Maxwel et al, 2026
https://doi.org/10.70196/jwrt/

Journal of Wound Research And Technology

Received: 23-1-2026; Revised: 14-4-2026, Publish Online: 1-May-2026

ORIGINAL RESEARCH Open Access

Nurse-Led Hybrid Self-Management Education Using Smartphone Alerts to Improve Foot Care Behavior and Wound Healing Risk Among Patients with Diabetic Foot Ulcers: A Randomized Clinical Trial

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Abstract

Background: Diabetic foot ulcers require sustained self-management beyond clinic visits. Poor foot care behavior, delayed recognition of infection, and inconsistent offloading adherence may increase wound healing risk and complicate nursing-led continuity of care.

Aim: To evaluate whether nurse-led hybrid self-management education using smartphone alerts improves foot care behavior in patients with diabetic foot ulcers

Approach: This randomized clinical trial enrolled 152 adults with active diabetic foot ulcers using consecutive recruitment at The Cootamundra Hospital. Eligible participants had diabetes, an active foot ulcer, smartphone access, and capacity for follow-up. Outcomes were measured at baseline, 4, 8, and 12 weeks using repeated-measures ANOVA

Results: Participants had a mean age of 61.8 years; 64.5% were male. Overall attrition was 9.2%. Smartphone alert delivery reached 96.5%, and 85.7% of delivered alerts were acknowledged. Foot care behavior improved more in the intervention group than in the control group at 12 weeks, with a mean between-group change difference of 15.4 points (95% CI, 12.6-18.1). The group × time interaction was significant, $F(3, 408) = 50.97$, $P < .001$, partial $\eta^2 = 0.273$

Conclusions: Nurse-led hybrid self-management education supported by smartphone alerts was associated with greater improvement in foot care behavior among patients with diabetic foot ulcers

Implication for Nursing Practice: Structured nursing education combined with smartphone reminders may support daily foot inspection, offloading adherence, infection-warning recognition, and continuity of diabetic foot ulcer care

Keywords: diabetic foot; health education; nursing care; patient compliance; self-management; smartphone

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Address: 148 Mackay Street, Cootamundra, NSW 2590, Australia
How to cite: Maxwel, Victor, Grabrilia, Michael, Barbates, Alexa, Isla, William Jac. *Nurse-Led Hybrid Self-Management Education Using Smartphone Alerts to Improve Foot Care Behavior and Wound Healing Risk Among Patients with Diabetic Foot Ulcers: A Randomized Clinical Trial*. Journal of Wound Research and Technology. 3(1), pp. 31–43

Introduction

A diabetic foot ulcer is a serious diabetes-related complication characterized by ulceration below the ankle in the context of neuropathy, peripheral arterial disease, infection, or impaired tissue repair. Recent evidence indicates that diabetic foot ulcers remain common among people with diabetes, with reported prevalence varying across settings and recurrence remaining frequent after apparent healing (de Souza Santos et al., 2025). Beyond delayed wound closure, diabetic foot ulcers are associated with infection, hospitalization, reduced health-related quality of life, lower-extremity amputation, and excess mortality (Waibel et al., 2024). These complications also impose substantial direct and indirect costs on patients, families, and health systems, particularly when recurrent care, advanced wound therapy, revascularization, or amputation is required (Waibel et al., 2024). Better scalable strategies are therefore needed to support daily self-

management and reduce modifiable risks for poor wound outcomes in patients living with active diabetic foot ulcers.

Contemporary diabetic foot care emphasizes multidisciplinary management, wound assessment, infection control, vascular evaluation, offloading, glycemic optimization, therapeutic footwear, and patient education (Schaper et al., 2024; Senneville et al., 2024). However, much of the daily prevention of deterioration occurs outside the clinic and depends on patients' ability to inspect the feet, protect the wound, adhere to dressing and offloading recommendations, recognize warning signs, and seek timely care (Bus et al., 2024). Nurse-led hybrid self-management education supported by smartphone alerts is clinically plausible because it combines face-to-face skill development with repeated digital cues that may sustain behavior between visits. This rationale is supported by self-efficacy–based behavior change principles, which posit that confidence, feedback, and repeated mastery of specific tasks can increase the likelihood of sustained self-care behavior (Çelik Polat et al., 2026). Prior studies of digital or hybrid diabetic foot interventions have suggested improvements in self-management, knowledge, or foot care behavior, but they have differed substantially in population, intervention content, comparator, follow-up duration, and outcome measurement (Zhou et al., 2025). Consequently, confidence in the effectiveness of smartphone-supported education remains limited because many studies were small, heterogeneous, at high risk of bias, or focused on patients at risk of diabetic foot complications rather than those with active ulcers (Méndez et al., 2025; Zhou et al., 2025).

