

# Foot ulcer risk screening in prevention campaign participants and detection of *diabetes mellitus*

Rastreamento de risco de ulceração nos pés em participantes de campanhas de prevenção e detecção do diabetes *mellitus*  
 Rastreo de riesgo de ulceración en los pies de participantes de campañas de prevención y de detección de diabetes *mellitus*

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## Abstract

**Objective:** To analyze the clinical and sociodemographic characteristics related to foot ulcer risk screening in participants of diabetes mellitus detection campaigns.

**Methods:** This is a cross-sectional study conducted during diabetes mellitus detection campaigns carried out by the Brazilian National Association for Diabetic Care (ANAD - *Associação Nacional de Atenção ao Diabetes*), between 2013 and 2017, in the city of São Paulo, to detect foot ulceration risk according to demographic and clinical variables. The study population consisted of people with or without a previous diagnosis of diabetes. The collection instruments used were the interview and the specific physical examination of participants' feet. Measurements relating to qualitative variables and chi-square and Fisher's exact tests were applied.

**Results:** We assessed 2,110 people, most of them female, mean age of 64 years, complete elementary school, predominance of type 2 diabetes mellitus. An association was identified between the degrees of foot ulcer risk and disease duration ( $p=0.021$ ), lack of foot hygiene ( $p=0.029$ ), dry skin, change in plantar protective sensation, absent peripheral pulses, presence of onychomycosis, deformities, ulcer and amputation ( $p<0.001$ ), and 65.5% of participants reported not having received previous guidance for foot care.

**Conclusion:** The signs of foot ulceration risk during diabetes detection campaigns were identified and contributed to screening complications, being strategies for prevention actions carried out by academic extension students.

## Resumo

**Objetivo:** Analisar as características clínicas e sociodemográficas relacionadas ao rastreamento de risco de ulcerações nos pés em participantes de campanhas de detecção do diabetes *mellitus*.

**Métodos:** Estudo seccional conduzido durante campanhas de detecção do diabetes *mellitus* realizadas pela Associação Nacional de Assistência ao Diabético ANAD, entre 2013 e 2017, na cidade de São Paulo para a detecção do risco de ulceração nos pés segundo variáveis demográficas e clínicas. A população do estudo foi composta por pessoas com ou sem diagnóstico prévio de diabetes. Os instrumentos de coleta utilizados foram a entrevista e o exame físico específico dos pés dos participantes. Aplicaram-se cálculos das medidas referentes às variáveis qualitativas e testes do qui quadrado e Exato de Fisher.

**Resultados:** Um total de 2.110 pessoas foram analisadas, a maioria do sexo feminino, média de idade de 64 anos, ensino fundamental, predominância de diabetes mellitus tipo 2. Identificou-se associação entre os graus de risco de ulcerações nos pés e duração da doença ( $p=0,021$ ), ausência de higiene nos pés ( $p=0,029$ ), pele ressecada, alteração da sensação protetora plantar, pulsos periféricos ausentes, presença de onicomicose, deformidades, úlcera e amputação ( $p<0,001$ ) e 65,5% dos participantes referiram não ter recebido orientações prévias para os cuidados com os pés.

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**Conflict of interest:** nothing to declare.

**Conclusão:** Os sinais de risco para ulcerações nos pés durante as campanhas de detecção do diabetes foram identificados e contribuem para o rastreamento das complicações e se constituem em estratégias para as ações de prevenção realizadas por estudantes de extensão acadêmica.

## Resumen

**Objetivo:** Analizar las características clínicas y sociodemográficas relacionadas al rastreo de riesgo de ulceraciones en los pies de participantes de campañas de detección de diabetes *mellitus*.

**Métodos:** Estudio seccional conducido durante campañas de detección de diabetes *mellitus* realizadas por la Asociación Nacional de Atención al Diabético ANAD, entre 2013 y 2017, en la ciudad de São Paulo, para la detección del riesgo de ulceración en los pies de acuerdo con variables demográficas y clínicas. La población del estudio estuvo compuesta por personas con o sin diagnóstico previo de diabetes. Los instrumentos utilizados para la recopilación fueron la entrevista y el examen físico específico de los pies de los participantes. Se aplicaron cálculos de las medidas referentes a las variables cualitativas y pruebas de Ji cuadrado y Exacta de Fisher.

