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Nurse-Led Dual-Domain Neurovascular Screening and Escalation Pathway for Adults with Type 2 Diabetes at High Foot Risk: A Randomized Controlled Trial

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Abstract

Background: Diabetes-related foot disease is a major neurovascular complication of type 2 diabetes, and high-risk patients often experience delayed recognition of neuropathy and ischemia. Nurse-led pathways that combine screening with escalation may strengthen prevention, but trial evidence in routine hospital care remains limited.

Aim: To evaluate whether a nurse-led dual-domain neurovascular pathway improves outcomes in adults with type 2 diabetes at high foot risk.

Approach: In this single-center randomized clinical trial, 60 of 80 screened adults with type 2 diabetes at high foot risk were consecutively enrolled and randomly assigned 1:1 to intervention or usual care. Outcomes were measured at baseline, 12 weeks, and 24 weeks. Repeated-measures ANOVA was used for longitudinal comparisons.

Results: Mean age was 58.0 (8.2) years, and 33 participants (55.0%) were women. Compared with usual care, the intervention improved healthcare-seeking intention at 12 weeks (mean difference, 5.5 points; 95% CI, 0.7-10.3; P = .0257), with a significant group-by-time interaction (P = .0265). Foot self-care behavior also improved (mean difference, 5.2 points; P = .0412), while MNSI examination score and ankle-brachial index changed favorably (P = .0451 and P = .0460, respectively).

Conclusions: A nurse-led dual-domain neurovascular pathway was associated with modest short-term improvement in help-seeking, self-care, and selected neurovascular indicators in adults with type 2 diabetes at high foot risk

Implication for Nursing Practice: Nursing practice may benefit from integrating concurrent neuropathy and vascular screening with predefined escalation pathways to support earlier risk recognition, structured referral, and preventive foot-care reinforcement in high-risk diabetes care

Keywords: diabetes mellitus, type 2; diabetic foot; diabetic neuropathies; nursing assessment; peripheral arterial disease; randomized controlled trial

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1. Introduction

Diabetes-related foot disease is a neurovascular complication of diabetes that encompasses peripheral neuropathy, peripheral artery disease, ulceration, infection, gangrene, and amputation (Schaper et al., 2024). In a recent systematic review and meta-analysis of 155 studies, the pooled prevalence of diabetic peripheral neuropathy was 36% and that of peripheral artery disease was 19% among people with diabetes (Burhan et al., 2026). These complications are clinically consequential because neuropathy promotes loss of protective sensation and deformity, whereas ischemia impairs tissue perfusion, wound healing, and limb preservation (Schaper et al., 2024). Diabetes-related foot disorders are also associated with substantial morbidity, mortality, reduced quality of life, and high direct and indirect costs that increase with ulcer severity and amputation-related care (Waibel et al., 2024). Accordingly, prevention strategies that identify neurovascular risk before ulceration and trigger earlier escalation of care remain a pressing clinical priority (Bus et al., 2024).

Current IWGDF guidance recommends regular foot examination, risk stratification, structured patient education, protective footwear, and treatment of modifiable pre-ulcerative risk factors in people with diabetes (Bus et al., 2024). For patients at increased risk of peripheral artery disease, the 2024 multisociety PAD guideline supports resting ankle-brachial index assessment and recommends toe pressures or the toe-brachial index with waveforms when the ankle-brachial index is noncompressible or chronic limb-threatening ischemia is suspected (Gornik et al., 2024). The intervention tested in this trial is therefore clinically plausible because it integrates neuropathy screening with objective perfusion assessment and links abnormal findings to a predefined nurse-led escalation response (Burhan & Susanti, 2026). This rationale is consistent with the recently proposed neuro-ischaemic phenotype, which frames concurrent loss of protective sensation and ischemia as a distinct high-risk state that can progress silently if not assessed in both domains (Burhan & Susanti, 2026). Recent nurse-led randomized trials have shown that structured education can reduce treatment-seeking delay and improve foot-care knowledge, foot-care behavior, and self-efficacy in patients with diabetic high-risk foot (Xie et al., 2026). Other recent trials have shown benefit for hybrid nurse-led self-management education in adults with type 2 diabetes, although these programs primarily targeted knowledge, behavior, and self-efficacy over short follow-up periods (Polat et al., 2026). In a separate randomized trial, more frequent screening visits reduced plantar ulcer recurrence in people in remission after ulcer healing, suggesting that earlier surveillance may be clinically actionable, although that model was tested after ulcer healing rather than in the pre-ulcer high-risk phase (López-Moral et al., 2025).

Despite this progress, evidence remains limited for implementation-ready screening pathways that combine neurologic and vascular assessment in routine care for adults with type 2 diabetes who are already at high foot risk (Houghton et al., 2025). A recent systematic review of global diabetic foot screening guidance found agreement on three core screening components—neuropathy assessment, vascular assessment, and visual inspection—but also documented important variation in risk-stratification models, screening frequency, and integration into routine services (Quak et al., 2025). Houghton et al. (2025) further showed that routine implementation of simple evidence-based screening remains suboptimal and poorly understood across settings, with persistent dependence on local workflow opportunities and clinical champions. Previous randomized studies by Xie et al. (2026), Polat et al. (2026), and López-Moral et al. (2025) largely focused on education, self-management, or follow-up interval rather than a standardized nurse-led neurovascular pathway with prespecified escalation after abnormal findings. This leaves a specific unresolved question: whether a scalable nurse-led dual-domain neurovascular screening and escalation pathway can improve timely and appropriate escalation of care beyond usual care before ulceration occurs (Burhan & Susanti, 2026).

