# Multicenter randomized clinical trial of supervised exercise therapy with or without feedback versus walking advice for intermittent claudication

**Saskia P. A. Nicolaï, MD, PhD,[a] Joep A. W. Teijink, MD, PhD,[b] and Martin H. Prins, MD, PhD,[c] on behalf of the Exercise Therapy in Peripheral Arterial Disease (EXITPAD) study group,*** *Heerlen, Eindhoven, and Maastricht, The Netherlands*

***Objective:*** **The initial treatment for intermittent claudication is supervised exercise therapy (SET). Owing to limited capacity and patient transports costs of clinic-based SET, a concept of SET provided by local physiotherapists was developed. We hypothesized that provision of daily feedback with an accelerometer in addition to SET would further increase walking distance.**

***Methods.*** **This multicenter randomized trial was set in vascular surgery outpatient clinics and included 304 patients with intermittent claudication. Patients were randomized to exercise therapy in the form of "go home and walk" advice (WA), SET, or SET with feedback. Local physiotherapists provided SET. The primary outcome measure was the change in absolute claudication distance. Secondary outcomes were the change in functional claudication distance and results on the Walking Impairment Questionnaire (WIQ) and Short-Form 36 (SF-36) Health Survey after 12 months.**

***Results:*** **In 11 centers, 102, 109, and 93 patients were included, respectively, in the WA, SET, and SET with feedback groups, and data for 83, 93, and 76, respectively, could be analyzed. The median (interquartile range) change in walking distance between 12 months and baseline in meters was 110 (0-300) in the WA group, 310 (145-995) in the SET group, and 360 (173-697) in the SET with feedback group ($P < .001$ WA vs SET). WIQ scores and relevant domains of the SF-36 improved statistically significantly in the SET groups.**

***Conclusions:*** **SET is more effective than WA in improving walking distance, WIQ scores, and quality of life for patients with intermittent claudication. Additional feedback with an accelerometer did not result in further improvement. SET programs should be made available for all patients with intermittent claudication. (J Vasc Surg 2010;52:348-55.)**

Atherosclerotic disease of the arteries of the lower extremities resulting in walking impairment, typically described as muscular leg pain during exercise and relieved by rest, is defined as intermittent claudication. According to national and international guidelines, the initial treatment of patients with intermittent claudication is (supervised) exercise therapy (SET) combined with cardiovascular risk management.[1,2]

The beneficial effect of exercise therapy is well known. Various exercise programs have been shown to improve maximal walking distance by 150%.[3] Exercise therapy is often prescribed in the form of "go home and walk" advice; however, compliance with this strategy is known to be low.[4] Although a Cochrane review suggested a benefit of SET over non-SET programs,[5] most of the reviewed studies were small and SET was offered in a clinical setting, either in an outpatient clinic for physiotherapy and rehabilitation or in a vascular laboratory. Clinic-based patient care has several disadvantages, including limited capacity of the institution and high transportation costs for the patient. For this reason, a network of physical therapists providing SET in settings closer to patients' homes was developed.[6] The first results suggested that SET provided by local physical therapists could be at least as effective as SET in a clinical setting.[7,8]

Although SET offers the benefit of adequate (weekly) coaching, the overall superior effect of SET is likely partially due to improved compliance with the exercise regimen. We hypothesized that the use of an accelerometer, which provides daily therapy feedback, with SET would afford more effective coaching and might result in a further increase in walking distance. Hence, a multicenter randomized clinical trial was conducted to compare "go home and walk" exercise therapy, as is still common practice, with SET provided by local physical therapists with or without daily therapy feedback.

## METHODS

This study was approved by the Institutional Review Board (IRB) of the Atrium Medical Center and by the IRBs

From the Departments of Surgery at Atrium Medical Center Parkstad, Heerlen[a]; the Department of Surgery, Catharina Hospital, Eindhoven[b]; and the Department of Epidemiology and Caphri Research School, Maastricht University, Maastricht.[c]

*Please see the Appendix for a complete list of the EXITPAD study group.

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Reprint requests: Dr J. A. W. Teijink, Catharina Hospital, Department of Surgery, PO Box 1350, 5602 ZA Eindhoven, The Netherlands (e-mail: joep.teijink@catharina-ziekenhuis.nl).

