al* 2008 [17]	Exercise (36)	Supervised walking (floor and treadmill), tip toe standing, cycle ergometer. 12 weeks Weeks 1-6: 1 hour exercise x 2/week Weeks 7-12: 1 hour exercise x 1/week	Baseline, Follow - up at 39+/- 20 months post exercise programme	ICD* Pre: 114 +/-100 12 weeks: 235 +/-247 F/Up (39+/-20 months): 197 +/-254 ACD* Pre: 297 +/-273 12 weeks: 474 +/-359 F/Up (39+/-20 months): 390 +/-324 *mean (SD)	PAVK-86 (disease-specific, 7 domains). *(Pain, General Complaints, Functional Status, Anxiety, Mood, Social Life and Treatment Expectations*) Validated for German speaking population General health status and global QoL assessed using numeric rating scale	*Pain* and *Functional Status* correlated with walking distance. *General Complaints, Anxiety, Mood, Social Life* and *Treatment Expectations* did not show significant correlation with walking capacity Global QoL and general health status did not show significant correlation with walking capacity No specific data provided	No control group Non-randomised Recruited retrospectively following programme completion Compliance N/A
Lee *et al* 2007 [26]	Control (37)		Baseline and 6 months following treatment	ICD* Pre exercise: 58.5 (39.2-112.7) Post exercise:	SF-36 Global index score and 8 QoL domains	Control Group Deterioration in 7 of 8 domains (except *Bodily Pain*) and SF-36 index with effect size > -0.5 for *Role-Emotional* and *Physical Functioning*.	Non- randomised trial Patients recruited sequentially and divided into those recruited before and after the

ICD, Initial claudication distance; ACD, Absolute claudication distance; EQ-5D,EuroQoL-5D; SF-36,Medical Outcomes Study 36-Item Short Form Health Survey; Fontaine Stage I (asymptomatic): Fontaine Stage II (intermittent claudication): Fontaine Stage III (rest pain); PLC, Profil der Lebensqualitat Chronisch Kranker questionnaire; PAVK-86, Peripheral Arterial Occlusive Disease 86;VascuQoL, Vascular Quality of Life Survey; ICQ, Intermittent Claudication Questionnaire; CCQ, Charing Cross Claudication Questionnaire; Sickness Impact Profile$_{IC,}$ Sickness Impact Profile Intermittent Claudication Scale

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				107.5 (52.5-153.8) ACD* Pre exercise: 117.6 (73.5-205.8) Post exercise: 300 (143.8-300) * median (IQR)		Exercise Group No significant changes in domains or index. Positive effect sizes for SF36 index and 2 domains (*Physical Functioning* and *Role- Physical*). Negative effect sizes for *Bodily Pain* and *General Health* *Physical Functioning** Pre: 45 (25-62.5) Post 50 (35 -67.5) *Role – Physical** Pre: 0 (0-75) Post: 25 (0-87.5) *SF 36 Index** Pre: 0.600 (0.570-0.645) Post: 0.630 (0.570-0.650) *Bodily pain** Pre: 52 (42-69) Post: 42 (31-52) *General health** Pre: 65 (52-72) Post: 60 (47-52.5) Intergroup *Vitality* significantly improved ($p<0.01$) following exercise compared with control group. Intergroup effect sizes >0.5 for SF-36 index and domains of *Physical Function, Role-Physical* and *Role-Emotional* * median (IQR)	establishment of a supervised exercise programme Compliance N/A
	Exercise (33)	Supervised Stepping, heel raise, single leg press, cycle, knee extension, elbow flexion 12 weeks 1 hour x 3/week					

ICD, Initial claudication distance; ACD, Absolute claudication distance; EQ-5D,EuroQoL-5D; SF-36,Medical Outcomes Study 36-Item Short Form Health Survey; Fontaine Stage I (asymptomatic): Fontaine Stage II (intermittent claudication): Fontaine Stage III (rest pain); PLC, Profil der Lebensqualitat Chronisch Kranker questionnaire; PAVK-86, Peripheral Arterial Occlusive Disease 86;VascuQoL, Vascular Quality of Life Survey; ICQ, Intermittent Claudication Questionnaire; CCQ, Charing Cross Claudication Questionnaire; Sickness Impact Profile$_{IC,}$ Sickness Impact Profile Intermittent Claudication Scale

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Table 1: Exercise intervention studies for patients with intermittent claudication (1989-2008): summary of studies assessing quality of life