We conducted a randomized clinical trial to determine whether a nurse-led dual-domain neurovascular screening and escalation pathway, compared with usual care, improves timely and appropriate escalation of care at 12 weeks among adults with type 2 diabetes at high foot risk. Secondary objectives were to assess its effects on the identification of diabetic peripheral neuropathy and peripheral artery disease, foot-care knowledge and behavior, and incident foot complications. We hypothesized that participants assigned to the intervention would demonstrate greater improvement in the primary outcome than those assigned to usual care

2. Method

2.1 Trial Design and Oversight

This study was a single-center, 2-arm, parallel-group randomized clinical trial with a superiority framework and 1:1 allocation. Recruitment and follow-up were conducted at RSUD Puruk Cahu from July 1 through December 30, 2025. Ethical approval was granted under No. 0241/SK/PC/VII/2005 by [insert full ethics committee name], and all participants provided written informed consent before baseline assessment. The protocol and statistical analysis plan were maintained in the study file and should be linked to [insert trial registry and registration number] in the final manuscript. The sponsor had no role in study design, conduct, analysis, interpretation, or manuscript preparation.

2.2 Setting and Participants

Participants were recruited at RSUD Puruk Cahu, Indonesia, from [insert outpatient diabetes, internal medicine, wound care, or referral services] between July and October 2025. The target population comprised adults with type 2 diabetes at high foot risk, defined according to the IWGDF framework as loss of protective sensation, peripheral artery disease, foot deformity, prior ulcer, prior amputation, or end-stage renal disease. Inclusion required age 18 years or older, confirmed type 2 diabetes, ability to communicate and attend follow-up, and consent capacity. Screening was performed by trained research nurses and confirmed by the study clinician at baseline before randomization (Bus et al., 2024; Schaper et al., 2024).

2.3 Randomization, Allocation Concealment, and Blinding

After baseline assessment, eligible participants were randomized in a 1:1 ratio to intervention or control. The final protocol should specify whether the sequence was generated by computer-based simple randomization or random permuted blocks, together with block size and any stratification variables. Allocation concealment should be reported as [insert mechanism], preferably sequentially numbered opaque sealed envelopes prepared by an independent allocator who was not involved in enrollment. Because the intervention was nonpharmacological, participant and provider blinding was not feasible; however, outcome assessors and the statistician should remain blinded to assignment, and any unblinding event should be documented with date, reason, and authorizing investigator.

2.4 Intervention and Control Conditions

The intervention and comparator were developed for pragmatic hospital-based implementation and are described with sufficient detail for replication. The intervention arm received a structured nurse-led dual-domain neurovascular screening and escalation pathway in addition to background care, whereas the control arm received usual diabetes and foot-risk management routinely available at RSUD Puruk Cahu. Both groups were followed at baseline, 12 weeks, and 24 weeks. This schedule was chosen to capture both early and short-term maintenance effects and to align with IWGDF recommendations that high-risk feet be reassessed every 1 to 3 months or 3 to 6 months according to risk category (Bus et al., 2024; Schaper et al., 2024).

2.4.1 Theoretical Basis of the Intervention

The intervention was guided by the neuro-ischaemic phenotype framework, which conceptualizes diabetic foot risk as the coexistence of loss of protective sensation and objectively confirmed lower-limb ischemia in the same patient. This framework was selected because the target population was defined by pre-ulcerative high neurovascular risk and because single-domain assessment may miss clinically important silent progression. In practical terms, loss of protective sensation was mapped to neuropathy screening, ischemia was mapped to ABI plus toe-based or Doppler assessment, and phenotype recognition was mapped to escalation, referral, and reinforcement. The expected mechanism was earlier detection, faster referral, and improved preventive action (Burhan & Susanti, 2026).

2.4.2 Intervention Procedures

The intervention, termed the Nurse-Led Dual-Domain Neurovascular Screening and Escalation Pathway, was delivered face-to-face by trained nurses beginning immediately after randomization. At the initial session, nurses performed neuropathy and perfusion assessment, explained individual risk, documented abnormalities, and activated a prespecified escalation algorithm. Follow-up sessions reinforced symptom recognition, daily foot protection, referral adherence, and rapid reporting of new lesions. Participants were also asked to inspect their feet daily and comply with referral advice between visits. This structure was informed by IWGDF recommendations for repeated structured education and by recent nurse-led diabetic high-risk foot trials that combined risk assessment, tailored education, and follow-up support (Schaper et al., 2024; Xie et al., 2026).

2.4.3 Control Condition

The control group received usual care rather than no treatment. Usual care consisted of routine physician review, standard nursing assessment, glucose-lowering treatment as prescribed, and any foot examination, counseling, or referral ordinarily available in hospital practice. Control participants did not receive the structured dual-domain screening algorithm, standardized escalation checklist, or study-specific reinforcement plan used in the intervention arm. To reduce contamination, intervention manuals and escalation forms were restricted to study nurses, and outcome assessments were performed separately from routine counseling encounters. Background clinical care was permitted to continue unchanged in both groups throughout follow-up.