**Resultados:** Se analizaron un total de 2.110 personas, en su mayoría del sexo femenino, promedio de edad de 64 años, educación primaria, predominio de diabetes mellitus tipo 2. Se identificó una asociación entre los grados de riesgo de ulceraciones en los pies y la duración de la enfermedad ( $p=0,021$ ), la ausencia de higiene en los pies ( $p=0,029$ ), piel seca, alteración de la sensación protectora plantar, pulsos periféricos ausentes, presencia de onicomicosis, deformidades, úlcera y amputación ( $p<0,001$ ). El 65,5 % de los participantes mencionó no haber recibido orientaciones previas sobre los cuidados de los pies.

**Conclusión:** Se identificaron las señales de riesgo de ulceraciones en los pies durante las campañas de detección de diabetes. Esto contribuye al rastreo de complicaciones y se refleja en estrategias para las acciones de prevención realizadas por estudiantes de extensión académica.

## Introduction

Campaigns to detect chronic conditions and their complications have been adopted by several countries and are a recommendation of the International Diabetes Federation. The participation of academics in these campaigns has enabled experiences, multi-professional interactions and work with the community in screening and identifying complications resulting from diabetes mellitus (DM).<sup>(1)</sup>

The participation of nursing undergraduate students enrolled in the Extension Project “*Cuidar-te*” of the *Escola Paulista de Enfermagem* (EPE) at the *Universidade Federal de São Paulo* (UNIFESP) in National Diabetes Detection and Education Campaigns with a focus on preventing complications, carried out by the Brazilian National Association for Diabetes Care (ANAD), has been taking place for over 20 years.<sup>(2)</sup>

The ANAD is a philanthropic institution that was founded in August 1979 and headquartered in the city of São Paulo, focused on multidisciplinary care for people with diabetes, and aims to guide, treat, educate and monitor patients and their families. Therefore, it is accredited by the International Diabetes Federation (IDF) as International Diabetes Federation, Centre of Excellence in Diabetes and International Diabetes Federation Centre of Education.<sup>(3)</sup>

Diabetes Mellitus is a metabolic disorder of multiple etiology, characterized by chronic hyper-

glycemia resulting from impaired insulin production and/or use.<sup>(4)</sup> The disease is classified into subgroups: Type 1 DM, of autoimmune or idiopathic nature, type 2 DM, which is characterized by a defect in insulin secretion and action, gestational and associated with other pancreatopathies.<sup>(5)</sup>

It is estimated that about 460 million people worldwide currently in the age group between 20 and 79 years have diabetes, and of these, 32 million are in South America and 16 million in Brazil, and the forecast for 2045 reaches 693 million, where more than a third of diabetes cases will be due to population growth and aging, 28% to increasing age prevalence and 32% to the interaction of these two factors.<sup>(1,4)</sup>

However, lack of knowledge about the disease, late diagnosis, inappropriate clinical management that are potential factors for developing complications from the disease, such as retinopathy, renal failure, coronary artery disease, stroke, polyneuropathy and peripheral vasculopathy, causing changes in the lower limbs.<sup>(4)</sup> During the campaigns, different clinical screening is performed for detecting such complications. In particular, in this research, the scope is to identify foot ulcer risk, which when associated with advanced age, habits such as smoking, physical inactivity, long disease duration, persistent glycemic variability, obesity, dyslipidemia, decreased visual acuity, among other environmental factors, increase the chance of ulcerations and amputations in the lower extremity<sup>(6-10)</sup>

Worldwide, it is estimated that every 20 seconds an individual undergoes partial or total lower limb amputation due to ineffective diabetes management. The annual incidence of diabetic foot ulcers (DFU) is 2 to 4%, while the prevalence is between 4 to 10%, both higher in countries with greater vulnerability and socioeconomic inequality.<sup>(11)</sup>

Early identification of foot complication risk, through screening programs and efficient health actions, can substantially reduce direct and indirect costs to the health system,<sup>(12)</sup> and one of the ways used to detect complications in people without or with a previous diagnosis of DM occurs through population-based screening campaigns.<sup>(13)</sup>

As mentioned, in Brazil, one of the campaigns with great scope is the Brazilian National Campaign for Diabetes Mellitus Detection, conceived by ANAD and carried out since 2001. This action was part of the plan for restructuring hypertension and DM care in Brazil, with a view to supporting earlier diagnosis and detection of new cases, and this type of action helped to detect 346,000 new cases of DM.<sup>(4)</sup>

Students from the EPE at UNIFESP, through “*Cuidar-te* University Extension Program”, have participated since the beginning of these campaigns, working to integrate screening and education actions in diabetes.