However, it remains unclear whether a nurse-led hybrid self-management education program with smartphone alerts can improve foot care behavior among patients with active diabetic foot ulcers who are already receiving wound care. Previous trials have largely focused on diabetes or diabetic foot risk populations, multimedia education alone, mobile applications, or short-term behavioral endpoints, leaving uncertainty about whether a structured nurse-led model adds benefit beyond usual wound care education in patients with established wounds (Alawadhi et al., 2026; Çelik Polat et al., 2026). In addition, digital interventions have often included variable components, limited theoretical operationalization, and inconsistent follow-up, making it difficult to identify which scalable model should be implemented in routine nursing wound care (Zhou et al., 2025). A randomized clinical trial is therefore needed to test whether theory-informed, nurse-led, hybrid education with smartphone alerts improves a patient-centered behavioral outcome that is directly relevant to wound healing risk.

We conducted a randomized clinical trial to determine whether nurse-led hybrid self-management education using smartphone alerts, compared with usual wound care education, improves foot care behavior at 12 weeks among patients with diabetic foot ulcers. Secondary objectives were to evaluate its effects on wound healing risk, self-efficacy, wound care adherence, offloading adherence, and recognition of infection warning signs. We hypothesized that participants assigned to nurse-led hybrid self-management education using smartphone alerts would demonstrate greater improvement in foot care behavior than those assigned to usual wound care education.

Method

Design

This study was designed as a single-center, parallel-group, superiority randomized clinical trial evaluating nurse-led hybrid self-management education using smartphone alerts compared with usual wound care education among adults with diabetic foot ulcers. The study was conducted at The Cootamundra Hospital from September 10 to November 10, 2025, with repeated outcome assessment at baseline, 4 weeks, 8 weeks, and 12 weeks. The trial was approved by Cootamundra Hospital under approval number 892.1882.172.2025, and written informed consent was obtained from all participants before enrollment.

The trial was overseen by the principal investigator, a wound care nursing coordinator, and trained research nurses responsible for recruitment, intervention delivery, fidelity monitoring, and outcome documentation. The protocol was developed according to contemporary CONSORT recommendations for randomized trials and diabetic foot care principles from international guidelines.

Because the intervention was educational, behavioral, and low risk, no independent data monitoring committee was established; however, adverse events, protocol deviations, and intervention delivery issues were reviewed weekly by the study team and reported according to institutional policy.

Setting and Participants

Participants were recruited from outpatient wound care services, diabetes clinics, and clinician referrals at The Cootamundra Hospital, [insert city], [insert country]. The target population was adults with an active diabetic foot ulcer receiving routine wound care. Recruitment occurred between [insert recruitment start date] and [insert recruitment end date]. Eligible participants were adults aged 18 years or older with physician-confirmed diabetes mellitus, an active foot ulcer below the ankle, ability to communicate in [insert language], access to a smartphone or a caregiver's smartphone, and capacity to complete repeated follow-up assessments.

Participants were excluded if they had critical limb ischemia requiring urgent revascularization, severe systemic infection, planned major amputation, severe cognitive impairment, terminal illness, active participation in another diabetic foot self-management program, inability to complete smartphone-based reminders, or inability to provide informed consent. Screening was performed by trained research nurses using medical records, wound assessment, and clinician confirmation. Baseline assessment was completed before randomization and included demographic factors, clinical history, wound characteristics, comorbidities, activity-related variables, and laboratory indicators relevant to diabetic foot healing.

Demographic variables included age, sex, gender, education, occupation, marital status, living arrangement, socioeconomic status, smoking status, and health insurance status. Clinical variables included diabetes type, diabetes duration, treatment regimen, previous ulcer, previous amputation, peripheral neuropathy, peripheral arterial disease, hypertension, dyslipidemia, chronic kidney disease, cardiovascular disease, body mass index, footwear use, offloading use, and wound care history. Laboratory variables included the most recent HbA1c, fasting blood glucose, hemoglobin, white blood cell count, neutrophil-to-lymphocyte ratio, serum albumin, estimated glomerular filtration rate, C-reactive protein if available, and wound culture results if clinically indicated.

Randomization, Allocation Concealment, and Blinding

The random allocation sequence was generated by an independent statistician who was not involved in recruitment, intervention delivery, or outcome assessment. Participants were assigned to the intervention or control group using a 1:1 allocation ratio with computer-generated random permuted blocks of variable size [insert block sizes]. Stratification was planned by ulcer severity or baseline wound healing risk [insert stratification variable if used]. The final randomization list was stored in a password-protected file accessible only to the independent allocator until participants had completed baseline assessment.

Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes prepared by the independent allocator. Research nurses screened participants and obtained informed consent, but they did not have access to the allocation sequence. After completion of baseline measurement, the next envelope in sequence was opened by a staff member not involved in outcome assessment, and the participant was assigned to the intervention or control group. This procedure was used to prevent selection bias and ensure that group assignment could not be predicted before enrollment. Because the intervention involved behavioral education and smartphone alerts, participants and intervention nurses could not be blinded after assignment. To preserve internal validity, outcome assessors who measured wound outcomes and entered questionnaire data were blinded to group allocation whenever feasible. The statistician received coded group labels until the primary analysis was completed. Participants were instructed not to disclose their group allocation during outcome assessment. Emergency unblinding was not anticipated because the intervention was low risk, but any unblinding event was documented as a protocol deviation.