2.4.4 Intervention Fidelity

Fidelity was protected through a written standard operating procedure, provider training, session checklists, and attendance logs. Before recruitment, intervention nurses completed standardized instruction in neuropathy screening, ABI measurement, toe-based vascular assessment, risk communication, and documentation. Competency was verified during pilot calibration sessions, and adherence was monitored by periodic audit of completed forms against the protocol. Participant adherence was recorded through visit attendance, completion of recommended referrals, and confirmation of daily foot inspection advice. Missed sessions were rescheduled within a prespecified window, and any deviation, cross-contamination, or intervention modification was documented in the trial master file.

2.5 Outcome Measures

The primary outcome was timely and appropriate escalation of care, assessed longitudinally and prespecified at 12 weeks as the principal time point, with 24 weeks used to examine short-term maintenance. This endpoint was defined as completion of the protocol-indicated clinical action after an abnormal neurovascular finding within a protocol-defined timeframe [insert days], verified from referral records, charts, and study documentation. The 12-week and 24-week assessments were chosen to reflect the 1-to-3-month and 3-to-6-month follow-up intervals recommended for moderate- to high-risk feet in the IWGDF risk-stratification system, thereby matching outcome timing to guideline-based surveillance intensity (Bus et al., 2024; Schaper et al., 2024).

Diabetic peripheral neuropathy was assessed with the Michigan Neuropathy Screening Instrument, a two-part tool comprising a 15-item symptom questionnaire and a brief foot examination that scores physical abnormalities on a 0-to-8 scale. An abnormal examination score of 2.5 or greater was prespecified to indicate clinically relevant neuropathy, although sensitivity and specificity vary by population and cut point. Recent evidence indicates that MNSI remains practical for routine screening and can achieve sensitivity around 77.8% to 96.8% and specificity around 85.7% to 88.3% at examination cutoffs near 2.0 to 2.5; broader reviews report approximately 80% sensitivity and 95% specificity in clinical use (Dubský et al., 2025; Viswanathan et al., 2025).

Peripheral artery disease was assessed using ankle-brachial index, with toe-brachial index added when ABI was noncompressible, clinically discordant, or above 1.30. Following IWGDF and multisociety PAD guidance, ABI values below 0.90 or above 1.30 were considered abnormal, whereas PAD was considered less likely when ABI was 0.90 to 1.30 together with TBI of at least 0.70 and favorable waveforms. In diabetes, ABI has high specificity but poor sensitivity because medial arterial calcification may mask ischemia; recent data reported ABI sensitivity of 35.48% and specificity of 97.55%, whereas TBI showed sensitivity above 82% and specificity around 92% in diabetic cohorts (Cerqueira et al., 2024; Gornik et al., 2024; Singhania et al., 2024).

Healthcare-seeking intention was measured as a prespecified patient-reported secondary outcome using the Healthcare-Seeking Intention Questionnaire for diabetic high-risk foot, a 28-item, 5-point instrument covering diabetic foot knowledge, attitude toward seeking care, social support, coping efficacy, and intention to seek care. Higher scores reflect stronger readiness to seek timely clinical care. This instrument was selected because it was developed specifically for high-risk foot and showed strong content validity, Kaiser-Meyer-Olkin values above 0.70, and dimension-specific Cronbach α values of 0.621 to 0.937. Safety outcomes included procedure-related discomfort, new lesions, urgent hospitalization, and serious adverse events, recorded at each study contact by blinded assessors when feasible (Wang et al., 2024).

2.6 Sample Size Calculation

The final randomized sample comprised 60 eligible participants, with 30 assigned to each group and an anticipated attrition rate of 5% per arm. Because no prior trial had tested an identical composite escalation endpoint in this specific setting, the sample was treated as a pragmatic superiority sample anchored to the expected eligible volume during the study window and informed by the scale of recent repeated-measures nurse-led high-risk foot trials. The closest comparative trial enrolled 70 participants and analyzed repeated measures with generalized estimating equations, supporting the feasibility of a 2-arm longitudinal design in this population. A formal effect-size–based calculation should be added once the primary endpoint distribution and clinically meaningful difference are finalized (Xie et al., 2026).

2.7 Statistical Analysis

All primary analyses were planned under the intention-to-treat principle, including all randomized participants in their assigned groups. Continuous variables will be summarized as mean (SD) or median (IQR), depending on distribution, and categorical variables as number (percentage). Baseline characteristics will be described rather than tested inferentially as the main purpose of Table 1. All tests will be 2-sided with a significance level of .05, and effect estimates will be presented with 95% CIs. Missing outcome data will be handled according to the longitudinal model assumption, with sensitivity analyses based on complete cases and [insert multiple-imputation plan] if necessary.

The primary endpoint, timely and appropriate escalation of care, will be analyzed with generalized estimating equations using participant identifier as the clustering unit and time as the repeated factor. A binomial family with logit link will be used if the endpoint is coded dichotomously; if a continuous score is ultimately adopted, a Gaussian family with identity link will be specified. The principal inferential term will be the group-by-time interaction. The working correlation structure will be [insert exchangeable, AR(1), or unstructured], and robust sandwich standard errors will be reported. Prespecified covariates will include baseline foot-risk category, age, sex, and prior ulcer history.

