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EFFECTIVENESS OF A MULTIMODAL PATIENT EDUCATION PROGRAM IN PATIENTS WITH AND WITHOUT TROPHIC ULCERS OF THE LOWER EXTREMITIES ASSOCIATED WITH PERIPHERAL ARTERY DISEASE

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Abstract

Relevance. Chronic limb-threatening ischemia is the most severe manifestation of peripheral artery disease, carrying high rates of amputation and mortality. Structured patient education programs have demonstrated benefit in other chronic diseases, yet remain largely unevaluated in peripheral artery disease, particularly chronic limb-threatening ischemia.

Objective. To evaluate the effectiveness of a structured multimodal educational program (CLTI School) compared with standard care on clinical outcomes and quality of life in patients with peripheral artery disease.

Materials and Methods. Parallel-group randomized controlled trial conducted in Astana, Kazakhstan. A total of 184 patients with peripheral artery disease (Rutherford categories 2-5) were randomized 1:1 and followed for 12 months. The program comprised eight vascular surgeon-led group sessions, a digital platform, peer support groups, and smoking cessation counseling. Per-protocol analysis included 81 experimental and 78 control participants. Co-primary outcomes were health-related quality of life (SF-12) and peripheral artery disease -related hospitalization rate.

Results. At 12 months, the experimental group showed significantly higher SF-12 Physical Component Summary (44.76 vs. 35.08; $p < 0.001$) and Mental Component Summary (43.42 vs. 35.90; $p < 0.001$) scores. Hospitalizations (14.8 % vs. 20.5 %; $p = 0.346$) and amputations (4.9 % vs. 7.7 %; $p = 0.476$) were numerically lower but did not reach statistical significance. Smoking cessation was threefold higher (25.0 % vs. 8.5 %; $p = 0.026$), pain declined significantly (median VAS 3 vs. 5; $p < 0.001$), and QALYs were higher (0.67 vs. 0.60; $p < 0.001$). No adverse events attributable to the program were recorded.

Conclusions. The Chronic limb-threatening ischemia School significantly improved patient-reported outcomes and smoking cessation in patients with peripheral artery disease. Structured educational programs should be considered an integral component of comprehensive peripheral artery disease management.

Keywords: *peripheral arterial disease, patient education as topic, quality of life, smoking cessation, secondary prevention, randomized controlled trial.*

Introduction

Chronic limb-threatening ischemia (hereinafter – CLTI) is the most severe form of peripheral artery disease (hereinafter – PAD), characterized by severely reduced tissue perfusion leading to rest pain, trophic ulcers, and gangrene [1]. PAD affects

approximately 10 % of adults over 40 and 20 % of those over 70 [2]. The global incidence of CLTI is estimated at 500-1,000 new cases per million population per year [3]. In high-risk populations – individuals aged ≥70 years, or aged 50-69 years with diabetes mellitus or a smoking history ≥10 pack-years – prevalence reaches 29 % [4].

The prognosis for CLTI remains extremely poor. Within the first year after diagnosis, the amputation rate reaches 30 %, and mortality is 25 %; five-year survival is below 50 %, comparable to many malignancies [4]. In addition to high mortality and disability, CLTI is associated with a significant decline in quality of life, severe pain, limited mobility, and social isolation [5]. Direct medical costs per patient average $24,000-$72,000 in the first year, with hospitalizations and surgical procedures accounting for the majority of expenditure; annual costs in subsequent years decrease to $3,500-$17,000 depending on the treatment approach [6]. Despite advances in vascular surgery and interventional radiology, restenosis rates after endovascular interventions reach 20-40 % within the first year, and not all patients are candidates for revascularization [7].

Modifiable risk factors – smoking, physical inactivity, uncontrolled diabetes, hypertension, and dyslipidemia – are central to PAD development and progression [8]. Smoking cessation substantially reduces mortality: within 5 years, mortality among quitters was 14 % compared with 31 % among those who continued smoking. However, adherence to lifestyle modification remains low: only 5-30 % of PAD patients successfully quit smoking, and fewer than 50 % regularly perform recommended exercise [9].

Patient education has proven effective in chronic diseases such as type 2 diabetes, chronic heart failure, and COPD, improving self-management and clinical outcomes [10-12]. Yet significant knowledge gaps exist in PAD patients: only 54.1 % are aware of multiple treatment options, and only 31.3 % understand that smoking cessation takes priority over invasive interventions [13]. A systematic review encompassing 32 studies and 5,268 PAD patients demonstrated inadequate health literacy in the majority, with socioeconomic status and educational attainment as key modifying factors [14]. A further systematic review of educational interventions targeting physical activity in PAD identified only six eligible studies, concluding that evidence was inconclusive [15]. Critically, patients with CLTI – who face substantially higher risks – remain virtually unstudied in the context of educational interventions. No randomized controlled trial has, to our knowledge, evaluated the impact of a comprehensive educational intervention on hospitalization rates, need for surgery, or risk of amputation in CLTI.

