

# Supervised exercise therapy for intermittent claudication in a community-based setting is as effective as clinic-based

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**Objective:** This cohort study was conducted to determine the effect on walking distances of supervised exercise therapy provided in a community-based setting.

**Methods:** The study included all consecutive patients presenting at the vascular outpatient clinic with intermittent claudication, diagnosed by a resting ankle brachial index <0.9, who had no previous peripheral vascular intervention for peripheral arterial disease, no major amputation, and sufficient command of the Dutch language. The exclusion criterion was the inability to walk the baseline treadmill test for a minimum of 10 m. The intervention was a supervised exercise therapy in a community-based setting. A progressive treadmill test at baseline and at 1, 3, and 6 months of follow-up measured initial claudication distance and absolute claudication distance. Changes were calculated using the mean percentages of change.

**Results:** From January through October 2005, 93 consecutive patients with claudication were eligible. Overall, 37 patients discontinued the supervised exercise therapy program. Eleven stopped because of intercurrent diseases, whereas for 10, supervised exercise therapy did not lead to adequate improvement and they underwent a vascular intervention. Three patients quit the program, stating that they were satisfied with the regained walking distance and did not require further supervised exercise therapy. Ten patients were not motivated sufficiently to continue the program, and in three patients, a lack of adequate insurance coverage was the reason for dropping out. Data for 56 patients were used and showed a mean percentage increase in initial claudication distance of 187% after 3 months and 240% after 6 months. The mean percentage of the absolute claudication distance increased 142% after 3 months and 191% after 6 months.

**Conclusion:** Supervised exercise therapy in a community-based setting is a promising approach to providing conservative treatment for patients with intermittent claudication. (*J Vasc Surg* 2007;45:1192-6.)

Exercise therapy is highly efficacious for symptomatic relief in peripheral arterial disease (PAD),<sup>1</sup> but is usually prescribed simply in the form of advice to “go home and walk,” without supervision or follow-up.<sup>2,3</sup> Yet, there is no evidence to support the efficacy of this advice, and compliance is known to be low.<sup>2,4</sup> A recent *Cochrane Review* identified a significant improvement in walking distance in patients undergoing a supervised exercise therapy (SET) program compared with those involved in a nonsupervised program, with an increased difference in maximal walking distance of approximately 150 m after 3 months.<sup>5</sup> Factors such as fear of pain, inadequate knowledge of the underlying disease, and poor general condition, contribute to the difficulty of starting, sustaining, and maintaining exercise therapy.<sup>2</sup> SET entails adequate coaching to increase the maximal walking distance as well as coaching in the necessary changes in lifestyle, such as smoking cessation, weight control, and increase in overall exercise.

Based on this difference with SET, we explored its local implementation in a clinic-based setting; however, we had to stop the study for various reasons. The main restriction was the limited capacity of the in-hospital department of rehabilitation and physiotherapy. Three half-hour sessions weekly per patient proved overly time consuming in an already busy department; as a consequence, only a limited number of patients could be offered clinic-based SET. Furthermore, transport to and from the hospital, especially using public transportation, was costly for many patients as well as time consuming. The initial phase of two to three sessions weekly especially appeared to be problematic for most of the patients. Some were too tired upon arriving at the hospital to start training at all. Recorded drop-out rates of up to 43% in the literature convinced us not to pursue further clinic-based SET.<sup>6-8</sup>

This experience resulted in the development and implementation of a new community-based concept of SET: the Network for Exercise Therapy, Parkstad (NETP).<sup>9</sup> In this study, we hypothesized that the community-based concept of well-distributed physiotherapeutic practices offers SET closer to patients' homes and thus lowers transport costs and time. The NETP consists of 29 physiotherapeutic practices equally dispersed over the southeastern part of Limburg as well as the Department of Rehabilitation

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Competition of interest: none.

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and Physiotherapy in our hospital. By using 30 practices, we also addressed the capacity problem.

## PATIENTS AND METHODS

**Study population.** After implementation of the NETP, patients with PAD who were eligible for SET were referred to a nearby physiotherapist participating in the network. All consecutive patients with intermittent claudication, diagnosed at the vascular laboratory by a resting ankle brachial index (ABI)  $<0.9$ , who had no previous vascular intervention for PAD, no major amputation (below knee or more proximal), and sufficient command of the Dutch language, were considered for community-based SET. Patients were excluded from the analyses when the absolute claudication distance (ACD) at baseline was  $\leq 10$  m.

All patients received a platelet inhibitor and a statin as recommended in the Dutch guidelines for PAD from the Dutch Association of Surgery within the scope of secondary prevention in patients with PAD.<sup>10</sup> Patients were included from January to October 2005.