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at each participating site. The study is registered at ClinicalTrials.gov (NCT00279994).

**Patients.** Eleven outpatient vascular surgery clinics distributed throughout The Netherlands participated in the Exercise Therapy in Peripheral Arterial Disease (EXITPAD) study.

Patients with stage II peripheral arterial disease according to Fontaine, who were considered for conservative treatment, were eligible. Inclusion criteria were an ankle-brachial index (ABI) <0.9 and an absolute claudication distance (ACD) of <500 meters as assessed with a standardized treadmill test. Exclusion criteria included a prior SET program for intermittent claudication, previous peripheral vascular intervention, insufficient command of the Dutch language, serious cardiopulmonary limitations (New York Heart Association functional class III or IV), previous lower limb amputation, psychiatric instability, and any other serious comorbidity that might hinder physical training. Chronic obstructive pulmonary disease (COPD) and coronary heart disease, defined as angina pectoris or myocardial infarction, were recorded by medical history. Eligible patients were asked to participate and provided written informed consent.

**Randomization and blinding.** Patients were randomized to exercise therapy in the form of a walking advice (WA) only, SET provided by local community-based physical therapists, or SET provided by local physical therapists with the additional use of an accelerometer to provide daily feedback. Randomization took place centrally by telephone, and numbers were generated by a computer-generated block randomization list (block size 9, first block opened at random) stratified by center.

The local vascular surgeons enrolling patients, the patients, and their physical therapists, if applicable, were inherent to the study design and so were not blinded to group assignment. However, the study personnel who administered the treadmill tests and collected the questionnaires were blinded for previous outcomes and group assignment. Patients were instructed to refrain from commenting on treatment assignment and therapy progress during the assessments.

**Interventions.** Before randomization, all patients received, according to the guidelines, cardiovascular risk management by their enrolling vascular surgeon, cholesterol-lowering medication, antiplatelet therapy, the advice to stop smoking, and modification of other atherosclerotic risk factors that were present.[1]

Patients randomized to the WA group received verbal walking advice and a brochure distributed by the Patients Association of Vascular Diseases explaining exercise therapy.[9] Patients were instructed by their attending vascular surgeons who enrolled them in the study to complete three training sessions per day. During each session, maximum pain level should be reached three times. Hence, patients were advised to walk until maximum pain level nine times a day, divided in three sessions.

Patients randomized to the SET groups were referred to a local physical therapist. For each participating center, a network of local physical therapists was trained in SET according to Royal Dutch Society for Physical Therapy and the Dutch Institute of Allied Health Care.[6] An average network consists of 20 to 30 physical therapists equally distributed throughout the region of the hospital. The educational program ensured that all patients received SET according to the guidelines of the Royal Dutch Society for Physical Therapy.[10]

Patients were instructed in the same way as those in the WA group but were also referred to a physical therapist for a supervised program. The main goal was to increase the patients' walking distance by interval training up to submaximum pain with short walking intervals. The program also consisted of walking pattern improvement and enhancement of endurance and strength. Patients generally started with a frequency of two to three sessions of 30 minutes weekly. This was tailored to the individual need of the patient during the treatment year. In conformity with the WA group, all SET patients were encouraged to perform at least three walking sessions every day.

Patients assigned to SET with feedback additionally received a Personal Activity Monitor (PAM) accelerometer (PAM B.V., Doorwerth, The Netherlands).[11,12] The PAM is a performance-based accelerometer to assess physical activity during normal life. PAM measures the acceleration of the body with an accelerometer and expresses the measured movements in a cumulative score that is continuously displayed for feedback. The accelerometer measures the force on the body (up-down direction) and can distinguish between an intensive movement, such as a step during running, and a less-intensive movement, such as a step during walking, expressed as a small increase in score or a great increase in score, respectively. The patient was instructed to wear this instrument continuously during the day for 1 year and to record the PAM scores every day. Physical therapists used the PAM scores to give feedback to patients regarding their walking efforts outside the SET program, and patients were encouraged to reach higher PAM scores the following days.

