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Comparison of 4, 8, and 12 week screening and foot care frequencies in persons in remission: The DIATIME comparative efficacy study – A randomized clinical trial

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ABSTRACT

Aims: This study aimed to evaluate the clinical efficacy of 1, 2, and 3 months-based screening periods for the prevention of plantar DFUs in patients in remission.
Methods: A randomized, three-arm, controlled trial was conducted in 148 patients at high – risk in remission with a healed plantar foot ulcer. For the three treatment groups, the procedures were the same; the only difference was the screening timeframe: group 1, 4 weeks; group 2, 8 weeks; and group 3, 12 weeks. Primary outcome measure was the percentage of participants with plantar recurrence by the 1-year follow-up period.
Results: During the 12-month follow-up period, 50 participants (33.8 %) experienced a recurrence. We observed that participants in the 12-weeks group experience DFU recurrence significantly more frequently (n = 27, 46 %) than the 4-weeks (n = 18, 18.4 %) and 8-weeks (n = 14, 28.6 %) groups (P < 0.001). Ulcer survival curves significantly differed between the study groups (log-rank test, P < 0.001). In the logistic regression model, allocation was the only variable associated with ulcer recurrence during the 1-year follow-up period (P < 0.001, 95 % confidence interval:1.509–4.001).
Conclusions: This trial found superior clinical efficacy in preventing plantar recurrence rates with the 4-weeks screening period compared to 8 and 12 weeks.
This trial was registered at Clinicaltrials.gov (identifier ID NCT06143215) within the Unique Protocol ID name of the Diatime randomized controlled clinical trial.

1. Introduction

Diabetes-related foot ulcers (DFU) reportedly occur in approximately 18.6 million people with diabetes annually [1], and the lifetime incidence of DFUs in individuals with diabetes is approximately 34 % [2]. According to the International Working Group on Diabetic Foot guidance (IWGDF) [3], patients with a DFU that has resolved or who have partial foot amputation, patients in remission, and high-risk patients all require pressure-relieving footwear and orthoses that accommodate foot shape and any foot deformity present to reduce the risk of ulcer recurrence [4]. It has been reported that even with structured plans for ulcer prevention, 42 % recurrence at 1 year, 58 % at 3 years, and 65 % at 5 years is expected in individuals at high risk of foot ulcers [2].

The IWGDF and American Diabetes Association define high-risk patients as those with a history of DFU, amputation (minor or major), or end-stage renal disease, in addition to the loss of protective sensation and/or the presence of peripheral artery disease [4]. It has been previously estimated that high-risk patients (IWGDF-3) have a prevalence of 1.8 % of patients with diabetes [5].

The literature describes a wide variety of therapies to prevent recurrent foot ulcers. The most important pillars in the preventive management of diabetes-related foot disease are offloading, self-control and auto-examination, structured education for self-care foot prevention, thermography screening, podiatric care, and finally, structured assessment every 1–3 months [6]. An important concept is the presence of pre-ulcerative lesions and excess calluses on the plantar surface of the foot, which have been previously described as predictive factors for DFU recurrence [7,8]. Minor trauma and inflammation from repetitive

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impact on the foot during weight-bearing can cause hemorrhage beneath the callus, which presents as a full-thickness ulcer (i.e., damage extending below the epidermis and dermis into the subcutaneous tissue) upon callus removal [2,9].

The clinical pathway for the prevention of DFUs is well defined in the literature and clinical guidelines. The recommended screening period for people with healed foot ulcers is every 1–3 months for professional foot care [4]. This recommendation is based on expert opinions, and to date, no study has evaluated the clinical efficacy of different screening periods for individuals with diabetes and healed plantar foot ulcers for the evaluation of ulcer recurrences. Therefore, this study aimed to evaluate the clinical efficacy of 1, 2, and 3 months-based screening periods for the prevention of plantar DFUs in patients in remission.

2. Material and methods

2.1. Study design

This randomized, three-arm, controlled trial was conducted at the Diabetic Foot Unit of the Universidad Complutense de Madrid, Spain. Patients were consecutively recruited from the outpatient clinic, and all visits were performed at the same site by a research group. The trial was registered at Clinicaltrial.gov (identifier ID NCT06143215) within the Unique Protocol ID name of the Diatime randomized controlled clinical trial. The trial was performed according to the principles of the Declaration of Helsinki [10], ethical principles for Good Clinical Practice, and applicable regulations. The Institutional Review Board of our teaching hospital (Hospital Clínico San Carlos) approved the study. All participants provided written informed consent before screening and were free to opt out of the study whenever they wished. This clinical trial was conducted in accordance with the CONSORT guidelines for reporting randomized controlled trials.