**Measurements.** At baseline, the ABI was measured at the vascular laboratory,<sup>11</sup> and vascular risk factors, defined as smoking, diabetes, hypertension, hypercholesterolemia, myocardial infarction, angina pectoris, and stroke, were registered by the vascular surgery nurse practitioner. For smoking, patients were categorized as current smokers, former smokers, and patients who never smoked. Diabetes was noted with a serum fasting glucose level  $\geq 6.0$  mmol/L or if glucose-lowering medication was prescribed, or both. Hypertension was noted for a blood pressure reading of  $\geq 140/90$  mm Hg or the use of antihypertensive medication, or both, and hypercholesterolemia was defined as a serum total cholesterol level of  $\geq 5.0$  mmol/L or the use of cholesterol-lowering medication.

Walking distances were measured by a progressive treadmill exercise test with a constant walking speed of 3.2 km/h beginning at 0% incline and increasing grade by 2% every 2 minutes.<sup>12</sup> The outcomes for walking distance were the initial claudication distance (ICD) and absolute claudication distance (ACD). ICD was defined as the moment at which the patient preferred to stop because of pain when no supervision was provided. ACD was defined as the maximal possible walking distance. ICD and ACD measurements were taken at baseline and at 1, 3, and 6 months.

**Exercise program.** SET was administered according to the guidelines of the Royal Dutch Society for Physiotherapy.<sup>13</sup> The mode of exercise was mainly treadmill walking up to maximal pain. Treadmill training was alternated with cardiovascular training and strength training. During the training sessions, walking patterns were corrected to improve the quality of walking. In general, patients received two to three sessions a week of approximately 30 minutes each in the initial phase, phasing down to once every 2 weeks. Patients were also encouraged to exercise daily by walking as much as possible to near-maximal pain.

Reimbursement from the tenth session through the remainder of the 12 months is financed by National Insurance of Health Care (AWBZ). Reimbursement for the

initial nine sessions depends on the patient's insurance policy.

**Statistical analyses.** The effects of community-based SET on ICD and ACD were measured as outcome measurements. These were expressed as the percentage increase in walking distance compared with baseline. For each patient, the increase in ACD and ICD was calculated, and the statistical significance of the increases was compared using the paired Student *t* test. Patients who underwent a vascular intervention during the SET period were excluded from further analyses. A value of  $P \leq .05$  was considered to be statistically significant. Statistical analyses were performed using SPSS 11.0 (SPSS Inc, Chicago, Ill).

We lacked a clinic-based SET control group because of the above-mentioned limiting factors; thus, we compared the increase in ICD and ACD of community-based SET participants and drop-out rates with published data for clinic-based SET from the *Cochrane Review*.<sup>5</sup> Because five of the seven studies in this review were limited to 6-month follow-up periods, we present and compare the results of 6 months of community-based SET.

## RESULTS

From January to October 2005, 93 consecutive patients with intermittent claudication were eligible for community-based SET and were included in the study cohort. During the 6-month study period, 37 patients (39.8%) discontinued the program:

- Ten experienced insufficient symptom relief and were unsatisfied with their claudication complaints and eventually underwent a vascular intervention. Six received a percutaneous transluminal angioplasty (PTA) in one or both iliac arteries, three received a PTA in the femoral artery, and one aortobifemoral bypass was performed.
- Three patients quit the program at 3, 4, and 5 months of SET, respectively, stating that they were satisfied with the regained walking distance and did not require further SET. Their 3-month results showed an increase between 110% and 170% in ACD.
- Ten patients were not motivated sufficiently to continue the program, and none of these sought medical attention for intermittent claudication elsewhere. In three patients, a lack of adequate insurance coverage was the reason for dropping out.
- Eleven quit the program because of emerging disease consisting of cardiovascular in 6, orthopedic in 2, and pulmonary, renal insufficiency, or ruptured abdominal aortic aneurysm in 1 patient each; and 1 patient died.

Data for the remaining 56 patients were used to analyze the change in walking distance during the 6-month study period. The baseline characteristics are summarized in Table I, and no statistical difference compared with the withdrawals was found in characteristics, with exception of the presence of hypercholesterolemia ( $P = .02$ ) and a prior neurovascular event ( $P = .02$ ). Two (3.6%) of the 56 patients had severe chronic heart failure. This cardiac co-