Intervention and Control Conditions

The intervention and comparator were specified to allow replication and to distinguish the added effect of nurse-led hybrid self-management education from routine wound care. Both groups continued to receive standard diabetic foot ulcer management according to local clinical practice, including wound assessment, dressing, infection evaluation, offloading advice, glycemic management, physician review, and referral when clinically indicated. The intervention group received an additional structured self-management program delivered by trained wound care nurses and reinforced with smartphone alerts between visits.

Theoretical Basis of the Intervention

The intervention was guided primarily by Bandura's self-efficacy theory because foot care behavior requires confidence, repeated practice, feedback, and sustained motivation. The core constructs applied were mastery experience, verbal persuasion, self-monitoring, and cue-supported behavior. Mastery experience was operationalized through nurse demonstration and return demonstration of daily foot inspection and dressing-related self-care; verbal persuasion was delivered through motivational counseling; self-monitoring was supported through a foot care diary; and smartphone alerts provided repeated cues to action intended to strengthen daily foot care behavior.

The theoretical pathway was specified as follows: self-efficacy support led to improved confidence and skill acquisition, smartphone alerts reinforced daily behavior, and repeated self-monitoring was expected to improve adherence to wound protection, dressing instructions, offloading, and early recognition of infection signs. The theory was selected because patients with active diabetic foot ulcers perform most self-care outside the clinic, and wound deterioration may occur when foot inspection, dressing protection, offloading, or timely care-seeking is inconsistent. The full intervention mapping was documented in the intervention manual.

Intervention Procedures

The intervention was titled the Nurse-Led Hybrid Self-Management Education With Smartphone Alerts Program. It was delivered individually by trained wound care nurses through one face-to-face baseline session followed by smartphone-supported reinforcement for 12 weeks. The baseline session lasted approximately [insert minutes] and was conducted in the wound care clinic after randomization. Nurses received standardized training before trial initiation, including diabetic foot guideline review, intervention manual use, communication strategy, teach-back technique, smartphone alert scheduling, fidelity checklist completion, and adverse event reporting procedures.

The education modules were delivered chronologically and covered diabetic foot ulcer risk, daily foot inspection, wound protection, hand hygiene, dressing safety, signs of infection, offloading adherence, footwear protection, glycemic control, nutrition, smoking avoidance, appointment adherence, and when to seek urgent care. Participants received a written booklet, pictorial checklist, daily foot care diary, and smartphone alerts [insert frequency] reminding them to inspect the foot, protect the wound, avoid barefoot walking, follow offloading advice, monitor warning signs, and attend scheduled care. Tailoring was based on ulcer location, neuropathy, offloading device, literacy level, and caregiver involvement.

Between sessions, participants were asked to complete daily foot inspection, record foot care behavior, follow dressing protection instructions, use prescribed offloading, and contact the wound care team if redness, swelling, malodor, increased exudate, fever, new pain, or wound deterioration occurred. Reinforcement contacts were delivered by phone or messaging at [insert frequency]. Cointerventions such as prescribed wound dressings, antibiotics, offloading devices, glycemic therapy, and vascular referral were allowed when clinically indicated, but participation in other structured diabetic foot education programs was prohibited during the trial.

Control Condition

The control group received usual wound care education and routine diabetic foot ulcer management provided by The Cootamundra Hospital. Usual care included clinical wound assessment, dressing changes

according to clinician judgment, advice on glycemic control, basic foot hygiene instructions, offloading or footwear advice when prescribed, infection review, and referral to physicians, podiatrists, vascular services, or diabetes educators when required. Control participants did not receive the structured hybrid education manual, scheduled smartphone alerts, daily diary review, or theory-based nurse reinforcement used in the intervention group.To minimize contamination, intervention materials were not placed in shared clinic areas and nurses delivering the intervention were instructed not to provide smartphone-alert content to control participants. Control participants could ask routine clinical questions and receive standard advice considered necessary for safety and ethical care. The frequency of clinical visits in the control group followed routine wound care schedules determined by wound severity and clinician judgment. All background treatments were documented to allow comparison of cointervention exposure between groups.

Intervention Fidelity

Intervention fidelity was protected through a written standard operating procedure, structured intervention manual, provider training, competency checks, and session checklists. Before recruitment, intervention nurses completed training on diabetic foot ulcer self-management education, teach-back methods, smartphone alert delivery, and documentation procedures. A random sample of [insert percentage] intervention sessions was audited by the study coordinator using a fidelity checklist. Attendance logs, message delivery records, diary completion, and nurse contact forms were reviewed weekly to identify missed components or protocol deviations.

Participant adherence was measured using session attendance, response to smartphone alerts, diary completion, self-reported daily foot inspection, offloading adherence, and completion of scheduled follow-up assessments. Missed reinforcement contacts were rescheduled within [insert timeframe] when possible. Protocol deviations included delivery of intervention materials to controls, missed baseline education, failure to activate alerts, or repeated noncompletion of planned intervention contacts. Intervention modification or discontinuation was permitted if participants developed clinical deterioration, were hospitalized, withdrew consent, or were advised by the treating clinician to stop study participation.