The manufacturer (PAM B.V.) provided us with technical support. PAM B. V. did not have access to outcome data and did not participate in data analysis or preparation of the manuscript.

**Outcome measurements.** The primary outcome measurement was the change in absolute claudication distance (ACD). Secondary outcome measurements were the change in functional claudication distance (FCD), the Walking Impairment Questionnaire (WIQ), and the Short-Form 36 (SF-36) Health Survey. After 3, 6, 9, and 12 months of follow-up, walking distance on the treadmill was assessed, and the WIQ and SF-36 were completed.

The ACD was defined as the moment the patient had to stop walking due to a maximum pain level. The FCD was defined as the moment the patient preferred to stop walking due to the pain. Treadmill testing is the most commonly used quantitative measure to assess walking ability.[1] ACD[13] and FCD[14] are both reliable tools to evaluate walking distance in patients with intermittent claudication.

Walking distances were determined by a standardized progressive treadmill test with a constant speed of 3.2 km/h starting with 0% inclination, increasing every 2 minutes by 2%.[13,15] For practical reasons, the maximum inclination was 10% and the maximum duration of the test was 30 minutes (1600 meters).

The WIQ is a short, validated questionnaire for patients with peripheral arterial disease that is easy to complete.[16-18] It contains three domains to assess walking impairment: walking distance, walking speed, and stair climbing. For each domain, a subscore of the Likert items was calculated. The mean of these domains represents the total WIQ score.[19] We used a self-administered revised version of the WIQ[18] recently adapted and validated for the European metric system and the Dutch language.[20]

The SF-36 is a general, frequently used quality-of-life questionnaire validated for the Dutch language.[21] The SF-36 contains eight subscales that reflect mental and physical functioning—physical functioning, social functioning, physical role impairment, emotional role impairment, mental health, vitality, pain and general health experience—and is calculated with a scoring algorithm.[22]

**Statistical analysis.** With a sample size of 81 patients per treatment arm, the trial had a power of 80%, to demonstrate an increase in ACD of 150 meters (standard deviation [SD], 300 meters) with two-sided $\alpha = 0.025$. Assuming a 15% to 20% withdrawal rate, 100 patients in each group had to be included.

Analysis was conducted according to the modified intention-to-treat principle. The analysis included all data from patients who were randomized and completed the treadmill assessment for quantifying walking distance after 12 months of treatment. Patients who transferred to another group or patients who stopped the intervention but performed the treadmill assessment were analyzed in their original group. The analysis excluded patients who dropped out <12 months of follow-up.

Categoric variables were presented as frequencies with percentages, and continuous variables were presented as means ± SD when normally distributed and as medians with interquartile ranges (IQR) in case of a skewed distribution. For baseline characteristics, comparisons between groups were performed using one-way analysis of variance (ANOVA) for continuous variables, and a $\chi^2$ test was used for categoric variables.

Missing values of walking distances at 3, 6, and 9 months were imputed based on a multivariate linear regression analysis. A backward elimination method was used to identify variables included in the final regression equation to impute data. Baseline walking distance, age, COPD, and cardiac disease as variables yielded $R^2$s for the ACD of between 22.1% and 28.1%, which are comparable with an earlier report.[23] Increases in walking distances within groups were analyzed with a repeated measurements ANOVA. Changes in walking distances between the groups over time were analyzed with a Wilcoxon rank-sum test.

Missing values of the WIQ and SF-36 were imputed with a mean substitution method. Differences of the WIQ and SF-36 within a group were analyzed with repeated measurements ANOVA. Statistical significance between the WA and SET with or without feedback group of the WIQ and the SF-36 was analyzed with repeated measurements analysis of covariance (ANCOVA) with the baseline measurement as covariate. Analyses were performed with SPSS 15.0 software (SPSS Inc, Chicago, Ill).

## RESULTS

**Study population.** Between December 2005 and May 2008, 304 patients were enrolled in the study, consisting of 102 patients in the WA group, 109 in the SET group, and 93 in the SET with feedback group. The number of included patients per center is shown in the Appendix. Follow-up ended May 2009. Baseline characteristics were generally well balanced among the study groups; there were more men in the SET group and more current smokers in the WA group. Patients in the three groups had comparable median baseline walking distances (Table I).