2.2. Participants

Eligible participants were described as IWGDF-risk 3 patients in remission with a healed plantar foot ulcer[11]. The inclusion criteria were confirmed type 1 or type 2 diabetes, age >18 years, and loss of protective foot sensation due to peripheral neuropathy. To be eligible, participants had to be free of any ulcers related to ill-fitting footwear or insoles (i.e., friction ulcers or bruises) for the previous six months; this does not include ulcers located in the plantar area of the foot. The exclusion criteria were ulceration during examination, transmetatarsal or major amputation (below or above the knee), history of rheumatoid disease, other causes of neuropathy, critical limb ischemia as defined by the IWGDF peripheral artery disease guidance and the European and American Society of Vascular Surgery [12], presence of Charcot foot, need for custom-made footwear due to severe foot deformity, and need for walking aids. Participants who could not regularly attend outpatient clinics were also excluded from the study. Participants who rejected the therapeutic shoe and custom-made insole were also excluded, based on previous studies reporting that patient dissatisfaction with the prescribed footwear resulted in low usage and adherence, which was related to worse outcomes [13,14].

2.3. Random assignment

Participants were randomly assigned by demographic characteristics (sex and age group) to one of the three treatment arms using a block stratification system generated by SPSS version 30.0 (SPSS, Chicago, IL, USA). Balanced randomization was then carried out using the software available at http://www.randomization.com by the principal investigator (MLM). Enrolled and randomly assigned participants underwent either of the following: group 1 participants were screened every 4 weeks, group 2 participants every 8 weeks, and group 3 participants every 12 weeks. Given the nature of the trial, blinding of participants was not feasible. Clinicians who reviewed the participants and took care of their feet were blinded to the revision times to decrease bias in the outcome measures.

2.4. Procedures

After the principal researcher explained the procedures of the trial to the participants and they signed the informed consent form, the inclusion and exclusion criteria were evaluated. Participants who met the inclusion criteria were randomly assigned to Groups 1, 2, or 3. For the three treatment groups, the procedures were the same; the only difference was the screening timeframe: group 1, 4 weeks; group 2, 8 weeks; and group 3, 12 weeks. Participants were asked to visit the outpatient clinic every 4, 8, or 12 weeks for foot care; if any participant did not attend the planned visits, the principal investigator withdrew the participant from the trial as a major reason for not meeting the trial requirements. All participants included in the trial met the criteria for wearing therapeutic footwear with a rigid rocker sole (Podartis s.r.l Unipersonale—Crocceta del Montello (TV), Italy) and a custom-made multilayer insole (40 shore degrees base of ethyl vinyl acetate). The dorsal cover was made of poron with a cut-out and a metatarsal bar in the affected metatarsal head [15]. Every participant was provided with outdoor and indoor footwear in addition to two pairs of custom-made insoles to reduce the risk of ulcer recurrence [16,17]. The type of indoor footwear was always the same: a rigid rocker outsole sandal with two rigid heel counters and two forefoot straps to ensure proper fit. Depending on sex and aesthetics, female participants were prescribed a blue sandal, while male participants were prescribed a grey sandal.

At every study visit, an investigator performed a full foot check looking for any callus, minor lesions, hemorrhages, ingrowing or thick nails, and fitting problems within their therapeutic footwear and custom-made insole, as these have been described as factors predictive of ulcer recurrence [2,18,19]. After the clinical screening, another investigator debrided excess calluses and minor lesions using a number 10 scalpel, and nail care was performed properly at every study visit. The frequency of callus removal varied according to group allocation: participants in the 4-week group underwent 12 sessions of callus removal (once per month), those in the 8-week group underwent 6 sessions (once every two months), and those in the 12-week group underwent 3 sessions (once every three months). The investigator debrided the calluses using a No. 10 scalpel blade. The procedure was stopped once the skin surface was smooth, and no callus remained on the superficial epidermis.

Participants were asked to check their feet daily for any foot lesions. If a new hemorrhage, excess callus, or ulcer recurrence was observed, they were informed to come to the outpatient clinic for proper management.

2.5. Outcomes

The primary outcome measure was the percentage of participants with plantar recurrence by the 1-year follow-up period. Ulcer recurrence was defined as a new foot ulcer in a person with a history of foot ulceration, irrespective of the location and time since the previous foot ulcer [11]. Secondary outcome measures included minor or preulcerative lesions, minor and major amputations, and death. Minor lesions were defined as foot lesions that have a high risk of developing into foot ulcers, such as intra-or subcutaneous hemorrhages, blisters, or skin fissures that do not penetrate the dermis [11]. A different clinician that was blinded to the randomization diagnosed plantar ulceration and minor lesions. This outcome assessor performed this assessment in the clinic, i.e. live and on the participant́s foot.