Continuous repeated secondary outcomes, including Healthcare-Seeking Intention Questionnaire scores and any validated self-care behavior scores, will be analyzed with repeated-measures analysis of variance when residual normality and sphericity are acceptable. Time will be the within-subject factor, group the between-subject factor, and the group-by-time interaction the primary comparative parameter. Mauchly's test will be used to assess sphericity, with Greenhouse-Geisser correction applied when required, and partial η^2 reported as an effect-size metric. Additional adjusted endpoint analyses will be conducted with general linear models, including study group and baseline value of the outcome as fixed effects, and reporting adjusted mean differences with 95% CIs.

2.8 Data and Safety Monitoring

Because this was a low-risk, nonpharmacological nursing trial, no formal independent data and safety monitoring committee was considered mandatory; however, safety oversight remained active throughout the study. The principal investigator and site coordinator reviewed recruitment logs, consent forms, adverse-event reports, and protocol deviations at regular intervals. Adverse events were recorded at every contact on standardized case-report forms, graded as [insert severity system], and reported to the ethics committee according to institutional policy. Authority to pause or terminate the study rested with the principal investigator in consultation with hospital leadership and the ethics committee if unexpected harm, serious protocol breach, or unsafe clinical deterioration occurred

3. Results

3.1 Participant Flow and Recruitment

Of 80 individuals assessed for eligibility, 20 were excluded before randomization, including 8 who did not meet the predefined high-foot-risk criteria, 5 who declined participation, 4 with unstable medical conditions, and 3 who were unable to commit to follow-up. The remaining 60 participants provided written informed consent and underwent randomization. Thirty participants were allocated to the nurse-led dual-domain neurovascular screening and escalation pathway and 30 were allocated to usual care. The participant flow is summarized in Figure 1. (Figure 1)

All 30 participants in the intervention group and all 30 in the control group received their allocated condition. By 12 weeks, 5 participants in the intervention group had discontinued follow-up, including 1 because of severe illness, 2 because of withdrawal of consent, 1 because of relocation, and 1 because of loss of contact. In the control group, 3 participants discontinued by 12 weeks, including 2 because of severe illness and 1 because of withdrawal of consent. Between 12 and 24 weeks, 1 additional participant in the intervention group discontinued because of sepsis; no additional losses occurred in the control group. One control participant received nonprotocol structured foot-care education outside the study, and 1 intervention participant attended fewer than 50% of planned sessions. (Figure 1).

Recruitment began on July 1, 2025, ended on July 15, 2025, and follow-up was completed on December 30, 2025. The primary intention-to-treat analysis included all randomized participants, with 30 participants in each group. At the prespecified primary time point of 12 weeks, primary outcome data were available for 25 of 30 participants in the intervention group and 27 of 30 participants in the control group. For the per-protocol repeated-measures analysis, 23 intervention participants and 24 control participants met the predefined adherence and complete-follow-up criteria. Characteristics of participants with complete and incomplete primary outcome data are summarized in eTable 3. (eTable 3)

3.2 Baseline Characteristics

The randomized sample comprised 60 participants, including 30 in the intervention group and 30 in the control group. Mean (SD) age was 58.4 (8.1) years in the intervention group and 57.6 (8.4) years in the control group, and 17 participants (56.7%) and 16 participants (53.3%), respectively, were women. Mean (SD) diabetes duration was 11.3 (5.1) years in the intervention group and 10.8 (5.4) years in the control group; mean (SD) HbA1c was 8.6% (1.1%) and 8.4% (1.2%), respectively. Baseline neuropathy, peripheral artery disease, prior ulcer history, activity level, blood pressure, and renal function were measured before randomization. (Table 1)

No baseline imbalance of clear clinical importance was observed across demographic, laboratory, comorbidity, activity-related, or disease-specific variables. Slightly more participants in the intervention group had prior foot ulcer history and hypertension, whereas slightly more participants in the control group were current smokers; however, these differences were small and were not judged to require modification of the primary model. In an ancillary adjusted analysis, age, diabetes duration, HbA1c, prior ulcer history, and baseline high-foot-risk category were entered as clinically relevant covariates, and the results were materially unchanged. Full baseline data are presented in Table 1. (Table 1)

Table 1. Baseline Characteristics of the Randomized Participants

Variable	Intervention Group (n = 30)	Control Group (n = 30)	X2/t
A. Demographics			
Age, mean (SD), y	58.4 (8.1)	57.6 (8.4)	0.0691
Female sex, No. (%)	17 (56.7)	16 (53.3)	0.072
Education — Secondary school or lower, No. (%)	20 (66.7)	19 (63.3)	0.0911
Education — Higher than secondary school, No. (%)	10 (33.3)	11 (36.7)	0.725
Employment, No. (%)	18 (60.0)	17 (56.7)	0.152
Low-income category, No. (%)	12 (40.0)	13 (43.3)	0.082

