Research Article

Effect of the LIFE program on ankle–brachial index and diabetic foot risk scores among patients with type 2 diabetes mellitus: a non-randomized controlled trial

Shalin Gnana Priya[1,2,*], J Jaslina Gnana Rani[1], Hilda Rose Mary[1], S. T. Mohana[1,2], Ando Bindo Rathina[1,3] & M. Raja [1,4]

[1]Apollo College of Nursing, The Tamil Nadu Dr. M.G.R. Medical University, Chennai, India; [2]CSI Kalyani College of Nursing, The Tamil Nadu Dr. M.G.R. Medical University, Chennai, India; [3]Professor, PSN College of Nursing, Tirunelveli; [4]Billroth College of Nursing, Chennai (affiliated to The Tamil Nadu Dr. M.G.R. Medical University), Chennai, Tamil Nadu, India; *Corresponding author

Author contacts: Shalin Gnana Priya

Abstract:

Impaired lower-extremity perfusion in type 2 diabetes mellitus (T2DM) raises the risk of foot ulcers and amputation. Therefore, it is of interest to evaluate a nurse-led Lifestyle Educational Intervention, Foot Care, and Exercise (LIFE) program, which includes Buerger–Allen exercise, on the ankle–brachial index (ABI) and diabetic foot risk scores. A non-randomized controlled trial was done among 150 patients with T2DM and an ABI below 0.90 (75 per group) in a mission hospital in Chennai. After one month, the mean ABI was 0.910 in the study group and 0.847 in the control group ($p < 0.001$), and all study participants were in the low-risk foot screen category. After adjusting for 14 covariates, the program effect on ABI was large (partial $\eta^2 = 0.148$), with no effect on fasting blood glucose. Thus, the LIFE program was associated with a higher ABI and lower foot risk scores over one month, and randomized trials with longer follow-up are needed.

Keywords: Type 2 diabetes mellitus, ankle–brachial index, lower extremity perfusion, Buerger–Allen exercise, diabetic foot screen, nursing intervention

How to cite this article: Priya SG, Rani JJG, Mary HR, Mohana ST, Rathina AB, Raja M., Effect of the LIFE Program on Ankle–Brachial Index and Diabetic Foot Risk Scores among Patients with Type 2 Diabetes Mellitus: A Non-Randomized Controlled Trial. Int J Drug Deliv Technol. 2026;16(90s): 1786-1790; DOI: 10.25258/ijddt.16.90s.180

Background:

Diabetes is one of the fastest-growing health problems in the world, with an estimated 536.6 million adults (10.5%) affected in 2021 and 783.2 million (12.2%) projected by 2045 [1]. In India, the ICMR-INDIAB study of 113,043 individuals reported a diabetes prevalence of 11.4% and a prediabetes prevalence of 15.3% [2]. Long-standing diabetes damages the blood vessels and nerves of the legs, and the resulting foot ulcers can lead to infection and lower-limb amputation [3]. Peripheral artery disease (PAD), a major cause of poor blood flow to the legs, is commonly defined by an ankle–brachial index (ABI) of 0.90 or less [4]. Current guidelines describe lower extremity PAD as a spectrum that ranges from asymptomatic disease to chronic limb-threatening and acute limb ischaemia [5]. In people with diabetes, neuropathy can mask pain and other warning symptoms, so poor perfusion may go unnoticed until a wound appears [6]. The International Working Group on the Diabetic Foot notes that amputations are still rising, more so in middle- and lower-income countries, and gives practical advice on prevention [7]. The Standards of Care of the American Diabetes Association also recommend regular foot examination and foot care for people with diabetes [8]. Inlow's 60-second diabetic foot screen is a simple tool that places patients in risk categories to guide the interval of follow-up [9]. Therefore, it is of interest to report the effect of a brief nurse-led LIFE program that combines lifestyle education, foot care and Buerger–Allen exercise on the ABI and diabetic foot risk scores, since structured foot education is known to improve self-care and lower the odds of amputation [10].

Materials and Methods:

Study design and setting: A quantitative approach with a non-randomized controlled pretest–post-test design was used (**Table 1**). The study was done at CSI Kalyani General Hospital, Chennai, a 220-bed mission hospital that offers in-patient and out-patient care. The LIFE program was developed as part of a doctoral study; knowledge scores and baseline comparability are reported separately.

