

Results from the Endovascular Revascularization And Supervised Exercise for claudication study

Farzin Fakhry, on behalf
of the ERASE Trial Investigators

Erasmus Medical Center
Departments of Radiology and Epidemiology
Rotterdam, The Netherlands

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Research and Development.



- Intermittent claudication
 - Symptomatic form of peripheral arterial disease, 20-40 million cases worldwide
- Functional- and quality of life limitations
- Supervised exercise therapy first-line treatment, endovascular revascularization increasingly performed
- Combination therapy of endovascular revascularization and exercise promising

Study Objective

ERASE Trial

To compare the clinical effectiveness of Endovascular Revascularization (EVR) plus Supervised Exercise Therapy (SET) versus the standard care of SET only in patients with intermittent claudication.



Study Population

- Stable (>3 months) intermittent claudication
- Vascular obstruction (> 50%) aortoiliac and/or femoropopliteal level
- Target lesion suitable for endovascular revascularization
- No limited ambulation due to any other condition
- No prior treatment (including exercise therapy)

Randomization



Endovascular Revascularization

- Balloon angioplasty aortoiliac and/or femoropopliteal lesion
- Selective stenting

Supervised Exercise Therapy

- Approximately 1 hour sessions of exercise, trained physiotherapist
- 2-3 s/wk 3 months, 1-2 s/wk 3-6 months and 1 s/4 wks 6-12 months, depending on patients' progress and preference



Outcome measures

Primary Endpoint

- Maximum walking distance, graded treadmill test (Gardner protocol, 30-min)

Secondary Endpoints

- Pain-free walking distance (Gardner protocol, 30-min)
- Ankle brachial index at rest and post treadmill walking
- Self-reported quality-of-life scores VascuQol, SF-36, Rating score and EuroQol
- Leg amputations and secondary interventions

Statistical analysis

- Intention to treat principle
- Tobit regression for walking distances
- Mixed models for repeated measures
- Kaplan Meier analysis
- Level of significance: $P \leq 0.01$



Follow up

- At 1, 6 and 12 months
- Completeness of follow up: SET 92%; EVR+SET 94%
- Deaths: SET 3; EVR+SET 1