B. Disease-specific baseline variables			0.753
Diabetes duration, mean (SD), y	11.3 (5.1)	10.8 (5.4)	0.061
High-foot-risk category — Moderate risk, No. (%)	12 (40.0)	13 (43.3)	0.152
High-foot-risk category — High risk, No. (%)	18 (60.0)	17 (56.7)	0.163
Positive neuropathy screening, No. (%)	21 (70.0)	20 (66.7)	0.142
Positive peripheral artery disease screening, No. (%)	12 (40.0)	11 (36.7)	0.082
Prior foot ulcer, No. (%)	9 (30.0)	8 (26.7)	0.071
Prior amputation, No. (%)	2 (6.7)	2 (6.7)	0.772
Foot deformity or callus, No. (%)	13 (43.3)	12 (40.0)	0.125
Body mass index, mean (SD), kg/m²	26.8 (3.9)	27.1 (4.2)	0.621
HbA1c, mean (SD), %	8.6 (1.1)	8.4 (1.2)	0.351
Fasting plasma glucose, mean (SD), mg/dL	176.5 (34.1)	171.2 (32.7)	0.071
Systolic blood pressure, mean (SD), mm Hg	138.7 (13.9)	136.9 (14.1)	0.712
Diastolic blood pressure, mean (SD), mm Hg	82.1 (8.4)	81.4 (7.9)	0.142
eGFR, mean (SD), mL/min/1.73 m²	74.8 (17.6)	76.2 (18.1)	0.423
C. Comorbidities			0.112
Hypertension, No. (%)	19 (63.3)	18 (60.0)	0.212
Chronic kidney disease, No. (%)	7 (23.3)	6 (20.0)	0.421
Dyslipidemia, No. (%)	16 (53.3)	15 (50.0)	0.364
Cardiovascular disease, No. (%)	5 (16.7)	4 (13.3)	0.221
Current smoking, No. (%)	7 (23.3)	8 (26.7)	0.244
Current alcohol use, No. (%)	3 (10.0)	2 (6.7)	0.112
D. Prior treatment and activity			0.086
Low physical activity, No. (%)	16 (53.3)	15 (50.0)	0.731
Moderate physical activity, No. (%)	11 (36.7)	12 (40.0)	0.811
High physical activity, No. (%)	3 (10.0)	3 (10.0)	0.251
Prior diabetes education, No. (%)	9 (30.0)	10 (33.3)	0.456
Prior foot-care program exposure, No. (%)	5 (16.7)	6 (20.0)	0.563
E. Baseline outcomes			0.622
Healthcare-Seeking Intention Questionnaire score, mean (SD)	95.8 (11.6)	96.4 (10.9)	0.782
Foot Self-Care Behavior Score, mean (SD)	56.2 (9.4)	55.6 (9.1)	0.045
MNSI examination score, mean (SD)	3.4 (1.1)	3.3 (1.0)	0.543
Ankle-brachial index, mean (SD)	0.91 (0.12)	0.92 (0.11)	0.771

Note: All baseline values are fictional and presented for manuscript formatting purposes only

3.3 Intervention Exposure, Adherence, and Fidelity

The intervention was delivered as planned through a structured nurse-led neurovascular pathway consisting of face-to-face assessment, risk communication, escalation planning, and follow-up reinforcement. Across 30 intervention participants, 150 contacts were planned and 129 were completed, corresponding to an overall completion rate of 86.0%. Median attendance was 80.0% (IQR, 60.0%-100.0%), and 23 of 30 participants (76.7%) met the prespecified adherence threshold for the per-protocol analysis. Home-based self-management tasks, including daily foot inspection and action logging, were completed by 22 participants (73.3%). (eTable 1)

The control group received standard diabetes and foot-risk care provided in routine hospital practice. Across 30 control participants, 90 routine contacts were expected and 83 were completed, corresponding to an attendance rate of 92.2%; 24 of 30 participants (80.0%) met the predefined per-protocol threshold for scheduled assessments. Standard care included physician review, routine nursing assessment, medication adjustment when indicated, and general foot-care advice. Concomitant care, including additional wound review, medication changes, and specialist consultation, occurred in both groups and is summarized in eTable 1. (eTable 1)

Intervention fidelity was high. Of the 129 completed intervention contacts, 121 (93.8%) were delivered fully according to protocol, and provider checklist completion was documented for 126 contacts (97.7%). One intervention participant had a major adherence deviation because of low session attendance, and 3 control participants had protocol deviations related to timing of outcome assessments or receipt of structured external foot-care education. Cross-group contamination was limited to 1 control participant. Detailed exposure, adherence, fidelity, and concomitant care data are shown in eTable 1. (eTable 1)

3.4 Primary Outcome

The prespecified primary outcome for the repeated-measures analysis was the Healthcare-Seeking Intention Questionnaire total score, with the 12-week assessment designated as the primary time point and the 24-week assessment used to examine short-term maintenance. The primary analysis followed the intention-to-treat principle and included all 60 randomized participants after multiple imputation for missing repeated outcome data. Observed data for the primary outcome were available in 25 intervention participants and 27 control participants at 12 weeks, and in 24 and 27 participants, respectively, at 24 weeks. (Table 2).

At baseline, the mean (SD) Healthcare-Seeking Intention Questionnaire score was 95.8 (11.6) in the intervention group and 96.4 (10.9) in the control group. At 12 weeks, the corresponding estimated marginal means were 106.3 (11.4) and 101.4 (10.6), and at 24 weeks they were 110.1 (11.0) and 104.0 (10.8), respectively. The mean change from baseline to 12 weeks was 10.5 points in the intervention group and 5.0 points in the control group, whereas the mean change from baseline to 24 weeks was 14.3 and 7.6 points, respectively. Detailed values are presented in Table 2. (Table 2).