**Table I.** Demographic and clinical characteristics

Characteristic*	Analyzed population (n = 56)	Withdrawals (n = 37)	P
Age (y)	64.0 ± 10.4	64.7 ± 10.8	NS
Men	35 (62.5)	25 (67.6)	NS
BMI	26.3 ± 3.9	26.1 ± 3.9	NS
Current smokers	24 (42.9)	11 (29.7)	NS
Ever smoked	19 (33.9)	13 (35.1)	NS
Never smoked	13 (23.2)	10 (27.0)	NS
Hypertension	45 (80.4)	31 (83.8)	NS
Diabetes mellitus	23 (41.1)	13 (35.1)	NS
Hypercholesterolemia	49 (87.5)	26 (70.3)	.021
Coronary heart disease	16 (28.6)	9 (24.3)	NS
Stroke or TIA	4 (7.1)	9 (24.3)	.019
COPD	9 (16.1)	4 (10.8)	NS
ABI	0.73 ± 0.18	0.70 ± 0.14	NS

ABI, Ankle brachial index; NS, not significant; BMI, body mass index; COPD, chronic obstructive pulmonary disease; TIA, transient ischemic attack.

\*Continuous data are presented as mean ± standard deviation; categorical data are presented as number (%).

morbidity resulted in both patients being referred for SET to the Department of Physiotherapy and Rehabilitation in our hospital instead of to a community-based physiotherapist.

**Walking distances.** At baseline, the mean ICD was 395 m (range, 55 to 1600 m), with a mean ACD of 563 m (range, 60 to 1700 m). After 3 months of SET, these values improved to a mean ICD of 840 m (range, 180 to 2260 m) and a mean ACD of 1154 m (range, 290 to 3740 m). The means for both distances further increased after 6 months, with a mean ICD of 1005 m (range, 210 to 3810 m) and a mean ACD of 1312 m (range, 270 to 3980 m).

Translating these results to percentage increases, ICD increased 187% and ACD increased 142% after 3 months. After 6 months, the increase from the initial reading was 240% for ICD and 191% for ACD (Table II).

**Community-based vs clinic-based supervised exercise therapy.** Earlier studies have reported ACD results after SET compared with non-SET in patients with intermittent claudication<sup>4,6-8,14-16</sup>; however, in these studies, SET was provided in a clinic-based setting and sample sizes were small (range, 8 to 28 subjects). To compare these results with those of our community-based SET study, we summarized the reported ACD or absolute claudication time (ACT) of the clinic-based SET groups for each follow-up time point. For each trial, the percentage increase in ACD or ACT was calculated as summarized in Table III. After 3 months of clinic-based SET, increases between 35.3% and 137.0% were found, with a mean increase of 76%. After 6 months, an increase of 90% occurred (range, 42% to 159%).

## DISCUSSION

SET provided in a patient's home neighborhood in a community-based physiotherapeutic setting resulted in a highly statistically significant improvement in ACD after 3

and 6 months. These results support the results of the *Cochrane Review* comparing SET with non-SET, showing clinical relevant differences in improvement of ACD after SET.<sup>5</sup> Although a comparison of our favorable results with historical studies should be regarded with caution because of the variability in the prescribed exercise regimens and treadmill walking tests used, SET in a community-based setting seems to be at least as efficacious as the programs provided in a clinical setting.<sup>4,6-8,14-17</sup>

A difference between the clinic-based SET studies and our cohort may be because our patients received SET during the entire 6 months, whereas the exercise period in three of seven of the earlier studies lasted only 3 months.

Because we studied consecutive patients who were routinely referred to this new community-based supervised exercise program, we were able to document carefully the reasons for program discontinuation, as can also be done in routine clinical practice. In our case, 37 patients (39.8%) who were referred to the community-based SET did not continue the program for the full 6-month period. About a quarter of these patients stopped because of intercurrent diseases, whereas for another quarter, SET did not lead to adequate improvement and the patients had to undergo a vascular intervention. Our overall recorded withdrawal rate seems to be comparable with those of trials studying SET in a clinic-based setting, which reported drop-out rates of up to 43%.<sup>4,6,7</sup>

One of the possible pitfalls of community-based SET is the use of numerous physiotherapeutic practices (n = 30) and physiotherapists (n = 41), which results in a lower patient volume for each physiotherapist than occurs in a clinic-based setting. Consequently, this could lead to the inability to build experience. For this reason, we decided to implement a NETP and referred patients only to physiotherapists who participated in this network, instead of to any physiotherapist. Regular training sessions with all participating physiotherapists in the NETP ensures shared knowledge and experience. In addition, community-based SET creates a larger capacity compared with clinic-based SET, which means that a greater number of patients with intermittent claudication can be treated.

Percutaneous transluminal angioplasty (PTA) of iliac artery stenoses showed a weighted average 12-month patency rate of 78%, whereas PTA of the femoropopliteal artery stenosis showed a weighted average primary patency rate at 12 months of 61%.<sup>18</sup> Our 60% success rate, which might even be higher when successful drop-outs are included, is comparable with the 12-month results of the interventional therapy of intermittent claudication.