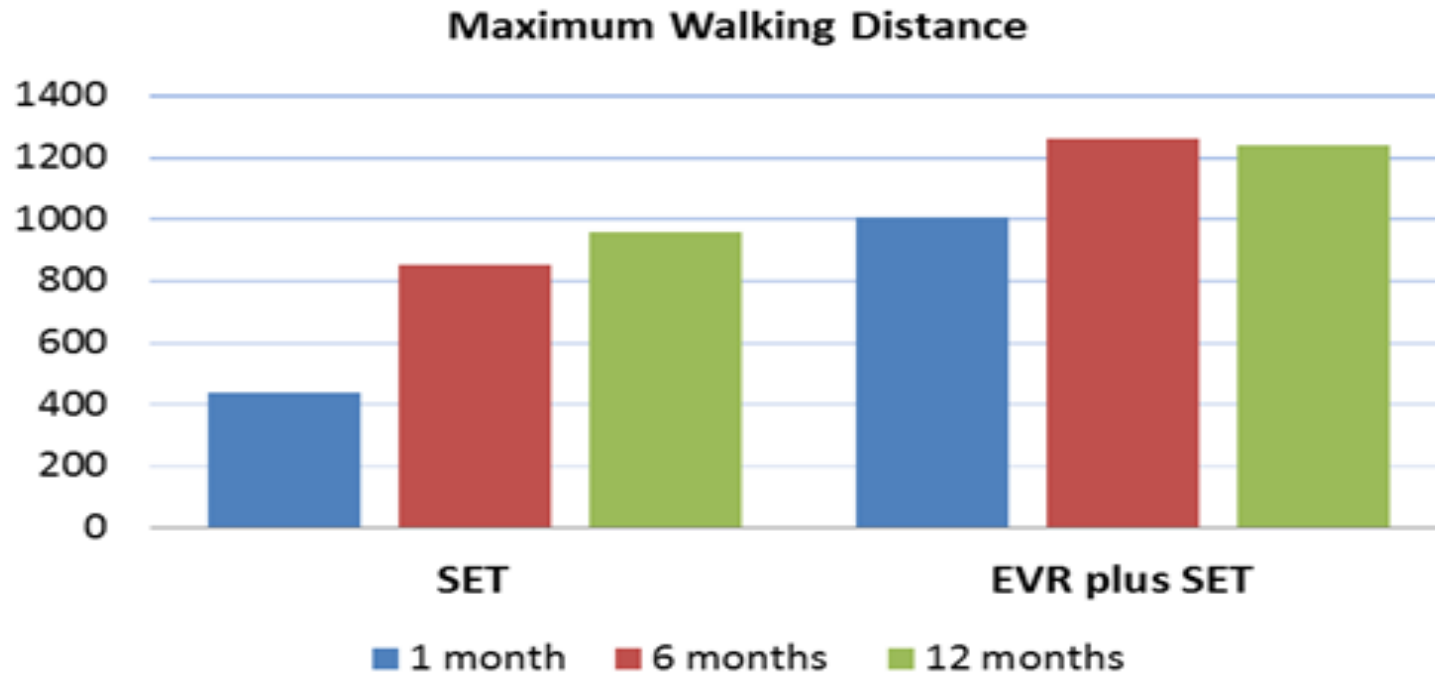
Treatment compliance

- SET: Average 43 sessions (71% > 26 sessions)
- EVR+SET: 102 patients (96%) successful EVR, 63 patients (62%) stented
- Average 30 sessions SET (44% >26 sessions)

Baseline characteristics of the randomized patients

	SET (n= 106)	EVR+SET (n= 106)
Age (years)	66 (\pm 10)	64 (\pm 9)
Gender (Male)	67%	58%
Smoking (Current/Former)	92%	93%
Hypertension	63%	60%
Diabetes	26%	16%
Dominant Lesion		
	Aortoiliac	51%
	Femoropopliteal	49%
Maximum Walking Distance (meters)	272 (\pm 124)	251 (\pm 117)
Pain Free Walking Distance (meters)	130 (\pm 77)	112 (\pm 68)
Vascular QoL score (1-7)	4.5 (\pm 1.0)	4.5 (\pm 0.9)