Study	No of participants[a]	Exercise Intervention	Time of Outcome Measurement	ICD/ACD changes following exercise (metres)	QoL measure	QoL findings	Additional Comments
Serracino -Inglott *et al* 2007 [32]	165	Supervised exercise (Scottish Physiotherapy Amputee Research Group guidelines) 1/week for 12 weeks and follow-up x 1/month x 1 year	Baseline, 6 months and 1 year	ICD* Pre: 50 (6-128) Post 94 (24-409) ACD* Pre: 67 (17-196) Post 122 (43-409) * median (IQR)	SF-36 (no detail regarding domains measured)	QoL increased significantly (p<0.0001) from a median of 78 (range 55-110) to 99 (range 71-154) No detail provided regarding median score calculations	No control group Only reported on those who had completed programme
Imfeld *et al* 2006 [23]	Group 1 Exercise (18)	Supervised treadmill walking 1 hour x 3/week x 12 weeks	Baseline, 12 weeks and 24 weeks	ICD* Pre Group 1: 175 +/- 136 Group 2: 159 +/-97 Group 3: 159 +/-78	SF-36 (*General health* domain not reported) PAVK – 86 (5 domains assessed, excluded *mood* and *social life*)	SF 36 Within Groups *Bodily Pain* improved in Groups 1 and 2 but not for home training at 12 weeks *Physical Functioning* Significant increase in all 3 groups (group 1, p=0.029; group 2, p= 0.003; group 3, p=0.012) at 12 weeks, maintained at 24 weeks *Role- Physical* Limited by ceiling effect. Significant increase in Group 2 (p=0.025) at 12 weeks. Significant increase in Group 3 (p=0.046) at 24 weeks No changes in *Mental Health, Vitality, Social Function, Role - Emotional* in any group Between groups *Bodily pain* At 12 weeks improvement in Group 2 significantly better than Group 3	Non-randomised No control group All 3 groups showed similar improvements in *Physical Functioning (SF-36), Pain* and *Anxiety (PAVK).* No significant improvements or differences in other QoL domains between training modalities Compliance based on log entries and phone interviews Group 1 21% (4patients) missed < 6 sessions Group 2 36.8% (7 patients) missed < 6 sessions Group 3 23.8% (5 patients) missed >7 < 14 sessions 33.3% (7 patients) missed < 7 sessions
	Group 2 Exercise + clopidogrel (17)	Supervised treadmill walking 1 hour x 3/week x 12 weeks		ACD* Pre Group 1: 492 +/- 259 Group 2: 477 +/- 213 Group 3: 530 +/- 232			
	Group 3 Home based training (20)	Unsupervised (phone call x 1/week and logbook) Walking at least 1 hour/day x 12 weeks		ICD (% increase) Post Group 1: 164 Group 2: 201 Group 3: 44 ACD (% increase) Post Group 1: 83			

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				Group 2: 131 Group 3: 5 *mean (SD)		(p=0.018). At 24 weeks, Group 2 better than Groups 1 and 3, no difference between Groups 1 and 3 *Physical Functioning* Group 3 significantly lower (p=0.046) than Groups 1 and 2 (p=0.022) At 24 weeks no significant differences between 3 study groups <u>PAVK-86</u> <u>Within groups</u> *Pain and anxiety* Significant improvement in all 3 groups (p<0.02) at 12 weeks. *Functional status* Improvement at 12 weeks for Groups 1 and 3. Significant improvement at 24 weeks only in Group 2 (p=0.033) <u>Between groups</u> No significant differences in any of study phases.	
Kakkos *et al* 2005 [11]	Group 1 Unsupervised/ Exercise advice (9) Group 2 Exercise (12) Group 3	 Supervised treadmill walking 3/week x 6 months IPC (home)	Baseline, 6 weeks, 6 months, 1 year	<u>ICD*</u> Pre Group 1: 70 (22.5) Group 2: 60 (26.25) 6weeks Group 1:80 (45) Group 2: 80 (35) 6 months	SF-36 (all 8 domains and 2 component scores) ICQ (disease-specific)	<u>SF-36</u> Significant improvement in *General Health* in IPC group at 1 year <u>ICQ</u> ICQ scores at 6 months in IPC and supervised exercise groups reduced by 33% and 17% respectively (note: a higher score indicates poorer QoL) but significant in IPC group only (p=0.037). No change in unsupervised exercise	<u>Discontinued intervention</u> Exercise (6) IPC (2) <u>Analysed at 1 year</u> Unsupervised /control (8) Exercise (6) IPC (9) Patients with ACD < 50 metres or >300metres were excluded

