# Original Article =

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# Advanced practices in comprehensive nursing care for people with skin ulcer

Práticas avançadas no cuidado integral de enfermagem a pessoas com úlceras cutâneas Prácticas avanzadas de atención integral de enfermería a personas con úlceras cutáneas

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#### **Keywords**

Community health nursing; Skin ulcer; Integrality in health

#### Descritores

Enfermagem em saúde comunitária; Úlcera cutânea; Integralidade em saúde

#### Descriptores

Enfermería en salud comunitária; Úlcera cutânea; Integralidad en salud

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#### Abstract

Objective: To identify clinical outcomes of people with chronic skin ulcer seen in nursing consultations.

Methods: Cross-sectional study of the analysis of nursing consultation records for people with chronic wound treated at a Nursing Care Center from 1994 to 2015, from the perspective of Collective Health. The variables investigated were epidemiological, wound advanced treatment centers, abandonment and death.

Results: There was a high proportion of elderly, female, with complete elementary and middle school, white self-reported color, retirees, dependents on the Brazilian Unified Health System (Sistema Unico de Saúde) and with chronic health diseases identified among the 343 patients medical records. Etiology of skin ulcer was higher in the neuropathic and venous areas without previous clinical resolution in the health services network. Healing occurred in 67.6% of wound by adoption focused on nursing care. A low rate of abandonment and death was observed. Conclusion: There were satisfactory clinical outcomes of people with chronic skin ulcer as evidenced in nursing care records. Nursing consultation showed a potential strategy for advanced wound care.

#### Resumo

Objetivo: Identificar os desfechos clínicos de pessoas com úlceras cutâneas crônicas atendidas em consultas de enfermagem.

Métodos: Estudo transversal da análise dos registros de consultas de enfermagem a pessoas com úlceras crônicas atendidas em um Centro de Assistência de Enfermagem entre 1994 a 2015, sob a perspectiva da Saúde Coletiva. As variáveis investigadas foram epidemiológicas, clínicas de cicatrização da úlcera, abandono e óbito de usuários.

Resultados: Dentre os 343 prontuários de pessoas atendidas no serviço, identificou-se maior proporção de idosos, do sexo feminino, com ensino fundamental, de cor autorreferida branca, aposentados, dependentes do Sistema Único de Saúde e com condições crônicas de saúde. A etiologia das úlceras cutâneas foi maior nas neuropáticas e venosas sem resolutividade clínica prévia na rede de serviços de saúde. A cicatrização ocorreu em 67,6% das úlceras pela adoção centrada nos cuidados de enfermagem, e observou-se pequena taxa de abandono e óbito.

Conclusão: Desfechos clínicos satisfatórios de pessoas com úlceras cutâneas crônicas foram evidenciados nos registros de cuidados de enfermagem. A consulta de enfermagem mostrou-se potencial estratégia para a cicatrização de úlceras cutâneas.

#### Resumen

Objetivo: Identificar los resultados clínicos de personas con úlceras cutáneas crónicas atendidas en consultas de enfermería.

Métodos: Estudio transversal de análisis de registros de consultas de enfermería realizadas por personas con úlceras crónicas en un Centro de Atención de Enfermería entre 1994 y 2015, bajo la perspectiva de la Salud Colectiva. Las variables investigadas fueron epidemiológicas, clínicas, de cicatrización de la úlcera, cesación del tratamiento y deceso del paciente.

Resultados: De las 343 historias clínicas de personas atendidas en el servicio, se identificó mayor proporción de ancianos, de sexo femenino, con enseñanza primaria, de color autorreferido como blanco, jubilados, dependientes del Sistema Único de Salud, con condiciones crónicas de salud. La etiología de las úlceras cutáneas fue mayor en las neuropáticas y venosas sin resolutividad clínica previa en la red de servicios de salud. La cicatrización ocurrió en el 67,6% de las úlceras por adopción enfocada en la atención de enfermería. Se observaron bajas tasas de cesación del tratamiento y decesos.

Conclusión: Los resultados clínicos satisfactorios de personas con úlceras cutáneas crónicas fueron evidenciados en los registros de atención de enfermería. La consulta de enfermería se constituyó en estrategia potencial para la cicatrización de úlceras cutáneas.