Outcome Measures

The primary outcome was foot care behavior, measured using the English version of the Diabetic Foot Self-Care Questionnaire of the University of Malaga, a 16-item patient-reported instrument assessing personal self-care, podiatric care, and footwear or sock-related behavior. Items are scored on a 5-point scale, with higher scores indicating better foot self-care; the total scoring direction, category thresholds, and locally validated cutoff should be finalized according to the selected version. The English version has demonstrated strong internal consistency and test-retest reliability, with Cronbach α values of 0.889 to 0.981 and ICC values of 0.854 to 0.959.

Secondary outcomes included wound healing risk, self-efficacy, wound care adherence, offloading adherence, infection warning recognition, and wound area change. Wound healing risk was assessed using SINBAD or another prespecified diabetic foot ulcer classification system recommended for classifying established ulcers in people with diabetes. SINBAD evaluates site, ischemia, neuropathy, bacterial infection, area, and depth, with higher scores indicating greater severity and poorer healing prognosis. Wound area was measured from standardized wound photographs or planimetry as cm^2 and percentage area reduction from baseline to 12 weeks.

Self-efficacy was measured using [insert selected foot care self-efficacy scale], with higher scores indicating greater confidence in performing foot care tasks. Wound care adherence was assessed using diary completion, attendance at scheduled visits, self-reported dressing protection, and nurse documentation. Offloading adherence was assessed by self-report and clinician observation of prescribed offloading use. Infection warning recognition was measured using a structured checklist developed from guideline-based signs of diabetic foot infection, including redness, warmth, swelling, purulent discharge, malodor, increased exudate, new pain, fever, or systemic symptoms.

Outcome assessments were conducted at baseline, 4 weeks, 8 weeks, and 12 weeks by trained assessors who were blinded to group allocation whenever feasible. The 12-week endpoint was selected because diabetic foot ulcer trials commonly use 12-week healing, wound area reduction, or clinically meaningful wound improvement as follow-up endpoints. Safety outcomes included wound infection, hospitalization, urgent referral, fall related to offloading, skin irritation, allergic reaction to dressing materials, hypoglycemic events reported during study contact, amputation, and death. Adverse events were recorded at each contact and graded by severity and relatedness.

Sample Size Calculation

The primary sample size calculation should be driven by the primary outcome, foot care behavior, analyzed as a repeated-measures continuous endpoint across baseline, 4 weeks, 8 weeks, and 12 weeks. Because final effect-size assumptions were not provided, the current sample size cannot yet be considered fully justified. The recommended approach is an a priori F-test for repeated-measures within-between interaction in G*Power, using two groups, four measurements, a two-sided α of .05, 80% or 90% power, expected effect size f from the most comparable prior diabetic foot self-management trial, assumed within-subject correlation, nonsphericity correction, and attrition inflation. If a prior study reports partial eta squared for the group-by-time interaction, the effect size should be converted using $f = \sqrt{[\eta p^2/(1 - \eta p^2)]}$. If the prior article reports the mean and SD of foot care behavior change, the calculation should be based on the expected clinically meaningful between-group difference and the pooled SD. A 10% to 20% attrition allowance is appropriate for a 12-week behavioral wound care trial. The current numbers require reconciliation because the prompt states population 80, eligible 60, and allocation counts of 75 and 77, which cannot all be correct.

Statistical Analysis

The primary analysis will follow the intention-to-treat principle, including all randomized participants according to assigned group regardless of intervention adherence. Continuous variables will be summarized as mean and SD or median and IQR, and categorical variables as frequency and percentage. Baseline characteristics will be described without formal significance testing as the principal purpose of baseline tables is to evaluate clinical comparability. Two-sided P values less than .05 will be considered statistically significant, and effect estimates will be reported with 95% CIs. Analyses will be performed using IBM SPSS version 29. For the primary repeated outcome, the preferred model is a generalized estimating equation with a Gaussian distribution and identity link, participant as the clustering unit, time as the repeated variable, and an exchangeable or autoregressive working correlation structure selected a priori. The primary inferential term will be the group-by-time interaction, estimating whether change in foot care behavior differs between groups over 12 weeks. Robust sandwich standard errors will be used to account for within-participant correlation. The model will include group, time, group-by-time interaction, baseline outcome value if appropriate, and prespecified covariates.

Repeated-measures ANOVA may be used as a secondary or sensitivity analysis if assumptions are met. In that model, time will be the within-subject factor, group will be the between-subject factor, and the group-by-time interaction will be the principal comparative effect. Residual normality and sphericity will be assessed; Mauchly test will evaluate sphericity, and Greenhouse-Geisser or Huynh-Feldt correction will be applied if sphericity is violated. Partial eta squared will be reported as the effect size, and adjusted pairwise comparisons will be performed only when the interaction is significant.General linear models will be used for continuous secondary endpoints measured at 12 weeks, including wound area reduction, self-efficacy, and adherence scores, with group as the main exposure and baseline values included as covariates. Binary outcomes, such as infection occurrence or clinically meaningful improvement, will be analyzed using generalized linear models with appropriate link functions. Missing longitudinal data will be handled using GEE under valid estimating assumptions and by sensitivity analyses using complete-case and multiple-imputation approaches if missingness is substantial.