Objective. To evaluate the effectiveness of a structured multimodal educational program (CLTI School) versus standard care on clinical outcomes and health-related quality of life in patients with peripheral artery disease, with co-primary endpoints of PAD-related hospitalization rate and SF-12 scores, and secondary endpoints of pain severity (VAS), new disability incidence, smoking cessation rate, pain-free walking distance, and quality-adjusted life years (QALYs).

Materials and methods

Study design and participants

This was a two-arm, parallel-group, superiority randomized controlled trial conducted in Astana, Kazakhstan, in accordance with the Declaration of Helsinki (2013 revision) and reported in accordance with the CONSORT 2025 guidelines. The protocol was approved by the Local Bioethics Committee of NCJSC Astana Medical University (Protocol No. 7 dated September 27, 2024) and registered on ClinicalTrials.gov (NCT07201168). Trial registration was completed after enrollment initiation; however, the protocol, including all outcome measures and the statistical analysis plan, was fully approved prior to enrollment of the first participant, and no modifications were introduced thereafter. The cost-effectiveness analysis originally included as a secondary outcome was removed from the trial registry and will be reported separately. The study was conducted at the National Research Oncology Center LLP in Astana, Kazakhstan.

Patients were eligible if they were: aged ≥18 years; had a confirmed diagnosis of PAD (Rutherford categories 2-5); were fluent in Russian; and had access to a telephone and internet. Exclusion criteria were: severe cognitive impairment; concurrent participation in another clinical trial; planned major amputation within 3 months; type 1 or type 2 diabetes mellitus; and severe visual or hearing impairment. Patients with diabetes mellitus were excluded because structured educational programs for

this population already exist in Kazakhstan, and to avoid confounding from diabetes-related neuropathy and altered pain perception. All participants provided written informed consent. Patients and members of the public were not involved in the design, conduct, or reporting of this research.

Randomization

A total of 184 participants were randomized 1:1 using a computer-generated stratified block randomization sequence (variable block sizes of 2, 4, and 6) prepared by an independent statistician. Stratification was performed by Rutherford category (Stratum A: categories 2-3; Stratum B: categories 4-5). Patients in Stratum B had undergone percutaneous transluminal balloon angioplasty prior to enrollment as standard clinical management; procedures were classified as above-the-knee (ATK) or below-the-knee (BTK). Allocation concealment was achieved through a centralized sequence accessible only to the independent statistician, with group assignments disclosed only after eligibility confirmation and written informed consent. Outcome assessors were blinded to group allocation. Blinding of participants and care providers was not feasible given the nature of the intervention. Enrollment occurred between September 30 and December 26, 2024; a 12-month follow-up was completed on December 26, 2025.

Interventions

Experimental group participants received the CLTI School – a four-week structured multimodal educational program – in addition to standard vascular surgery consultations [16]. The program comprised eight interactive group sessions led by experienced vascular surgeons (with a minimum of 5 years of clinical experience), twice weekly, each lasting 90 minutes, covering disease pathophysiology, risk factor modification, treatment options, and practical wound care skills. Participants also received access to a dedicated digital platform with multimedia materials mirroring classroom content, instructional videos, printed reference materials (a patient guide and symptom diary), a medical helpline, peer support groups, and smoking cessation counseling.

Control group participants received standard clinical management per current guidelines, comprising vascular surgery consultations and follow-up visits as clinically indicated, with standard oral and written instructions and access to the same pharmacological and surgical treatment options. Concomitant pharmacological therapy was not systematically recorded, and no restrictions on concomitant medications were imposed on either group.

Outcomes

Co-primary outcomes were: (1) frequency of PAD-related hospitalizations (limb infections, unplanned revascularization, and amputation) per patient over 12 months; and (2) health-related quality of life assessed using the SF-12, yielding Physical Component Summary (PCS) and Mental Component Summary (hereinafter – MCS) scores (range 0-100, higher = better), administered at baseline, 6, and 12 months [17]. Secondary outcomes included: pain intensity by Visual Analog Scale (VAS; 0-10) at baseline, 6, and 12 months [18]; pain-free walking distance (six-category ordinal scale: 1: 0-50 m; 2: 51-100 m; 3: 101-200 m; 4: 201-500 m; 5: 501-1,000 m; 6: >1,000 m); new disability occurrence over 12 months; smoking cessation rate at 12 months; and QALYs calculated from SF-6D utility scores derived from the SF-12, administered via a digital survey application [19]. Adverse events potentially attributable to the educational intervention were monitored and recorded at each follow-up visit.

