



Alternatives to Surgery for Peripheral Arterial Disease

Philip Stather

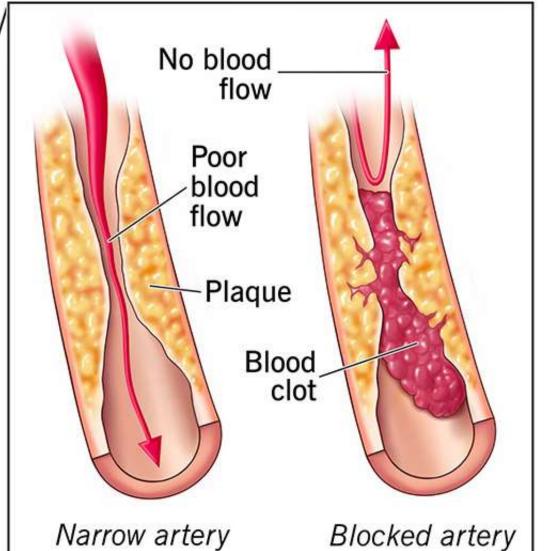






Peripheral Arterial Disease

- 20% over over 60's
- Mostly asymptomatic
- Male
- Smoking
- Diabetes
- Hypertension



Walk A Cise

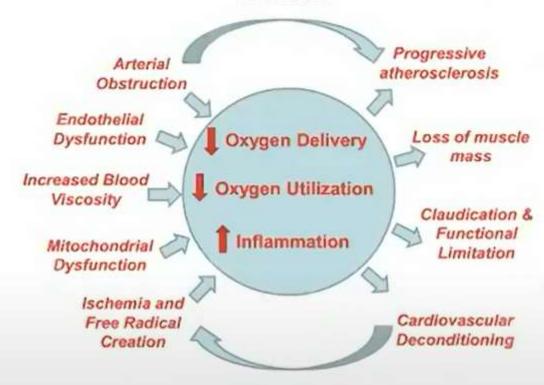
Presentation





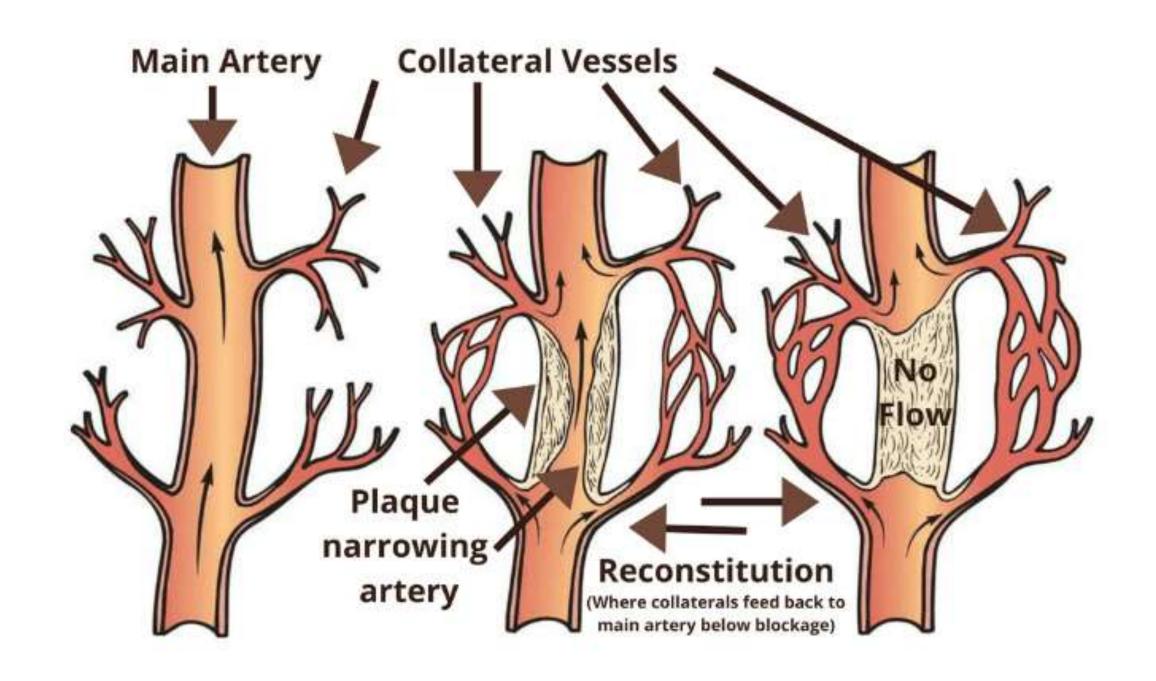


Mechanisms of Functional Impairment in Peripheral Artery Disease



Potential Mechanisms of Benefit of Exercise in Peripheral Artery Disease





Funding from the NHS



Figure 1 NICE PAD Pathway: management of intermittent

Access to supervised exercise services in the UK NHS for patients with peripheral vascular disease

Article (PDF Available) in Annals of The Royal College of Surgeons of England - July 2016 with 287 Reads ①

38% have access to supervised exercise classes!