Table 1: Research design of the study

Group	Pretest	Intervention	Post-test I	Post-test II
Study group	O_1	X_1	O_2	O_3
Control group	O_1	—	O_2	O_3

O_1: pretest (ABI and diabetic foot screen); O_2: post-test I at discharge (ABI); O_3: post-test II after one month (ABI and diabetic foot screen); X_1: LIFE program.

Sample size and sampling: The sample size was estimated in OpenEpi with ABI as the primary outcome, using a standard deviation of 0.13 from earlier published work, a 95% confidence level, 80% power and a 1:1 allocation ratio. The minimum sample was 55 patients per group; 150 patients were enrolled (75 study, 75 control) by purposive sampling, and the groups were formed without randomization.

Selection criteria: Patients aged 45 to 65 years of either sex with T2DM for more than 2 years, an ABI below 0.90, an HbA1c of 6.5% or more, on oral hypoglycaemic drugs or

insulin, and medically stable and fit for mild exercise were included. Critically ill patients (Glasgow Coma Scale below 14/15), those with an active foot ulcer, gangrene or amputation, those with deep vein thrombosis, varicose veins or leg ulcers, and those unwilling to take part were excluded.

Variables and instruments: The independent variable was the LIFE program, and the dependent variables were the ABI and the diabetic foot screen score. Demographic variables (age, gender, education, nature of activity, smoking, alcohol and tobacco use, body mass index [BMI] and duration of diabetes) and clinical variables (fasting blood glucose [FBS], post-prandial blood glucose [PPBS] and HbA1c) were recorded on a structured proforma. The ABI is the ratio of ankle to brachial systolic pressure, and a value below 0.90 was taken as reduced perfusion [4]. Foot risk was assessed with a modified Inlow's 60-second diabetic foot screen [9], scored 0 to 25 per foot: 0–6 low risk (yearly screening), 7–12 moderate (6-monthly), 13–19 high (3-monthly) and 20 or more very high risk (every 1–3 months). Content validity was established by experts, inter-rater reliability of the perfusion assessment was r = 0.82, and a pilot study of 60 patients (30 per group) confirmed feasibility and reliability.

LIFE program: The program was delivered one-to-one on three consecutive days: lifestyle modification by lecture-cum-discussion with a PowerPoint presentation (Day 1), foot care by demonstration (Day 2) and Buerger–Allen exercise by demonstration and practice (Day 3), each for about 15 minutes. Buerger–Allen exercise moves the legs in sequence through elevation, dependency and a horizontal position; it was done for 20 minutes, three times a day at three-hour intervals, for five days or until discharge, and patients were advised to continue it at home. The control group received usual hospital care.

Data collection and ethics: Ethical clearance was obtained from the Institutional Ethics Committee of Apollo College of Nursing, permission was obtained from the hospital, and all participants gave informed consent; data were kept confidential. The pretest (O_1) included demographic and clinical data, ABI and the foot screen. ABI was repeated at discharge (O_2) and after one month (O_3), and the foot screen after one month (O_3), on the same schedule in both groups.

Statistical analysis: Data are presented as mean ± standard deviation and as numbers with percentages. Baseline comparability was tested with the chi-square and independent t tests, and ABI at each assessment was compared between groups with the independent t test. Change across the three ABI assessments within each group was tested with repeated-measures ANOVA followed by post hoc pairwise comparisons, and change in foot screen scores with the paired t test; Cohen's d was calculated from group means and standard deviations. A multivariate analysis of covariance (MANCOVA) with group as the fixed factor estimated the adjusted effect on FBS, ABI and left and right foot scores, with knowledge as a secondary outcome. Fourteen covariates were entered: age, gender, education, nature of activity, smoking, alcohol use, tobacco use, BMI, duration of diabetes and the pretest values of FBS, ABI, left and right foot scores and knowledge. Partial η^2 values of 0.01, 0.06 and 0.14 were taken as small, medium and large effects, and $p < 0.05$ was considered significant.

Results:

The two groups (n = 75 each) were comparable at baseline in demographic and clinical variables (all $p > 0.05$). The mean FBS was 205.43 ± 31.40 mg/dL in the control group and 203.79 ± 33.65 mg/dL in the study group ($p = 0.758$), the mean PPBS was 170.47 ± 36.16 and 169.08 ± 35.43 mg/dL ($p = 0.813$), and the mean HbA1c was 9.00 ± 1.00% and 8.81 ± 0.94% ($p = 0.241$), respectively.