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# Introduction

Person-centered care is a challenge and a need/demand in the Brazilian Unified Health System (SUS – *Sistema Único de Saúde*) based on the principle of comprehensiveness. From this point of view, health promotion focuses on primary care, which is highlighted in the prevention of complications due to chronic diseases.<sup>(1-3)</sup>

In general, care for people with skin injuries is centered on skin disease/injury, mediated by specialties and disconnected from comprehensive care, with assessment of the person only for wound treatment, whether in primary, secondary or tertiary care.<sup>(3)</sup>

Nursing consultation had its entrance in Brazil in the 80's. Since then, numerous documents and articles have been published, demonstrating its potentialities and highlighting that it does not overlap another clinical activity, but it potentiates the process for building bond and autonomy for treatment.<sup>(3-5)</sup> Nursing actions should follow a systematization in the scope of comprehensive care based on concepts and practices of the Expanded Clinic and the Projeto Terapêutico Singular (STP- Singular Therapeutic Project), it is a set of proposals of articulated therapeutic behaviors for an individual or collective subject). These actions emerge as a radical commitment to subjects and their singularities, seeking intersectoriality in actions, and assuming co-responsibility in health care.<sup>(5-7)</sup>

Social inequalities and access to goods, low levels of education, beliefs, values, and modifiable risk factors such as smoking, consumption, physical inactivity and inadequate nutrition constitute potential/determinants and contribute to the emergence of chronic noncommunicable diseases (CNCDs) and their complications. These factors increase the chance of skin ulcer occurring.<sup>(8,9)</sup>

It is estimated that by 2050, about 25% of the elderly population will have chronic skin injuries.<sup>(10)</sup> Chronic skin ulcer are those whose etiologies are due to late diagnosis or inadequate treatment of long-term infectious or NCDs. Often, these wounds do not respond to usual treatments, failing to heal despite adequate interventions.<sup>(11)</sup> The most prevalent

types of wounds in primary health care are diabetic, venous, arterial, followed by pressure injury.<sup>(12)</sup> The presence of these affections represents a loss in the quality of life because it causes limitation in the activities of daily life, work, leisure, and family and social coexistence.<sup>(13)</sup>

It is necessary that care for people with skin ulcer be adopted from early diagnosis, technical ability of the nursing team and specific knowledge. This care was subsidized by care protocols, with integration and global evaluation of multiprofessional team for articulation between different levels of health care, with effective participation of the person and his relatives.<sup>(14,15)</sup>

Consistent with the practice of care, it is observed in scientific research care is focused on the use of hard technologies, such as curative and adjuvant therapies.<sup>(16)</sup> The nurse has an essential role in the care for people with wounds and in the work with the team developing planning, organization and execution actions of advanced practices in nursing in the skin care.<sup>(3,16-19)</sup>

An investigation has described that the nurse's autonomy in caring for people in advanced wound care as the strategy to promote autonomy and self-esteem of people affected. This autonomy expands to the perspective of adhesion and resolution of the grievance manifested, because it acts positively on feelings, spirituality, emotions beyond the care centered on the biological model and the exchange of dressing. Thus, nursing consultation constitutes a timely strategy to address these aspects that influence the coping and healing of injuries.<sup>(17)</sup>

Difficulties in the maintenance of care, living conditions and health service evaluations, in relation to access availability, available resources and motivation of professionals involved in care are a challenge nowadays.<sup>(18)</sup>

This study is justified by the impact that chronic skin ulcer/wounds and complications cause in the quality of life of people living with the disease, family and society; and the way in which nursing care is offered to the population.

In this perspective, the question is: what are the clinical outcomes of people with chronic skin prob-

lems and complications, seen at a nursing consultation in a care center?

This study aimed to identify the clinical outcomes of people with chronic skin ulcer seen in nursing consultations from the perspective of Collective Health.

# Methods

This is a cross-sectional study, based on the documentary analysis of records of people diagnosed with chronic skin ulcer treated between 1994 and 2015, at *Centro de Assistência e Educação em Enfermagem* (CAENF), a service integrated with a public university of the city of São Paulo.

This site was created in 1994 as a support, care and embracement service for people in the health service network, whose wounds were not clinically resolvable and required continuity of treatment. It was also used as a place to train nursing undergraduates and professionals from the health services network.

Population care was carried out through nursing consultations, based on the principles and assumptions of SUS, nursing process and guidelines of Collective Health actions, in which the exchange of popular/technical and scientific experiences/knowledge is valued.