Supervised v Unsupervised Exercise Programmes



Cochrane Database Syst Rev. 2013 Aug 23;(8):CD005263. doi: 10.1002/14651858.CD005263.pub3

Supervised exercise therapy versus non-supervised exercise therapy for intermittent claudication.

Fokkenrood HJ1, Bendermacher BL, Lauret GJ, Willigendael EM, Prins MH, Teijink JA.

Supervised Exercise Therapy confers a significant improvement in walking distance compared to non-supervised regimes, size effect 0.48, or twice as good)

Cochrane Database Syst Rev. 2014 Jul 18;(7):CD000990. doi: 10.1002/14651858.CD000990.pub3.

Exercise for intermittent claudication.

Lane R1, Ellis B, Watson L, Leng GC.

Supervised Exercise Therapy confers a significant improvement in walking distance by 50-200% compared to placebo

Recommendations for Exercise Therapy for PAD Referenced studies that support the recommendations are summarized in the Commendations are

COR	LOE	Recommendations
1	Α	 In patients with chronic symptomatic PAD, SET is recommended to improve walking performance, functional status, and QOL.^{7,16-28}
1	А	 In patients with chronic symptomatic PAD, a structured community-based exercise program with behavioral change techniques is effective to improve walking performance, functional status, and QOL.⁵⁻¹⁵
1	Α	 In patients who have undergone revascularization for chronic symptomatic PAD, SET after revascularization is effective to improve walking performance, functional status, and QOL.²⁹⁻³⁹
1	B-R	 In patients with functionally limiting claudication, SET or a structured community-based exercise program should be offered as an initial treatment option.^{17,18,25,40}
2a	A	 In patients with chronic symptomatic PAD, alternative programs of nonwalking structured exercise therapy (eg, arm ergometry, recumbent stepping) can be beneficial to improve walking performance, functional status, and QOL.^{19,20,41-47}
2b	B-R	 In patients with chronic symptomatic PAD, the use- fulness of structured walking exercise therapy that avoids moderate to severe ischemic symptoms is uncertain.^{5,45,46}
2b	B-R	7. In patients with chronic symptomatic PAD, the usefulness of unstructured exercise to improve walking performance, functional status, and QOL is uncertain. 10,12,28

SET good for PAD

Home based is Ok

Good after surgery

Should be initial treatment option

Alternative therapies may be Ok

Unstructured programmes are uncertain

SET recommendations

Supervised Exercise Therapy^{5,7,16–28,42,52,53}

Primarily focuses on intermittent walking exercise on a treadmill, interspersed with rest periods when pain becomes moderate or severe.

Program takes place in a hospital or outpatient facility and is often placed within a cardiac rehabilitation program setting; can be standalone if necessary.

Program is directly supervised by qualified health care professional(s); generally clinical exercise physiologists or nurses with exercise training experience.

Training is performed for a minimum of 30-45 min per 60-min session. Supervised sessions are performed at least 3 times/wk for a minimum of 12 wk.

Training involves intermittent bouts of walking to moderate-to-maximum claudication pain or discomfort, alternating with periods of rest, with incremental increases as function and symptoms improve. Goal is to progress to 30-45 min of active walking exercise during each session.

Nontreadmill modalities (eg, stationary bicycle) can used when appropriate and continually assessed to determine when or if the patient can use a treadmill.

Supervised exercise therapy is a covered benefit by Medicare and most commercial insurances.

Home based recommendations

Structured Community-Based Exercise Program^{5,6,8,9,12,15,19,57,63–66}

Program takes place in the personal setting (eg, home, community, neighborhood) of the patient rather than in a clinical setting.

Qualified health care professional(s) prescribe an exercise regimen similar to that of a supervised program.