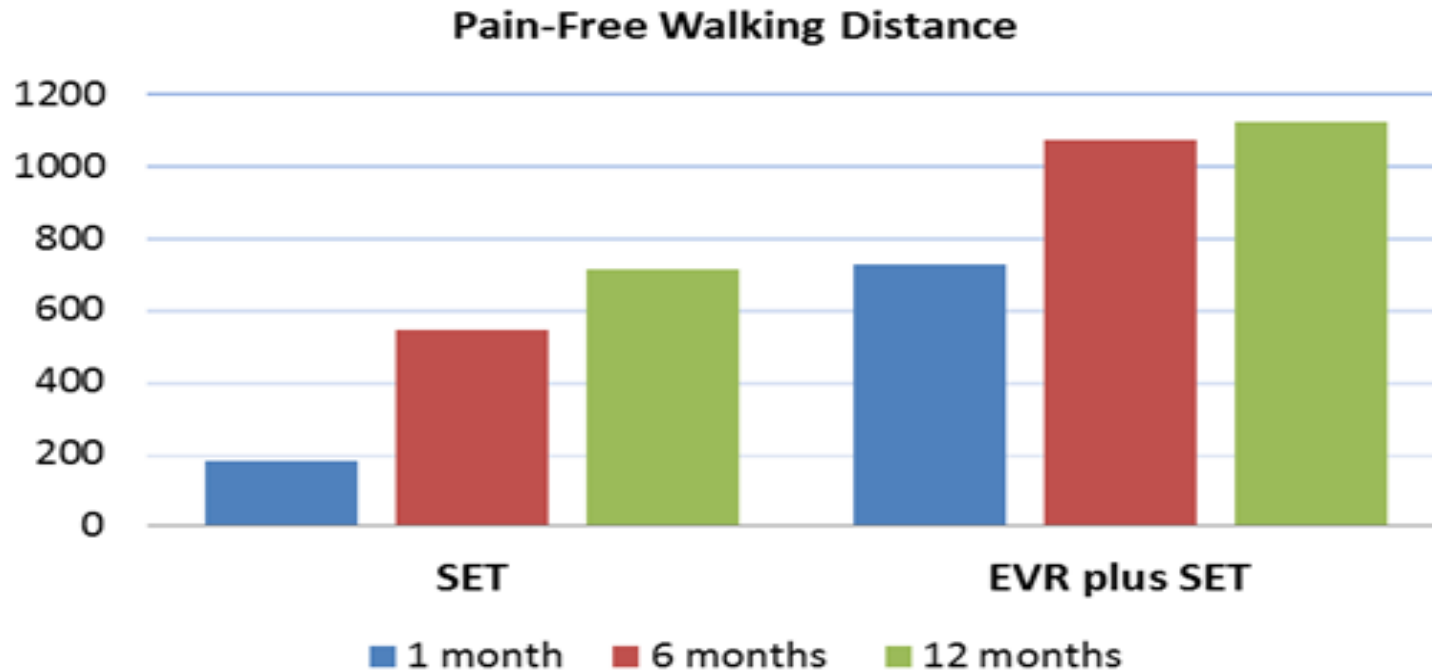




	Mean Difference EVR plus SET vs. SET	P-value
1 month	566 (358 ; 774)	<0.001
6 months	409 (183 ; 436)	<0.001
12 months	282 (60 ; 505)	0.001

Fig. 1 Bars represent mean change (meters) compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



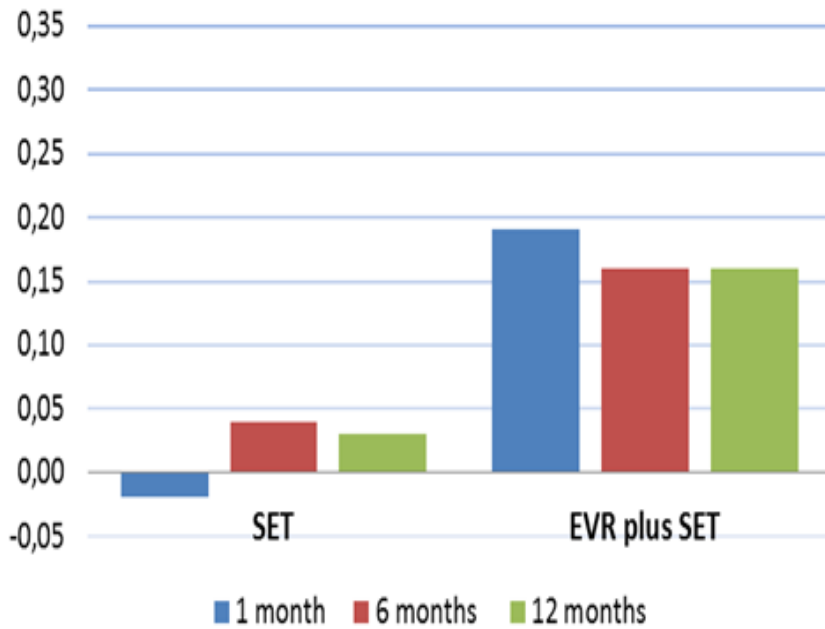


	Mean Difference EVR plus SET vs. SET	P-value
1 month	543 (340 ; 744)	<0.001
6 months	529 (315 ; 743)	<0.001
12 months	408 (195 ; 622)	<0.001

Fig. 2 Bars represent mean change (meters) compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



Ankle Brachial Index (at rest)

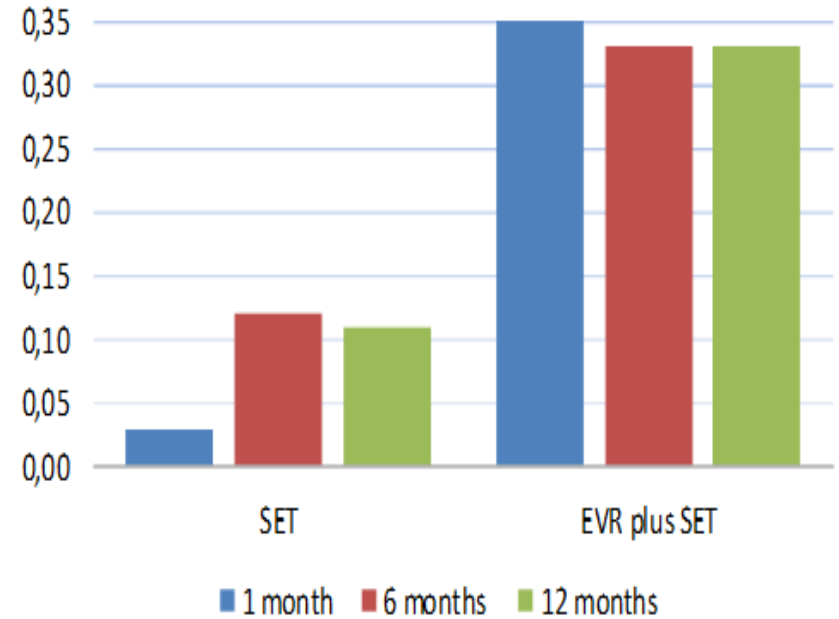


Mean Difference
EVR plus SET vs. SET P-value

1 month	0.21 (0.15 ; 0.27)	<0.001
6 months	0.12 (0.05 ; 0.17)	<0.001
12 months	0.13 (0.06 ; 0.19)	<0.001