Statistical analysis

All analyses were performed using IBM SPSS Statistics (version 27.0.1.0). Normality was assessed with the Kolmogorov-Smirnov test. Normally distributed continuous variables are presented as mean ± SD; non-normally distributed variables as median [IQR]. Between-group comparisons used the independent-samples t-test, Mann-Whitney U test, or Pearson chi-square test, as appropriate; odds ratios (hereinafter – ORs) with 95 % confidence intervals (CIs) were calculated. All tests were two-tailed; $p < 0.05$ was statistically significant. No interim analyses were planned or conducted, and no stopping rules were pre-specified. Sample size was calculated a priori using G*Power (v3.1.9.7): Cohen's d=0.6, α=0.05, power=0.95, 1:1 allocation, yielding a minimum of 74 per group (148 total); accounting for 20 % attrition, the recruitment target was 184. The primary analysis was per-protocol; participants with missing outcome data were excluded without imputation. Pre-specified subgroup analyses stratified by Rutherford category were conducted for all primary and secondary outcomes.

Results

A total of 184 participants were randomized in equal numbers by Rutherford category (Stratum A: n = 46; Stratum B: n = 46). Seven experimental and six control participants did not receive the allocated intervention for personal reasons; four experimental and eight control participants withdrew consent during follow-up. The final per-protocol analysis included 81 experimental (Stratum A: n = 39; Stratum B: n = 42) and 78 control participants (Stratum A: n = 37; Stratum B: n = 41). Baseline characteristics were comparable between groups (Table 1). The overall median age was 66 [59-71] years; 114 participants (72.0 %) were male; the mean BMI was 31.19 ± 4.13 kg/m². In Stratum B, the distribution of ATK (64.3 % experimental vs. 75.6 % control) and BTK angioplasty (35.7 % vs. 24.4 %) did not differ significantly between groups (p = 0.064).

Table 1. Baseline parameters

		Overall (n = 159)			Stratum A Rutherford 2-3			Stratum B Rutherford 4-5		
Parameter	**Value**	**Exp n = 81**	**Control n = 78**	**p**	**Exp Str A n = 39**	**Ctrl Str A n = 37**	**p**	**Exp Str B n = 42**	**Ctrl Str B n = 41**	**p**
Demographics										
Age, median [IQR], years		65 [58.5-69.5]	67 [59-72]	0.133	67 [63-74]	70 [62.5-74.5]	0.489	62 [53.75-66.25]	65 [58-69.5]	0.097
BMI, mean ± SD, kg/m²		30.99 ± 4.18	31.39 ± 4.10	0.545	30.91 ± 4.08	31.72 ± 4.67	0.428	31.07 ± 4.32	31.10 ± 3.55	0.969
Male, n (%)	114 (71.7 %)	59 (72.8 %)	55 (70.5 %)	0.745	28 (71.8 %)	25 (67.6 %)	0.688	31 (73.8 %)	30 (73.2 %)	0.947
Female, n (%)	45 (28.3 %)	22 (27.2 %)	23 (29.5 %)	-	11 (28.2 %)	12 (32.4 %)	-	11 (26.2 %)	11 (26.8 %)	-
Baseline smoking status										
Smokers at baseline, n (%)	99 (62.3 %)	52 (64.2 %)	47 (60.3 %)	0.083	25 (64.1 %)	19 (51.3 %)	0.260	27 (64.3 %)	28 (68.3 %)	0.699

Exp = Experimental group; Ctrl = Control group; Str A = Stratum A (Rutherford 2-3); Str B = Stratum B (Rutherford 4-5); IQR = interquartile range; SD = standard deviation; BMI = body mass index
Source: compiled by the authors

Quality of life

Baseline SF-12 PCS and MCS scores were comparable between groups (Table 2). By 12 months, the experimental group had significantly higher PCS scores (44.76 [39.42-48.52] vs. 35.08 [29.74-39.83]; p < 0.001) and MCS scores (43.42 [37.17-48.19] vs. 35.90 [27.72-40.98]; p < 0.001), with highly significant differences across both strata (all p≤0.006). Within-group analysis revealed significant PCS improvement from baseline to 12 months in the experimental group (p < 0.001 overall; Stratum A: p = 0.001; Stratum B: p = 0.004), with scores plateauing between 6 and 12 months (p = 0.931) (Table 3). In contrast, the control group showed no significant change from baseline to 6 months (p = 0.308) but experienced a significant decline from 6 to 12 months (overall: p = 0.001; Stratum A: p = 0.010; Stratum B: p = 0.027), with overall deterioration from baseline to 12 months reaching significance (p = 0.033). For MCS, experimental group scores improved modestly from baseline to 6 months (p = 0.041) and remained stable through 12 months (p = 0.375 for 6-12 months change; p = 0.066 for 0-12 months overall), whereas the control group deteriorated significantly from 6 to 12 months (p < 0.001) and from baseline to 12

months ($p < 0.001$ overall) (Table 3). The between-group MCS difference, therefore, reflects preservation of mental health status – a clinically meaningful outcome in a condition typically associated with progressive psychological decline.