2.6. Statistical analysis

The sample size calculation was estimated based on a desired power

of 80 %, with a two-sided significance level of 0.05, to detect a difference in the incidence of ulcer recurrence among the three study groups (SPSS software, version 30.0 (SPSS, Chicago, IL, USA)). Based on the reported outcomes of similar studies, we expected that 40 % [2] of group 3 (12-week group) would experience recurrence and a reduction of at least 25 % in groups 1 & 2 (4- and 8-week groups) during the 1-year follow-up period. Therefore, we expected to include at least 49 participants per group, and 148 participants to be included in the trial.

Univariate analysis of risk factors associated with allocation was performed using the chi-square test for categorical variables and Student's *t*-test for quantitative variables using SPSS version 29.0 (SPSS, Chicago, IL, USA). The strength of the differences in effect size was calculated using the phi coefficient for the chi-square test and the r coefficient for the non-parametric test, with values greater than 0.01, 0.30, and 0.50 considered as indicating small, medium, and large effects, respectively. Cohen's d was calculated as the effect size of parameters, and values greater than 0.2, 0.5, and 0.8 were considered to indicate small, moderate, and large effects, respectively [20]. The trial was conducted using a per-protocol approach, as participants who were non-compliant were excluded from the analyses. Relative risk reduction (RRR) and number needed to treat (NNT) were calculated to estimate the size of the effects.

RRR = treatment group risk – control group risk / control group risk

NNT = 1 / treatment group risk – control group risk

Differences in survival between the groups were evaluated using the log-rank test and expressed using Kaplan–Meier curves. Continuous and categorical variables with $P < 0.10$ were selected as covariates in the univariate analysis to develop a Cox proportional hazards survival model for determining ulcer recurrence-free survival time; these variables were expressed using hazard ratios with a forward stepwise selection method. Missing values were handled using multiple imputation by Fully Conditional Specification with five imputed datasets. Variables included in the imputation model were main outcome measures (recurrence and minor amputation).

2.7. Data and resource availability

The datasets generated during and/or analyzed during the current study are not publicly available due to but are available from the corresponding author upon reasonable request.

3. Results

Between November 2023 and March 2025, a total of 194 participants were screened for eligibility. After excluding those who did not meet the inclusion criteria, 148 participants were enrolled and randomly assigned to the study groups. The study flowchart is shown in Fig. 1. The demographic characteristics and diabetes and foot complications of the enrolled patients are outlined in Table 1. Most participants had type 2 diabetes (94.6 %) with more than 12 years of diabetes evolution. Participants in group 1 showed a higher rate of palpable pulses, which may indicate a trend toward a healthier population. No significant differences were observed between the study groups in terms of baseline and foot characteristics. The most prevalent location of plantar foot ulcers was the metatarsal head (79.7 %), followed by the hallux (7.4 %), minor toes (6.8 %), midfoot (3.4 %), and rearfoot (2.7 %). No significant