Fig. 3 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization

Ankle Brachial Index (post-exercise)

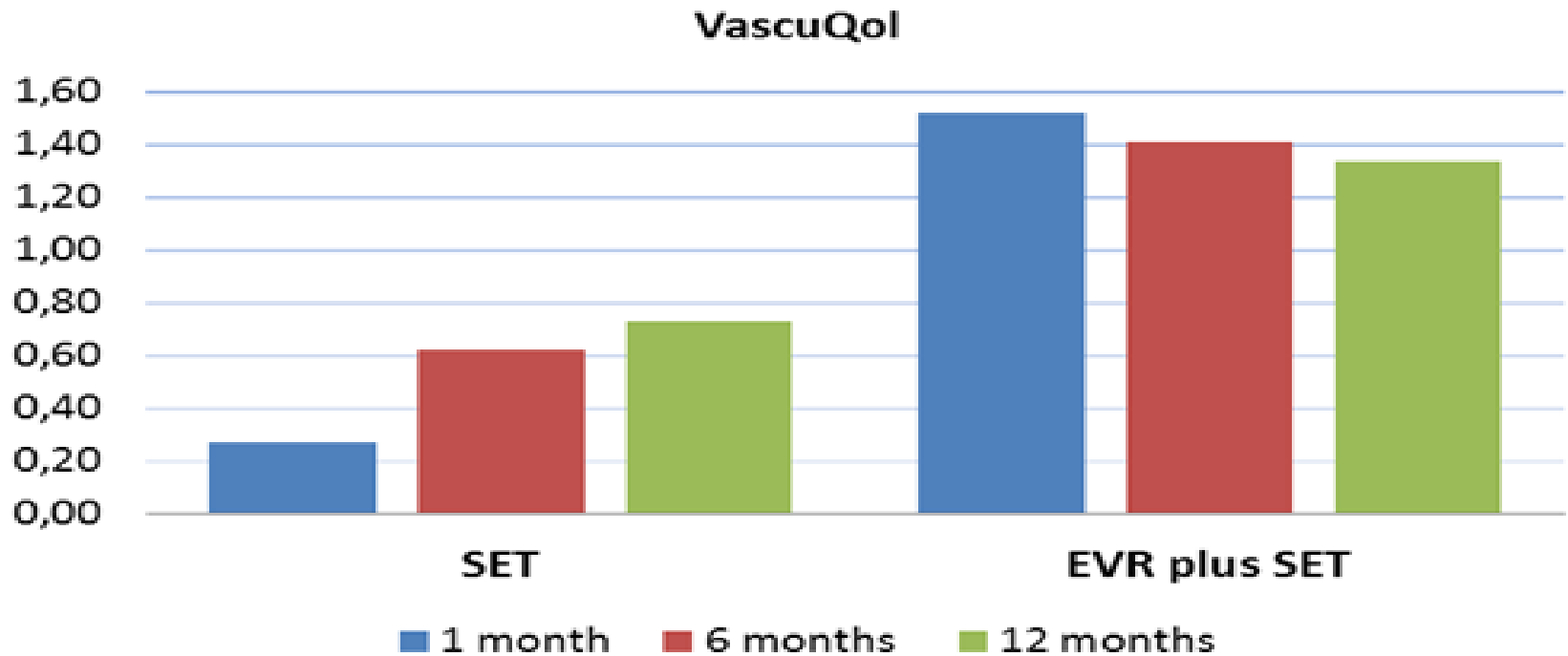


Mean Difference
EVR plus SET vs. SET P-value

1 month	0.33 (0.25 ; 0.40)	<0.001
6 months	0.21 (0.13 ; 0.29)	<0.001
12 months	0.22 (0.13 ; 0.31)	<0.001