Ankle–brachial index: At the pretest, the mean ABI was almost the same in the control (0.776 ± 0.073) and study groups (0.773 ± 0.074; $p = 0.798$; $d = -0.04$) (**Table 2; Figure 1**). A difference appeared at discharge (0.829 ± 0.089 vs 0.860 ± 0.079; $p = 0.029$; $d = 0.37$) and became larger after one month (0.847 ± 0.091 vs 0.910 ± 0.079; $p < 0.001$; $d = 0.74$). At the end of the study, the mean ABI of the study group was above the 0.90 cut-off, whereas that of the control group remained below it.

Table 2: Comparison of ankle–brachial index between the control and study groups (n = 75 each)

Assessment	Control Mean ± SD	Study Mean ± SD	Mean diff.	t	p	d
Pretest	0.776 ± 0.073	0.773 ± 0.074	−0.003	0.26	0.798	−0.04
Post-test I (discharge)	0.829 ± 0.089	0.860 ± 0.079	0.031	2.20	0.029	0.37
Post-test II (1 month)	0.847 ± 0.091	0.910 ± 0.079	0.063	4.53	<0.001	0.74

Mean difference = study minus control; d = Cohen's d calculated from group means and standard deviations.

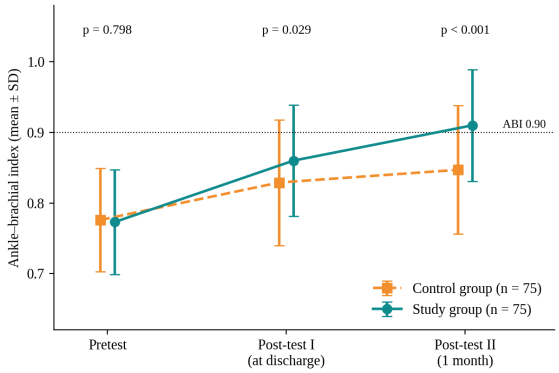


Figure 1: Mean ankle–brachial index at pretest, post-test I and post-test II in the control and study groups

The ABI changed significantly over time in both groups (control: $F = 26.777$, $p < 0.001$; study: $F = 1790.84$, $p < 0.001$), and the gain in the study group was larger at every interval (**Figure 2**). From pretest to post-test II, the ABI rose by 0.137 in the study group (95% CI 0.131 to 0.142) and by 0.071 in the control group. In the study group, post hoc comparisons showed significant increases from pretest to post-test I (0.087; 95% CI 0.083 to 0.091) and from post-test I to post-test II (0.050; 95% CI 0.046 to 0.054), all $p < 0.001$. The control group improved by 0.053 during the hospital stay

and by a further 0.018 during the follow-up month, showing that usual care was linked to some improvement; the study group improved more, and the difference of 0.063 at one month was of medium to large size.

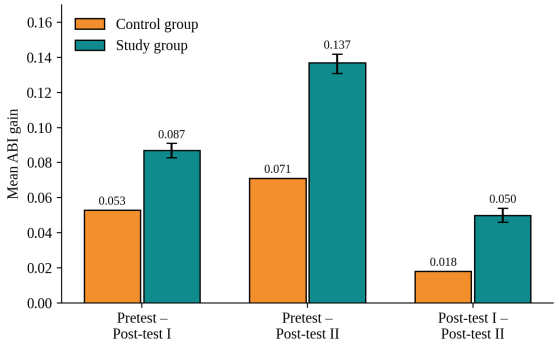


Figure 2: Mean gain in ankle–brachial index between assessments in the control and study groups

Diabetic foot screen scores: At the pretest, the groups did not differ in the left (17.04 ± 2.34 vs 17.12 ± 2.11; p = 0.826) or right foot (17.36 ± 2.03 vs 16.75 ± 1.98; p = 0.063) (**Table 3; Figure 3**). Both groups improved by post-test II (all p < 0.001), but the fall was much larger in the study group: 14.01 vs 3.31 points for the left foot and 13.93 vs 4.51 points for the right foot. After one month, the mean between-group difference was 10.63 points for the left foot (t = 26.48, p < 0.001) and 10.04 points for the right foot (t = 23.62, p < 0.001), with calculated Cohen's d of about 4.3 and 3.9. Values of this size are rarely seen in nursing trials and should be interpreted with caution.