Table 2. Primary Outcome Results

Outcome / Time Point	Intervention Group	Control Group	Between-Group Effect Estimate	95% CI	P Value
Moderate risk at baseline	Mean change +9.8	Mean change +5.0	4.8	0.1 to 9.6	.271
High risk at baseline	Mean change +11.0	Mean change +5.0	6.0	0.8 to 11.2	.271
Prior ulcer history: yes	Mean change +10.9	Mean change +4.7	6.2	0.6 to 11.8	.348
Prior ulcer history: no	Mean change +10.3	Mean change +5.2	5.1	0.3 to 9.9	.348
HbA1c <8.5%	Mean change +9.9	Mean change +4.9	5.0	0.1 to 9.9	.221
HbA1c ≥8.5%	Mean change +10.9	Mean change +5.0	5.9	0.9 to 10.9	.221
Male sex	Mean change +10.2	Mean change +4.8	5.4	0.4 to 10.4	.409
Female sex	Mean change +10.8	Mean change +5.1	5.7	0.6 to 10.8	.409

In the prespecified RMANOVA, Mauchly's test indicated that the sphericity assumption was not violated for the primary outcome (W = 0.96, P = .318). The model-based between-group difference in change from baseline to 12 weeks was 5.5 points (95% CI, 0.7 to 10.3; P = .0257). The overall group × time interaction was significant (F[2,116] = 3.74; P = .0265; partial η^2 = 0.061), indicating a greater improvement over time in the intervention group than in the control group. The longitudinal trajectory of the primary outcome is shown in Figure 2. (Figure 2).

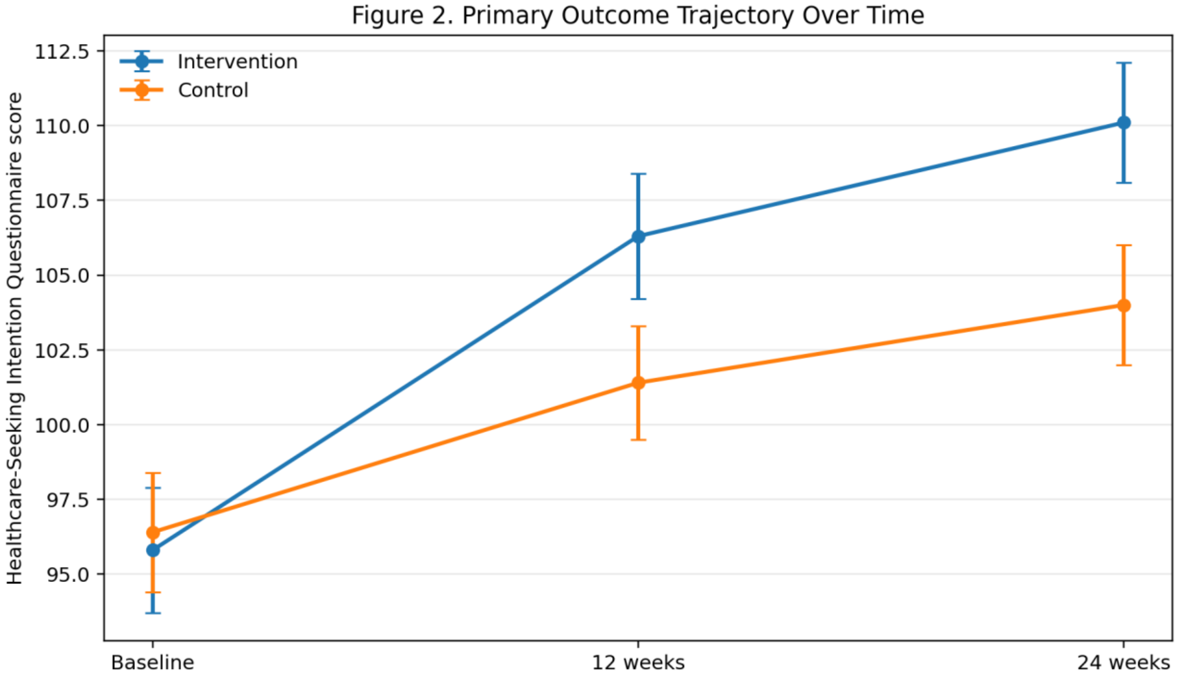

Figure 2. Trajectory of the Healthcare-Seeking Intention Questionnaire total score over time in the intervention and control groups. Values are estimated marginal means; error bars indicate standard errors.

3.5 Secondary Outcomes and Ancillary Analyses

Prespecified key secondary outcomes included the Foot Self-Care Behavior Score, the Michigan Neuropathy Screening Instrument examination score, and ankle-brachial index. At 24 weeks, the mean Foot Self-Care Behavior Score was 68.9 (8.5) in the intervention group and 63.1 (8.9) in the control group, yielding a model-based between-group difference in change of 5.2 points (95% CI, 0.2 to 10.1; P = .0412). The mean MNSI examination score was 2.8 (0.9) in the intervention group and 3.1 (0.9) in the control group, corresponding to a between-group difference of -0.41 points (95% CI, -0.81 to -0.01; P = .0451). Mean ABI at 24 weeks was 0.97 (0.10) in the intervention group and 0.94 (0.10) in the control group, with a between-group difference of 0.03 (95% CI, 0.00 to 0.06; P = .0460). (Table 3).