**Adherence to the intervention and follow-up.** One patient in the WA group did not start with the study after randomization. Five patients randomized to the WA group started with SET during the course of the study, two on their own initiative and three after a prescription from their vascular surgeon. These patients were, based on the applied modified intention-to-treat principle, analyzed in the WA group. Fifteen patients were lost to follow-up and 3 died, leaving 83 patients for analysis (Fig 1).

In the SET group, 26 patients discontinued the program: 12 were lost to follow-up, 4 died, and the remaining 11 stopped SET for other reasons than satisfaction with the regained walking distance but were eligible for analysis. Lack of motivation was the main recorded reason to discontinue the program. In total, 93 patients in the SET group were analyzed.

In the SET with feedback group, 3 patients did not start with the study and 27 stopped the SET program, of whom 14 were lost to follow-up and 13 patients discontinued the program but were eligible for analysis. Of the 76 analyzed patients, 22 (28.9%) reported not having used the PAM accelerometer at all or only for part of the study year. Because almost 30% reported nonuse of the PAM, we decided to analyze the SET and SET with feedback group together (n = 169).

During the study, 9 patients (10.8%) of the WA group and 13 (7.7%) of both SET groups together underwent a peripheral vascular intervention due to worsening of complaints or dissatisfaction with the results of the exercise program ($P = .38$).

**Walking distance.** The median ACD for the patients included in the modified intention-to-treat analysis increased from 260 to 400 meters in the WA group and from 260 to 600 meters in the SET groups. The increase in median FCD showed a similar pattern, from 150 to 320 meters in the WA group and from 150 to 460 meters in the SET groups. The ACD and the FCD both increased significantly in all groups (Table II). Fig 2 presents the percentage of patients per group with an increase in ACD of <100,

**Table 1.** Patient baseline characteristics

| *Variable* | *WA (n = 102)* | *SET ( n = 109)* | *SET with feedback (n = 93)* | P *value* |
|---|---|---|---|---|
| Men, % | 55.9 | 72.5 | 60.2 | .08[a] |
| Age, mean (SD), y | 66.9 (8.6) | 66.1 (9.0) | 65.6 (10.5) | .59[b] |
| BMI, mean (SD), kg/m$^2$ | 28.2 (4.7) | 27.4 (4.2) | 28.2 (5.1) | .34[b] |
| ABI, mean (SD) | 0.65 (0.17) | 0.67 (0.19) | 0.67 (0.16) | .63[b] |
| ACD, median (IQR), m | 240 (160-345) | 260 (167-395) | 250 (160-340) | .48[b] |
| FCD, median (IQR), m | 150 (90-250) | 150 (90-250) | 150 (100-230) | .75[b] |
| Smoking, % | | | | |
| Current smoking | 47.1 | 38.5 | 41.9 | .28[a] |
| Former smoker | 41.2 | 49.5 | 46.2 | .42[a] |
| Never smoked | 9.8 | 12 | 4.3 | .20[a] |
| Unknown | 2 | 0 | 7.5 | |
| Diabetes mellitus, % | 23.5 | 25.7 | 18.3 | .47[a] |
| LE orthopedic disease, % | 14.7 | 14.7 | 17.2 | .84[a] |
| Coronary heart disease, % | 27.5 | 26.6 | 20.4 | .43[a] |
| CVA or TIA, % | 12.7 | 14.7 | 9.7 | .58[a] |
| COPD, % % | 26.5 | 18.3 | 17.2 | .22[a] |

*ABI,* Ankle-brachial index; *ACD,* absolute claudication distance; *COPD,* chronic obstructive pulmonary disease; *CVA,* cerebrovascular disease; *FCD,* functional claudication distance; *IQR* interquartile range; *LE,* lower extremity; *SD,* standard deviation; *SET,* supervised exercise therapy; *TIA,* transient ischemic attack; *WA,* walking advice.

[a]By $\chi^2$ test.

[b]By one-way analysis of variance.