In the Netherlands, reimbursement of SET is currently not a main issue for most patients. The main difficulty of implementing SET seems to be convincing physicians that SET is superior to non-SET; this difficulty is compounded because the Dutch guidelines for general practitioners for PAD (2003)<sup>19</sup> and the guidelines for PAD of the Dutch Society of Surgery (2005)<sup>10</sup> advise starting non-SET instead of SET. This advice probably persists because a *Cochrane Review* that showed a significant difference in in-

**Table II.** Mean percentage increase in walking distances

Follow-up	Initial claudication distance		Absolute claudication distance	
	Mean % ± SD*	Range (%)	Mean % ± SD*	Range (%)
1 month	80.9 (402.0)	-53.9 to 579.0	73.8 (105.5)	-32.1 to 515.4
3 months	187.3 (187.1)	-25.5 to 772.7	142.2 (150.0)	-24.8 to 728.3
6 months	240.2 (284.2)	-39.8 to 1282.5	190.6 (229.5)	-22.9 to 1187.6

SD, Standard deviation.  
\*P < .0001 for all data.

**Table III.** Increase in absolute claudication distance or absolute claudication time in prior studies using supervised exercise therapy in patients with primary claudication

Trial	Patients (n)	Duration of supervised ET therapy (months)	Increase in ACD or ACT (%) (months)	
			3	6
Cheetham <sup>6</sup>	28	6	66.6	128.8
Degischer <sup>14</sup>	19	3	82.4	70.4
Kakkos <sup>7</sup>	8	6	to	51.7
Savage <sup>16</sup>	11	6	59.8	42.3
Nielsen <sup>8</sup>	25	3	35.3	to
Patterson <sup>4</sup>	25	3	75.5	158.9
Regensteiner <sup>15</sup>	10	3	137.0	to
Mean % increase overall			76.1	90.4

ET, Exercise therapy; ACD, absolute claudication distance; ACT, absolute claudication time.

crease between supervised and non-supervised exercise therapy in favor of the supervised group had not yet appeared when these guidelines were developed.<sup>5</sup> Currently, the prospective, multicenter Exercise Therapy for Peripheral Arterial Disease (EXITPAD) trial is being performed to study the effectiveness and cost-effectiveness of SET in a community-based setting compared with non-SET.

## CONCLUSION

Supervised exercise therapy in a community-based setting seems a promising approach to providing conservative treatment for patients with intermittent claudication. Once the reproducibility of our results has been established in other parts of the Netherlands, such as in the ongoing EXITPAD study or by initiatives elsewhere, the possibilities for implementing community-based SET must be explored.

## AUTHOR CONTRIBUTIONS

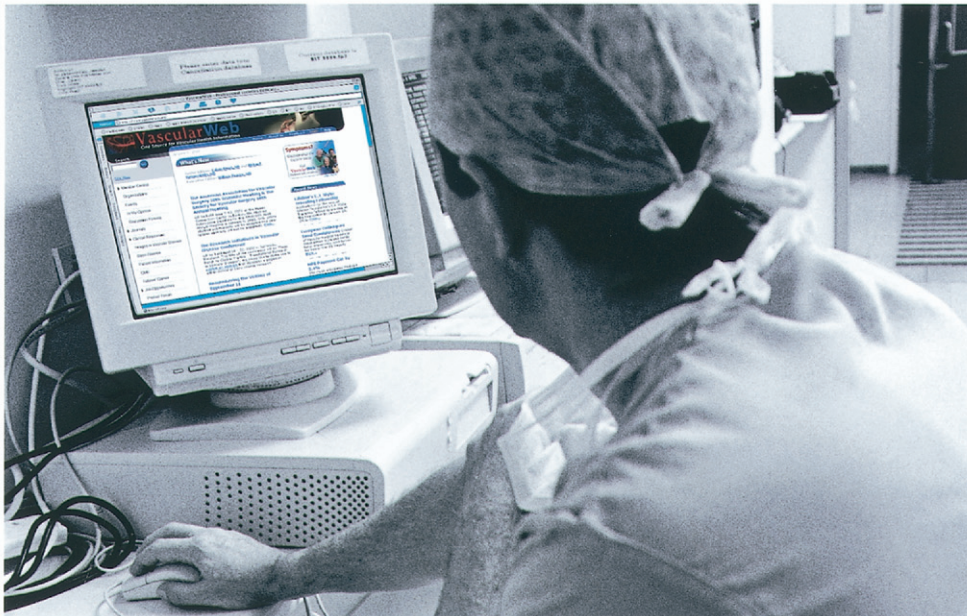
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