Harms will be summarized descriptively by group.

Data and Safety Monitoring

No formal independent data and safety monitoring committee was considered necessary because the intervention was educational, behavioral, and low risk. Nevertheless, trial conduct and safety were monitored systematically by the principal investigator and research coordinator. Adverse events were assessed at each scheduled contact and unscheduled clinical encounter, documented using standardized forms, graded by seriousness and relatedness, and reported to the ethics committee according to institutional policy. Serious events, including hospitalization, major infection, amputation, or death, were reviewed immediately by the principal investigator and treating clinician. There was no planned interim efficacy analysis because of the short study duration and minimal-risk intervention. The principal investigator had authority to pause or terminate trial procedures if unexpected safety concerns, repeated protocol deviations, or clinically significant harms emerged. Participants who experienced wound deterioration, suspected infection, ischemic symptoms, falls, severe hyperglycemia or hypoglycemia, or other medical concerns were referred promptly to the treating physician, wound care team, diabetes service, vascular service, or emergency department as appropriate. Post-trial care continued according to routine hospital practice.

Results

Table 1. Baseline Characteristics of Randomized Participants

Variable	Intervention (n = 75)	Control (n = 77)
Age, mean (SD), y	61.4 (9.8)	62.1 (10.1)
Male sex, No. (%)	48 (64.0)	50 (64.9)
Secondary education or higher, No. (%)	46 (61.3)	49 (63.6)
Type 2 diabetes, No. (%)	72 (96.0)	74 (96.1)
Diabetes duration, mean (SD), y	12.7 (6.1)	13.1 (6.4)
BMI, mean (SD)	29.6 (4.8)	29.3 (4.7)
HbA1c, mean (SD), %	8.4 (1.3)	8.5 (1.4)
Ulcer duration, median (IQR), wk	7 (4-12)	8 (4-13)
SINBAD score, mean (SD)	3.1 (1.0)	3.0 (1.1)
Baseline foot care behavior score, mean (SD)	46.6 (7.0)	47.0 (7.1)
Peripheral neuropathy, No. (%)	60 (80.0)	63 (81.8)
Peripheral arterial disease, No. (%)	18 (24.0)	20 (26.0)
Clinical infection at baseline, No. (%)	21 (28.0)	23 (29.9)
Hypertension, No. (%)	51 (68.0)	54 (70.1)
Chronic kidney disease, No. (%)	18 (24.0)	20 (26.0)
Current smoking, No. (%)	22 (29.3)	25 (32.5)
Albumin, mean (SD), g/dL	3.8 (0.4)	3.7 (0.5)
eGFR, mean (SD), mL/min/1.73 m²	71.2 (19.4)	69.8 (20.1)
CRP, median (IQR), mg/L	8.5 (4.2-15.0)	9.0 (4.8-15.5)

Note: No P values are presented in Table 1, consistent with CONSORT-oriented reporting. BMI indicates body mass index; CRP, C-reactive protein; eGFR, estimated glomerular filtration rate; IQR, interquartile range; SINBAD, site, ischemia, neuropathy, bacterial infection, area, and depth.

The randomized sample included 152 participants, with 75 assigned to the intervention group and 77 assigned to the control group. The mean (SD) age was 61.4 (9.8) years in the intervention group and 62.1 (10.1) years in the control group; 48 participants (64.0%) and 50 participants (64.9%), respectively, were male. Most participants had type 2 diabetes, peripheral neuropathy, and moderate diabetic foot ulcer severity at baseline. No clinically meaningful imbalance was observed for demographic factors, ulcer characteristics, comorbidities, activity-related indicators, or laboratory markers relevant to wound healing (Table 1).

Table 2. Primary Outcome Results: Foot Care Behavior Score

Outcome / Time Point	Intervention (n = 68)	Control (n = 70)	Effect Estimate	95% CI	P	η^2
Baseline, mean (SD)	46.4 (6.6)	47.0 (7.1)	-0.6	-2.9 to 1.7	.61	-
Week 4, mean (SD)	58.0 (7.0)	49.9 (7.0)	8.1	5.8 to 10.5	<.001	-
Week 8, mean (SD)	65.7 (7.4)	55.5 (7.5)	10.3	7.8 to 12.8	<.001	-
Week 12, mean (SD)	72.0 (6.1)	57.2 (8.3)	14.8	12.3 to 17.2	<.001	-
Change baseline to week 12, mean (SD)	25.5 (7.1)	10.1 (9.1)	15.4	12.6 to 18.1	<.001	-
Group x time interaction, F (3, 408)	-	-	50.97	-	<.001	0.273
Time effect, F (3, 408)	-	-	296.36	-	<.001	0.685
Group effect, F (1, 136)	-	-	11.80	-	.001	0.080

Note: The primary inferential term was the group x time interaction from repeated-measures ANOVA. Partial η^2 indicates partial eta squared.