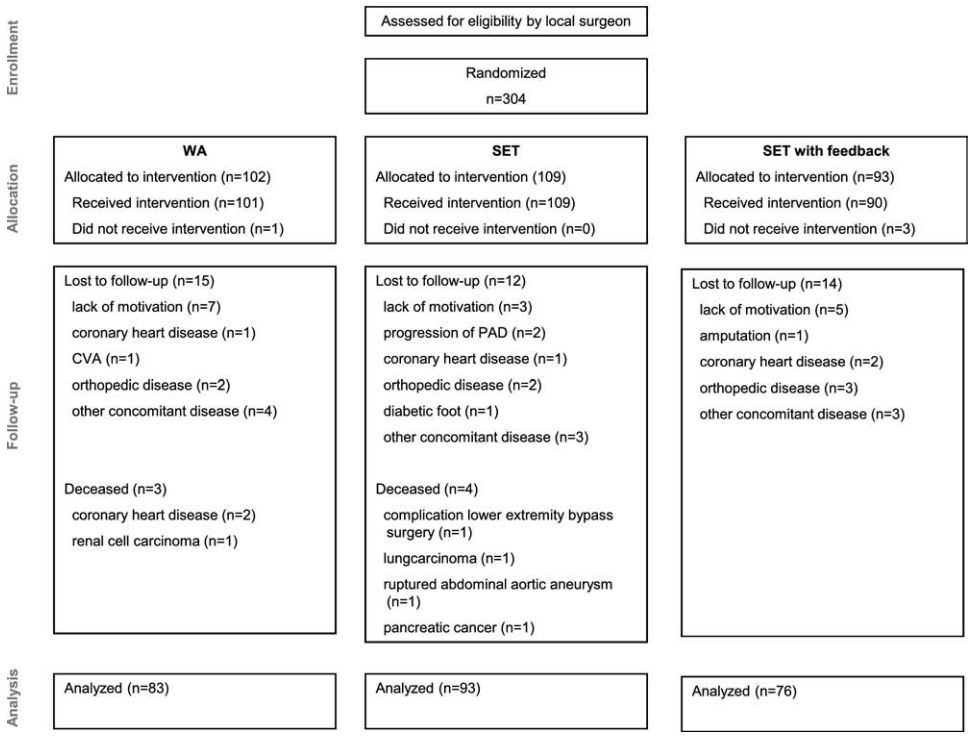


**Fig 1.** Flow chart shows study details according to Consolidated Standards of Reporting Trials statement.[38,39] *CVA,* Cerebrovascular accident; *PAD,* peripheral arterial disease; *SET,* supervised exercise therapy; *WA,* walking advice.

100 to 200, 200 to 300, 300 to 400, and ≥500 meters. In the WA group, 48.2% increased <100 meters and 18.1% increased ≥500 meters; in the SET groups, this was 15.4% and 34.4%, respectively. The median IQR meter increases in ACD and FCD were, respectively, 110 (0-300) and 100 (0-310) in the WA group and 350 (152-810) and 300 (128-575) in the SET groups, respectively. Patients following a SET program with or without feedback regained significantly more walking distance (ACD, $P < .001$; FCD, $P < .001$) than patients in the WA group. The SET groups

**Table II.** Walking distances in meters (interquartile range)

| *Group* | *No.* | *Baseline* | *3 mon* | *6 mon* | *9 mon* | *12 mon* | P *value*[a] | *Change*[b] |
|---|---|---|---|---|---|---|---|---|
| WA | 83 | | | | | | | |
| ACD | | 260 (160-370) | 320 (210-500) | 400 (230-630) | 473 (260-735) | 400 (230-590) | <.001 | 110 (0-300) |
| FCD | | 150 (100-220) | 230 (170-360) | 320 (180-480) | 380 (220-574) | 320 (180-500) | <.001 | 100 (0-310) |
| SET | 169 | | | | | | | |
| ACD | | 260 (165-370) | 530 (341-804) | 610 (383-1000) | 620 (467-1155) | 600 (435-1040) | <.001 | 350 (152-810) |
| FCD | | 150 (95-245) | 380 (255-555) | 470 (280-668) | 493 (330-745) | 460 (295-720) | <.001 | 300 (128-575) |

*ACD,* Absolute claudication distance; *FCD,* functional claudication distance; *SET,* supervised exercise therapy; *WA,* walking advice.
[a]Repeated measurements analysis of variance.
[b]Median change in walking distance with interquartile ranges.

