

Patients and Family Caregivers' Perceptions on Two Stress Reduction Interventions with Patients with Chronic Diabetic Foot Ulcers: A Qualitative Study

M.Graça Pereira (✉ gracep@psi.uminho.pt)

Universidade do Minho - Campus de Gualtar: Universidade do Minho <https://orcid.org/0000-0001-7987-2562>

Susana Pedras

Porto Hospital Centre: Centro Hospitalar Universitario do Porto EPE

André Louro

Universidade do Minho - Campus de Gualtar: Universidade do Minho

Alberto Lopes

Portuguese Association of Clinical Hypnosis and Hypnoanalysis

Margarida Vilaça



Universidade do Minho - Campus de Gualtar: Universidade do Minho

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Abstract

Background

The present study aimed to assess the perceptions of patients with chronic diabetic foot ulcers (DFUs) and their informal caregivers regarding the impact of two stress reduction interventions, such as a progressive muscle relaxation and hypnosis, on patients' DFU and psychological wellbeing.

Methods

This multicenter study used a qualitative exploratory design and included individual interviews with eight patients with chronic DFUs and six family caregivers, using a semi-structured interview guide. Transcripts analysis employed thematic content analysis.

Results

Four key themes common to patients and their caregivers were found: 1) perspectives regarding the intervention; 2) intervention effectiveness; 3) the role of psychology on the DFU treatment; and 4) emotions and consequences associated with the DFU. Although themes were common to both treatment groups, sub-themes from the last two themes differed for patients that received muscle relaxation versus those who received hypnosis. One additional theme emerged from the caregiver's interviews: 5) promotion of self care behaviors.

Conclusion

According to patients and caregivers, overall the two stress reduction interventions were beneficial for the DFU healing progression and emotional wellbeing. The hypnosis group also reported lasting effects. Participants suggested that psychological interventions such as stress reduction interventions could be included in the DFU standard treatment as an adjuvant to the clinical protocol for DFU treatment, preferably offered early on, when the patient begins treatment at the diabetic foot consultation.

Background

Diabetes is a chronic systemic disease with a steadily increasing prevalence worldwide. There are currently 537 million people with diabetes mellitus (DM), of which around 61 million are living in Europe. [1] Portugal is one of the five European countries with high prevalence of people between the ages of 20 to 79 years with diabetes (9.1%), with an estimated treatment cost per patient of 2293.3 USD. [1]

One of the most common, serious, and feared complications of people with DM is a diabetic foot ulcer (DFU), frequently resulting from poor glycemic control and repetitive trauma to a sensory or vascular compromised foot. [2] Over half of diabetic patients with foot injuries will develop an infection, which may result in the

amputation of the lower extremities, and ultimately, in death. [3–5] In fact, previous studies suggest a five-year survival rate for approximately half of patients with DFU who undergo major or minor amputations. [6] Today, DFUs remain a public health problem, representing a considerable financial burden to health care systems and the society. [7]

The high rates of disability and mortality in patients with DFU cause a great burden to patients, their families, and the society. Patients dealing with DFU report a variety of physical and emotional difficulties such as bodily pain, mobility limitations, dependence on others, increased health care needs, risk of amputation, decreased sociability, frustration, grief, anxiety, and depression, with an adverse impact on their quality of life (QoL). [8–9] This further leads to significant changes in patients' lifestyle, often, causing emotional distress. In fact, patients with DM are twice more likely to suffer from anxiety and depression than non-diabetics, [10] while patients with foot wounds show a greater tendency to experience anxiety and depression compared to patients with DM without wounds. [11] The prevalence of psychological morbidity is also larger in patients with DFU that suffer from other diabetes complications. [12]

At home, the treatment of chronic DFUs frequently requires the involvement of family members. Family or informal caregivers are often offspring or a spouse that provides unpaid support to the patient, with an important role in monitoring patients' self-management, detecting improvements or deteriorations in the wound progression, as well as in providing daily care. Although family caregivers often feel unprepared to provide care, they accept their role mostly because of feelings of moral or social obligation. [13] Consequently, their QoL declines, and the psychological burden increases over time. [14–16] Despite all challenges that family caregivers face, they undoubtedly play a crucial role in the recovery of patients with DFU, and have an important voice regarding their relative's progression.