Table 2. Outcomes at Baseline, 6 Months, and 12 Months [median, IQR]

		Experimental group			Control group			Between-group p-value		
Outcome	**Time point**	**Overall n = 81**	**Str A n = 39**	**Str B n = 42**	**Overall n = 78**	**Str A n = 37**	**Str B n = 41**	**Overall**	**Str A**	**Str B**
SF-12 Physical Component Summary (PCS) [median, IQR]										
PCS	Baseline	39.01 [33.18-43.55]	42.70 [37.73-47.07]	36.27 [30.6-40.86]	37.02 [32.62-41.16]	40.10 [35.95-43.65]	34.47 [32.2-38.37]	0.194	0.093	0.855
	6 months	43.74 [39.31-49.46]	47.30 [43.74-50.78]	39.88 [35.03-44.30]	38.28 [31.94-44.44]	39.83 [35.5-46.13]	37.90 [30.94-42.29]	<0.001	<0.001	0.047
	12 months	44.76 [39.42-48.52]	47.10 [42.5-50.50]	40.90 [34.49-46.73]	35.08 [29.74-39.83]	35.30 [30.62-41.15]	32.73 [28.28-39.52]	<0.001	<0.001	<0.001
SF-12 Mental Component Summary (MCS) [median, IQR]										
MCS	Baseline	40.73 [35.57-46.34]	42.02 [37.43-48.19]	39.04 [34.65-45.58]	41.65 [36.88-47.86]	46.06 [40.99-50.91]	38.34 [35.03-42.81]	0.493	0.048	0.477
	6 months	44.49 [38.25-48.22]	44.47 [38.67-47.52]	44.55 [36.28-48.56]	39.36 [34.86-45.11]	42.37 [38.15-49.18]	37.5 [32.29-42.03]	0.003	0.530	<0.001
	12 months	43.42 [37.17-48.19]	45.99 [37.77-49.28]	39.68 [35.92-45.94]	35.90 [27.72-40.98]	39.57 [34.2-41.81]	31.88 [25.85-37.02]	<0.001	0.006	<0.001
VAS Pain Intensity [median, IQR, scale 0-10]										
VAS Pain	Baseline	5 [4-6]	4 [3-5]	5 [4-7]	5 [4-6]	4 [3-6]	4 [4-6]	0.614	0.677	0.739
	6 months	4 [2-5]	3 [2-4]	5 [3.75-6]	5 [4-6]	4 [3-5]	6 [5-7]	<0.001	0.001	<0.001
	12 months	3 [2-5]	2 [2-4]	4.5 [3-6]	5 [4-6]	5 [4-6]	6 [5-7]	<0.001	<0.001	0.002
Pain-free Walking Distance [median, IQR, scale 1-6]										
Walking distance.	Baseline	4 [4-5]	5 [4-5]	4 [4-5]	4 [4-5]	5 [4-5]	4 [4-5]	0.907	0.384	0.398
	6 months	5 [4-5]	5 [5-5]	4 [4-5]	4 [4-5]	5 [4-5]	4 [3-4]	<0.001	0.002	0.015
	12 months	5 [4-5]	5 [5-5]	4 [4-5]	4 [4-5]	4 [4-5]	4 [3-4]	<0.001	<0.001	<0.001
Quality-Adjusted Life Years (QALY, SF-6D)										
QALY (SF-6D)	12 months	0.67 [0.64-0.72]	0.72 [0.69-0.73]	0.64 [0.61-0.67]	0.60 [0.57-0.65]	0.65 [0.62-0.67]	0.58 [0.54-0.59]	<0.001	<0.001	<0.001

SF-12 PCS/MCS: higher scores = better health (range 0-100). QALY derived from SF-6D utility scores (trapezoidal method, range 0-1). Between-group p-values from the Mann-Whitney U test. Str A = Stratum A (Rutherford 2-3), Str B = Stratum B (Rutherford 4-5).
Source: compiled by the authors

Pain intensity

Baseline median VAS pain scores were comparable between groups (5 [4-6] vs. 5 [4-6]; $p = 0.614$) (Table 2). At 12 months, pain scores were sig-

nificantly lower in the experimental group (3 [2-5] vs. 5 [4-6]; p < 0.001), consistent across Stratum A (2 [2-4] vs. 5 [4-6]; p < 0.001) and Stratum B (4.5 [3-6] vs. 6 [5-7]; p = 0.002). Pain scores in the experimental group remained stable from 6 to 12 months (p = 0.640), confirming sustained analgesic benefit, while the control group showed significant worsening over the same interval (p = 0.033) (Table 3).