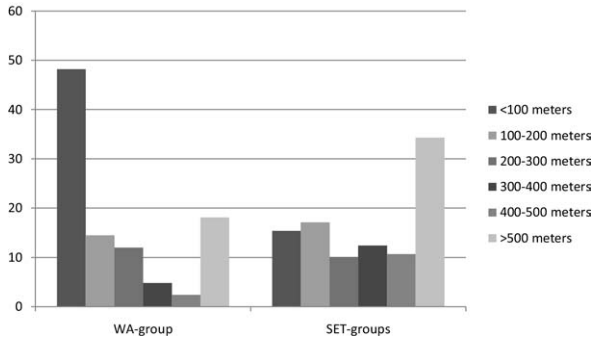


**Fig 2.** Percentage of patients is shown with walking distance improvement in meters of <100, 100-200, 200-300, 300-400, 400-500, and >500 in the actual claudication distance in the walking advice *(WA)* and supervised exercise therapy *(SET)* groups.

increased 240 meters in ACD (95% confidence interval, 152-366), more than the WA group. There was no difference in improvement of walking distances between the two SET groups. Results did not substantially change after data imputation. Similar results between the WA and SET groups were obtained using ANCOVA with baseline walking distance as the covariate.

**Walking Impairment Questionnaire.** The total WIQ score improved from 0.46 to 0.59 in the WA group and from 0.47 to 0.67 in the SET group. A repeated measurements ANCOVA between the WA and SET groups showed significantly more improvement in favor of the SET groups ($P = .004$; Table III). A Pearson correlation coefficient of 0.396 ($P < .001$) was found between the change in ACD and the change in total WIQ score between baseline and 12 months.

**Quality of life.** The physical summary score of the SF-36 improved significantly within the SET groups ($P < .001$). This was mainly due to improvements in the subscales of physical functioning, physical role, and pain. The physical summary score showed a trend toward improvement in the SET groups compared with the WA group ($P = .02$). The subscale of physical functioning and pain showed significant improvements in the SET groups compared with the WA group. The mental health summary score did not improve over time. The eight subscales and the physical and mental health components of the SF-36 are presented in Table III.

## DISCUSSION

The results of this multicenter randomized clinical trial show that walking distances improved in the WA group, but that SET, provided by local physical therapists, improved walking distances, WIQ scores, and scores on relevant domains of the SF-36 >12 months. Compared with simple walking and exercise instructions combined with information leaflets, SET results in an increase of about 200 meters in the walking distance, which reflects a clinically relevant improvement. The use of daily feedback by an accelerometer was not associated with further improvement.

The observed effect of SET vs WA on the ACD is well in line with results of a Cochrane meta-analysis that calculated a difference of approximately 150 meters between SET and unsupervised exercise programs in studies analyzing a small number of patients.[5] Similarly, six more recently published small trials with between 14 and 70 patients reported mainly a benefit of SET over unsupervised exercise programs on walking distance.[24-29] Studies assessing the effect of SET on quality of life expressed as relevant domains of the SF-36 are scarce, and inconclusive published data suggest that SET offers none or only modest improvement on quality of life compared with unsupervised exercise programs.[5,28,30] Although patients who used an accelerometer for feedback might have been more active,[31] a recent meta-analysis suggests that training more than three times per week does not provide further benefit for patients with intermittent claudication.[32]

SET programs vary in setting, duration, and content. Two meta-analyses found the optimal frequency was three times a week[32] or three times a week or more.[33] There is no consensus regarding the minimum duration of SET programs, with reported recommendations varying from 10 to 14 weeks[34] and 12 to 24 weeks[32] to >26 weeks.[33] A randomized trial evaluating various durations and frequencies would be required to address this question satisfactorily and optimize the intervention.