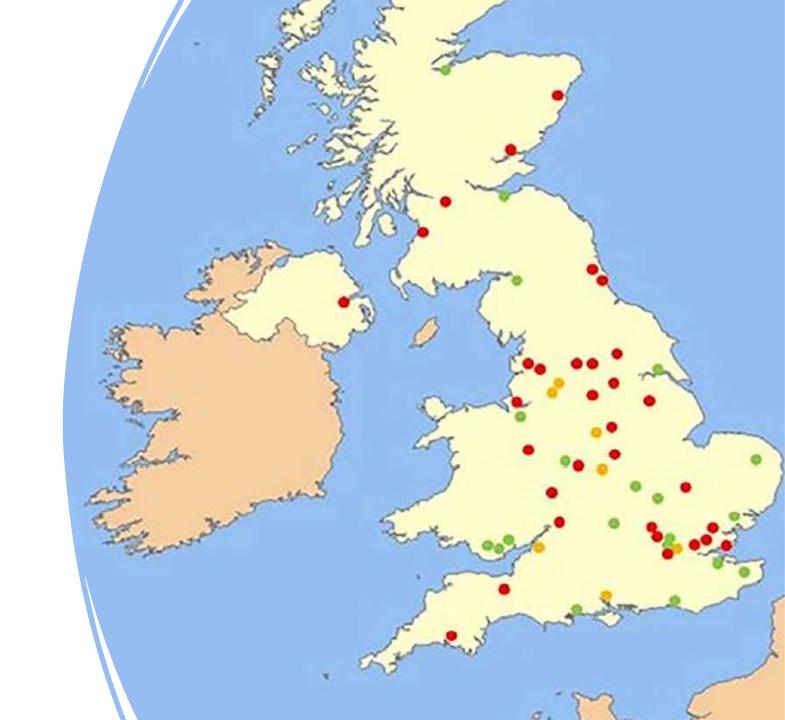
Program is self-directed with the guidance of qualified health care professional(s) and is generally walking-based.

Patient counseling ensures understanding of how to begin and maintain the program and how to progress the difficulty of the walking (by increasing distance or speed).

Program may incorporate behavioral change techniques, delivered by in-person or virtual health coaching or the use of activity monitors.

Program may include periodic supervised exercise sessions to assess progress, reinforce adherence, and make exercise prescription alterations when appropriate.

- Not all SET classes comply with NICE recommendations
- Unable to provide more than once per week
- Unable to provide 12 classes per patient



Supervised Exercise v Angioplasty

Walk Cise

Long-term clinical effectiveness of supervised exercise therapy versus endovascular revascularization for intermittent claudication from a randomized clinical trial

F. Fakhry, E. V. Rouwet, P. T. den Hoed, M. G. M. Hunink, S. Spronk

First published: 10 July 2013 Full publication history

Supervised Exercise, Stent Revascularization, or Medical Therapy for Claudication Due to Aortoiliac Peripheral Artery Disease: A Randomize Clinical Trial

Timothy P. Murphy, MD, Donald E. Cutlip, MD, Judith G. Regensteiner, PhD, Emile R. Mob Cohen, MD, MSc. Matthew R, Reynolds, MD. Joseph M, Massaro, PhD. MB Beth A, Le Niki C, Oldenburg, DrPH, 11 Claudia C, Thum, MA, I Michael R, Jaff, DO, II Antho Steffes, MD, 11 Ingrid H. Abrahamsen, MS, 1 Suzanne Goldberg, MSN, 11 a





LONG TERM NO DIFFERENCE BETWEEN SUPERVISED EXERCISE AND ANGIOPLASTY 12-7. Efficacy of Endovascular diarization Versus Supervised exercise Training in Patients With Intermittent Claudication: Meta-Analysis of Randomized Controlled Trials

Ambarish Pandey MD *, Subhash Banerjee MD *, Christian Ngo MD *, Purav Mody MD *, Steven P. Marso MD *, Emmanouil S. Brilakis MD, PhD *, Ehrin J. Armstrong MD, MS b, Jay Giri MD, MPH S, Marc P. Bonaca MD, MPH d, Aruna Pradhan MD, MPH d, Anthony A, Bavry MD, MPH C, Dharam J.

First published: 16 September 2011 Full publication history

NICE



Table 1. NICE CG 147 recommendations regarding IC.1

- 1.5.1 Offer a supervised exercise programme (SEP) to all people with intermittent claudication (IC).
- 1.5.2 Consider providing a SEP for people with IC which involves: 2 hours of supervised exercise a week for a 3-month period and encourages people to exercise to the point of maximal pain.
- 1.5.3 Offer angioplasty for treating people with SEP only when: advice on the benefits of modifying risk factors has been reinforced (see recommendation 1.2.1) and a SEP has not led to a satisfactory improvement in symptoms and imaging has confirmed that angioplasty is suitable for the person.