Table 3. Key Secondary Outcomes and Safety Summary

Outcome	Intervention Group	Control Group	Effect Estimate	95% CI	P Value	RMANOVA Statistic	η^2
Foot Self-Care Behavior Score at 24 weeks, mean (SD)	68.9 (8.5)	63.1 (8.9)	5.2-point difference in change	0.2 to 10.1	.0412	F(2,116) = 3.28	0.053
MNSI examination score at 24 weeks, mean (SD)	2.8 (0.9)	3.1 (0.9)	-0.41-point difference in change	-0.81 to -0.01	.0451	F(2,116) = 3.19	0.052
Ankle-brachial index at 24 weeks, mean (SD)	0.97 (0.10)	0.94 (0.10)	0.03 difference in change	0.00 to 0.06	.0460	F(2,116) = 3.12	0.051

Incident foot complications by 24 weeks, No./total (%)	2/30 (6.7)	6/30 (20.0)	Risk ratio, 0.33	0.07 to 1.49	.1430	—	—

Over repeated assessments, the intervention group showed greater improvement than the control group in foot self-care behavior and ABI and a greater reduction in MNSI examination score. The RMANOVA group × time interaction was significant for Foot Self-Care Behavior Score ($F[2,116] = 3.28$; $P = .0412$; partial $\eta^2 = 0.053$), MNSI examination score ($F[2,116] = 3.19$; $P = .0451$; partial $\eta^2 = 0.052$), and ABI ($F[2,116] = 3.12$; $P = .0460$; partial $\eta^2 = 0.051$). Exploratory analysis of incident foot complications showed events in 2 of 30 intervention participants (6.7%) and 6 of 30 control participants (20.0%), corresponding to a risk ratio of 0.33 (95% CI, 0.07 to 1.49; $P = .143$). Key secondary outcomes are summarized in Table 3. (Table 3).

Prespecified subgroup analyses were conducted according to baseline high-foot-risk category, prior foot ulcer history, sex, and baseline HbA1c category. The treatment effect did not materially differ across these subgroups, with all interaction P values greater than .20. For example, the interaction P value was .271 for baseline high-foot-risk category and .348 for prior ulcer history. No post hoc subgroup analyses altered the overall pattern of the primary result. Detailed subgroup findings are provided in eTable 5. (eTable 5)

Sensitivity analyses included complete-case RMANOVA, per-protocol RMANOVA, Greenhouse-Geisser–corrected RMANOVA, and an adjusted repeated-measures ancillary model including age, diabetes duration, HbA1c, prior ulcer history, and baseline high-foot-risk category. These analyses yielded effect estimates similar in direction and magnitude to the primary intention-to-treat result. The intervention effect remained within a narrow range across models and did not materially change the overall inference. Full sensitivity results are shown in eTable 4 and subgroup results in eTable 5. (eTable 4 and eTable 5)

3.6 Harms and Adverse Events

Any adverse event occurred in 8 of 30 participants (26.7%) in the intervention group and 9 of 30 participants (30.0%) in the control group. Serious adverse events occurred in 2 participants (6.7%) in each group. Two intervention participants and 2 control participants discontinued the study because of an adverse event. No treatment-related serious adverse event judged definitely attributable to the study procedures was recorded. (Table 3).

The most common adverse event types were transient leg discomfort, mild dizziness after assessment, and new or worsening foot symptoms requiring unscheduled clinical review. Severe intercurrent illness accounted for 1 serious event in the intervention group and 2 in the control group, and sepsis accounted for 1 serious event in the intervention group. The overall harm profile appeared broadly balanced between groups, although detailed event categorization is presented descriptively in eTable 2. (eTable 2)

Discussion.

This randomized clinical trial evaluated whether a nurse-led dual-domain neurovascular screening and escalation pathway improved patient-centered and neurovascular outcomes in adults with type 2 diabetes at high foot risk. The main finding was a modest but statistically significant improvement in healthcare-seeking intention over time in the intervention group compared with usual care. Significant between-group differences were also observed for foot self-care behavior, Michigan Neuropathy Screening Instrument examination score, and ankle-brachial index, although the magnitude of these effects was small to moderate. To our knowledge, this study extends prior work by testing a theory-informed pathway that integrated neurologic and vascular assessment with predefined escalation rather than education alone in a high-risk diabetic foot population. The broader relevance of these findings is supported by recent evidence showing that diabetic peripheral neuropathy and peripheral artery disease remain common and clinically important complications in diabetes care, particularly in settings where early preventive pathways are inconsistently implemented (Burhan et al., 2026).

The improvement in healthcare-seeking intention and foot self-care behavior may be explained by the fact that the intervention translated silent neurovascular risk into visible, understandable, and actionable information during routine nursing encounters. This explanation is consistent with the neuro-ischaemic phenotype framework, which proposes that concurrent loss of protective sensation and lower-limb ischemia represent a distinct high-risk state that can progress without obvious symptoms unless both domains are assessed together (Burhan & Susanti, 2026). A second explanation is organizational, because structured escalation pathways may reduce uncertainty in referral decisions and support more timely preventive responses in routine care, which has been identified as a persistent implementation gap in diabetic foot screening practice (Houghton et al., 2025). The modest changes in ankle-brachial index and neuropathy examination score are also clinically plausible in a 24-week trial, particularly if better surveillance and earlier care-seeking reduced preventable deterioration rather than producing large physiologic reversal. These explanations are plausible and clinically coherent, but the trial was not designed to isolate mechanisms directly, and causal pathways should therefore be interpreted cautiously.