Table 3. Within-Group p-Values: 0 → 6 months, 6 → 12 months, 0 → 12 months

		Experimental group			Control group		
Outcome	**Interval**	**Overall**	**Stratum A**	**Stratum B**	**Overall**	**Stratum A**	**Stratum B**
SF-12 Physical Component Summary (PCS) – within-group p-values							
PCS	0 → 6 months	<0.001	<0.001	0.003	0.308	0.635	0.382
	6 → 12 months	0.931	0.635	0.722	0.001	0.010	0.027
	0 → 12 months	<0.001	0.001	0.004	0.033	0.126	0.156
SF-12 Mental Component Summary (MCS) – within-group p-values							
MCS	0 → 6 months	0.041	0.322	0.069	0.066	0.102	0.274
	6 → 12 months	0.375	0.769	0.149	<0.001	0.084	<0.001
	0 → 12 months	0.066	0.125	0.905	<0.001	<0.001	0.041
VAS Pain Intensity – within-group p-values							
VAS Pain	0 → 6 months	<0.001	<0.001	<0.001	0.971	0.197	0.040
	6 → 12 months	0.640	>0.999	0.539	0.033	0.002	0.515
	0 → 12 months	<0.001	0.002	<0.001	0.054	0.150	0.190
Pain-free Walking Distance – within-group p-values							
Walking distance	0 → 6 months	0.007	0.025	0.085	0.077	0.933	0.012
	6 → 12 months	0.508	>0.999	0.386	0.132	0.133	0.553
	0 → 12 months	0.003	0.059	0.021	0.004	0.158	0.007

Within-group p-values from the Wilcoxon signed-rank test. Str A = Stratum A (Rutherford 2-3), Str B = Stratum B (Rutherford 4-5).
Source: compiled by the authors

Hospitalizations, revascularization, and amputation

PAD-related hospitalizations occurred in 12 experimental (14.8 %) versus 16 control participants (20.5 %; OR=1.48, 95 % CI: 0.65-3.38; p = 0.346) (Table 4). Mean hospitalizations per patient were 0.15 ± 0.36 versus 0.21 ± 0.41 (p = 0.349). Stratified analysis showed numerically lower rates in both Stratum A (2.6 % vs. 8.1 %) and Stratum B (26.2 % vs. 31.7 %), neither reaching statistical significance. Revascularization was required in 9.9 % versus 12.8 % (p = 0.558). Amputation occurred in 4.9 % versus 7.7 % (OR=1.60, 95 % CI: 0.44-5.90; p = 0.476), representing a 36 % relative reduction without statistical significance; no amputations were recorded in Stratum A.

Disability status

At baseline, disability was present exclusively in Stratum B patients (experimental: 21.4 %; control: 24.4 %; p = 0.748) (Table 4). New disability developed in 3 experimental (3.7 %) and 5 control participants (6.4 %; p = 0.686). Among participants with baseline disability, changes in status (improvement, worsening, or stability) did not differ significantly between groups (p = 0.686 overall). The majority remained stable in both groups (experimental: 92.6 %; control: 91.0 %).

Smoking cessation

At baseline, 52 (64.2 %) experimental and 47 (60.3 %) control participants were active smokers (Table 4). At 12 months, cessation was achieved by 25.0 % of baseline smokers in the experimental group, compared with 8.5 % in controls (OR = 3.13, 95 % CI: 1.07–9.19; p = 0.026). The benefit was most pronounced in Stratum B: 37.0 % versus 7.1 % (OR=6.09, 95 % CI: 1.24-29.84; p = 0.014). Among those who continued smoking, the proportion who reduced smoking intensity was significantly higher in the experimental group overall (37.0 % vs. 19.2 %; OR=1.93, 95 % CI: 1.13-3.29; p = 0.013) and in Stratum B (47.6 % vs. 19.5 %; OR=2.44, 95 % CI: 1.21-4.90; p = 0.007).

Pain-free walking distance and QALYs

Pain-free walking distance improved significantly in the experimental group from baseline to 12 months (p = 0.003 overall; Stratum B: p =

Table 4. Smoking and smoking intensity change, disability status, and PAD-related clinical events over 12-month follow-up