NICE Guideline but not funded in most hospitals!

What Else Can We Do? Heat Therapy

	Hank Abanian	6 minu@walk test	115						
Study or ! Akerman	Study	Intervention Details							
Monroe 20 Total (959	Akerman (2019)	Supervised hot immersion (3-5/week 39°C)	1						
Heterogen Test for ov		Water circulating trousers (90 mins, 3/wk, 47-50°C)							
	Monroe (2021)	Water circulating trousers (90 mins, 3/wk, 43°C)							
	Shinsato (2010)	Woan dry sauna (15 mins, 5/wk, 60°C)							
Study or ! Akerman	Tei (2007)	Woan dry sauna (15 mins, 5/wk, 60°C)							
Shinsato Total (95)	Guirro (2022)	Continuous short wave diathermy (20 mins, mod heat)							
Heteroger Test for o	Pellinger (2019)	Acute – Lower limb heated immersions (15 min v 45 min).							
	Neff (2016)	Acute – Lower body water perfused suit (90 min, 48°C)							
	Thomas (2021)	Acute – Waist level immersion (30 min, 42°C)							
			1						

What Else Can We Do? NMES





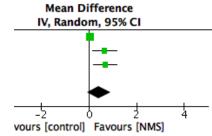
NMES What Else Can We Do?

Randomized Controlled Trial

> Br J Surg. 2023 Nov 9;110(12):1785-1792.

doi: 10.1093/bjs/znad299.

Neuromuscular Electrical Stimulation for Intermittent Claudication (NESIC): multicentre, randomized controlled trial



```
Laura Burgess 12, Adarsh Babber 12, Joseph Shalhoub 12, Sasha Smith 12,
Consuelo N de la Rosa 3, Francesca Fiorentino 1 3 4, Bruce Braithwaite 5, Ian C Chetter 6,
James Coulston 7, Manjit S Gohel 8, Robert Hinchliffe 9, Gerard Stansby 10, Alun H Davies 12;
```

200 patients randomised. 160 analysed. Although NMES improved walking distance at 3 months It was not statistically significant. The best improvement was seen in mild claudication

Improved initial claudication distance = 40.4 v 7.5 m

CQ

What Else Can We Do? IPC







What Else Can We Do? IPC

Initial Claudication Distance

		IPC		C	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean [m]	SD [m]	Total	Mean [m]	SD [m]	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Breu	37	50.63	33	20.7	28.32	33	25.1%	16.30 [-3.49, 36.09]	
Chang	31	99	23	0.6	4.7	8	18.5%	30.40 [-10.19, 70.99]	 •
Delis 2000	113.5	151.5193	25	15	24.7892	12	12.9%	98.50 [37.47, 159.53]	-
Delis 2005	147.5	207.8441	20	-5	11.4926	21	7.8%	152.50 [61.28, 243.72]	
Hoel	68	97.08	32	18	51.8	31	19.3%	50.00 [11.74, 88.26]	
Kakkos	30	77.5	13	0	35	9	16.3%	30.00 [-17.93, 77.93]	-
Total (95% CI)			146			114	100.0%	48.85 [19.03, 78.67]	•
Heterogeneity: Tau ² =	= 818.84; CI	$ni^2 = 14.54,$	df = 5	(P = 0.01)	$1^2 = 66\%$			-	-100 -50 0 50 100
Test for overall effect	Z = 3.21 (F	0 = 0.001		Δhso	lute C	laud	icatio	n Distance	-100 -50 0 50 100 Favours [control] Favours [IPC]

Absolute Claudication Distance

Study or Subgroup	Mean	IPC SD	Total	Mean	Control SD	Total	Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI
Delis 2000	131	174.8813	25	15	24.7892	12	34.9%	116.00 [46.03, 185.97]	-
Delis 2005	243	342.41	20	-10	22.99	21	19.9%	253.00 [102.61, 403.39]	
Hoel	62	118.89	32	20	99.09	31	38.1%	42.00 [-11.98, 95.98]	 • -
Kakkos	265	565	13	5	60	9	7.2%	260.00 [-49.62, 569.62]	+
Total (95% CI)			90			73	100.0%	125.36 [34.84, 215.89]	•
Heterogeneity. Tau ² = Test for overall effect				-500 -250 0 250 500 Favours [control] Favours [IPC]					

Ultrasound Therapy

Am J Surg. 2021 June; 221(6): 1271–1275. doi:10.1016/j.amjsurg.2021.02.017.