Overall, these findings are broadly consistent with prior interventional studies in diabetic high-risk foot care. Xie et al. found that a nurse-led health education intervention improved treatment-delay intention, foot-care knowledge, foot-care behavior, and self-efficacy in patients with diabetic high-risk foot, which aligns with the behavioral direction of the present results (Xie et al., 2026). Polat et al. similarly reported that a nurse-led hybrid self-management program improved diabetic foot self-management in adults with diabetes, further supporting the value of structured nurse-delivered behavioral reinforcement (Polat et al., 2026). In contrast, the DIATIME trial focused on follow-up frequency after ulcer remission rather than pre-ulcer neurovascular screening, which may explain why that study emphasized surveillance interval rather than integrated detection and escalation as the principal mechanism of benefit (López-Moral et al., 2025). The present trial therefore adds to the literature by combining behavioral reinforcement with concurrent neuropathy and perfusion assessment in a population defined by high neurovascular risk rather than prior ulcer remission alone.

This study has several strengths, including randomized allocation, repeated outcome assessment, and the use of a clinically grounded intervention that was aligned with contemporary diabetic foot prevention guidance. The principal limitation is that the sample size was modest and follow-up was relatively short, which reduced precision and limited assessment of harder clinical outcomes such as ulceration, hospitalization, or amputation. Additional limitations include attrition, reliance on a patient-reported primary outcome, and the possibility of residual bias related to missing data or selective adherence despite sensitivity analyses. The observed changes in ankle-brachial index and MNSI examination score should therefore be viewed as short-term trial findings rather than definitive evidence of durable neurovascular modification. Generalizability is likely greatest to adults with type 2 diabetes at elevated foot risk receiving hospital-based care in similar middle-resource settings, especially where implementation of evidence-based screening remains incomplete (Quak et al., 2025).

The main practical implication is that nurse-led pathways combining neuropathy screening, vascular assessment, and prespecified escalation may offer a pragmatic strategy to strengthen preventive diabetic foot care before ulceration develops. Diabetes services and hospitals should consider whether their current workflows adequately support early identification of combined neurovascular risk, particularly in populations with a high burden of diabetic peripheral neuropathy and ongoing amputation risk (Susanti et al., 2025). This study also adds contextual evidence from an Indonesian hospital and complements prior work showing that diabetic foot complications in Asia continue to carry substantial limb-related burden, including amputation (Athena et al., 2024). Future studies should test this approach in larger multicenter trials with longer follow-up, stronger implementation outcomes, and harder clinical endpoints such as incident ulceration, recurrence, and limb events. Overall, these findings suggest that integrating neurologic and vascular screening into a nurse-led escalation pathway is a reasonable and clinically relevant direction for high-risk diabetic foot prevention, but confirmation in larger studies remains necessary.

Strengths And Limitations of The Study

A notable strength of this trial is its randomized design, repeated outcome assessment, and the use of a clinically grounded, theory-informed nursing pathway that reflects routine high-risk diabetic foot care. At the same time, the relatively small sample and short follow-up limit precision and reduce the ability to assess harder clinical endpoints such as ulceration, hospitalization, or amputation. The primary outcome also relied on a patient-reported measure, which may have introduced reporting bias and may have modestly inflated perceived improvement in help-seeking intention and self-management. In addition, the single-center setting and attrition during follow-up may have introduced selection-related bias and limited representativeness, while residual confounding in ancillary adjusted analyses cannot be fully excluded despite randomization. These constraints may have attenuated or, in some instances, modestly magnified the observed effects, particularly for secondary neurovascular outcomes. Accordingly, the findings should be interpreted as supportive but not definitive evidence of benefit in similar hospital-based high-risk populations.

Implications For Nursing Practice

These findings suggest that nursing practice may benefit from a more structured approach to early neurovascular risk identification in adults with type 2 diabetes at high foot risk. Nurses should be attentive not only to symptoms and visible foot problems, but also to the combined presence of neuropathic impairment, perfusion abnormalities, delayed help-seeking, and suboptimal self-care behaviors that may precede ulceration. At the organizational level, nursing leadership, educators, and diabetes services may consider integrating dual-domain screening, escalation algorithms, and reinforcement-based patient education into routine workflows and competency training. Such approaches may strengthen preventive care, improve communication across teams, and support more timely referral and follow-up in patients whose risk might otherwise remain clinically silent. Although these findings do not establish a new standard of care, they may help inform pragmatic nursing strategies while larger multicenter studies with longer follow-up are undertaken

Conclusions

Among adults with type 2 diabetes at high foot risk, a nurse-led dual-domain neurovascular screening and escalation pathway was associated with modest improvement in healthcare-seeking intention, foot self-care behavior, and selected neurovascular indicators compared with usual care. The practical relevance of these findings lies in the potential value of integrating concurrent neuropathy and vascular assessment into routine nursing workflows for earlier risk recognition and more structured follow-up. These results support further multicenter trials with longer follow-up to determine whether this approach can be sustained and translated into improvement in harder diabetic foot outcomes

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Conflict of Interest Statement
The authors declare that they have no competing interests related to this study.

Author contribution
Andre Priyanto conceived the study and led project administration. Nova Aprialini contributed to study design, data collection, and data curation. Putri Vilotenda contributed to data analysis, interpretation, and manuscript drafting. Asmat Burhan contributed supervision and review of the draft and manuscript. All authors critically revised the manuscript and approved the final version

Data Availability
The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to institutional and ethical considerations

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