Table 3: Change in diabetic foot screen scores from pretest to post-test II (n = 75 each)

Foot	Group	Pretest Mean ± SD	Post-test II Mean ± SD	Change	Paired t	p
Left	Control	17.04 ± 2.34	13.73 ± 3.26	3.31	7.31	<0.001
Left	Study	17.12 ± 2.11	3.11 ± 1.21	14.01	48.62	<0.001
Right	Control	17.36 ± 2.03	12.85 ± 3.44	4.51	10.46	<0.001
Right	Study	16.75 ± 1.98	2.81 ± 1.31	13.93	51.35	<0.001

Higher scores indicate higher foot risk (range 0 to 25). Change = pretest minus post-test II.

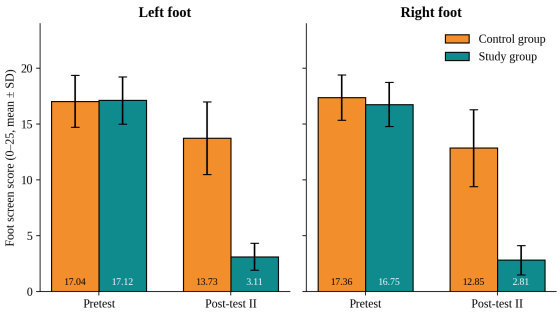


Figure 3: Mean diabetic foot screen scores of the left and right foot at pretest and post-test II in the control and study groups

Diabetic foot risk categories: Before the intervention, most patients were at high risk (**Figure 4**). For the left foot, 65 (86.7%) control and 66 (88.0%) study patients were at high risk and 8 (10.7%) and 9 (12.0%) at very high risk; for the right foot, 65 (86.7%) and 69 (92.0%) were at high risk and 10 (13.3%) and 4 (5.3%) at very high risk. Only two control patients (left foot) and two study patients (right foot) were at moderate risk, and none was at low risk. After one month, all 75 study patients (100%) were at low risk for both feet. In the control group, the left foot was at low risk in 2 (2.7%), moderate in 22 (29.3%), high in 50 (66.7%) and very high in 1 (1.3%), and the right foot at low risk in 2 (2.7%), moderate in 30 (40.0%) and high in 43 (57.3%), with none at very high risk.

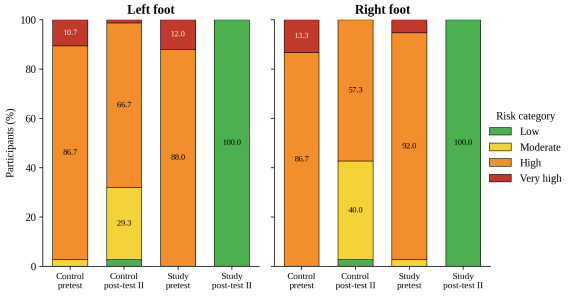


Figure 4: Distribution of diabetic foot risk categories of the left and right foot at pretest and post-test II in the control and study groups

Covariate-adjusted effect: After adjusting for the 14 covariates, the program had a significant and large effect on ABI (F = 23.218, p < 0.001, partial η^2 = 0.148) and very large effects on the left (F = 687.400, partial η^2 = 0.837) and right foot scores (F = 492.955, partial η^2 = 0.786) (**Table 4; Figure 5**). The effect on knowledge, the secondary outcome, was also large (F = 31.624, partial η^2 = 0.191), whereas there was no effect on FBS (F = 0.043, p = 0.837, partial η^2 = 0.000). The pretest value was the main predictor of the same outcome (FBS: F = 58.288; ABI: F = 48.720; both p < 0.001), and BMI (F = 7.456, p = 0.007) and pretest knowledge (F = 10.243, p = 0.002) were also related to the left foot score. The models explained 36.4% of the variance in ABI and 83.7% and 78.3% of the variance in the left and right foot scores.

Table 4: Adjusted effect of the LIFE program on the outcomes (MANCOVA, univariate tests)

Outcome	F (1, 134)	p	Partial η^2	Adjusted R^2
Fasting blood glucose	0.043	0.837	0.000	0.310
Ankle–brachial index	23.218	<0.001	0.148	0.364
Left foot score	687.400	<0.001	0.837	0.837
Right foot score	492.955	<0.001	0.786	0.783
Knowledge (secondary)	31.624	<0.001	0.191	0.240

Knowledge was a secondary outcome in the model.