Fig. 4 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



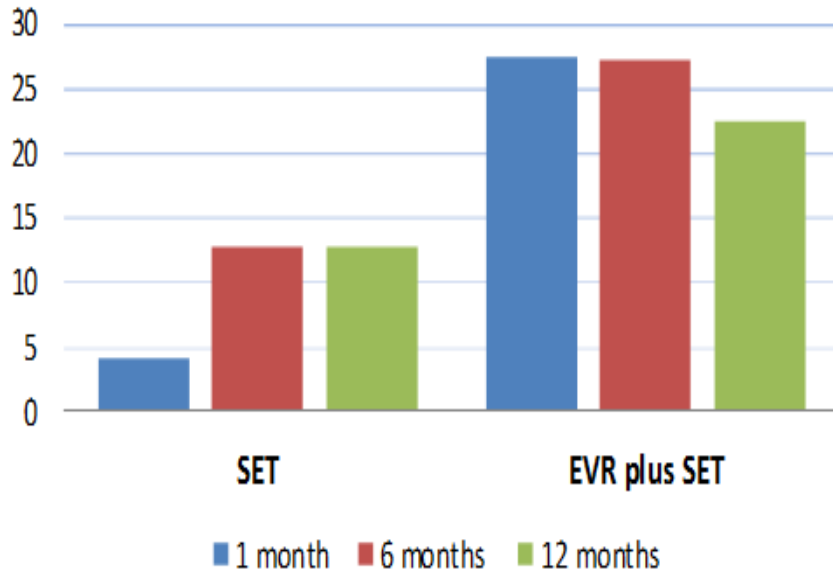


	Mean Difference EVR plus SET vs. SET	P-value
1 month	1.25 (0.94 ; 1.56)	<0.001
6 months	0.79 (0.45 ; 1.13)	<0.001
12 months	0.62 (0.20 ; 1.03)	<0.001

Fig. 5 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



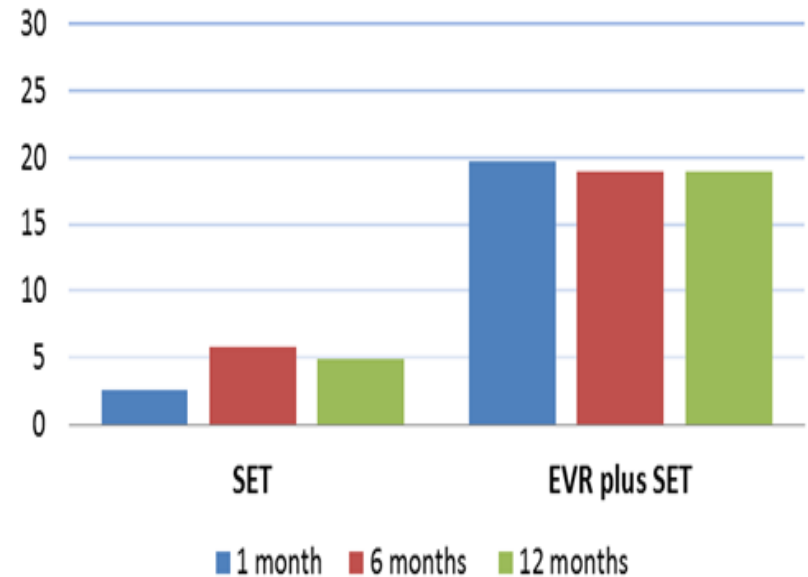
SF-36 Physical Functioning



	Mean Difference EVR plus SET vs. SET	P-value
1 month	23.3 (17.3 ; 29.4)	<0.001
6 months	14.6 (7.9 ; 21.2)	<0.001
12 months	9.8 (1.4 ; 18.2)	0.002

Fig. 7 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization;