Ultrasound therapy for treatment of lower extremity intermittent claudication

Gregory J. Landry, MD, David Louie, BS, David Giraud, MD, Azzdine Y Ammi, PhD, Sanjiv Kaul, MD

Knight Cardiovascular Institute Oregon Health & Science University

Ultrasound Therapy

10 Subjects

Water interface between US and legs

Pulsed US therapy at 250kHz

30 mins 3x per week for 6 weeks

Increased 6MWT from 353-372m

ABPI 0.53-0.64

WIQ 2.00-2.63

Improvement in SF36

Shockwave Lithotripsy

- Acoustic shockwaves
- Catheter inserted to deliver angioplasty balloon with ultrasound element to affected artery
- Helps to crack the calcium within the arterial wall

The Future

- High Frequency Ultrasound
- ▶ BMJ Open. 2022 May 2;12(5):e058418. doi: 10.1136/bmjopen-2021-058418

Int J Hyperthermia. 2020;37(1):903-912. doi: 10.1080/02656736.2020.1795278.

Safety and feasibility of arterial wall targeting with robot-assisted high intensity focused ultrasound: a preclinical study

M H A Groen ¹, F J B Slieker ², A Vink ³, G J de Borst ², M V Simons ², E S Ebbini ⁴, P A Doevendans ¹ ⁵ ⁶, C E V B Hazenberg ², R van Es ¹

Safety and feasibility study of non-invasive robot-assisted high-intensity focused ultrasound therapy for the treatment of atherosclerotic plaques in the femoral artery: protocol for a pilot study

Michelle V Simons ^{1,™}, Marijn H A Groen ², Gert J de Borst ³, Tim Leiner ⁴, Pieter A F Doevendans ^{2,5}, Emad Ebbini

⁶, Fons J B Slieker ⁷, René van Es ², Constantijn E V B Hazenberg ³

Editorial > Curr Med Res Opin. 2020 Mar;36(3):509-512. doi: 10.1080/03007995.2019.1699518.
 Epub 2019 Dec 6.

High intensity focused ultrasound (HIFU) for the treatment of varicose veins and venous leg ulcers - a new non-invasive procedure and a potentially disruptive technology

Mark S Whiteley 1
Affiliations + expand

ABSTRACT | Originally Published 25 November 2014 | 🙃



Abstract 12973: High-Intensity Focused Ultrasound (HIFU) Promotes Angiogenesis in a Rat Model of Peripheral Arterial Disease