Data were collected between 2014 and 2015. The strategy used was the construction and application of an instrument based on the scientific literature and the researchers' work with people with chronic skin ulcer. The secondary source consisted of the information contained in printed records of nursing care systematization, in systematizations charts, of the nursing consultations of people treated between 1994 and 2015. This information was consolidated in a database in 2015.

The variables investigated were sociodemographic, risk factors and life habits, presence of comorbidities, etiology and evaluation of the injury as to the type of tissue, exudate and diameter, identified through standardized scores in care protocols and guidelines. Possible outcomes were complete healing, abandonment of treatment or death, and access to referral and counter-referral services were confirmed by telephone survey in 2014 and 2015.

Data analysis was performed from 2015 to 2016, using Excel 2007<sup>\*</sup> and EPI-INFO programs. In addition to the descriptive analyzes, the hypothesis test of the nominal variables was performed, applying the student's t test and the chi-square statistics ( $\chi 2$ ; CI=95%).

The ethical requirements established in Resolution 466/2012 of the National Health Council were met. This research was approved by the Ethics Committee on Research Involving Human Beings of *Universidade Federal de São Paulo*, on December 12, 2013, under Opinion 482,039.

# **Results** =

A total of 343 records of people with chronic skin ulcers, with a mean age of 61.2 years, median age of 64 years (CI=9-91 years, SD=16.22 years) were analyzed. 51.3% were female and 75.6% lived in the country's southeastern region. 65.9% was white. 47.8% had study time of eight years. Occupational data indicated that 62.8% of the people were retired; from the home; on medical leave or unemployed. 55.4% were married and the per capita income was three minimum wages for 83.2% of these. The presence of religion was enunciated in 80% of the users (Table 1).

Clinical variables indicated arterial hypertension (64.2%), followed by Diabetes Mellitus (DM) (71.5%) and type II Diabetes Mellitus (76.3%), smoking in the past (37.5%) and current 16%; past alcohol consumption (26.3%) and current (14.8%), with an average duration of illness of 15.2 years. Chronic pressure lesions were detected, being 37% neuropathic, 23.4% venous, 12.3% oncological, 7.6% mixed, 6.3% arterial; 4.8% due to pressure lesion, 3.7% leprosy and 3.3% traumatic, with average duration of up to 120 days and without previous clinical resolution. Regarding outcomes, it was observed that 67.6% of the patients presented complete healing of their injuries after attending the service; 21.3% continued with therapeutic treatment; 7.1% did not heal; 0.5% of the people

patients treated at CAENF. São Paulo- Brasil

Table 2. Characteristics of wounds and clinical outcomes of

Table 1. Sociodemographic characteristics of CAENF patients

Sociodemographic variables	n(%)
	100(343)
Mean Age (n=343)	60.1
Gender (n=343)	
Male	168(48.9)
Female	175(51.1)
Marital Status (N=233)	
Single	40(17.1)
Married	129(55.4)
Divorced	24(10.4)
Widow(er)	40(17.1)
Education level (N= 230)	
Illiterate	19(8.3)
Incomplete elementary and middle school	44(19.1)
Complete elementary and middle school	66(28.7)
Incomplete High School	39(17)
Complete High School	18(7.8)
Higher Eduation	44(19.1)
Color (N=220)	
White	145(65.9)
Black	22(10)
Others	53(24.1)
Occupation (N=285)	00(2111)
Retired	112(39.3)
Employed	106(7.2)
From the home	43(15.1)
Medical leave	13(4.6)
Unemployed	11(3.8)
Nationality (N=295)	11(0.0)
Center-west	4(1.3)
Northeast	51(17.3)
North	5(1.7)
Southeast	223(75.6)
South	5(1.7)
Others	
	7(2.4)
Origin (N= 321)	
Central Fast	266(82.9)
	49(15.2)
North	3(1)
West	2(0.6)
South	1(0.3)
Income (N= 197)	0(1 5)
Less than 1 minimum wage	3(1.5)
From 2 to 3 minimum wages	161(81.7)
From 3 to 4 minimum wages	18(9.2)
From 5 to 6 minimum wages	8(4)
More than 6 minimum wages	7(3.6)
Religion (N=164)	
Catholic	86(52.4)
Evangelical	26(15.8)
Spiritist	15(9.2)
Others	37(22.6)

suffered amputation due to acute obstruction of the popliteal artery; and 1.5% died due to aging or other comorbidities (Table 2).