The prevention and management of DFUs is a major therapeutic challenge and concern for patients with diabetes, family caregivers, and health care professionals. [17–18] Since DFUs tend to have a poor prognosis, to be recurrent, and can take weeks or months to heal, [19] an integrated and multidisciplinary approach is crucial for a successful DFU management. Despite the negative effect psychological distress can have on wound healing, and overall health, being associated with an increased risk of mortality, [20–21] diabetic foot specialists rarely focus on the patients' mental health status. Indeed, psychological interventions, such as relaxation training techniques or hypnosis have already shown positive results in the management of DM [22–24] and in patients with DFU, [25] thus representing promising effective adjuvant interventions in the treatment of DFUs.

The aim of the present study was to capture: the perspectives of clinically distressed patients and family caregivers on the effectiveness of two stress reduction interventions towards DFU healing progression and psychological wellbeing, specifically, comparing progressive muscle relaxation with guided imagery versus hypnosis with guided imagery.

Methods

Design and methods

This is a qualitative study nested in a larger longitudinal randomized controlled trial (RCT) study focused on the effectiveness of two stress reduction interventions in patients with chronic DFUs (PSY-DFU). The RCT is already registered in the ClinicalTrials.gov platform (Registration number: NCT04698720), and the study protocol is published elsewhere [26] and summarized below. The use of qualitative research methods is particularly valuable when studying complex health-related topics, [27] such as the DFUs healing process, allowing a refinement of the statistical results from previous findings of the RCT, throughout a more in-depth exploration. Furthermore, according to Kuhnke et al. [28] the qualitative approach allows a deeper understanding of the experience of living with a DFU, compared with other research methods.

Patients that concluded at least 75% of the stress reduction sessions and completed the baseline (T0) and post-intervention/ approximately two months after (T1) assessments, were orally informed by the researcher about the purpose of this study, and invited to participate. After obtaining written informed consent, individual, in-person, and semi-structured interviews were conducted two weeks after completing interventions. At the end of the interview, patients were asked if they agree with the researcher coming into contact with their family caregiver in order to inform and invite him/her to participate in a similar interview. All study participants signed written informed consent forms, and agreed to be recorded during the interviews.

The interviews were conducted from December 2020 to November 2021, and ethical approval was obtained from the two hospitals where participants were recruited [198/2018; 2018 – 205 (180-DEFI/179-CES)].

Participants and recruitment

This nested exploratory qualitative study was conducted in two central hospitals with multidisciplinary diabetic foot consultations, in the North of Portugal. The two hospitals work independently, and both diabetic foot clinics are a reference in the DFU treatment. Participants were patients attending the first consultation of the outpatient diabetic foot clinics, as well as their family caregivers. Patients' inclusion criteria were: i) adult patients with type 2 DM, ii) one or two chronic active DFU (a non-healing ulcer for six or more weeks and less than 12 weeks) at the baseline evaluation, iii) significant clinical stress, anxiety, or depression levels, and iv) having completed at least three of the four intervention sessions. Clinical distress was defined according to the Hospital Anxiety and Depression Scale (HADS) [29–30] and the Perceived Stress Scale (PSS), [31–32] with patients with scores higher than 11 on the HADS subscales, or higher than 13 (men) or 17 (women) on the PSS, evaluated as being clinically distressed.

The exclusion criteria included patients i) whose DFU that at the baseline evaluation was a relapse, ii) undergoing hemodialysis, iii) with a cancer disease, iv) with a history of mental illness, v) with dementia or unable to communicate, and vi) receiving psychological support during the study period.