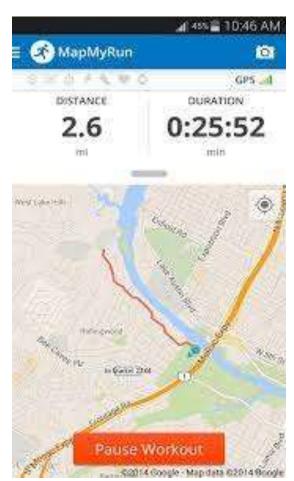
Super Available
Not Available

Alternot Funded
Not Funded

Virtual Supervised Exercise

Unsuper Effective exercise





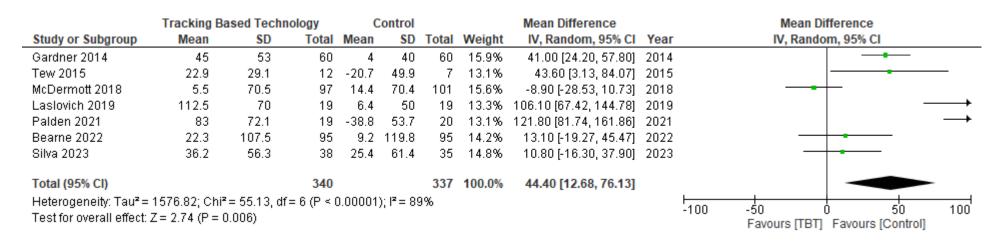






Apps and SmartWatches

6 minute walk test



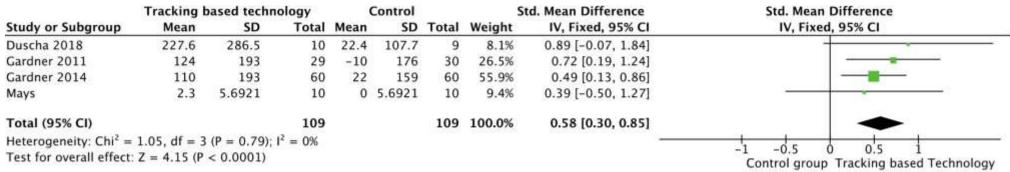
Claudication onset time

	Tracking b	ased techn	ology	9	Control		S	td. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Duscha 2018	204.6	280.6	10	-21	142.7	9	8.2%	0.95 [-0.01, 1.91]	
Gardner 2011	134	197	29	-16	125	30	26.2%	0.90 [0.36, 1.44]	- · ·
Gardner 2014	104	162	60	17	138	60	56.6%	0.57 [0.21, 0.94]	
Mays	1.6	4.8	9	-0.6	4.7434	10	9.0%	0.44 [-0.47, 1.35]	· · · · · ·
Total (95% CI)			108			109	100.0%	0.68 [0.40, 0.95]	•
Heterogeneity: Chi2 =	1.54, df = 3	(P = 0.67);	$I^2 = 0\%$						-
Test for overall effect	Z = 4.84 (P)	< 0.00001)							Control group Tracking based Technology



Apps and SmartWatches

Peak walking time



Walking impairment questionnaire

	Tracking	based techn	ology		Control			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	I IV, Random, 95% CI
Gardner 2011	10	25	29	1	34	30	23.4%	9.00 [-6.19, 24.19]	1
Mays	19.9	13.914	10	-7.3	13.914	10	28.0%	27.20 [15.00, 39.40]]
McDermott 2018	10.6	36.2203	97	4.8	36.4718	101	31.4%	5.80 [-4.33, 15.93]	1
Tew 2015	12.5	26.7	13	-0.9	21.9	9	17.2%	13.40 [-6.98, 33.78]	
Total (95% CI)			149			150	100.0%	13.84 [2.97, 24.71]	1
Heterogeneity: Tau2 =	= 71.15; Chi	$^{2} = 7.40$, df =	3 (P = 0	0.06); 12	= 59%				- t- t- t-
Test for overall effect				-50 -25 0 25 50 Control Group Tracking based Technology					



Apps and SmartWatches

Quality of Life

	Tracking ba	sed techn	ology	C	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Gardner 2011	8	15	29	-1	17	30	9.7%	9.00 [0.83, 17.17]	-
Mays	2.9	2	10	1.8	2	10	49.8%	1.10 [-0.65, 2.85]	+
Nicolai 2010	5.8	8.6	169	2.5	10.3	83	40.5%	3.30 [0.73, 5.87]	
Total (95% CI)			208			123	100.0%	2.75 [-0.01, 5.52]	•
Heterogeneity: Tau ² = Test for overall effect				-10 -5 0 5 10 Control group Tracking based technology					