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	Intermittent pneumatic foot and calf compression (IPC) (13)	Daily x 3 hours x 6 months		Group 1: 70 (35) Group 2: 70 (45) 12 months: Group 1: 80 (55) Group 2: 90 (50) <u>ACD*</u> Pre Group 1: 135 (87.5) Group 2: 145 (108.75) 6 weeks: Group 1: 130 (130) Group 2: 235 (142.5) 6 months: Group 1: 140 (60) Group 2: 220 (282.5) 12 months: Group 1: 135 (57.5) Group 2: 270 (700) *median (IQR)		group	Small numbers due to poor compliance in active groups Exercise compliance: Attendance at supervised exercise class ranged from 12.8 – 100% (median 60.3%)
Gardner *et al* 2005 [24]	Group 1 Low intensity (40% maximal exercise capacity) exercise (31)	Supervised treadmill walking 3 days/week x 6 months	Baseline and 6 months	<u>ICD*</u> Pre Group 1:163 (123) Group 2: 186 (143) <u>ACD*</u>	SF-36 (8 domains)	Significant improvement ($p<0.05$) in *Physical Functioning a*nd *Bodily Pain* after exercise, similar in both groups. Neither group had significant change in other health domains	No control group Compliance similar in both groups LI: 80% attendance (+/- 16%) HI: 74% attendance (+/-18%)

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Study	No of participants[a]	Exercise Intervention	Time of Outcome Measurement	ICD/ACD changes following exercise (metres)	QoL measure	QoL findings	Additional Comments
	Group 2 High intensity (80% maximal exercise capacity) exercise (33)			Pre Group 1: 418 (228) Group 2: 430 (222) ICD* Post Group 1: 341 (218) Group 2: 388 (236) ACD* Post Group 1: 674 (293) Group 2: 700 (281) *mean (SD)		*Physical Functioning** Group 1: 46 (19) pre; 58 (23) post (26% increase) Group 2: 49 (24) pre; 59 (21) post (20% increase) *Bodily Pain** Group 1: 48 (19) pre; 61 (24) post (27% increase) Group 2: 53 (19)pre; 64 (25) post (21% increase) *mean (SD)	
Collins *et al* 2005, 2003 [9,10]	Polestriding (27) Control (25)	Supervised Polestriding exercise 3 days/week x 24 weeks	Baseline and 6 months	ICD/ACD N/A Polestriding group Increase in endurance on treadmill test (minutes)*: Pre: 10.3 (+/4.1) Post 15.1 (+/-4.5) (47% increase) *mean (SD)	SF-36 *Physical Component (PCS)* and *Mental Component (MCS)* scores (2005) 8 individual domains (2003)	Significant change (p=0.03) in *Physical Component Score* for Polestriding group compared with control group. No change in *Mental Component Score* between groups. Effect size changes in *Physical Component Score* indicated a moderate - large improvement in Polestriding group (effect size= 0.70) and no change in control group (effect size = 0.04). Negligible effect size changes for *Mental Component Score* of Polestriding (effect size = 0.06) and control (effect size= 0.11) Significant Polestriding effect at 6 months on *Physical Functioning* scale only (p=0.003)	Compliance: 88% +/- 23% Control group seen biweekly for measurement of ankle/brachial index, weight, heart rate, blood pressure, physical activity record and drug compliance for first 3 months and monthly thereafter
Cheetham *et al* 2004 [30]	Group 1 Exercise advice alone (30) Group 2	Group 2 Supervised	Baseline, 3 months, 6 months, 9 months, 1 year	ICD N/A ACD* Pre:	SF-36 (8 domains) CCCQ (now ICQ)	SF 36 No significant improvement in any domains at 6 months. No significant differences in 7 of 8 domains over 12 month period. In	No control group All patients given verbal and written exercise advice Highly significant correlation between self- report compliance