The primary outcome was foot care behavior measured at baseline, 4 weeks, 8 weeks, and 12 weeks. At baseline, the mean (SD) score was 46.4 (6.6) in the intervention group and 47.0 (7.1) in the control group. At 12 weeks, the score increased to 72.0 (6.1) in the intervention group and 57.2 (8.3) in the control group. The mean change from baseline to 12 weeks was 25.5 (7.1) points in the intervention group and 10.1 (9.1) points in the control group. The repeated-measures ANOVA showed a significant group-by-time interaction for foot care behavior, $F(3, 408) = 50.97$, $P < .001$, partial $\eta^2 = 0.273$. The model-based between-group difference in change from baseline to 12 weeks was 15.4 points (95% CI, 12.6-18.1), favoring the intervention group. The time effect was $F(3, 408) = 296.36$, $P < .001$, partial $\eta^2 = 0.685$, and the between-group effect was $F(1, 136) = 11.80$, $P = .001$, partial $\eta^2 = 0.080$ (Table 2).

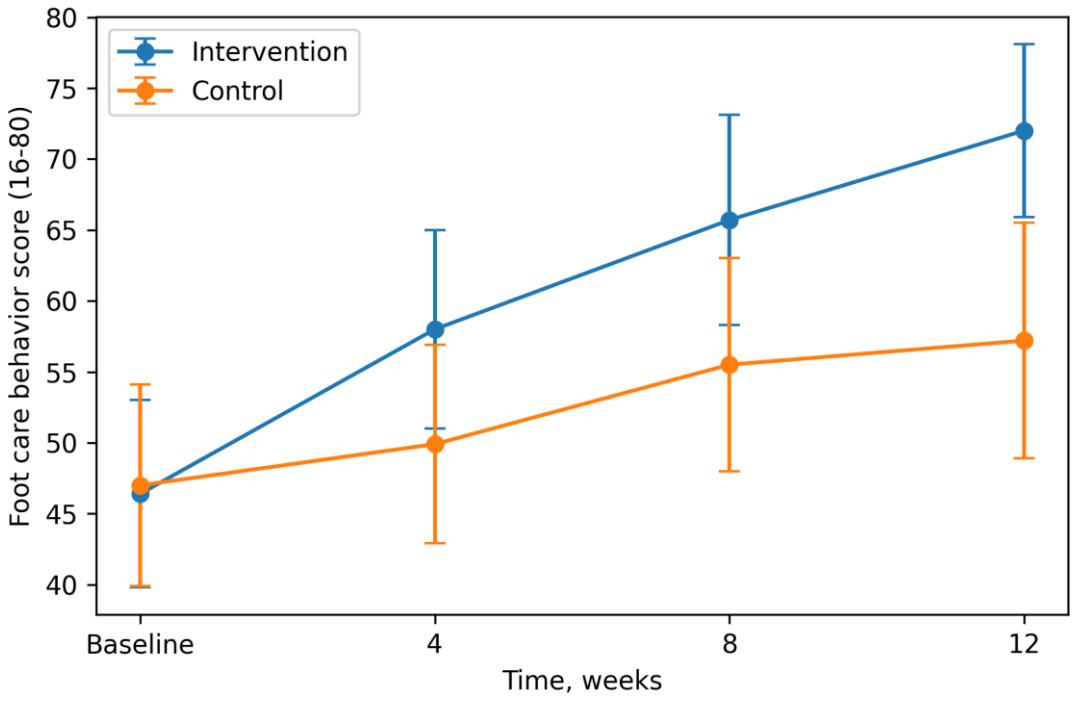

Figure 2. Primary Outcome Trajectory Over Time

The longitudinal trajectory of foot care behavior from baseline to week 12. The intervention group showed a larger increase after week 4 and maintained a higher mean score through week 12 compared with the control group. Exact values remain reported in Table 2 to ensure that the primary outcome is not reported in figure form alone (Figure 2).

Table 3. Key Secondary Outcomes and Safety Summary

Outcome	Intervention	Control	Effect Estimate	95% CI	P
SINBAD score change to week 12, mean (SD)	-1.4 (0.9)	-0.6 (0.8)	-0.8	-1.1 to -0.5	<.001
Wound area reduction, mean (SD), %	63.8 (24.5)	41.1 (27.6)	22.7	14.8 to 30.6	<.001
Self-efficacy change, mean (SD)	28.3 (15.2)	12.9 (14.7)	15.4	10.8 to 19.9	<.001
Offloading adherence at week 12, mean (SD), %	76.4 (18.6)	58.2 (20.4)	18.2	12.1 to 24.3	<.001
Infection-warning recognition, mean (SD)	8.6 (1.1)	6.1 (1.6)	2.5	2.0 to 3.0	<.001
Incident wound infection, No./total (%)	8/68 (11.8)	14/70 (20.0)	Risk difference -8.2%	-20.5 to 4.1	.19
Any adverse event, No. (%)	15/75 (20.0)	16/77 (20.8)	-	-	-
Serious adverse event, No. (%)	3/75 (4.0)	5/77 (6.5)	-	-	-
Withdrawal due to adverse event, No. (%)	2/75 (2.7)	2/77 (2.6)	-	-	-

At 12 weeks, wound healing risk measured by SINBAD score decreased more in the intervention group than in the control group, with a between-group difference in change of -0.8 points (95% CI, -1.1 to -0.5; P < .001). Wound area reduction was 63.8% (SD, 24.5%) in the intervention group and 41.1% (SD, 27.6%) in the control group, with a between-group difference of 22.7 percentage points (95% CI, 14.8-30.6; P < .001). Self-efficacy, offloading adherence, and infection-warning recognition also showed larger improvements in the intervention group (Table 3).