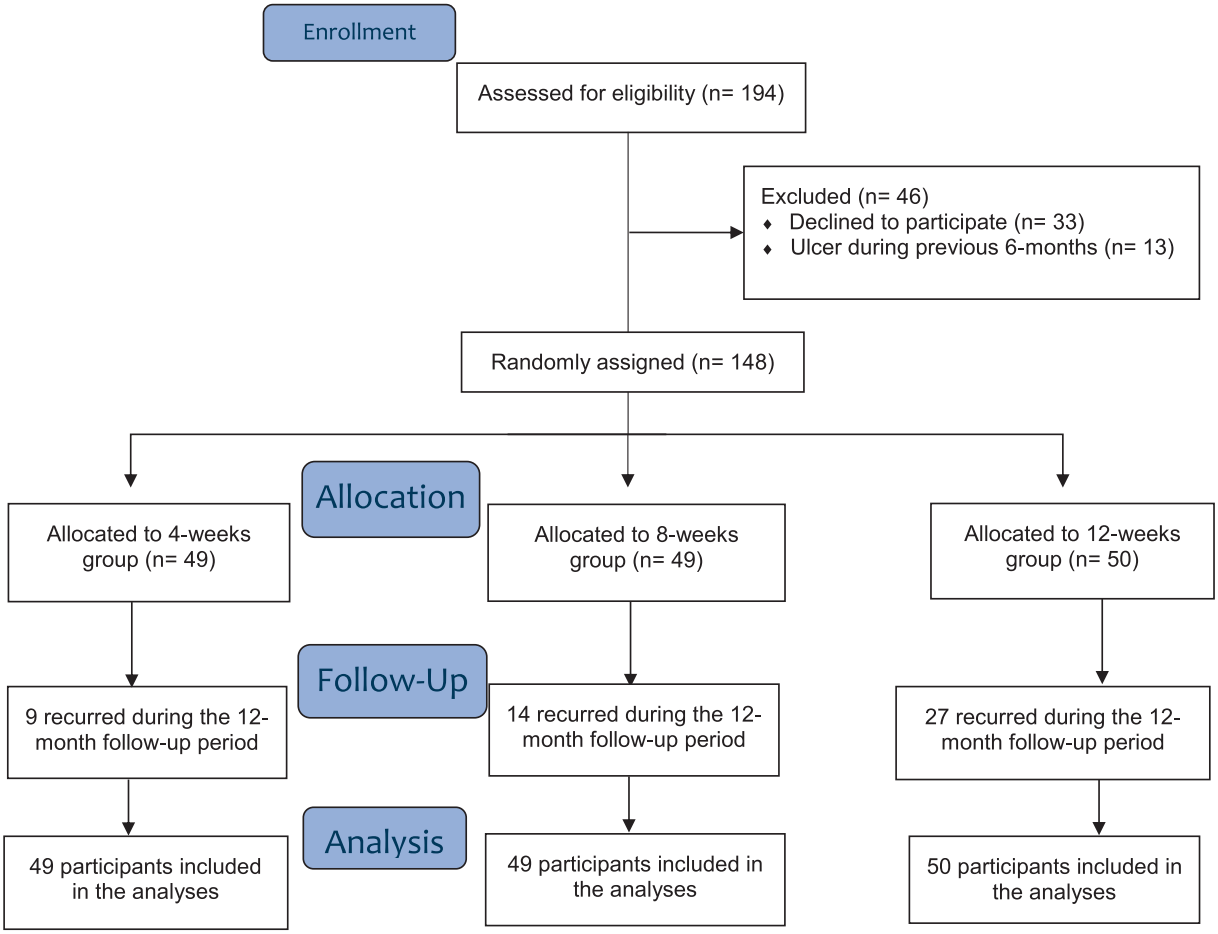

Fig. 1. Trial profile.

Table 1
Participants' baseline demographic characteristics and diabetes and foot complications.

	All participants (N = 148)	4-weeks Group (n = 49)	8-weeks Group (n = 49)	12-weeks Group (n = 50)	P-value [95 % CI]	Effect size
Baseline characteristics						
Male, n (%)	106 (71.6)	36 (73.5)	31 (63.3)	39 (78)	0.251	0.137
Female, n (%)	42 (28.4)	13 (26.5)	18 (36.7)	11 (22)		
Type 2 diabetes, n (%)	140 (94.6)	44 (89.8)	46 (93.9)	50 (100)	0.078	0.186
Type 1 diabetes, n (%)	8 (5.4)	5 (10.2)	3 (6.1)	–		
Retinopathy, n (%)	23 (15.5)	8 (16.3)	7 (14.3)	8 (16)	0.956	0.025
Renal disease, n (%)	21 (14.2)	6 (12.2)	7 (14.3)	8 (16)	0.866	0.044
Hypertension, n (%)	80 (50.4)	29 (59.2)	26 (53.1)	25 (50)	0.647	0.077
Hypercholesterolemia, n (%)	103 (69.6)	35 (71.4)	35 (71.4)	33 (66)	0.794	0.056
Cardiovascular disease, n (%)	24 (16.2)	8 (16.3)	7 (14.3)	9 (18)	0.882	0.041
Previous amputation, n (%)	76 (51.4)	24 (49)	25 (51)	27 (54)	0.881	0.041
Body mass index, mean ± SD	25.7 ± 3.7	25.2 ± 3.9	26.3 ± 3.5	25.8 ± 3.8	0.364	0.014
Mean age ± SD (years)	67.1 ± 11.6	64.7 ± 12.5	66.8 ± 13.1	69.9 ± 8.3	0.082	0.034
Glycated hemoglobin, mean ± SD	7.6 ± 1.1	7.6 ± 1.1	7.5 ± 1.2	7.6 ± 1.1	0.364	0.014
Diabetes mellitus (years), mean ± SD	12.7 ± 6.2	13.1 ± 6.9	12.3 ± 5.6	12.7 ± 6.1	0.814	0.003
Presence of dorsalis pedis pulse, n (%)	58 (39.2)	27 (55)	17 (34.7)	19 (38)	0.573	0.087
Presence of posterior tibial pulse, n (%)	45 (30.4)	37 (75.5)	16 (32.7)	33 (66)	0.540	0.091
Ankle-brachial pressure index, mean ± SD	1.2 ± 0.2	1.2 ± 0.4	1.1 ± 0.2	1.2 ± 0.2	0.658	0.006
Toe-brachial pressure index, mean ± SD	0.8 ± 0.2	0.9 ± 0.24	0.8 ± 0.2	0.8 ± 0.2	0.420	0.045
$TcpO_2$ (mmHg), mean ± SD	35.2 ± 6.6	33.9 ± 6.1	35 ± 6.6	36.7 ± 6.9	0.098	0.031
Foot characteristics						
History of >1 foot ulcer event, n (%)	137 (92.6)	44 (89.8)	46 (93.9)	47 (94)	0.664	0.074
Hallux abductus valgus, n (%)	28 (18.9)	8 (16.3)	10 (20.4)	10 (20)	0.851	0.047
Metatarsal bony prominence, n (%)	86 (58.1)	27 (55.1)	30 (61.2)	29 (58)	0.828	0.051
Hammer toe, n (%)	79 (53.4)	23 (46.9)	31 (63.3)	25 (50)	0.226	0.142
Tailor's bunion, n (%)	25 (16.9)	6 (12.2)	10 (20.4)	9 (18)	0.541	0.091
Charcot midfoot deformity, n (%)	5 (3.4)	2 (4.1)	2 (4.1)	1 (2)	0.831	0.050
Previous location of last foot ulcers						
Hallux, n (%)	11 (7.4)	2 (4.1)	5 (10.2)	4 (8)	0.504	0.096
Toes, n (%)	10 (6.8)	4 (8.2)	2 (4.1)	4 (8)	0.659	0.075
Metatarsal heads, n (%)	118 (79.7)	39 (79.6)	39 (79.6)	40 (80)	0.967	0.021
Midfoot, n (%)	5 (3.4)	2 (4.1)	2 (4.1)	1 (2)	0.803	0.054
Rearfoot, n (%)	4 (2.7)	2 (4.1)	1 (2)	1 (2)	0.767	0.060