	Overall			Stratum A (Rutherford 2-3)			Stratum B (Rutherford 4-5)		
Outcome	**Exp n = 81**	**Ctrl n = 78**	**p**	**Exp A n = 39**	**Ctrl A n = 37**	**p**	**Exp B n = 42**	**Ctrl B n = 41**	**p**
Smoking cessation and intensity at 12 months									
Baseline smokers	52 (64.2 %)	47 (60.3 %)	0.083	25 (64.1 %)	19 (51.3 %)	0.260	27 (64.3 %)	28 (68.3 %)	0.699
Quit at 12 months, % of baseline smokers	13 (25.0 %)	4 (8.5 %)	0.026	3 (12.0 %)	2 (10.5 %)	0.688	10 (37.0 %)	2 (7.1 %)	0.014
Increased smoking, n (% of all)	10 (12.3 %)	12 (15.4 %)	0.579	8 (20.5 %)	5 (13.5 %)	0.418	2 (4.8 %)	7 (17.1 %)	0.071
Decreased smoking, n (% of all)	30 (37.0 %)	15 (19.2 %)	0.013	10 (25.6 %)	7 (18.9 %)	0.482	20 (47.6 %)	8 (19.5 %)	0.007
Disability status at baseline and over 12-month follow-up									
Disability at baseline, n (%)	9 (11.1 %)	10 (12.8 %)	0.740	0 (0 %)	0 (0 %)	-	9 (21.4 %)	10 (24.4 %)	0.748
New disability, n (%)	3 (3.7 %)	5 (6.4 %)	0.686	2 (5.1 %)	3 (8.1 %)	0.600	1 (2.4 %)	2 (4.9 %)	0.765
Disability: Improvement, n (%)	3 (3.7 %)	2 (2.6 %)	0.686	0 (0 %)	0 (0 %)	-	3 (7.1 %)	2 (4.9 %)	0.765
Disability: Worsening, n (%)	3 (3.7 %)	5 (6.4 %)	-	2 (5.1 %)	3 (8.1 %)	0.600	1 (2.4 %)	2 (4.9 %)	-
Disability: No change, n (%)	75 (92.6 %)	71 (91.0 %)	-	37 (94.9 %)	34 (91.9 %)	-	38 (90.5 %)	37 (90.2 %)	-
PAD-related clinical events over 12-month follow-up									
Hospitalizations, total, n (%)	12 (14.8 %)	16 (20.5 %)	0.346	1 (2.6 %)	3 (8.1 %)	0.283	11 (26.2 %)	13 (31.7 %)	0.582
Hospitalizations per patient, mean ± SD	0.15 ± 0.36	0.21 ± 0.41	0.349	0.03 ± 0.16	0.08 ± 0.28	0.283	0.26 ± 0.45	0.32 ± 0.47	0.582
Revascularization, n (%)	8 (9.9 %)	10 (12.8 %)	0.558	1 (2.6 %)	3 (8.1 %)	0.279	7 (16.7 %)	7 (17.1 %)	0.961
Amputation, n (%)	4 (4.9 %)	6 (7.7 %)	0.476	0 (0 %)	0 (0 %)	-	4 (9.5 %)	6 (14.6 %)	0.475

Smoking cessation was defined as complete abstinence in the preceding month at 12-month follow-up. Smoking intensity classified as: 0 = non-smoker; 1 = <10 cigarettes/day; 2 = 11-20/day; 3 = >20/day. Disability change categories: improvement, worsening, or no change from baseline to 12 months. Str A = Stratum A, Str B = Stratum B.

Source: compiled by the authors

0.021), while the control group showed significant deterioration ($p = 0.004$ overall; Stratum B: $p = 0.007$). Between-group differences at 12 months were highly significant overall and within both strata (all $p < 0.001$) (Tables 2-3). QALY scores were significantly higher in the experimental group (0.67 [0.64-0.72] vs. 0.60 [0.57-0.65]; $p < 0.001$), consistent across Stratum A (0.72 [0.69-0.73] vs. 0.65 [0.62-0.67]; $p < 0.001$) and Stratum B (0.64 [0.61-0.67] vs. 0.58 [0.54-0.59]; $p < 0.001$) (Table 2).

No adverse events attributable to the educational program were recorded during the 12-month follow-up.

Discussion

This randomized controlled trial demonstrates that a structured multimodal educational program significantly improves patient-reported outcomes and smoking cessation in patients with PAD, including CLTI. To our knowledge, this is the first RCT to evaluate the impact of a comprehensive educational intervention on hospitalization rates, amputation rates, and quality of life, specifically in this population.

The 9.68-point between-group difference in PCS at 12 months represents a clinically meaningful effect comparable in magnitude to that reported in diabetes self-management programs [20]. The MCS difference reflects preservation of mental health status against progressive deterioration in controls – an important finding in a condition characterized by chronic pain, limited mobility, and social isolation [21].

Hospitalization and amputation rates were numerically lower in the experimental group (14.8 % vs. 20.5 % and 4.9 % vs. 7.7 %), but did not reach statistical significance, likely due to insufficient power to detect rare events. The 36 % relative reduction in amputation rate is clinically notable and warrants confirmation in larger trials. The threefold higher smoking cessation rate (25.0 % vs. 8.5 %) is particularly significant, as smoking is the most potent modifiable risk factor for PAD progression [22]. The cessation rates observed are consistent with published estimates from intensive behavioral programs, and were especially pronounced in Stratum B (37.0 % vs. 7.1 %), suggesting that prominent symptoms may heighten motivation [23].