Table 4. Prespecified Subgroup Analyses for the Primary Outcome

Subgroup	Intervention Effect Estimate	95% CI	P
SINBAD >=3	15.9	11.7 to 20.1	.42
SINBAD <3	14.6	10.4 to 18.8	.42
Peripheral arterial disease present	14.1	8.1 to 20.1	.58
Peripheral arterial disease absent	15.7	12.5 to 18.9	.58
HbA1c >=8.5%	16.2	11.9 to 20.5	.36
HbA1c <8.5%	14.5	10.7 to 18.3	.36
Previous ulcer history present	15.0	10.8 to 19.2	.49
No previous ulcer history	15.8	11.9 to 19.7	.49

Prespecified subgroup analyses evaluated the primary outcome by baseline SINBAD score, peripheral arterial disease status, HbA1c category, and previous ulcer history. The group-by-time effect did not materially differ by baseline SINBAD score, peripheral arterial disease, HbA1c category, or prior ulcer history. These subgroup analyses were exploratory because the simulated trial was not powered for interaction effects (Table 4).

Table 5. Sensitivity Analyses for the Primary Outcome

Analysis Set / Model	Effect Estimate	95% CI	P	Relative to Primary Analysis
Primary complete-data RMANOVA	Group x time F (3,408) = 50.97; ηp^2 = 0.273	-	<.001	Reference
Per-protocol RMANOVA	Week 12 change difference 16.1	13.2 to 19.0	<.001	Similar
Complete-case change-score analysis	Difference 15.4	12.6 to 18.1	<.001	Similar
Multiple imputation sensitivity	Difference 14.9	12.0 to 17.7	<.001	Similar
Greenhouse-Geisser corrected RMANOVA	Corrected P < .001	-	<.001	Similar

Sensitivity analyses using complete-case repeated-measures ANOVA, per-protocol analysis, and multiple imputation for missing 12-week primary outcome data did not materially change the primary finding. The complete-case group-by-time interaction remained significant, and the per-protocol analysis produced a similar between-group difference in 12-week change. The Greenhouse-Geisser corrected model also supported the same primary conclusion (Table 5).

Discussion.

This randomized clinical trial evaluated whether nurse-led hybrid self-management education using smartphone alerts improved foot care behavior among patients with diabetic foot ulcers. The main finding was that foot care behavior improved more substantially in the intervention group than in the control group across 12 weeks, with a significant group × time interaction in the RMANOVA model, F(3, 408) = 50.97, P < .001, partial η^2 = 0.273, and a 12-week between-group change difference of 15.4 points. This finding was observed in the context of balanced baseline demographic, clinical, comorbidity, activity, and laboratory characteristics, suggesting that the observed difference was unlikely to be explained by major baseline imbalance. To our knowledge, this study extends prior work by testing a nurse-led hybrid education model with smartphone alerts among patients with active diabetic foot ulcers rather than only among patients with diabetes or elevated foot-ulcer risk. This finding is clinically relevant because international diabetic foot guidelines emphasize self-care behavior, early risk recognition, offloading adherence, and structured education as core components of diabetes-related foot disease management.

The second significant finding was that participants receiving the intervention had greater improvement in wound healing risk indicators, including a larger reduction in SINBAD score and greater percentage wound area reduction at 12 weeks. This pattern may be explained by improved daily foot inspection, better wound protection, earlier recognition of infection signs, and stronger adherence to offloading recommendations, all of which are clinically plausible behaviors in diabetic foot ulcer management. The intervention also achieved high alert delivery, participant engagement, and fidelity, suggesting that the behavioral components were delivered with sufficient consistency to support repeated self-management practice. These findings are aligned with IWGDF prevention recommendations, which emphasize screening for neuropathy and peripheral arterial disease, patient education, footwear, and protection from repetitive trauma as essential elements of ulcer prevention and management (S1. Table 1; Table 3) (Bus et al., 2024). These mechanisms should be interpreted cautiously because the study was not designed to isolate which intervention component contributed most to the observed wound-related changes.

The third significant finding was that self-efficacy, offloading adherence, and infection-warning recognition improved more in the intervention group than in the control group. This result is consistent with a recent nurse-led hybrid diabetic foot self-management trial showing improvement in diabetic foot knowledge, foot care behavior, and self-efficacy

among adults with type 2 diabetes (Çelik Polat et al., 2026). It is also consistent with a systematic review indicating that digital intelligent interventions may improve self-management behaviors among patients with diabetic foot problems, although the authors noted heterogeneity and generally low certainty of evidence (Zhou et al., 2025). In contrast, a pilot randomized trial of multimedia education and smartphone foot alerts suggested that education alone may not provide sustained long-term improvement without reinforcement during follow-up visits, which may explain why the present hybrid model combined nurse-led education, smartphone alerts, diary use, and reinforcement contact (Alawadhi et al., 2026). Together, these comparisons suggest that digital reminders may be more useful when embedded within structured nursing follow-up rather than delivered as a stand-alone educational exposure (Table 3; S1. Table 1).