SF-36 Physical Role Functioning

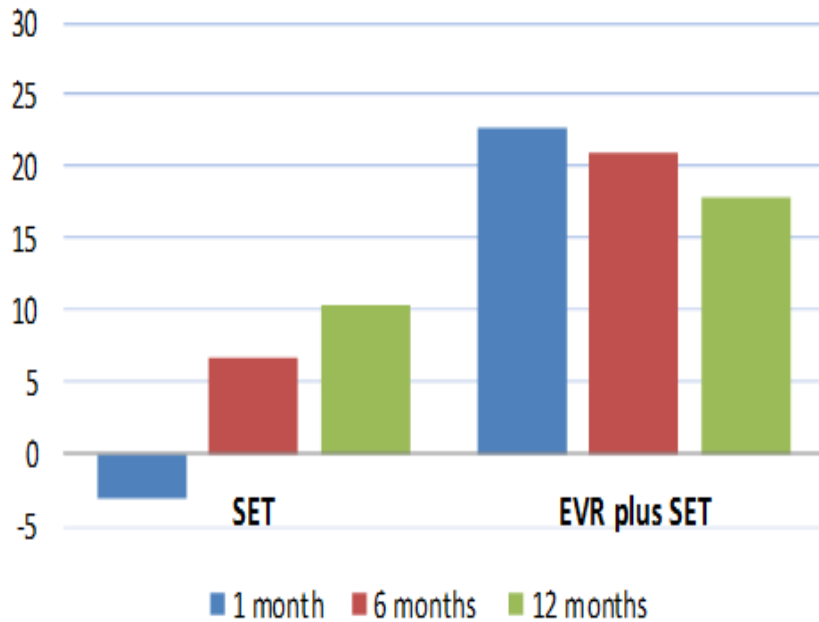


	Mean Difference EVR plus SET vs. SET	P-value
1 month	17.1 (4.5 ; 29.7)	<0.001
6 months	13.0 (-0.1 ; 26.1)	0.011
12 months	14.0 (-0.8 ; 28.7)	0.015

Fig. 8 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



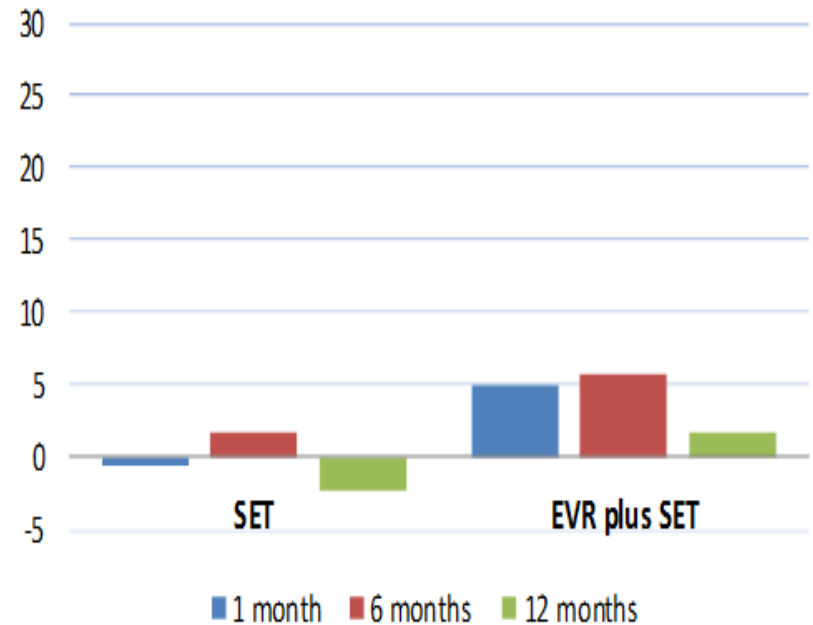
SF-36 Bodily Pain



	Mean Difference EVR plus SET vs. SET	P-value
1 month	25.8 (19.2 ; 32.4)	<0.001
6 months	14.4 (7.4 ; 21.5)	<0.001
12 months	7.6 (-0.6 ; 15.7)	0.017