This article aims to analyze the clinical and sociodemographic characteristics related to foot ulcer risk screening in participants of DM detection campaigns.

## Methods

This is a cross-sectional study conducted during DM detection campaigns carried out by ANAD, between 2013 and 2017, in the city of São Paulo, to detect foot ulceration risk according to demographic and clinical variables.

The data source was obtained according to information from people with or without a previous diagnosis of DM who participated in these campaigns. Nursing students, previously trained through technical training for a period of eight hours

and/or participation in internships in the Academic League of Diabetes/Wounds and Extension Project “*Cuidar-te*”, EPE-UNIFESP, collected the information. They assessed a total of 2,110 people.

For participant characterization, we used the variables as follows: demographic variables, such as sex, age, education, work activities; clinical variables, such as habits, diagnosis and type of diabetes, disease duration, comorbidities, drug treatments compliance with clinical treatment, and previous guidance on DM diagnosis; disease and foot care, such as hygiene habits, dermatological changes, symptoms of neuropathy, plantar protective sensitivity test, presence of bone deformities, foot shape, presence of dorsalis pedis and posterior tibial pulses, and type of footwear, prioritized by diabetic foot international guidelines.<sup>(8)</sup>

We included individuals who participated in the campaigns between 2013 and 2017, with age groups over 18 years, with or without a previous diagnosis of diabetes, of both sexes and with cognitive conditions (alert individuals, with mental capacity to voluntarily fulfill the requirements for participating in the campaign).

Blood sugar testing was performed prior to referral for foot risk screening, thus detecting those not previously diagnosed with the disease. Both the interview and the specific foot physical examination were performed by undergraduate students, professors and nurses specializing in the field. Foot protective sensitivity was assessed following the criteria recommended by the International Working Group on the Diabetic Foot,<sup>(8)</sup> using the Semmes-Weinstein 10 g monofilament. The points chosen for applying the monofilament corresponded to the heads of first, third, fifth metatarsal and posterior distal phalanx of the hallux, being applied twice in the same place alternating with a randomized simulated application, totaling three questions per application site. Protective sensation was considered present when a person correctly answered two of the three applications. Sensation was considered absent when there were two of the three incorrect responses.<sup>(14)</sup> Palpation of peripheral pulses follows propaedeutic orientation based on guidelines for the presence of dorsalis pedis and posterior tibial

pulses. Inspection made it possible to identify hygiene, presence of nail changes, deformities, ulcerations and type of footwear.

Individuals whose actions were correct and established by guidelines related to metabolic control, adequate hygiene, intact skin and nails, absence of deformities, ulcers and adequate shoes were considered compliant with the foot care program.

The data was collected into a specific study form and into an Excel spreadsheet database. The analysis was supported by R version 4.0.4 for the calculation of measures referring to the study of qualitative variables and frequency distribution, expressed as mean and standard deviation ( $X \pm SD$ ). Analysis of variance was used for group comparison and for associations of neuropathy risk ratings by the chi-square test or Fisher's exact test, with a significance value equal to or less than 0.05 being accepted.

The research was submitted for analysis by the Research Ethics Committee of UNIFESP, indexed to Brazil Platform (*Plataforma Brasil*), according to the norms of Resolution 466/2012 of the Brazilian National Health Council and CAAE (*Certificado de Apresentação para Apreciação Ética - Certificate of Presentation for Ethical Consideration*) 1.855.875.

## Results

This study assessed 2.110 individuals who participated in the campaigns carried out by ANAD in the city of São Paulo, SP, and who had previously or not been diagnosed with DM. Most were female (52.7%), with a mean age of  $64.05 \pm 17.5$  years, mean time of diagnosis of  $19.66 \pm 10.78$  years and had type 2 DM (80%). About 39.1% of participants completed elementary school, were retired (33.6%), did not report being smokers (91.9%) and alcoholics (86.7%). As for comorbidities, the most frequent were hypertension (31.3%) and dyslipidemia (10.9%). For diabetes management and treatment, study participants reported following a diet (43.2%) and doing physical activity (41.3%), taking oral antidiabetics (64.8%) such as metformin and sulfonylureas, and taking insulin (17.3%). Unfortunately, 87.5% of individuals did

not comply with any type of treatment. Regarding feet assessment among participants, an alarming fact indicates that 382 people (65.5%) reported that they had never been instructed on foot care, and 2,086 (98.9%) did not perform any specific care. The practice of foot self-examination was reported by 1,218 (57.7%). Incorrect nail cutting, with curvature, was observed in 41.5%, and the use of inappropriate footwear, in 97.6% of those examined (Table 1).