All patients with a caregiver gave permission to contact their relative. To participate in the study, caregivers only had to accept and sign the informed consent. Participants were selected according to participants' capacity to provide in-depth and rich-texture information regarding the intervention's effectiveness since qualitative purposive sampling is considered to be more efficient than random sampling. [33] Participants were also purposefully selected according to the patients' type of diabetic foot (neuropathic versus

neuroischemic) and DFU progression (positive versus negative) in order to obtain balanced groups of cases per intervention, and to allow for exploration of clinically different cases.

Although the sample was expected to include four single-per-participant interviews per intervention group (4 conditions × 2 groups), in a total of eight patients and eight caregivers' interviews, given that two patients did not have a caregiver, the final sample included eight patients and six caregivers.

Interventions

Four participants allocated in the treatment group 1 (T.G.1) completed progressive muscle relaxation with guided imagery intervention (PMR + GI), and three participants allocated in the treatment group 2 (T.G.2) completed the hypnosis with guided intervention (H + GI). One participant from the T.G.2 only received three sessions because the DFU healed before the fourth session.

PMR + GI sessions began with diaphragmatic breathing, followed by Jacobson's progressive muscle relaxation, a technique that consists in consequently tensing and relaxing individual all muscle groups of the body. After completing the relaxation exercises, initiates the guided imagery focused on the DFU healing. H + GI sessions followed a Hypnotic Protocol that included the following steps: pre-talk, absorption, ratification, aliciation, dissociation, and awakening. In T.G.2, participants' perceptions on the DFU healing were also educated in visual, auditory, and kinesthetic terms.

Both treatment groups included four scripted bi-weekly sessions, of 45 minutes duration each, in approximately a 2-month treatment course. Sessions were conducted in a private room, with a specialist treatment couch, provided by the two hospitals where data collection took place.

Data collection

Instruments. Patient's sociodemographic information (e.g., gender, age, education, residence, marital and professional status) was collected directly with patients at the T0 assessment moment, using a sociodemographic questionnaire developed by the research team for this study. Clinical information was collected through a clinical questionnaire, also developed specifically for this study, to obtain a detailed clinical history of patients. Clinical data was provided by the patients' physician or nurse at the baseline assessment (T0), and included the type and duration of diabetes, glycemic control, other pre-existing complications of diabetes, diabetic foot type, DFU location and duration, previous DFUs, and concomitant treatment.

Caregiver's sociodemographic information was gathered through a brief questionnaire that included questions regarding the caregivers' age, residence, education, marital status, professional status, and years of caregiving. Caregivers answered this questionnaire just before audio-recording the interview.

Interview. The interview guide was developed by the research team through literature review. Questions explored patients and caregivers' perceptions of the efficacy of the stress reduction sessions on the patients' wellbeing and DFU healing progression, whether directly or indirectly. Specifically, the interview addressed the perspectives of patients and caregivers on:

- I) Expectations and thoughts regarding the stress reduction interventions;
- II) The contribution of the stress reduction interventions towards the DFU healing and the person as a whole;
- III) The way the stress reduction intervention sessions were delivered;
- IV) The importance for the multidisciplinary diabetic foot consultation of having this type of service being offered on a regular basis.

Two trained researchers with a PhD in Health Psychology conducted the interviews in a private room reserved by the hospital to this study. The interview guide was used flexibly in order to follow the natural course of the participants' discourse. Each interview was approximately 30 minutes in length. Interviews were audio-recorded and transcribed verbatim.

Data analysis

Two authors trained in qualitative research methods used deductive thematic analysis to generate predominant themes and sub-themes. [34] To ensure reliability and effectiveness, the two researchers coded the transcripts of eight participants independently, and then met throughout the coding process to solve coding issues through consensus, thus ensuring agreement on themes derived from the data and interview guide. According to Miles and Huberman's formula [35] inter-rater reliability was .84% at this stage. Two more meetings were held during the coding process to discuss themes found in the remaining transcripts. Finally, the first author reviewed excerpts linked to main themes and sub-themes, after reading full transcripts to contextualize those excerpts within the complete narratives. Although the sample size was determined in advance, the three researchers involved in the data analysis agreed that the generated data was adequate, as the replication of themes and comments by participants indicated a level of completeness. The results show all themes and sub-themes that emerged from the interview with both patients and caregivers.