Dermatological propaedeutics guides the care and topical therapies for skin ulcers, as well as the records in medical records of the clinical evolution

Variables	n(%)
Wounds (n=332)	
Yes	290(87.3)
No	42(12.7)
Number of wounds (n=286)	
One	219(76.5)
Two	47(16.4)
Three	8(2.9)
Multiple	12(4.2)
Etiology (n= 300)	
Pressure injury	14(4.7)
Neuropathic ulcer	111(37)
Venous ulcer	70(23.4)
Mixed ulcer	23(7.6)
Arterial ulcer	19(6.3)
Cancer	37(12.3)
Traumatic	10(3.3)
Leprosy	11(3.7)
Others	5(1.7)
Evolution time (n=297)	
Up to 30 days	92(31)
From 30 to 90 days	103(34.6)
From 91 to 120 days	53(18)
Over 120 days	12(4)
Over 180 days	20(6.7)
More than 365 days	17(5.7)
Outcome (n=197)	
Healing	133(67.6)
No healing	14(7.1)
Amputation	1(0.5)
Death	3(1.5)
Abandonment	4(2)
Under treatment	42(21.3)

n=343

make possible the longitudinal care. Information on the presence, etiology, and evaluation of wound regarding tissue type, exudate and diameter pointed to clinical outcomes. In the analysis of outcomes, people achieved healing by adopting clinical evidence of topical therapies pointed out by specialist societies such as podiatric care for neurotrophic and neuropathic injuries, relief of plantar pressure by orthotics, application of compression with Unna boot for venous ulcer, biofilm control in infectious wounds and referral to vascular surgery for people with arterial ulcer. It was possible to identify that part of the people used only the SUS equipment and services for care, and were referred to CAENF by: University Hospital - (31.4%), basic health unit (BHU) (13%), campaigns for the detection of Diabetes Mellitus (55.6%). For the counter-referral analysis, it was observed that 50% returned to the hospital for different specialties and 41% for

Variables	Healed	Not Healed	Total	p-value
Valiaui05	n(%)	n(%)	Total	p-value
Gender				
Male	60(65.2)	32(34.8)	92	0.639
Female	73(69.5)	32(30.5)	105	
Ignored	64			
Age bracket				
<60 years	51(68)	24(32)	75	0.939
>60 years	83(67.5)	40(32.5)	123	
Ignored	63			
Marital Status				
Single	16(57.1)	12(42.9)	28	0.129
Married	47(59.5)	32(40.5)	79	
Divorced	17(85)	3(15)	20	
Widow(er)	10(52.6)	9(47.4)	19	
Ignored	107			
Educattion level				
Illiterate	5(55.6)	4(44.4)	9	0.598
Incomplete elementary and middle school	26(66.7)	13(33.3)	39	
Complete elementary and middle school	12(50)	12(50)	24	
Incomplete High School	7(70)	3(30)	10	
Complete High School	18(75)	6(25)	24	
Higher Eduation	19(67.9)	29(32.1)	48	
Ignored	110			
Monthly Family income				
Less than 1 minimum wage	0(0)	100(1)	1	0.527
From 2 to 3 minimum wages	68.9(62)	31.1(28)	90	
From 3 to 4 minimum wages	56.3 (9)	43.8(7)	16	
From 5 to 6 minimum wages	75(3)	25(1)	4	
More than 6 minimum wages	60(3)	40(2)	5	
Ignored	110			
Arterial hypertension				
Yes	68(64.8)	37(35.2)	105	0.761
No	38(65.5)	20(34.5)	58	
Ignored	91			
Diabetes				
Yes	85(66.4)	43(33.6)	128	0.793
No	41(68.3)	19(31.7)	60	
Ignored	71			
Other Comorbities				
Yes	2(100)	0(0)	2	0.414
No	55(62.5)	33(37.5)	88	
Ignored	69			
Past smoking				
Yes	38(70.4)	16(29.6)	52	0.529
No	72(65.5)	38(34.5)	110	
Ignored	87			
Current smoking				
Yes	16(69.6)	7(30.4)	23	0.784
No	94(66.7)	47(33.3)	141	
Ignored	87			
Past alcohol consumption				
Yes	25(67.6)	12(32.4)	37	0.942
No	85(66.9)	42(33.1)	127	
Ignored	110			
Current alcohol consumption				
Yes	17(89.5)	2(10.5)	19	0.027
No	93(64.1)	52(35.9)	145	
Ignored	67			