**Table 1.** Frequency and percentage in relation to foot care of people who have participated in diabetes mellitus detection campaigns

Type of self-care	Presence	n(%)
Have you ever received foot care orientation?	Yes	728(34.5)
	No	1382(65.5)
Do you perform self-care on your feet?	Yes	24(1.1)
	No	2086(98.9)
Do you examine your feet daily?	Yes	1218(57.7)
	No	892(42.3)
Do you dry between your fingers after bathing?	Yes	1794(85.0)
	No	316(15.0)
Do you use creams to moisturize your feet daily?	Yes	981(46.5)
	No	1129(53.5)
Do you moisturize between your fingers?	Yes	350(16.6)
	No	1760(83.4)
How do you cut your toenails?	Straight	877(41.5)
	Curve	952(45.1)
	Others	281(13.3)
Do you check your shoes before wearing them for elements that could injure you?	Yes	1226(58.1)
	No	884(41.9)
Do you usually ventilate or clean your shoes after wearing them?	Yes	1457(69.0)
	No	653(31)
Appropriate footwear	Yes	50(2.4)
	No	2060(97.6)

The results demonstrate physical examinations of dermatological inspections, deformities and protective sensation and presence of peripheral pulses. The complaint of feet tingling was the most reported symptom (35.5%); the plantar protective sensitivity identified by the monofilament test was absent in 20% of individuals examined; the other risk signs were also identified in part of the people examined, such as onychomycosis, deformities, presence of ulcers and amputations.

Most participants showed no signs of peripheral neuropathy due to DM (72.7%) and among those who already had type 2 DM (present neuropathy, deformity and/or peripheral vascular disease),



**Table 2.** Arrangement of sensory, dermatological, motor and vascular assessment of participants' feet in diabetes mellitus detection campaigns

Variables	n=2,110 n(%)
Sensory changes	
Protective plantar tenderness	1688(80.0)
Present	422(20.0)
Absent	
Neuropathy symptoms	
Tingling	
Present	1360(35.5)
Absent	749(64.5)
Burning	
Present	497(23.6)
Absent	1612(76.4)
Tugging/pricking	
Present	446(21.1)
Absent	1663(78.8)
Pain	
Present	143(6.8)
Absent	1966(93.2)
Cramp	
Present	125(4.1)
Absent	1985(95.9)
Dermatological changes	
Foot hygiene	
Present	1801(85.4)
Absent	309(14.6)
Dry skin	
Present	787(37.3)
Absent	1323(62.7)
Onychomycosis	
Present	199(9.4)
Absent	1911(90.6)
Ulcers	
Present	21(1.0)
Absent	2089(99.0)
Motor changes	
Change in foot morphology/deformity	482(22.8)
Present	1680(77.2)
Absent	
Amputation	
Present	13(0.6)
Absent	2097(99.4)
Vascular changes	
Increase in skin temperature	
Present	1688(20.0)
Absent	422(80.0)
Posterior tibial pulse	
Present	1827(83.7)
Absent	68(3.2)
Pedal pulse	
Present	1638(77.7)
Absent	472(6.5)

there was a prevalence of 273 (12.9%) individuals; this data is alarming, as in the short term, disabling complications such as ulcerations and amputations can occur. A statistically significant association was identified between degrees of risk and type 2 DM ( $p=0.015$ ), having more than 15 years of diagnosis or duration of diabetes ( $p=0.021$ ), symptoms of neuropathy, having plantar protective sensitivity and decreased or absent peripheral pulses, main-

taining foot hygiene ( $p=0.029$ ), having dry skin, presence of onychomycosis and the deformities, foot ulcers and amputation ( $p<0.001$ ) (Table 3).