SD, standard deviation; CI, confidence interval; IQR, interquartile range; $TcpO_2$, transcutaneous oxygen pressure [a] For categorical variables: Chi-square test, as the Phi coefficient, where an effect size of 0.01 represents a small effect; 0.30 a medium effect; and 0.50 a large effect. [b] For normally distributed variables: for independent samples, Student's *t*-test; effect size as Cohen's d: represents effect size values: >0.2 as small effect, >0.5 as moderate effect; and >0.8 as large effect; d is positive if the mean difference is in the predicted direction. *P < 0.05 indicates a significant association.

differences were observed between the study groups regarding the previous locations of foot ulcers in the participants. However, during the follow-up period only five participants showed low compliance with the planned visits: two in Group 1 (4 weeks), two in Group 2 (8 weeks), and one in Group 3 (12 weeks).

Table 2 reports primary and secondary outcome measures of the study groups. During the 12-month follow-up period, 50 participants (33.8 %) experienced a recurrence. We observed that participants in the 12-weeks group experience DFU recurrence significantly more frequently (n = 27, 46 %) than the 4-weeks (n = 18, 18.4 %) and 8-weeks (n = 14, 28.6 %) groups (P < 0.001, effect size 0.318). Additionally, 17 participants (11.5 %) had minor lesions, with more patients in the 8-weeks group (n = 10, 20.4 %), compared to the 4-weeks (n = 2, 4.1 %) and 12-weeks (n = 5, 10 %) groups (P = 0.037, effect size 0.211). Minor amputations were reported in nine participants (6.1 %) due to foot ulcers complicated by osteomyelitis: six patients in the 12-weeks group (12 %), and one and two patients in the 4-weeks (2 %) and 8-weeks (4.1 %) groups, respectively (P = 0.091, effect size 0.180). Death or need for major amputation did not occur in any of the groups during the 12-month follow-up period.

When evaluating the relationship between ulcer recurrence and the study groups (Table 3), we observed that most participants had ulcers located beneath the metatarsal head (n = 40, 27 %). Participants in the 12-weeks group experienced recurrence in the metatarsal head area of the forefoot more frequently (n = 24, 48 %) than the other groups (P = 0.013, effect size 0.418).

Table 2
Outcome measures of study groups.

	All participants (N = 148)	4-weeks Group (n = 49)	8-weeks Group (n = 49)	12-weeks Group (n = 50)	P-value [95 % CI]	Effect size
Outcome measures						
Recurrence, n (%)	50 (33.8)	9 (18.4)	14 (28.6)	27 (46)	**0<.001***	0.318
Minor lesion, n (%)	17 (11.5)	2 (4.1)	10 (20.4)	5 (10)	**0.037***	0.211
Minor amputation, n (%)	9 (6.1)	1 (2)	2 (4.1)	6 (12)	0.90	0.180
Major amputation, n (%)	0	0	0	0	–	–
Death, n (%)	0	0	0	0	–	–

CI, confidence interval; IQR, interquartile range. [a] For categorical variables: Chi-square test, as the Phi coefficient, where an effect size of 0.01 represents a small effect, 0.30 a medium effect, and 0.50 a large effect. [b] For normally distributed variables: for independent samples, Student's *t*-test; effect size as Cohen's d: represents effect size values: >0.2 as small effect, >0.5 as moderate effect; and >0.8, large effect; d is positive if the mean difference is in the predicted direction. *P < 0.05, significant association.