Table 3. Comparative analysis between sociodemographic,
clinical and wound healing patients characteristics

n=197

604

Acta Paul Enferm. 2018; 31(6):600-8.

home care and BHU. All patients were instructed and encouraged to adopt habits that promoted clinical control, skin care and therapeutic monitoring. According to medical records, it was observed that most of the individuals adopted habits for self-care, with subsequent returns to the service, pointing out the bond with the team. There were no statistically significant differences between the individuals with and without ulcer healing for sociodemographic, clinical and access variables. Complete healing of chronic injuries, with evolution of 120 days, was identified in (67.6%) of the people served at CAENF. A discrete protective effect was identified for healing when the habit of ingesting alcoholic beverage was present, as shown in table 3.

## Discussion

Person-centered care guided by health education does not overlap another clinical activity, but it potentiates actions for self-care, changes in behavior for exposure to risk factors, and collaborates with the clinical adhesion process.<sup>(17-19)</sup> Nursing consultations imbued with the perspective of comprehensive care were spaces of interlocution with the intersectorial actions in the search for solutions to the problems detected, such as self-monitoring, therapeutic care, podiatry, mobility, ortetization and adoption of advanced therapies.<sup>(20,21)</sup>

Adoption of the nursing consultation allowed, in addition to guiding the performance not only focused on the accomplishment of dressings, to implement therapeutic resources as the valorization of the power of listening and of the word, potentializing the effect of health education and allowing the subject to assume his care with autonomy for the treatment.

It is true to recognize that the manifestations of chronic diseases have increased substantially over the years, since environmental factors, such as life habits, food, increased sedentary lifestyle, stress, tobacco use predisposes and aggravates these conditions and their complications. Clinical variables revealed a high prevalence of comorbidities such as arterial hypertension, DM and vascular complications, mainly among the long-lived, which corroborates the literature to affirm the correlation between CNCDs and functional disabilities.<sup>(12)</sup>

In the medical records analysis, this study identified the social use of alcoholic beverage with protective effect for the healing of skin ulcer, however, it is necessary to carry out more scientific investigations by comparison with control groups to better elucidate the effect of these beverages.

In 2011, approximately 94% of the amputations performed by SUS were on the lower limb. It is estimated that lower amputations correspond to 85% of all limb amputations, although there is no accurate information on this topic in Brazil. The most frequent indications for these amputations are due to the complications of chronic diseases and occur more frequently in the elderly. In the literature, it is identified that approximately 80% of them are performed in patients with peripheral vascular disease and/or DM, mostly related to recurrences of chronic injuries.<sup>(22,23)</sup>

Wounds with a long duration of treatment and, as a function of diabetes and arterial hypertension, was detected in this study, with injuries of neuropathic and plantar etiology being the most frequent. Neuropathy is a complication of poorly controlled diabetes that causes loss of sensory, motor and autonomic function, factors related to the genesis of ulcerations and deformities. Neuropathic injuries require a model of care that assumes podiatric qualification and referral for rehabilitation, preparation of orthoses and healing prostheses and involve a care complexity that requires the adoption of light and hard technologies.<sup>(24)</sup>

Actions carried out by nurses and staff guidance as advanced practices for self-care require the individualization of care, care centered on therapeutic action, orientation of changes in habits, pillars of foot management by daily inspection and dermatological care. Such care must be exercised with competence and technical specificity of the skin, requiring the nursing consultation to perform comprehensive, effective therapy that promotes the best practice in the area of skin health care.<sup>(23,25,26)</sup> In fact, nursing consultations allow an interpersonal interaction that stimulates the adoption of care for the metabolic control and treatment of chronic injuries. In this case, the consultations demand high therapeutic acuity and technical specificity, determinants for comfort, confidence, decrease of pain, case resolution and greater clinical adhesion.