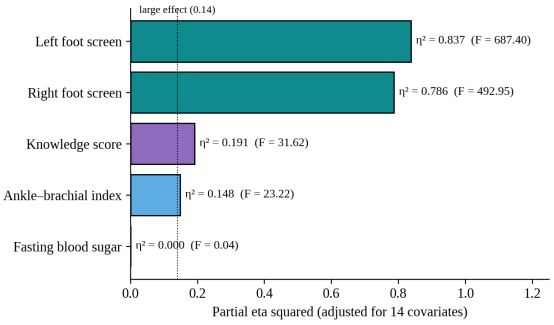


Figure 5: Effect size (partial η²) of the LIFE program on each outcome after adjusting for 14 covariates

Discussion:

This trial examined a short nurse-led program in 150 hospitalized patients with T2DM and a low ABI. After one month, the ABI of the study group was 0.063 higher and the foot screen scores were about 10 points lower than in the control group, and these differences remained after adjustment for 14 covariates. The gain in ABI in the study group (0.137) is close to the pooled mean increase of 0.14 (95% CI 0.08 to 0.19) reported for Buerger–Allen exercise in a meta-analysis of ten studies with 586 participants [11]. It is larger than the 0.04 rise in ABI after six months of supervised aerobic and resistance training in a randomized trial of 140 adults with T2DM [12], although the trials differed in the type and duration of exercise, the population and the control condition. A 20-week program of three physical therapy modalities also improved ABI and Doppler flow velocity in 68 patients with T2DM and PAD [13]. In contrast, home-based foot–ankle flexibility and resistance exercise reduced the recurrence of plantar ulcers without a significant difference in ABI [14], which suggests that exercises built on leg position changes, such as Buerger–Allen exercise, may act more directly on perfusion. Better microcirculation has also been reported after a single 15-minute walk in people with diabetes [15], supporting the idea that even brief activity can benefit the lower limb.

Buerger–Allen exercise is thought to improve flow through gravity-assisted filling and emptying of the leg vessels, but this mechanism was not measured here, and the design cannot separate the effects of the education, foot care and exercise components. The control group also improved, possibly because of in-hospital glycaemic treatment, rest and nursing care, repeated measurement and regression to the mean; the concurrent control group accounts for these effects, and the study group improved more at every interval. The absence of an effect on FBS is expected for a mild, perfusion-focused program and suggests that the ABI gain was not simply the result of better glucose control. The very large change in foot screen scores needs careful reading, since several screen items respond quickly to foot care behaviour, assessor blinding was not reported, and the screen is a risk score rather than a clinical outcome. Limitations include the non-randomized single-centre design with purposive sampling, lack of blinding, one-month follow-up without ulcer or amputation outcomes, possible false elevation of ABI in calcified arteries, and foot screening at only two time points. Even so, three 15-minute bedside sessions and an exercise that needs no equipment make the program practical for medical and surgical wards and out-patient clinics.

Conclusion:

The LIFE program, which combines lifestyle education, foot care teaching and Buerger–Allen exercise, was associated with a higher ABI and a lower diabetic foot risk score at one month in patients with T2DM and a low ABI. The effect on ABI remained large after adjustment for patient characteristics and baseline values, while fasting blood glucose was unaffected. The program is simple and low in cost for routine nursing care, but randomized controlled trials with blinded assessment, longer follow-up and clinical outcomes are needed to confirm these findings.

Conflict of interest:

The authors certify that they have no involvement in any organization or entity with any financial or non-financial interest in the subject matter or materials discussed in this paper.

Funding:

There was no funding source for this study.