Table 3
Relationship between ulcer occurrence and location by study groups.

	Recurrent participants (N = 50)	4-weeks Group (n = 9)	8-weeks Group (n = 14)	12-weeks Group (n = 27)	P-value [95 % CI]	Effect size
Outcome measures						
Hallux, n (%)	6 (4.1)	2 (4.1)	2 (4.1)	2 (4)	0.473	0.173
Toes, n (%)	1 (0.7)	1 (2)	0	0	0.098	0.305
Metatarsal heads, n (%)	40 (27)	4 (8.2)	12 (24.5)	24 (48)	**0.013***	**0.418**
Midfoot, n (%)	3 (2)	2 (4.1)	0	1 (2)	0.069	0.327
Rearfoot, n (%)	0	0	0	0	–	–

CI, confidence interval; IQR, interquartile range. [a] For categorical variables: Chi-square test, as the Phi coefficient, where an effect size of 0.01 represents a small effect, 0.30 a medium effect, and 0.50 a large effect. [b] For normally distributed variables: for independent samples, Student's *t*-test; effect size as Cohen's d: represents effect size values: >0.2 as small effect, >0.5 as moderate effect; and >0.8, large effect; d is positive if the mean difference is in the predicted direction. *P < 0.05, significant association.

The Kaplan-Meier survivorship analysis for the time to recurrent events is presented in Fig. 2. The 4-, 8-, and 12-weeks-based groups showed mean ± SD recurrence-free survival times of 308.9 ± 128.5 days, 278.7 ± 145 days, and 189.4 ± 163.9 days, respectively. Ulcer survival curves also significantly differed between the study groups (log-rank test, P < 0.001).

The Kaplan-Meier survivorship analysis for the time to minor lesion events is presented in Fig. 3. The 4-, 8-, and 12-weeks-based groups showed mean ± SD minor lesions-free survival times of 351 ± 67 days, 301.7 ± 127 days, and 335 ± 90 days, respectively. Ulcer survival curves also significantly differed between the study groups (log-rank test, P = 0.037).

The relative risk (RR) for the 4-weeks group compared to the 8 and 12 weeks was 0.2. The RRR for the 4-weeks group was 81 %, while the NNT was 6.62.

Variables with P < 0.1 in the univariate analysis (age, transcutaneous oxygen pressure, diabetes type, and group allocation) were included in the Cox multivariate model. We found that allocation was the only variable associated with ulcer recurrence during the 1-year follow-up period (P < 0.001, 95 % confidence interval:1.325–2.859), Hazzard ratio = 1.95.

After multiple imputation, the treatment effect remained statistically significant and of similar magnitude (recurrence; adjusted difference = −0.20 %; 95 % CI: −0.66 to − 0.15; p = 0.002 and minor lesions; adjusted difference = −0.30 %; 95 % CI: −0.45 to − 0.12; p = 0.003), confirming that the main study conclusions were robust to missing data.

4. Discussion

When considering the clinical outcomes in patients at risk of foot ulceration, it is important to properly prescribe a specific screening appointment. The results of the current trial demonstrated that 4-weeks screening appointments resulted in fewer foot ulcer recurrences than 8 and 12- weeks screening periods. Additionally, we observed that a shorter revision period in at-risk feet resulted in a longer ulcer-free period and reduced the number of minor lesions. The accumulative pressure in the plantar area of the foot might explain this, as previous studies have demonstrated a significant reduction in plantar pressure following callus removal (in-shoe pressures in three groups respectively improved from 375/352/241 kPa [before] to 251/241/176 kPa [after removal] [21]; barefoot pressures reduced from 14.2 to 10.3 kg/cm) [22]. Thus, reducing the revision period prevents cumulative callus beneath bony prominences and could reduce peak pressures and further ulcer occurrences and minor lesions. A revision period of 4 weeks seems to be a reasonable timeframe for preventing foot ulcers in the plantar area of the foot; our findings revealed that minor lesions start to appear from 4 to 8 weeks, and at 12 weeks, minor lesions become foot ulcers due to excessive plantar pressure secondary to callus formation.