In the present study, most of the injuries were diabetic foot and neuropathic etiology, followed by vascular ones, compatible with other findings. Wounds due to diabetes are caused by late diagnosis, poor metabolic control, and loss of protective plantar sensation. In a follow-up study of 185 people with diabetes who underwent intensive follow-up and education on the prevention of complications for two years, there was a significant reduction in the incidence of wounds higher healing rates, and fewer surgical interventions.<sup>(25)</sup>

Health recovery can be achieved if there is a service network with professionals engaged, especially with primary care as the gateway to the system with a focus on health promotion and protection.<sup>(25)</sup>

Presence of venous injuries that are of long duration and high rates of relapse, have affected more women and have average time greater than four years. Studies estimate that approximately 1.5 to 3% of the adult population worldwide have active venous injuries, which leads to loss of quality of life, pain, psychosocial suffering and limitation in work.<sup>(27,28)</sup> The gold standard of venous ulcer treatment is compressive therapy, but a lifestyle orientation program is critical. A recent randomized study pointed to the effectiveness of a guidance program for the healing of venous ulcers. This study emphasized the importance of health professionals qualified to perform compressive therapy and guide daily living habits and continuous monitoring, actions also recommended in the nursing consultation.<sup>(29)</sup>

Regarding the health care network and the presence of the social support network, this study showed that most of users depend on SUS, referred by primary care and outpatient specialties. Among those affected, most needed support from other community members on commuting to receive care. These results allowed elaborating, following up and organizing users flow in health care networks, between University Hospital and primary care. They also pointed out protocols for home care and follow-up at the health unit, ensuring referral and counter-referral.<sup>(30,31)</sup>

Epidemiological studies in the United Kingdom show that between 2 and 3% of the population with chronic wounds live in poor districts without access to information, consumer goods and therapeutic means. These characteristics significantly alter the quality of life of those affected in the community, mainly due to the presence of pain, absence at work and the precariousness of activities of daily living.<sup>(32,33)</sup> In the treatment of users with chronic wounds the causal multifactorial must be observed and investigated. Recognition of nursing practices in Collective Health that achieve situations of improvement of the well-being and clinical adhesion has been constituted as a goal of the evaluation indicators in the area.

Due to the homogeneity of the population, no meaningful differences were observed for social, demographic and clinical variables regarding the presence or absence of healing.

Nursing care has made it possible to point out that nursing consultation is an activity with an important educational function, which may enable health promotion.<sup>(34)</sup> Such care encourages people to become protagonists of their stories and empower them to search for innovative solutions for improving living conditions and validating the actions of the service. Health education promoted by the team during nursing consultations favors and directs the action in the prevention and treatment of chronic diseases. It promotes the reduction of complications and deserves to be experienced in the teaching-learning process of the training of nurses and continue to be practiced in health care.

The results of this study, added to the historical rescue of the CAENF creation allowed to glimpse the nursing performance and evaluate the care. They contributed to the training of numerous primary care professionals, in which culminated in the implementation of the *Protocolo Proibido Feridas* (Prohibited Wounds Protocol), supporting nursing actions in the area of the Municipal Health Department of São Paulo through the promulgation of Law 14.984/2009, which guarantees this right to the population. $^{(35)}$ 

Rescuing the historicity of nursing actions in the care for people with chronic ulcers allows reflections not only in the field of daily practice, but in the politics, education, and research and extension, in order to increase visibility of the performance of this professional and ensure a comprehensive care to the individual, and professional valorization.

The study limitations are related to the method chosen, by the use of secondary data from the systematization records of non-computerized nursing care. Data verification was often not confirmed due to fluctuation of the users' location, and there was no control group for the comparison of possible association data. Although the methodological design does not allow generalizations, results aim to present experiences of nurses and nursing students in health care from the effective implementation of comprehensiveness to hundreds of people who had triggered the chance to have their limbs amputated.

# Conclusion

This research showed that people treated were mostly female, with a mean age of 61 years, white, retired, with low education level and income, and Public System of Health patients. They had wounds of varied etiologies, of long duration and with previous indications that would lead them to physical deficiencies. Clinical outcomes demonstrated that most of the people followed in nursing consultation achieved complete healing. Nursing consultation is a strategy that deserves to be better elucidated as an effective care practice that can contribute to advanced wound care.

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# **Collaborations** =

Trivellato MLM, Kolchraiber FC, Frederico GA, Morales DCAM, Silva ACM and Gamba MA declare that they contributed to the design of the study; analysis and interpretation of data; writing of the article, and approval of the final version to be published.

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