Fig. 9 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization

SF-36 General Health

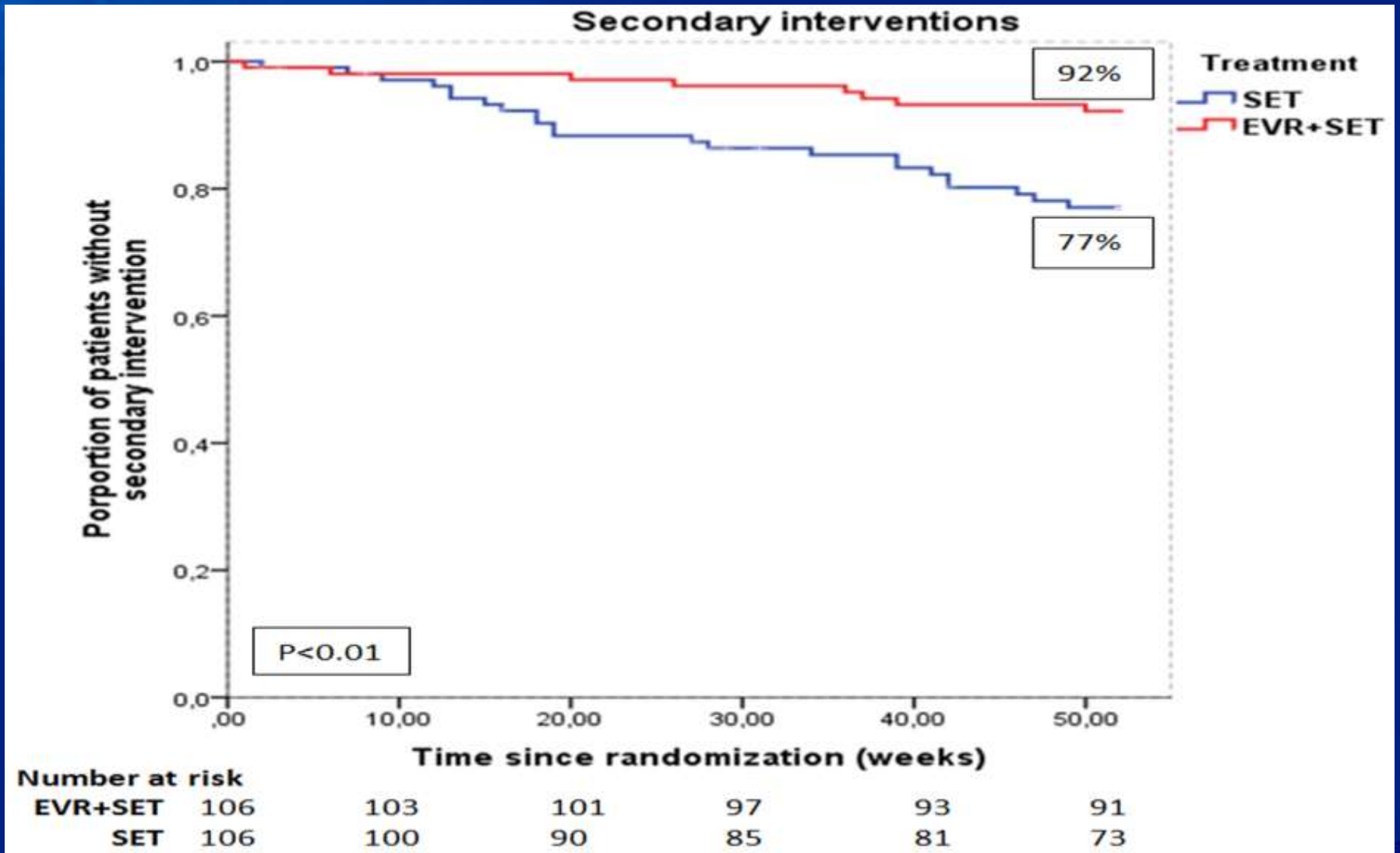


	Mean Difference EVR plus SET vs. SET	P-value
1 month	5.6 (0.1 ; 11.0)	0.009
6 months	4.2 (-1.6 ; 9.9)	0.061
12 months	4.1 (-2.4 ; 10.6)	0.106

Fig. 10 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



Secondary interventions during follow up



Summary

- In patients with intermittent claudication a combination therapy of endovascular revascularization followed by supervised exercise therapy resulted in significant greater improvements in functional performance and quality-of-life compared to the standard care of supervised exercise therapy only.
- Planned Cost-effectiveness analysis

Centers and principal investigators

- Amphia Hospital Breda, Lijckle van der Laan, MD, PhD
- Bernhoven Hospital Oss, Taco Smits, MD, PhD
- Catharina Hospital Eindhoven, Joep Teijink, MD, PhD
- Elkerliek Hospital Helmond, Guido Stultiens, MD
- Erasmus Medical Center Rotterdam, Farzin Fakhry, MSc, Sandra Spronk, PhD, Ellen Rouwet, MD, PhD and Myriam Hunink, MD, PhD
- Haga Hospital The Hague, Jan Wever, MD, PhD
- Ikazia Hospital Rotterdam, Ted den Hoed, MD, PhD
- Reinier de Graaf Gasthuis Delft, Wolter Hoffmann, MD, PhD
- Sint Fransiscus Gasthuis Rotterdam, Arie van der Ham, MD, PhD
- Zorgsaam Hospital Terneuzen, Alex Derom, MD