What we have made

Walk A Cise

Clinician Dashboard designed with HCPs

Mobile phone application designed with patients



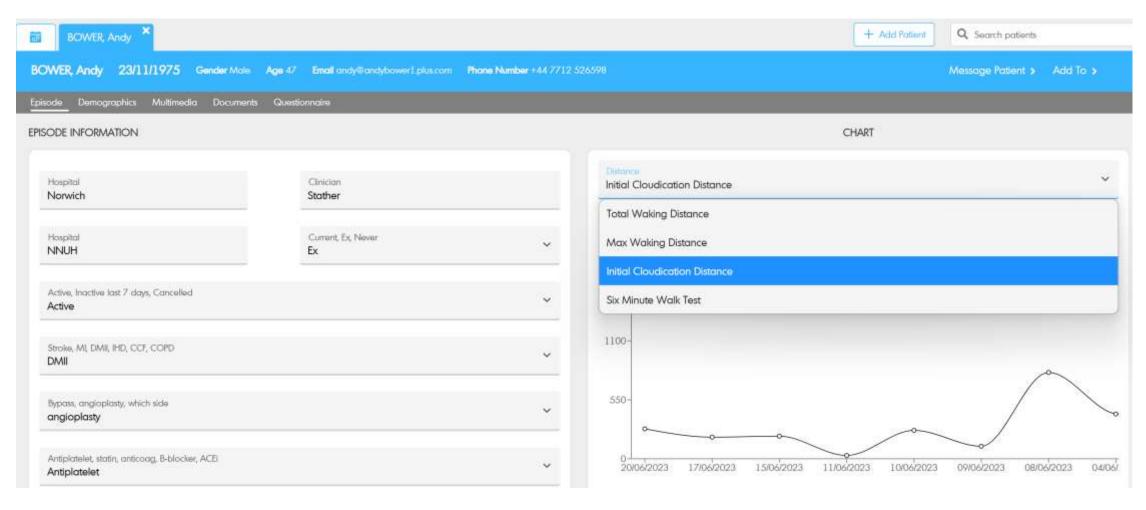




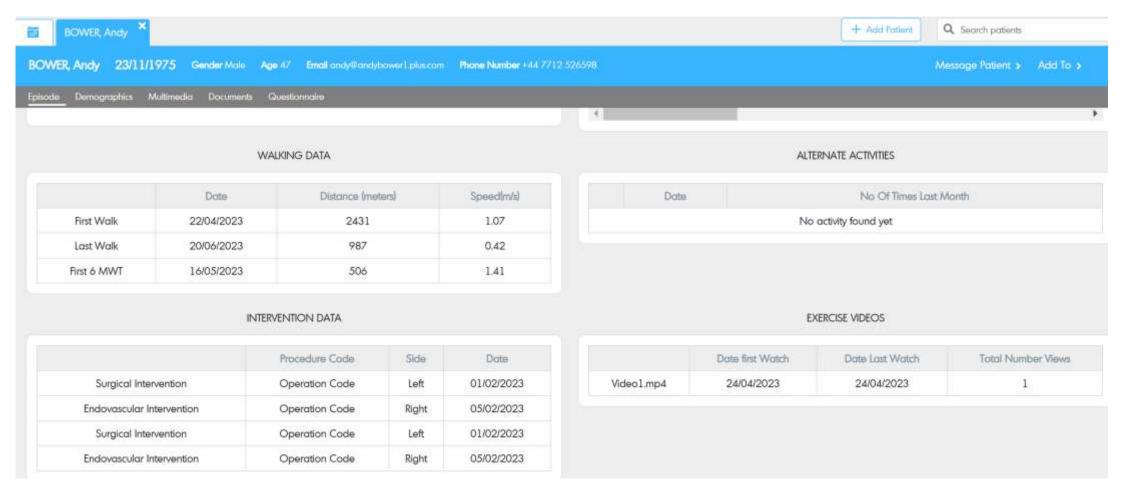












বঃ ∥ 60%≘ 12:01



Walk Cise

Powered by Granite







Patient

Information

My Walking

Data

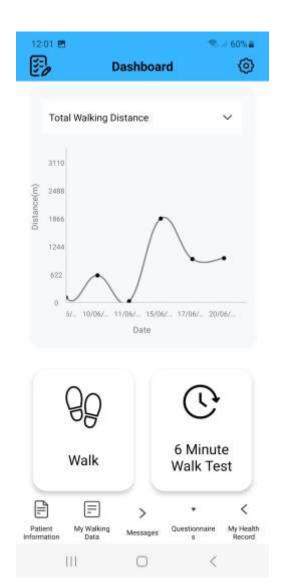
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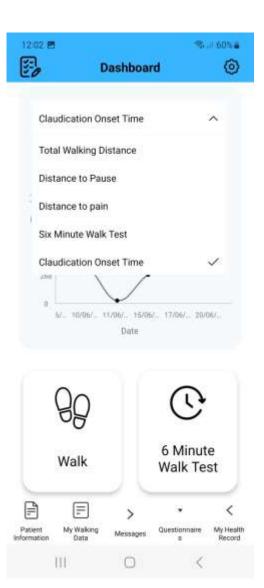
Messages

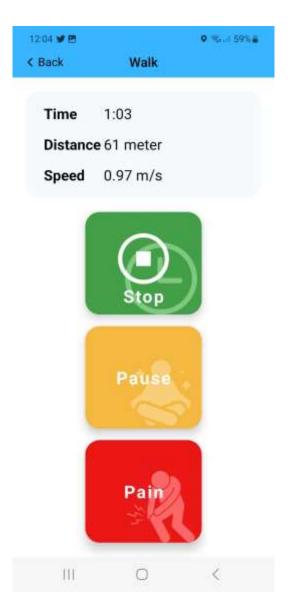
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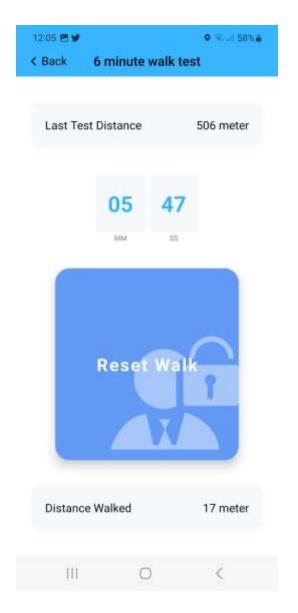
My Health Record