## Discussion

The social and epidemiological relevance of health education campaigns and the disabilities generated by foot complications related to diabetes, it is imperative to investigate strategies to face the problem and detect potential risks early.<sup>(14)</sup> In fact, diabetes detection campaigns contribute to this purpose, as they make it possible, through clinical screening, in this case, carried out by students and faculty, to identify signs of gradation of foot ulcer risk.<sup>(15-17)</sup>

Health detection and education campaigns play an important role in society, as they disseminate a global problem to the community through the media, newspapers, print and television, together with training organizations. One of the most widely disseminated campaigns is the World Diabetes Day, in which health education actions, blood glucose testing and assessment of acute and chronic complications of the disease are carried out, pointing out the need to implement public policies in the area, motto of such actions.<sup>(3)</sup>

The literature points out that about 50% of foot injuries in people with DM could be prevented with preventive actions and the provision of simple care provided by guidance regarding the disease, blood glucose and blood pressure monitoring, regular foot inspection, in addition to examination for risk classification for ulcerations, early diagnosis and treatments.<sup>(9)</sup> Collective actions, with population engagement, are determinant for improving health literacy, as they point out criteria for changes in modifiable lifestyle habits and for the adoption of self-care practices.<sup>(18)</sup>

The results of this study showed a significant association between the degrees of risk for the development of DFU and: diabetes classification (type 2), having more than 15 years of diagnosis or disease duration, symptoms of tingling, plantar protective sensitivity and altered or absent peripheral pulses, dry skin, presence of onychomycosis, deformity,

**Table 3.** Correlation between the degrees of risk for the development of diabetic foot ulcers and the clinical characteristics of participants in DM detection campaigns

Variables	Degree 0 n(%)	Degree 1 n(%)	Degree 2 n(%)	Degree 3 n(%)	Total	p-value
Type of diabetes						
Type 1 DM	114(5.40)	17(0.80)	24(1.13)	0	155	0.015 <sup>~</sup>
Type 2 DM	1216(57.63)	229(10.85)	214(10.14)	28(1.32)	1687	
Time since diagnosis (years)						
0 to 15	143	16	17	0	176	0.021 <sup>**</sup>
Over 15	1192	232	221	29	1674	
Comorbidities						
Hypertension	479	68	96	17	660	0.081 <sup>**</sup>
Hypertension and dyslipidemia	265	63	49	4	381	
Dyslipidemia	178	26	21	4	229	
Smoking						
No	1360	243	237	29	1869	0.787 <sup>**</sup>
Yes	123	20	26	2	171	
Alcohol consumption						
No	1246	223	224	26	1719	0.736 <sup>**</sup>
Yes	213	31	34	3	281	
Treatment compliance						
Yes	36	4	11	2	53	0.098 <sup>**</sup>
No	1499	266	262	30	2057	
Neuropathy symptoms						
No	1471	241	246	25	1983	<0.001 <sup>**</sup>
Yes	64	29	27	7	127	
Foot self-care						
No	1477	264	260	32	2033	0.362 <sup>**</sup>
Yes	58	6	13	0	77	
Foot shape						
With change	303	58	115	6	482	<0.001 <sup>*</sup>
No change	1232	212	158	26	1628	
Foot hygiene						
Yes	1331	221	224	25	1801	0.029 <sup>**</sup>
No	204	49	49	7	309	
Adherent skin						
No	918	174	205	26	1323	<0.001 <sup>*</sup>
Yes	617	96	68	6	787	
Onychomycosis						
Yes	163	29	5	2	199	<0.001 <sup>**</sup>
No	1372	241	268	30	1911	
Ulcer						
No	1535	270	273	11	2089	<0.001 <sup>**</sup>
Yes	0	0	0	21	21	
Amputation						
No	1535	270	273	19	2097	<0.001 <sup>**</sup>
Yes	0	0	0	13	13	
Appropriate footwear						
No	1503	262	265	30	2060	0.223 <sup>**</sup>
Yes	32	8	8	2	50	
Peripheral pulses						
Absent	127	0	139	17	283	<0.001 <sup>**</sup>
Present	1408	270	134	15	1827	
Plantar protective sensitivity						
Absent	4	182	218	18	422	<0.001 <sup>**</sup>
Present	1531	88	55	14	1688	