In this large randomized clinical, we were able to demonstrate a beneficial effect of SET compared with WA on walking distance. The benefits were apparent as early as 3 months after initiation of therapy and persisted for at least 12 months. More importantly, SET offered a sustained benefit on the physical domains of quality of life, which was

**Table III.** Results for Walking Improvement Questionnaire *(WIQ)* and Short Form 36 *(SF-36)* Health Survey[a]

| | *WA* | | | | *SET* | | | | |
|---|---|---|---|---|---|---|---|---|---|
| *Instrument* | *Baseline* | *12 mon* | P *value*[b] | *Change* | *Baseline* | *12 mon* | P *value*[b] | *Change* | P *value*[c] |
| WIQ | | | | | | | | | |
| Distance | 0.36 ± 0.22 | 0.57 ± 0.30 | <.001 | 0.21 ± 0.34 | 0.34 ± 0.25 | 0.68 ± 0.27 | <.001 | 0.34 ± 0.30 | .007 |
| Speed | 0.43 ± 0.20 | 0.51 ± 0.22 | <.001 | 0.10 ± 0.23 | 0.45 ± 0.22 | 0.58 ± 0.22 | <.001 | 0.13 ± 0.24 | .005 |
| Stairs | 0.58 ± 0.27 | 0.69 ± 0.28 | <.001 | 0.11 ± 0.29 | 0.61 ± 0.27 | 0.76 ± 0.24 | <.001 | 0.15 ± 0.26 | .085 |
| Total score | 0.46 ± 0.17 | 0.59 ± 0.24 | <.001 | 0.13 ± 0.23 | 0.47 ± 0.20 | 0.67 ± 0.21 | <.001 | 0.21 ± 0.21 | .004 |
| SF-36 | | | | | | | | | |
| Physical function | 52.4 ± 15.0 | 59.0 ± 19.0 | <.001 | 6.6 ± 18.5 | 52.8 ± 14.3 | 65.1 ± 16.8 | <.001 | 12.3 ± 18.3 | .004 |
| Physical role | 51.0 ± 40.8 | 55.8 ± 39.8 | .71 | 4.8 ± 49.4 | 45.8 ± 39.1 | 65.3 ± 36.2 | <.001 | 16.6 ± 45.2 | .19 |
| Pain | 52.0 ± 18.0 | 55.8 ± 22.7 | .36 | 3.9 ± 26.6 | 51.1 ± 16.6 | 64.8 ± 22.5 | <.001 | 13.4 ± 24.5 | .002 |
| General health | 54.9 ± 13.0 | 54.2 ± 12.8 | .53 | –0.7 ± 14.0 | 53.7 ± 12.6 | 53.6 ± 14.3 | .10 | 0.7 ± 13.5 | .82 |
| Physical summary score | 35.2 ± 8.1 | 37.7 ± 8.8 | .01 | 2.5 ± 10.3 | 34.6 ± 7.1 | 40.4 ± 8.4 | <.001 | 5.8 ± 8.6 | .02 |
| Social function | 79.9 ± 19.6 | 75.4 ± 25.3 | .06 | –4.5 ± 27.4 | 77.1 ± 22.8 | 81.7 ± 22.8 | .04 | 4.3 ± 26.6 | .09 |
| Emotional role | 85.1 ± 29.0 | 82.4 ± 34.9 | .81 | –2.7 ± 41.5 | 85.2 ± 32.6 | 86.1 ± 29.1 | .80 | 0.3 ± 38.7 | .31 |
| Mental health | 76.4 ± 17.2 | 74.6 ± 19.1 | .25 | –1.8 ± 15.6 | 75.5 ± 17.8 | 74.9 ± 20.3 | .42 | 0.3 ± 16.8 | .15 |
| Vitality | 63.0 ± 20.3 | 59.2 ± 19.8 | .05 | –3.9 ± 18.7 | 61.6 ± 18.7 | 62.0 ± 18.9 | .46 | –0.6 ± 17.5 | .17 |
| Mental summary score | 55.9 ± 9.9 | 53.0 ± 11.4 | .006 | –2.8 ± 10.1 | 55.3 ± 10.5 | 53.5 ± 10.4 | .009 | –1.8 ± 10.4 | .38 |

*SET*, Supervised exercise therapy; *WA*, walking advice.
[a]Data at 3, 6, and 9 months are not shown.
[b]Repeated measurements analysis of variance.
[c]Repeated measurements analysis of covariance with baseline measurement as covariate.

not seen after unsupervised training. Participating in a trial that stimulates physical activity affects patient behavior,[35] and patients who were willing to participate in this study might have had an intrinsic motivation to increase their activity level that might limit generalizability. Finally, owing to the nature of the interventions, this was an open study. We attempted to obtain an unbiased observation of the ACD, but it is difficult to ascertain complete blinding of this outcome measurement.