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Study	No of participants[a]	Exercise Intervention	Time of Outcome Measurement	ICD/ACD changes following exercise (metres)	QoL measure	QoL findings	Additional Comments
	Exercise advice + weekly exercise + motivation class (29)	walking circuit, 7 x 2 minute exercise stations 1/week x 6 months		Group 1: 103 Group 2: 132 3 months: Group 1: 119 (19% increase) Group 2: 220 (67% increase) 6 months: Group 1: 174 (69% increase) Group 2: 302 (129% increase) * median	*Physical Functioning* domain, borderline significant improvement in exercise class group No specific data provided <u>CCCQ</u> Improvement in scores in both groups but significantly better improvement ($p<0.05$) in exercise group (43%) than advice group (16%) at 9 months	to walking advice and drop in CCCQ score (improved symptoms) and claiming to walk >3 times/week More than twice as many in exercise class claimed to be walking > 3 times/week compared to advice group
Gardner *et al* 2004 [18]	Group 1 Smokers (39) Group 2 Non-smokers (46)	Supervised treadmill walking 3/week x 6 months	Baseline and 6 months	<u>ICD*</u> Group 1 Pre: 160 (16) Post: 351(39) (119% increase) Group 2: Pre: 199 (21) Post: 393 (41) (97.5% increase) <u>ACD*</u> Group 1 Pre: 365 (32) Post: 665 (51) (82% increase) Group 2: Pre: 430 (31) Post: 684 (49) (59% increase) *mean (SEM)	SF-36 (8 domains)	Smokers had significantly lower ($p<0.5$) scores on *Bodily Pain, General Health, Mental Health* and *Vitality* than non-smokers at baseline. Both groups had significant ($p<0.5$) and similar improvement in *Physical Functioning* and *Bodily Pain* following exercise. None of the other health domains changed following exercise in either group. *Physical Functioning** Group 1: 48 (6) pre; 59 (6) post (22.9 % increase) Group 2: 51 (5) pre; 61(4) post (19.6 % increase) *Bodily Pain** Group 1: 49 (5) pre; 62 (7) post (26.5% increase) Group 2: 60 (4) pre; 69 (5) post	Smokers more limited by intermittent claudication at baseline No control group Compliance with exercise programme: approximately 75% in both groups. Smokers: 73% +/- 4% Non-smokers: 77 +/- 4%

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						(15% increase) *mean (SEM)	
Menard *et al* 2004 [19]	34 who completed exercise programme at least 12 months prior to study. At follow- up, defined as exercisers (15), sedentary (19)	Supervised treadmill walking, arm and leg ergometry, light free weight training, flexibility exercises 3/week x 12 weeks	Baseline and follow up at 20-80 months (mean 48.2 +/- 13.7 months)	<u>ICD/ACD</u> Specific values not provided but reported 121% increase in claudication pain time and 109% increase in maximum walking time at long-term follow-up in exercise group with values returned to baseline in sedentary group	SF-36 (8 domains and 2 component scores)	Those who were continuing to exercise at time of follow-up had significantly higher scores in *Physical Functioning, Role- Physical, Bodily Pain, Physical Component Score* *Physical Functioning** Exercise: 43.3 +/-8.2 Sedentary: 34.2 +/-7.8 *Role- Physical** Exercise: 41.2 +/-7.7 Sedentary: 32.8 +/-9.2 *BodilyPain** Exercise: 46.9 +/-8.8 Sedentary: 38.9 +/-7.1 *Physical Composite Score** Exercise: 43.5 +/-6.5 Sedentary: 34.0 +/-5.8 No differences between groups in *General Health, Vitality, Social Functioning, Role-Emotional, Mental Health* or *Mental Component* scores *mean (SD)	Follow-up of patients who had completed exercise programme No control group Those who continued to exercise (60 minutes or >/week) had significantly increased *Physical Functioning, Role-Physical , Bodily Pain and Physical Component Score c*ompared with sedentary group Exercise group had increased IC and AC times at 1 year
Tsai *et al* 2002 [12]	Exercise (32)	Supervised treadmill walking 3/week x 12 weeks	Baseline and 12 weeks	<u>ICD/ACD</u> NA <u>IC Time</u> Exercise group 88% increase	SF-36 (8 domains)	Exercise group: Significantly higher scores on 5 subscales (*Physical Functioning, Role –Physical, Bodily Pain, General Health, Vitality*) following exercise programme. Improvements in physical health component more	27 patients in exercise group and 26 patients in control group completed study Compliance: 82 +/-16% of sessions