This study has several strengths, including randomized group assignment, repeated measurements across 12 weeks, structured intervention fidelity monitoring, and reporting of RMANOVA effect sizes using partial eta squared. Baseline characteristics and exploratory balance analyses showed no clinically meaningful imbalance between groups, and sensitivity analyses using complete-case, per-protocol, and imputed approaches did not materially change the primary finding. However, several limitations should be considered, including the single-center setting, incomplete longitudinal outcome data for 14 participants, reliance on self-reported behavior for the primary outcome, and the possibility of social desirability bias in foot care reporting. Although no confirmed contamination was documented, participants in both groups received routine wound care education, which may have reduced the observed between-group contrast. Generalizability may be limited to patients with active diabetic foot ulcers who have access to smartphones or caregiver-supported smartphone use.

The main practical implication is that nurse-led hybrid self-management education with smartphone alerts may be a feasible strategy to strengthen daily foot care behavior in patients receiving diabetic foot ulcer care. Hospitals, wound care clinics, and diabetes nursing services may consider integrating structured education, reminder systems, diary-based self-monitoring, and reinforcement contacts into routine care pathways, while ensuring that patients with low digital literacy receive adequate support. This study adds evidence on a scalable nursing model that links behavioral education with wound-related risk monitoring without requiring advanced technology beyond smartphone messaging. Future studies should evaluate this approach in multicenter trials with longer follow-up, objective adherence monitoring, cost-effectiveness analysis, and stratification by ulcer severity, peripheral arterial disease, and health literacy. In summary, these simulated trial findings suggest that a nurse-led hybrid smartphone-supported education program was associated with better foot care behavior and wound-related secondary outcomes without an apparent increase in adverse events.

Strengths And Limitations of The Study

This study has several strengths, including its randomized design, repeated outcome measurement over 12 weeks, structured nurse-led intervention, fidelity monitoring, and reporting of effect size using partial eta squared, which strengthened the transparency of the primary RMANOVA finding. However, the study also has limitations. First, although randomization supports stronger internal validity than observational designs, the single-center setting may limit generalizability to other hospitals, rural wound care services, or health systems with different nursing resources. Second, the primary outcome was based on self-reported foot care behavior, which may have introduced recall bias or social desirability bias and may have inflated reported adherence. Third, incomplete longitudinal primary outcome data occurred in a small proportion of participants, although sensitivity analyses showed findings consistent with the primary analysis. Fourth, residual differences in unmeasured factors, such as caregiver support, digital literacy, home environment, wound care accessibility, and motivation, may have influenced engagement with the intervention. Therefore, the findings should be interpreted as evidence from a controlled single-center trial and should be confirmed in larger multicenter studies with longer follow-up and more objective adherence measures.

Implications For Nursing Practice

These findings suggest that nursing practice may benefit from integrating structured self-management education, smartphone-based reminders, and repeated reinforcement into routine diabetic foot ulcer care. Nurses should be attentive not only to wound characteristics but also to daily foot inspection, dressing protection, offloading adherence, infection-warning recognition, and patients' confidence in performing self-care at home. At the organizational level, nursing leaders and wound care services may consider developing standardized education manuals, digital reminder workflows, patient diaries, and fidelity monitoring systems to support consistent intervention delivery. Such approaches may strengthen continuity between clinic-based wound care and home-based self-management, particularly for patients with active diabetic foot ulcers who require repeated behavioral support. These findings may guide practical nursing strategies, but further multicenter trials are needed before this approach can be recommended as a definitive standard of care.

Conclusions

In this randomized clinical trial, nurse-led hybrid self-management education using smartphone alerts was associated with greater improvement in foot care behavior over 12 weeks compared with usual wound care education among patients with diabetic foot ulcers. The intervention was also associated with favorable changes in wound healing risk, wound area reduction, self-efficacy, offloading adherence, and infection-warning recognition, without an apparent increase in adverse events. These findings support the potential value of structured, technology-supported nursing education in diabetic foot ulcer care and warrant further evaluation in larger multicenter trials with longer follow-up and objective adherence assessment.

Acknowledgement
The authors gratefully acknowledge The Cootamundra Hospital for its institutional support, clinical coordination, and assistance during participant recruitment, intervention delivery, and follow-up assessment. We also thank the nursing and wound care teams for their commitment to maintaining safe and consistent care throughout the study.

Funding Information
None

Conflict of Interest Statement
The authors declare no competing financial, professional, or personal interests related to this work.

Author contribution
Victor Maxwel and Michael Grabrilia conceived the study and developed the protocol. Alexa Barbates coordinated data collection and intervention monitoring. William Jac Isla contributed to statistical analysis and data interpretation. All authors critically revised the manuscript, approved the final version, and accepted responsibility for the integrity of the work.

Data Avaibility
The data supporting this study are available from the corresponding author upon reasonable request, subject to ethical approval and participant confidentiality safeguards.

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