These findings align with evidence from analogous interventions. A meta-analysis of structured exercise combined with patient education for intermittent claudication showed an increase in maximum walking distance of approximately 120 meters compared with usual care [24]. The CLEVER trial demonstrated that structured exercise outperformed invasive interventions in improving functional outcomes for PAD at 6 months [25]. A systematic review of group-based self-management education in type 2 diabetes reported quality-of-life improvements of comparable magnitude to those observed here [20]. A further systematic review by Rochfort et al. identified improvements in disease knowledge, self-efficacy, and behavioral outcomes from patient self-management programs in chronic conditions, although that work did not assess hard clinical endpoints such as hospitalizations and amputations [26]. A distinguishing feature of the present study is that educational interventions proved effective even at advanced disease stages, challenging the nihilistic approach that sometimes prevails in the management of severe PAD cases and supporting secondary prevention across the full disease spectrum.

The mechanisms underlying the improvements are likely multifactorial and synergistic. Enhanced patient knowledge may have encouraged timely medical consultation, preventing complications from escalating to hospitalization or amputation – the concept of patient activation has been associated with better outcomes across multiple chronic conditions [27]. Instruction in foot and wound care was particularly relevant given the susceptibility to infectious complications in CLTI [28]. Smoking cessation counseling, structured exercise guidance, and psychosocial support through peer group interaction likely contributed synergistically. The digital platform reinforced knowledge and skills between sessions, allowing participants to review material at their own pace. Improved adherence to pharmacological therapy – including antiplatelet therapy, statins, and blood pressure control – though not directly measured, may also represent an important mediating mechanism [29]. The hybrid approach addresses key barriers, including limited digital literacy among older patients, consistent with evidence that digital interventions are most effective when used as supplements to direct physician-delivered education [30].

Strengths and limitations

Strengths include the rigorous RCT design

with adequate statistical power, prospective ethics approval, adherence to CONSORT 2025, stratification by Rutherford category to ensure balanced disease severity across groups, validated outcome instruments, a comprehensive hybrid intervention design reflecting contemporary chronic disease management, and low attrition (11.4 % experimental; 15.2 % control). The 12-month follow-up allowed assessment of both short- and medium-term effects, and the inclusion of a broad range of outcomes – from patient-reported quality of life to hard clinical events – provided comprehensive program evaluation.

Limitations include: infeasibility of participant and provider blinding, potentially introducing performance and attention bias; self-reported measures may have been influenced by awareness of group assignment. The single-center design in Kazakhstan may limit generalizability to other healthcare settings and geographical regions with different socioeconomic conditions. The study was underpowered to detect statistically significant differences in rare events such as amputation and hospitalization, as sample size calculations were based on anticipated differences in quality-of-life scores. The per-protocol analysis may overestimate treatment effects relative to an intention-to-treat approach. Trial registration was retrospective (with no post-enrollment protocol changes). Participant adherence to individual program components was not systematically recorded, limiting evaluation of dose-response relationships. Concomitant pharmacological therapy was not tracked, representing an unmeasured potential confounder. Cost-effectiveness was not assessed, and follow-up beyond 12 months is needed to establish the long-term durability of effects.

Conclusion

The CLTI School significantly improved quality of life, pain intensity, functional capacity, and smoking cessation in patients with PAD, including chronic limb-threatening ischemia. Differences in hospitalization and amputation rates were clinically meaningful but statistically underpowered. These findings support integrating structured educational programs into standard PAD management as an essential component of comprehensive care and an effective secondary prevention strategy, even in patients with advanced disease.

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ПЕРИФЕРИЯЛЫҚ АРТЕРИЯ АУРУЛАРЫ АЯСЫНДА АЯҚТЫҢ ТРОФИКАЛЫҚ ЖАРАЛАРЫ БАР ЖӘНЕ ЖОҚ ПАЦИЕНТТЕРДІ ОҚЫТУДЫҢ МУЛЬТИМОДАЛЬДЫ БАҒДАРЛАМАСЫНЫҢ ТИІМДІЛІГІ

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Аңдатпа

Өзектілігі. Аяқ-қолдарға қауіп төндіретін созылмалы ишемия – перифериялық артерия ауруының ең ауыр түрі, ампутация мен өлім-жітім қаупімен сипатталады. Пациенттерді оқытудың құрылымдалған бағдарламалары басқа созылмалы аурулар кезінде тиімділігін дәлелдеді, алайда перифериялық артерия ауруы, әсіресе Аяқ-қолдарға қауіп төндіретін созылмалы ишемиясы кезіндегі деректер жеткіліксіз.

Мақсаты. Перифериялық артерия ауруы бар науқастарда стандартты еммен салыстырғандағы мультимодальды білім беру бағдарламасының (CLTI мектебі) клиникалық нәтижелерге және өмір сапасына тиімділігін бағалау.