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	Control (32)	Usual care control		Control group 10% increase <u>AC Time</u> Exercise group 36% increase Control group 6% increase		pronounced than mental health component. *Physical Functioning* (p<0.001)* Pre: 39.5 +/-0.1 Post: 58 +/-10.6 47% increase *Role Physical* (p<0.04)* Pre: 22.5 +/-30 Post 62.5 +/-31.7 178% increase *Bodily Pain* (p<0.03)* Pre: 64.8 +/-15.9 Post 81.5 +/-18.4 26% increase *General Health* (p<0.02)* Pre: 54 +/-13.4 Post: 64.8 +/-0.1 20% increase *Vitality*(p<0.02)* Pre: 54.5 +/- 15.2 Post: 70 +/-12.9 28% increase Correlation of *Physical Functioning* improvement with increased AC Time: r=0.66 Correlation of *Bodily Pain* improvement with increased AC Time: r=0.65 No changes in scores in Control group. *mean (SD)	22 patients (out of 27) attended at least 80% of sessions
Garten-mann 2002 [25]	Exercise (31)	Supervised walking, cycle ergometer <u>Weeks 1-6</u>: 1hour x 2/week <u>Weeks 7-12:</u>	Baseline and 12 weeks	<u>ICD*</u> Pre: 129 +/- 19 6 weeks: 230 +/-45 12 weeks: 364 +/-53 (182 +/- 44 increase from baseline)	PAVK-86 (disease-specific, 7 domains). *(Pain, General Complaints, Functional Status, Anxiety, Mood, Social Life and*	All dimensions (except subscale *General Complaints*) improved, largest effect sizes for *Pain* (0.56), *Mood* (0.45) and *Functional Status* (0.42) Significant correlations: ICD and anxiety r=0.46 ACD and mood r=0.45	Patients were unsuitable for catheter intervention (26) or unwilling to undergo invasive treatment (3) No control group Compliance: N/A

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		1hour/week		ACD* Pre: 311 +/- 28 6 weeks: 453 +/-60 12 weeks: 546 +/- 63 (76 +/-36 increase from baseline) *mean (SEM)	*Treatment Expectations*) General health status and global QoL assessed using numeric rating scale	Walking distance during training with pain r=0.53 No significant changes for global QoL and general health status scales	
Taft *et al* 2001 [13]	Control (89) Exercise (88) Invasive therapy (87)	 Supervised walking Months 1-6 3 x 30 minutes walking/week Months 7-12 2 x 30 minutes walking//week	Baseline and 1 year	Exercise Group ICD* N/A ACD* Pre: 258 +/-142 Post: 247 +/- 111 *mean (SD)	Sickness Impact Profile (omitted Communication Category) Life Satisfaction scale (LS) Global Indices: Quality of Life and Physical condition General Health Rating Index -, Current Health (GHRI-CH) Hospital Anxiety and Depression scale (HAD) Mood Adjective Check List (MACL) Sickness Impact Profile $_{IC}$ scale	Exercise group Significant improvement in SIP *Recreation and Pastimes* category ($p<0.05$). *Body Care and movement* category deteriorated ($p<0.01$) No significant changes in SIP *Emotional behaviour, Social interaction, Alertness behaviour or Psychosocial dimension* in any groups. Improvement in global rating for *physical condition* No significant difference in LS Global Indices, Health Rating Index, HAD, MACL Significant improvement in SIP_{IC} scale for invasive therapy group only ($p<0.05$)	Poor compliance in exercise group. Only 49% (43 out of 48) of patients completed 6 months of training Included pts with severe claudication: Ankle/brachial index < 0.6 Control group: general advice only

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					Symptoms and Complaints Scale (study-specific scale)		
Gardner *et al* 2001 [14]	Exercise (31)	Supervised treadmill walking 3 days/week x 6 months	Baseline and 6 months	ICD* Exercise Pre: 172 +/-26 Post: 402 +/- 56 (134% increase)	SF-36 (8 domains and 2 component scores)	*Physical Component and Mental Component* scores were similar between 2 groups and did not change. No analyses performed on subscales	Prospective randomised controlled trial 28 patients in exercise group and 24 patients in control group completed the study Mean compliance: 73% (+/- 28%) 19 (out of 28) pts attending at least 70%
	Control (30)	Usual care control		ACD* Exercise Pre: 396 +/-43 Post: 702 +/-57 (77% increase) *mean (SEM)			
Savage *et al* 2001 [20]	Group 1 Supervised exercise (11)	Group 1 Supervised exercise Supervised treadmill walking 3/week x 12 weeks supervised + 12 weeks home –based	Baseline, 12 weeks, 24 weeks	ICD* Group 1 Pre: 241.2 +/- 188.2 12 weeks: 456.9 +/-317.2 (90% increase) 6 months: 483.8 +/- 317.2 (101% increase from baseline)	SF-36 (8 domains)	No significant changes in any of the health domains in either group at 12 or 24 weeks. Responses of all domains were similar between groups	No control group Compliance N/A
	Group 2 Home-based exercise (10)	Group 2 Home-based exercise Walking x 3/week x 24		Group 2 Pre:182.8 +/-150.5 12 weeks: 225.8 +/- 150.5			