The results of this large randomized clinical trial are consistent with a meta-analysis of previously performed smaller studies.[5] Both indicate that SET is an effective treatment for intermittent claudication and should be offered as first-line treatment. However, the availability of SET in clinical practice is far from optimal.[36,37] This can be related to reimbursement policies of insurance companies and availability of adequately trained professionals who can provide SET. Hence, there seems to be an obligation for professionals in the vascular field to take action to make this effective intervention available for all patients with intermittent claudication.

## CONCLUSIONS

SET is more effective for patients with intermittent claudication than walking advice alone in improving walking distance, WIQ scores, and quality of life as assessed in the relevant domains of the SF-36. A supervised exercise program should be made available for all patients with intermittent claudication.

## APPENDIX

**The EXITPAD Study Group participants.** Saskia P. A. Nicolaï, MD, PhD, Joep A. W. Teijink, MD, PhD, Edith M. Willigendael, MD, PhD, Bianca L. W. Bendermacher, MD, PhD, Lotte M. Kruidenier, MD, PhD, Manuela Joore, PhD, Rob J. van Det, MD, Paul J. G. Jörning, MD, PhD, Anco Vahl, MD, PhD, MsC, Rudolph P. Tutein Nolthenius, MD, PhD, Philippe W. M. Cuypers, MD, PhD, Marie-Louise E. L. Bartelink, MD, PhD, Erik J. M. Hendriks, PhD, Rob A. de Bie, PhD, and Martin H. Prins, MD, PhD.

**Participating centers.** Participating investigators and number of patients (in parenthesis) included in the EXITPAD study. The Netherlands: J. A. W. Teijink and A. Habets, Atrium Medical Centre Parkstad, Heerlen (125); R. J. van Det, A. Stam, and M. Blokhuis, Medical Spectrum Twente, Enschede (46); P. J. G. Jörning, I. Siebelt, L. Kasperink, and R. Haze, Isala Klinieken, Zwolle (30); A. C. Vahl and J. M. de Vries, Onze Lieve Vrouwe Gasthuis, Amsterdam (27); R. P. Tutein Nolthenius, I. Nicaise, and P. de Jong, Albert Schweitzer Hospital, Dordrecht (23); P. W. M. Cuypers and G. Kiebert, Catharina Hospital, Eindhoven (22); L. H. J. van den Akker and W. Hermans, Orbis Medical Centre, Sittard (14); M. G. Samyn, G. de Bruijn, S. van Roij-Piredda, and S. Wijnands, VieCurie, Venlo (7); P. Brummel, S. Brandwijk, and P. Kosters, Franciscus Hospital, Roosendaal (6); Th. A. A. van den Broek, G. A. Vos, M. van Boxtel, and R. Smit, Waterland Hospital, Purmerend (3); and G. H. Ho, L. Schoones, and M. Oerlemans, Amphia Hospital, Breda (1).

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## AUTHOR CONTRIBUTIONS

Conception and design: JT, EW, BB, MJ, MB, EH, RB, MP
Analysis and interpretation: SN, MP
Data collection: SN, JT, LK, RD, PJ, AV, RT, PC
Writing the article: SN, MP
Critical revision of the article: JT, EW, BB, LK, MJ, RD, PJ, AV, RT, PC, MB, EH, RB, MP
Final approval of the article: SN, JT, EW, BB, LK, MJ, RD, PJ, AV, RT, PC, MB, EH, RB, MP
Statistical analysis: SN, MP
Obtained funding: JT, EW, BB, MJ, MB, EH, RB, MP
Overall responsibility: JT

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