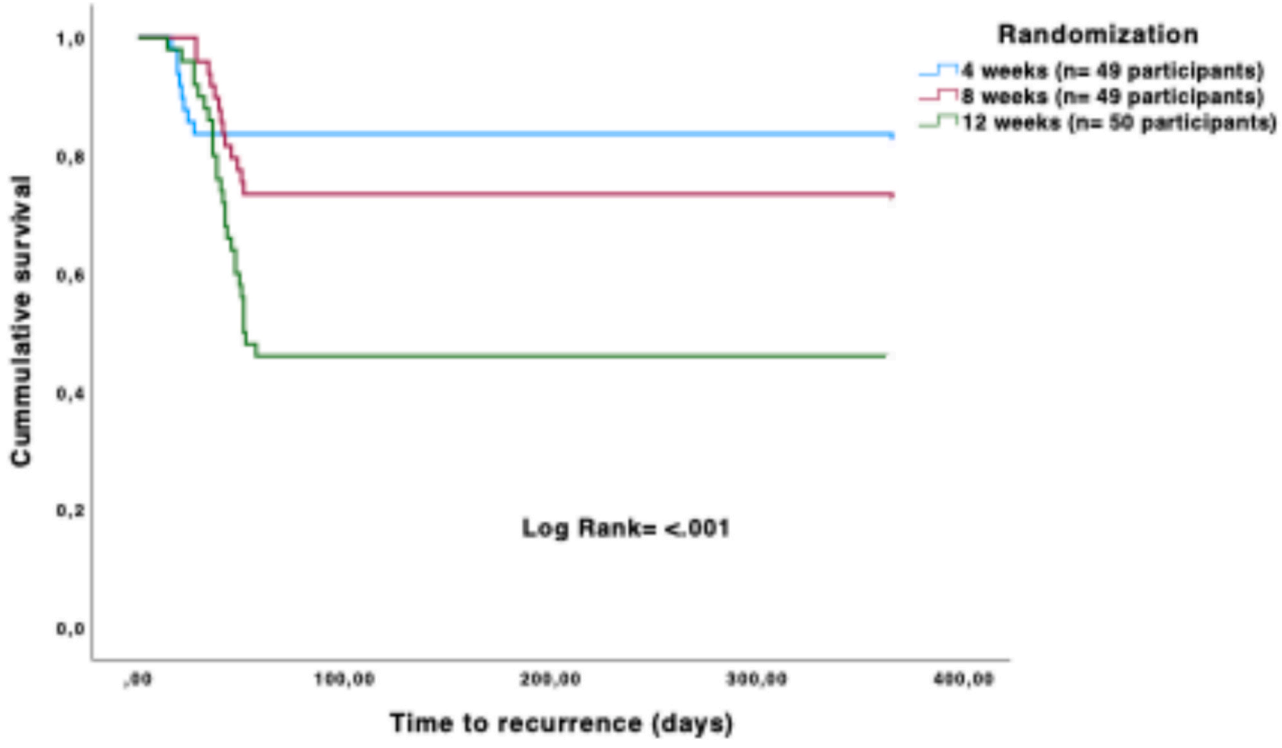

Fig. 2. Kaplan-Meier plots for different revision times on cumulative survival of foot ulcer recurrence over 12 months of follow-up (N = 148).

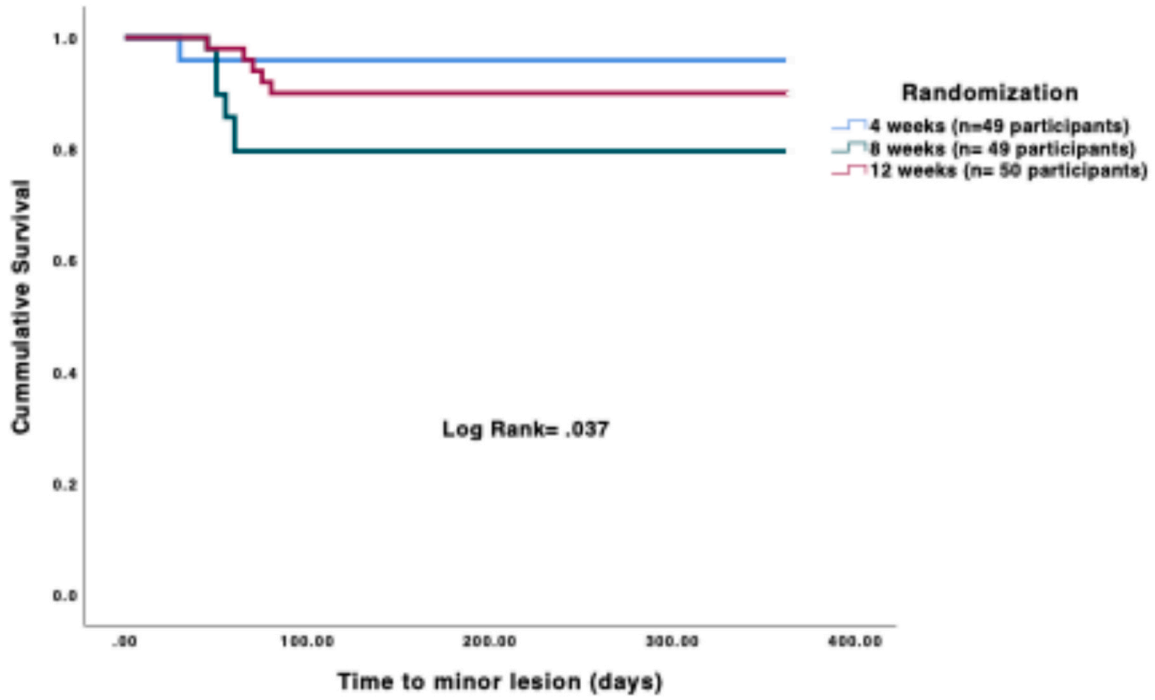

Fig. 3. Kaplan-Meier plots for different revision times on cumulative survival of minor lesions over 12 months of follow-up (N = 148).