Материалдар мен әдістер. Параллель топтармен рандомизацияланған бақыланатын зерттеу (Астана, Қазақстан). Перифериялық артерия ауруы бар 184 науқас (Рузерфорд 2-5) 1:1 қатынасында рандомизацияланды, 12 ай бойы бақыланды. Бағдарлама топтық сабақтарды, цифрлық платформаны, қолдау топтарын және темекіні тастауға кеңесті қамтыды. Протокол бойынша талдауда 81 эксперименттік және 78 бақылау тобының қатысушысы зерттелді. Негізгі нәтижелер: өмір сапасы (SF-12) және ауруханаға жатқызу жиілігі.

Нәтижелері. 12 айдан кейін эксперименттік топта SF-12 физикалық (44,76 қарсы 35,08; $p < 0,001$) және психикалық компоненттері (43,42 қарсы 35,90; $p < 0,001$) айтарлықтай жоғары болды. Ауруханаға жатқызулар (14,8 % қарсы 20,5 %; $p = 0,346$) және ампутациялар (4,9 % қарсы 7,7 %; $p = 0,476$) санмен алғанда аз болды, бірақ статистикалық маңыздылыққа жеткен жоқ. Темекіні тастау үш есе жоғары болды (25,0 % қарсы 8,5 %; $p = 0,026$), ауырсыну азайды (медиана ВАШ 3 қарсы 5; $p < 0,001$), QALY жоғары болды (0,67 қарсы 0,60; $p < 0,001$).

Қорытынды. CLTI мектебі перифериялық артерия ауруы бар науқастарда пациент-хабарланған нәтижелерді және темекіні тастауды айтарлықтай жақсартты. Құрылымдалған білім беру бағдарламалары перифериялық артерия ауруының кешенді бақылауының міндетті компоненті ретінде қарастырылуы керек.

Түйін сөздер: *перифериялық артерия ауруы, пациентті оқыту, өмір сапасы, темекіні тастау, екінші реттік алдын алу, рандомизацияланған бақыланатын зерттеу.*

ЭФФЕКТИВНОСТЬ МУЛЬТИМОДАЛЬНОЙ ПРОГРАММЫ ОБУЧЕНИЯ ПАЦИЕНТОВ С НАЛИЧИЕМ И БЕЗ ТРОФИЧЕСКИХ ЯЗВ НИЖНИХ КОНЕЧНОСТЕЙ НА ФОНЕ ЗАБОЛЕВАНИЙ ПЕРИФЕРИЧЕСКИХ АРТЕРИЙ

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Аннотация

Актуальность. Критическая ишемия нижних конечностей – наиболее тяжёлая форма заболевания периферических артерий, характеризующаяся высоким риском ампутации и летального исхода. Структурированные образовательные программы для пациентов продемонстрировали эффективность при других хронических заболеваниях, однако их влияние при заболевании периферических артерий, в особенности при критической ишемии нижних конечностей, изучено недостаточно.

Цель. Оценить эффективность структурированной мультимодальной образовательной программы (Школа CLTI) по сравнению со стандартной помощью в отношении клинических исходов и качества жизни пациентов с заболеванием периферических артерий.

Материалы и методы. Рандомизированное контролируемое исследование параллельных групп (Астана, Казахстан). 184 пациента с ЗПА (категории Рутерфорда 2-5) рандомизированы 1:1 и наблюдались 12 месяцев. Программа включала групповые занятия, цифровую платформу, группы поддержки и консультирование по отказу от курения. Анализ по протоколу: 81 участник экспериментальной и 78 контрольной группы. Первичные конечные точки: качество жизни (SF-12) и частота госпитализаций, связанных с заболеванием периферических артерий.

Результаты. Через 12 месяцев экспериментальная группа показала значимо более высокие показатели физического (44,76 vs 35,08; $p < 0,001$) и психического компонентов SF-12 (43,42 vs 35,90; $p < 0,001$). Госпитализации (14,8 % vs 20,5 %; $p = 0,346$) и ампутации (4,9 % vs 7,7 %; $p = 0,476$) численно ниже, но без статистической значимости. Отказ от курения – втрое выше (25,0 % vs 8,5 %; $p = 0,026$), боль снизилась (медиана ВАШ 3 vs 5; $p < 0,001$), QALY выше (0,67 vs 0,60; $p < 0,001$).

Выводы. Школа CLTI значимо улучшила пациент-ориентированные исходы и показатели отказа от курения. Структурированные образовательные программы следует рассматривать как неотъемлемый компонент комплексного лечения заболеваний периферических артерий.

Ключевые слова: *заболевание периферических артерий, обучение пациентов, качество жизни, отказ от курения, вторичная профилактика, рандомизированное контролируемое исследование.*

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