References:

[1] Sun H, Saeedi P, Karuranga S, Pinkepank M, et al., IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045, Diabetes Res Clin Pract 183 (2022) 109119. https://doi.org/10.1016/j.diabres.2021.109119

[2] Anjana RM, Unnikrishnan R, Deepa M, Pradeepa R, et al., Metabolic non-communicable disease health report of India: the ICMR-INDIAB national cross-sectional study (ICMR-INDIAB-17), Lancet Diabetes Endocrinol 11(7) (2023) 474–489. https://doi.org/10.1016/S2213-8587(23)00119-5

[3] Armstrong DG, Tan T-W, Boulton AJM, Bus SA, Diabetic Foot Ulcers: A Review, JAMA 330(1) (2023) 62. https://doi.org/10.1001/jama.2023.10578

[4] Pavithra TR, Kaliyaperumal R, Epidemiology, pathophysiology, and management of diabetic foot: a comprehensive review, The Foot 66 (2026) 102225. https://doi.org/10.1016/j.foot.2026.102225

[5] Song P, Rudan D, Zhu Y, Fowkes FJI, et al., Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis, Lancet Glob Health 7(8) (2019) e1020–e1030. https://doi.org/10.1016/S2214-109X(19)30255-4

[6] Gornik HL, Aronow HD, Goodney PP, Arya S, et al., 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease, Circulation 149(24) (2024). https://doi.org/10.1161/CIR.0000000000001251

[7] Boulton AJM, Armstrong DG, Kirsner RS, Attinger C, et al., Diagnosis and Management of Diabetic Foot Complications, ADA Clinical Compendia 2018(2) (2018) 1–20. https://doi.org/10.2337/DB20182-1

[8] Schaper NC, van Netten JJ, Apelqvist J, Bus SA, et al., Practical guidelines on the prevention and management of diabetes-related foot disease (IWGDF 2023 update), Diabetes

Metab Res Rev 40(3) (2024) e3657. https://doi.org/10.1002/dmrr.3657

[9] ElSayed NA, McCoy RG, Aleppo G, et al., 12. Retinopathy, Neuropathy, and Foot Care: Standards of Care in Diabetes—2025, Diabetes Care 48(Suppl 1) (2025) S252–S265. https://doi.org/10.2337/dc25-S012

[10] Blanchette V, Kuhnke JL, Botros M, Rosenthal S, Inlow's 60-second Diabetic Foot Screen: Update 2022, Limb Preservation Journal 4(1) (2023). https://doi.org/10.56885/hrju7789

[11] Murphy CA, Laforet K, Da Rosa P, et al., Reliability and predictive validity of Inlow's 60-second diabetic foot screen tool, Adv Skin Wound Care 25(6) (2012) 261–266. https://doi.org/10.1097/01.asw.0000415343.45178.91

[12] Thakur A, Sharma R, Sharma SK, Thakur K, et al., Effect of Buerger Allen exercise on foot perfusion among patients with diabetes mellitus: a systematic review and meta-analysis, Diabetes Metab Syndr 16(2) (2022) 102393. https://doi.org/10.1016/j.dsx.2022.102393

[13] Barone Gibbs B, Dobrosielski DA, Althouse AD, Stewart KJ, The effect of exercise training on ankle-brachial index in type 2 diabetes, Atherosclerosis 230(1) (2013) 125–130. https://doi.org/10.1016/j.atherosclerosis.2013.07.002

[14] Castro-Sánchez AM, Matarán-Peñarrocha GA, Feriche-Fernández-Castanys B, Fernández-Sola C, et al., A program of 3 physical therapy modalities improves peripheral arterial disease in diabetes type 2 patients, J Cardiovasc Nurs 28(1) (2013) 74–82. https://doi.org/10.1097/JCN.0b013e318239f419

[15] Drovandi A, Seng L, Golledge J, Effectiveness of educational interventions for diabetes-related foot disease: a systematic review and meta-analysis, Diabetes Metab Res Rev 40(3) (2024) e3746. https://doi.org/10.1002/dmrr.3746

[16] Richardson JTE, Eta squared and partial eta squared as measures of effect size in educational research, Educ Res Rev 6(2) (2011) 135–147. https://doi.org/10.1016/j.edurev.2010.12.001

[17] Suryani M, Samekto W, Heri-Nugroho, Susanto H, et al., Effect of foot-ankle flexibility and resistance exercise in the secondary prevention of plantar foot diabetic ulcers, J Diabetes Complications 35(9) (2021) 107968. https://doi.org/10.1016/j.jdiacomp.2021.107968

[18] Palacios-Abril L, Tardáguila-García A, Álvaro-Afonso FJ, Tejeda-Ramírez S, et al., Fifteen-minute walk improves microcirculation in people with diabetes mellitus, Microvasc Res 164 (2026) 104897. https://doi.org/10.1016/j.mvr.2025.104897