Questionnaire

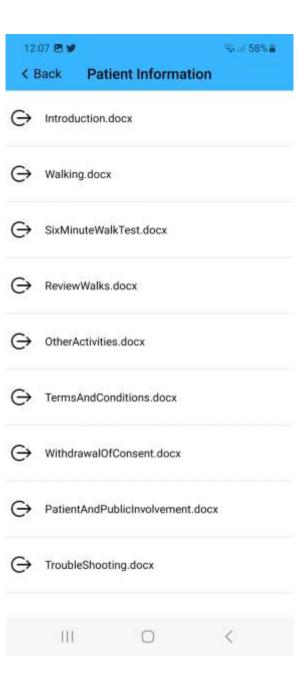


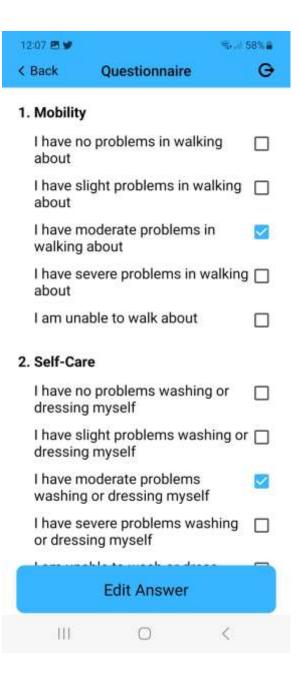














Animations – 30 minute classes

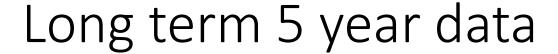














Supervised Exercise Therapy for Intermittent Claudication: A Propensity Score Matched Analysis of Retrospective Data on Long Term Cardiovascular Outcomes

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Bharadhwaj Ravindhran 🖰 🖾 · Arthur J.M. Lim · Thomas Kurian· ... · Daniel Carradice · Ian C. Chetter · Sean Pymer... Show more
Affiliations & Notes ∨ Article Info ∨ Linked Articles (1) ∨
```

6МWT р 266 patient referred for SET. 64 completed SET. Those that completed SET were less likely to require revascularisation at 5 years.

Long term 5 year data

> Eur J Vasc Endovasc Surg. 2020 Dec;60(6):881-887. doi: 10.1016/j.ejvs.2020.07.074. Epub 2020 Seg

Successful Implementation of the Exercise First Approach for Intermittent Claudication in the Netherlands is Associated with Few Lower Limb Revascularisations Decreased risk of CLTI
Lower MALE
Improved walking distance
Lower risk of surgery

Sandra CP Ja Effects of Long-Term Home Exercise in Participants With Peripheral Artery Disease

Andrew W. Gardner, PhD Journal of the American Heart The Association Between Completion of Supervised Exercise
Therapy and Long-Term Outcomes in Patients with Intermittent
Claudication, Concomitant Sarcopenia, and Cardiometabolic
Multimorbidity

Bharadhwaj Ravindhran A¹ A· Chukwuemeka Igwe¹· Jonathan Prosser¹· ... · George E. Smith¹· Ian C. Chetter¹· Sean Pymer¹... Show more

What do we need to know?

All data to date is from short term intervention

An app can provide long term intervention

- Does this help?
- What is compliance?

An app can be used to provide monitoring

- Frequency of use
- Engagement
- Uptake

Restart use if symptoms deteriorate

How to use Walk-A-Cise

Set-up on referral, review data in nurse-led clinic

Set-up on clinical review – SVN/secretary

Remote follow up

Patient Initiated Follow up

Conclusion

- Exercise therapy is the first treatment option for PAD
- It should be used both before and after surgical intervention
- Provision of exercise therapy is poor
- Using tracking based technology enables
 - Greater access removes postcode lottery
 - Longer term use
 - Green solution
- Alternative therapies are available but large trials are needed



Next Steps with Walk-A-Cise





Starting in multiple hospitals



Real World Use data



Clinical trials



Primary Care



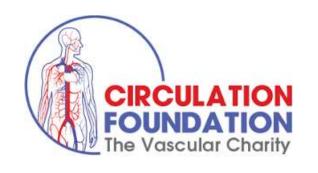
- Isabelle Sanders
- Pavithira Sivagangan
- Mike Robinson

























Norfolk and Norwich WHS
University Hospitals