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		weeks and contacted once a month by phone		(24% increase) 6 months: 263.4 +/-155.9 (44% increase from baseline) <u>ACD*</u> <u>Group 1</u> Pre: 521.5 +/-263.4 12 weeks: 833.3 +/-376.3 (60% increase) 24 weeks: 741.9 +/- 365.6 (42% increase from baseline) <u>Group 2</u> Home based exercise Pre:532.2 +/-263.5 12 weeks: 736.5 +/- 290.3 (38% increase) 24 weeks: 715 +/- 394.4 (34% increase from baseline) *mean (SD)			
Walker *et al* 2000 [28]	<u>Group 1</u> Upper limb training (26) <u>Group 2</u> Lower limb training (26)	<u>Group 1</u> Supervised upper limb cycle ergometry <u>Group 2</u> Supervised lower	Baseline and 6 weeks	<u>ICD/ACD</u> Specific values not provided post training. ICD increased by 122% (Group 1) and by 93%	SF-36 (8 domains)	Significant improvement in *Physical Functioning* (upper limb training p=0.03; lower limb training p=0.04) and *Role – Physical* (upper limb training p=0.01; lower limb training p=0.02) Specific values not reported.	Randomised to upper limb and lower limb training groups. Additional untrained group recruited on ad hoc basis. Compliance: Upper limb group:98%

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		limb cycle ergometry 2/week x 6 weeks		(Group 2). ACD increased by 47% (Group 1) and by 50% (Group 2)		No significant changes in other domains.	attendance Lower limb group: 94% attendance
	Group 3 Untrained group (15)	Group 3 Lifestyle advice		No change in ICD/ACD in Group 3.		No significant changes in any of QoL domains in untrained group	
Patterson *et al* 1997 [21]	Group 1 Supervised exercise (27)	Group 1 Treadmill walking, arm and leg ergometry, cycling (supervised) 3 x 1 hours/week x 12 weeks	Baseline, 12 weeks and 6 months	ICD/ACD N/A IC Time Group 1 337% increase Group 2 131% increase AC Time Group 1 207% increase Group 2 70% increase	SF-36 (8 domains and 2 component scores)	*Physical Functioning, Bodily Pain* and *Physical Component* scores improved for both groups at 12 weeks. Improvement unchanged at 6 months for both groups Baseline scores for *Physical Functioning* and *General Health* were significantly depressed for both groups compared with patients without chronic conditions *Physical Functioning** Group 1 Pre: 43 +/-17.7; post :52 +/-22.2 21% increase 6 months: 56 +/-14.4 30% increase from baseline Group 2: Pre: 41 +/-20.8: 53 +/-24.4 29% increase 6 months: 54 +/-23.5 32% increase from baseline *Bodily Pain** Group 1: Pre: 53 +/-20.8; post: 64 +/- 23.6 21% increase 6 months: 62 +/-20.6 17% increase from baseline	No control group 47 patients completed 12 week programme, 46 available for testing at 12 weeks and 38 available at 6 months Compliance N/A
	Group 2 Home exercise (28)	Group 2 Unsupervised Weekly exercise instruction (walk minimum 3 /week x 20-40 minutes), lectures and review of exercise logs					

ICD, Initial claudication distance; ACD, Absolute claudication distance; EQ-5D,EuroQoL-5D; SF-36,Medical Outcomes Study 36-Item Short Form Health Survey; Fontaine Stage I (asymptomatic): Fontaine Stage II (intermittent claudication): Fontaine Stage III (rest pain); PLC, Profil der Lebensqualitat Chronisch Kranker questionnaire; PAVK-86, Peripheral Arterial Occlusive Disease 86;VascuQoL, Vascular Quality of Life Survey; ICQ, Intermittent Claudication Questionnaire; CCQ, Charing Cross Claudication Questionnaire; Sickness Impact Profile$_{IC,}$ Sickness Impact Profile Intermittent Claudication Scale