<sup>\*</sup>Chi-square test (p<0.001); <sup>\*\*</sup>Fisher's exact test (p=0.05)

ulcer and/or amputation. These findings denote the absence of screening and prevention of risks of complications of the disease, recommended in the

care protocol with comprehensive and longitudinal attention among those affected. It is necessary to recognize early signs reported by participants, such

as tingling, burning, change in skin temperature and foot stinging/prickling, characteristic signs and symptoms of peripheral diabetic neuropathy and DFU determinants.<sup>(19,20)</sup>

The risk classification for DFU is recommended by the International Consensus on the Diabetic Foot<sup>9</sup>, and fortunately points to degree zero as the most frequent (72.74%). The Brazilian literature presents Brazilian studies, one carried out in Foz do Iguaçu (PR) and another in São Paulo (SP), where 47.9% and 66.0% of people assessed, respectively, were classified as zero risk.<sup>(21,22)</sup>

Silva et al (2020) identified that people with degrees 1, 2 and 3, i.e., decreased or absent plantar protective sensitivity, presence of bone deformities in the foot, peripheral arterial disease, ulcerations and amputations, did not receive any previous guidance on foot care, pointing to the absence of prevention actions in the field.<sup>(23)</sup>

Change in plantar sensitivity is a predictive factor for the formation of DFU. The results of this screening corroborate the study by Brinati et al. (2017),<sup>(24)</sup> pointing out the absence of plantar protective sensation (22.3%), presence of deformities (22.8%), emphasizing the importance of early detection of DM as well as its complications.

Palpation of peripheral, dorsalis pedis and posterior tibial pulses is mandatory in feet examination in people with DM and a crucial assessment for detecting peripheral vascular disease (PAD). Among those assessed, 10% showed signs of peripheral vasculopathy due to the absence of pulse perception. Moreover, 1% already had an ulceration and 0.63% had an amputation in any part of the lower limb. Soares et al (2017) detected even higher frequencies, with about 33% of peripheral vasculopathy and 19% with the need for limb amputation, pointing out the severity of the damage.<sup>(25,26)</sup>

To adopt self-care and complication prevention practices, knowledge in the field is essential and is part of treatment. Unfortunately, most of those assessed (98.9%) reported not having or adopting specific foot care practices; this data is relevant because it has greater risk, due to the non-identification of precursor signs and the adoption of specific protection for DFU prevention.<sup>(27)</sup>

The Ministry of Health of Brazil<sup>(15)</sup> recommends changes in life habits, regular practice of physical exercises, healthy eating, moderation of alcohol consumption, smoking cessation, blood glucose monitoring, drug treatment, with the main objective of managing the disease, decreasing blood glucose levels and preventing risks and complications.<sup>(28,29)</sup> In general, programs must act on these assumptions, and education campaigns can collaborate for early detection and screening of DM and enable the prevention of acute and chronic complications resulting from the disease.

In view of this action, nurses, staff and students carry out skills in the health education field and collaborate by empowering subjects and communities through integrated interdisciplinary work, encouraging compliance with clinical and therapeutic treatment.

It is important to point out that the campaigns have limits, such as difficulties in following out a careful diagnostic assessment; therefore, they can at most be supportive in the DM protocol and do not permanently fill the gaps in the health system in guaranteeing comprehensive and longitudinal care, which must be adopted in the long term.<sup>(30)</sup>

## Conclusion

This study pointed address the main aspects assessed in an education and detection campaign for DM related to foot complications in people with diabetes, conducted with the participation of undergraduate nursing students during university extension activities, together with the activities of *ANAD*. Data analysis made it possible to profile campaign participants as follows: older adults, mostly female, low education, with type 2 DM for more than fifteen years and who reported not having received guidance or adopting foot care, which denotes a risk for complications. The study points to a high rate of people with signs of diabetic neuropathy, which is a warning sign for intensifying screening actions, especially in primary care, responsible for ordering and coordinating care for the population attached to the territories. Signs for foot ulcer risk were iden-

tified during diabetes detection campaigns, which contribute to tracking complications, constituting strategies for prevention actions carried out by academic extension students. Such activities contributed to preventing and managing DM and foot complications and training future health professionals.

## Collaborations

Arrigotti T, Silva Júnior JA, FraigeFilho F, Cavicchioli mgs, Rosa AS, Jorgetto JV and Gamba MA declare that they contributed to the study design, data analysis and interpretation, article writing, relevant critical review of intellectual content and approval of the final version to be published.

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