In this trial, almost 80 % of participants had a previous foot ulcer beneath the metatarsal head, which can be explained by worldwide trends; previous research has demonstrated that more than 50 % of DFUs appear in the plantar area of the forefoot, particularly beneath the metatarsal heads [23]. Thus, the results of this trial can be generalized to most of the population, as most ulcers appear in the plantar area of the foot; however, we recruited few participants with toe, midfoot, and rearfoot ulcers compared to those with metatarsal head ulcers. Further research should confirm whether reducing the screening period in participants with non-plantar DFUs can help reduce the rate of ulcer recurrence.

Additionally, and from a health economic point of view, this needs to be studied using a cost-economic analysis to evaluate whether reducing screening periods in this population (non-plantar DFUs) is cost-effective in reducing foot complications. The fact that reducing the frequency of follow-up visits increases direct costs can be an important factor to consider, as it may contribute to healthcare system overload. For this reason, new monitoring strategies and technological approaches should be implemented in daily clinical practice [24]. Furthermore, a deeper analysis of our results showed that Kaplan–Meier analyses indicated no recurrences after 90 days, regardless of allocation. This finding has important implications, suggesting that patients should be closely monitored at one-month intervals during the first 90 days to prevent foot complications. It also highlights for clinicians that efficient resource utilization is crucial, as participants who do not experience recurrence within the first 90 days are unlikely to develop reulceration for at least one year.

Notably, the entire population was homogeneous in terms of baseline characteristics and diabetes and foot complications. It has been suggested that participants with previous minor amputations are more likely to develop ulcer recurrences [25–29]. In this study, the rate of minor amputations was very high (≈50 %), and the rates between study groups were similar without any statistical significance. This can refute the hypothesis that even with a high-risk group of participants, reducing the revision periods can reduce recurrences and minor amputations. To reduce bias, all participants in the trial must be free of ulcers for at least 6 months to ensure the proper fitting of therapeutic footwear and custom-made insoles. This empowers the research results to reduce confounding factors of recurrence, such as ill-fitting footwear [30].

This study had some limitations: First, participants were not blinded due to the nature of the time frame in the revision periods. Second, adherence to therapeutic footwear and daily life activities was not measured in this research, and further trials should focus on the relationship between different revision times and adherence or activity. The representativeness and generalizability of the trial are limited, as it was conducted at a single center, further trials should focus on evaluating these methods in other settings. Foot pressures were not evaluated, as it has been previously described that peak pressure increases in the plantar area when a thick callus appears. Participants included in the trial were unable to use custom-made footwear due to the constraints of the healthcare regulatory system. All patients wore prefabricated therapeutic footwear, which has demonstrated plantar pressure relief. Finally, participants who did not attend the planned visits were excluded from the analyses. This can be considered a limitation, as the RCT was conducted only as a per-protocol analysis and no intention-to-treat analysis was performed. Blinding of clinicians in behavioral trials is challenging due to the time frame of the planned visits, and this may introduce bias in the interpretation of outcome measures. This research adds some new insights, such as the relationship between time and callus formation. The main strength of our study is that it is the first randomized clinical trial to clinically examine the ulcer recurrence rate depending on different screening times, where podiatric care is the key to the prevention of recurrence. We observed no deaths or major amputations during the follow-up, suggesting the importance of regular monitoring and foot care frequency in patients in remission.

In conclusion, this trial found superior clinical efficacy in preventing plantar recurrence rates with the 4-weeks screening period compared to 8 and 12 weeks. Clinicians should consider including a 4-weeks screening timeframe in structured plans for ulcer prevention in high-risk participants with diabetes.

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CRediT authorship contribution statement

Mateo López-Moral: Writing – review & editing, Writing – original draft, Validation, Supervision, Software, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Marta García-Madrid:** Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Data curation, Conceptualization. **Esther García-Morales:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis. **Yolanda García-Álvarez:** Writing – review & editing, Writing – original draft, Methodology. **Francisco J. Álvaro-Afonso:** Writing – review & editing, Software, Investigation. **José Luis Lázaro-Martínez:** Writing – review & editing, Writing – original draft, Validation, Resources, Project administration, Methodology, Investigation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Dr. Mateo López Moral is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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