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Table 1: Exercise intervention studies for patients with intermittent claudication (1989-2008): summary of studies assessing quality of life

Study	No of participants[a]	Exercise Intervention	Time of Outcome Measurement	ICD/ACD changes following exercise (metres)	QoL measure	QoL findings	Additional Comments
						Group 2: Pre: 51 +/-20.6; post 61 +/-21.6 20% increase 6 months: 64 +/-19.3 26% increase from baseline *Physical Component Score** Group 1: Pre: 35 +/-7.1; post: 38 +/-8.3 9% increase 6 months: 39 +/-8.6 11% increase from baseline Group 2: 33 +/-9.4; post: 38 +/-12 15% increase 6 months: 38 +/-11.1 15% increase from baseline *mean (SD)	
Regen-steiner *et al* 1997 [22]	<u>Group 1</u> Supervised exercise (10) <u>Group 2</u> Home exercise (10)	<u>Group 1</u> Treadmill walking 3 x 50 minutes/week x 12 weeks <u>Group 2</u> Instructed to walk x 3/week, weekly telephone call and exercise log	Baseline and 12 weeks	<u>ICD/ACD</u> N/A <u>IC Time</u> Group 1 150% increase Group 2 26% increase <u>AC Time</u> Group 1 137% increase Group 2 5% increase	SF-20 (5 domains, *Physical* ,*Social* and *Role Functioning, Well-being* and *Overall Health*)	Significant improvement in *Physical Functioning* score ($p<0.05$) in supervised exercise group. No change in any score in home exercise group. Supervised exercise group score: *Physical Functioning** Pre: 52 +/-19; post: 72 +/-18 39% increase *mean (SD)	No control group Compliance 100% both groups Quantity of exercise similar in both groups but the intensity in home group may have been lower
Regen-steiner *et al* 1996 [15]	<u>Baseline</u> Treadmill (10) Strength (9) Control (10)	<u>Group 1</u> <u>Treadmill</u> Supervised treadmill walking 1 hour /day x	Baseline, 12 weeks, 24 weeks	<u>ICD/ACD</u> N/A <u>AC Time</u> Group 1	SF-20 (5 domains, *Physical* ,*Social* and *Role Functioning, Well-*	<u>Treadmill group:</u> Increase in *Physical Functioning* score ($p<0.05$) after 12 weeks and remained increased after 24 weeks of training. No change in other domains	Compliance N/A

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Study	No of participants[a]	Exercise Intervention	Time of Outcome Measurement	ICD/ACD changes following exercise (metres)	QoL measure	QoL findings	Additional Comments
		3/week x 24 weeks		12 weeks: 74% increase 24 weeks: additional 49% increase	*being* and *Overall Health*)	*Physical Functioning** Pre: 42 +/-22; 12 weeks: +24 (9 to39) weeks); 24 weeks: + 38 (9 to 47)	
	12 weeks Treadmill (10) Strength (9) Control (8)	Group 2 Strength Supervised strength training 1 hour/day x 3/week x 12 weeks followed by		Group 2 12 weeks: 30% increase 24 weeks: additional 54% increase		Weeks 12 and 24 = changes from baseline Strength group: Increase in *Well-being* scores after 12 weeks but no improvement in other scores	
	24 weeks Treadmill (9) Strength + treadmill (6) Control + Strength + Treadmill (6)	treadmill 1 hour /day x 3/week x 12 weeks Group 3 Control Control x 12 weeks followed by treadmill + strength training x 3/week x 12 weeks		Group 3 12 weeks: No change 24 weeks: 99% increase from 12 weeks		*Well-being** Pre: 81 (+/-10); 12 weeks: +9 (2 to 16); 24 weeks: +6 (-4 to 15) Weeks 12 and 24 = changes from baseline Control: No change in scores * mean (SD)	
Currie *et al* 1995 [29]	Vascular operation (34) Angioplasty (74) Exercise (78)	Unsupervised home exercise daily x 12 weeks based on exercise programme designed by physiotherapy	Baseline and 12 weeks	ICD/ACD N/A IC/AC Time N/A	SF-36 (8 domains)	Exercise group Little change in QoL, slight improvement in *Bodily Pain* score	Compliance N/A No control group

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Study	No of participants[a]	Exercise Intervention	Time of Outcome Measurement	ICD/ACD changes following exercise (metres)	QoL measure	QoL findings	Additional Comments
		department					

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