Results

Sample characteristics

Eight patients with chronic DFUs, and six of their caregivers, were included in the study. Participants' clinical and sociodemographic characteristics are summarized in Table 1. Patients were generally middle-aged men (the sample included only one woman), while caregivers were younger women.

Table 1. *Demographic and clinical characteristics of patients with chronic DFU (N = 8) and their caregivers (N = 6)*

		Patients		Caregivers
		<i>n (%) / M±SD</i>	Min– Max	<i>n (%) / M±SD</i>
Gender	Women	1 (12.5)		6 (100.0)
	Men	7 (87.5)		0 (0.0)
Age		56.63 ± 12.01		48.83 ± 8.52
Residence	Rural	6 (75.0)		5 (83.3)
	Urban	2 (25.0)		1 (16.7)
Marital status	Single	0 (0.0)		1 (16.7)
	Married/ non married partnership	5 (62.5)		5 (83.3)
	Divorced/ separate	3 (37.5)		0 (0.0)
Education (years)		6.13 ± 2.17		
	≤ Primary studies	3 (37.5)		1 (16.7)
	≤ Secondary studies	5 (62.5)		5 (83.3)
Professional situation	Employed	2 (25.0)		1 (16.7)
	Unemployed	3 (37.5)		5 (83.3)
	Disability pension	3 (37.5)		0 (0.0)
Monthly income	< 600 €	5 (62.5)		
	600 € to 1200 €	2 (25.0)		
	> 1200 €	1 (12.5)		
Adequate health literacy	Yes	3 (37.5)		
	No	5 (52.5)		
DM 2 duration (years)		18.63 ± 11.05	5.0 – 38.0	
HbA1c (%) at the first consultation		9.80 (2.28)	6.7 – 14.0	
First DFU		4 (50.0)		
DFU duration (weeks)		8.50 (2.56)	6.0 – 13.0	
Diabetic foot type	Neuropathic	5 (62.5)		
	Neuroischemic	3 (37.5)		

Number of comorbidities ^a	4	4 (50.0)
	6	4 (50.0)
Healed DFU after completing the intervention ^b		3 (37.5)
Although not healed, the DFU improved after completing the intervention ^c		3 (37.5)
Relationship with the patient	Wife/ partner	4 (66.7)
	Daughter	2 (33.3)
Caregiving duration (years)		10.58 ± 14.78

Note. ^aComorbidities included diseases such as high blood pressure, dyslipidemia, obesity, diabetic retinopathy, sensorimotor neuropathy, nephropathy, ischaemic heart disease, peripheral arterial disease, among others; ^bhealing was defined as the complete epithelization of the wound, assessed through the RESVECH 2.0-PT; ^cDFU improvement was considered when there was a reduction of the wound area.

Insert Table 1

Patients' themes and sub-themes

Interviews with all patients yielded four key themes: 1) perspectives regarding the intervention; 2) intervention effectiveness; 3) the role of psychology in the DFU treatment; and 4) emotions and consequences associated with the DFU. Although themes were common to both treatment groups, sub-themes differed for patients that received PMR + GI versus H + GI in the last two themes. Table 2 presents themes, sub-themes, and supporting quotes from patients' interviews.

Table 2
Patient's Themes, Sub-Themes, and Extracts

Themes	Sub-themes	Patients' Quotes
Perspectives regarding the intervention	Prior contact	T.G. 1: <i>I have never heard about it</i> (Male, aged 49)
		T.G. 2: <i>I did not know about these sessions</i> (Male, aged 43)
	Usefulness	T.G. 1: <i>I think it is helpful because sometimes the disease is in the mind</i> (Male, aged 62)
		T.G. 2: <i>Patients get other psychological disposition to face the disease</i> (Male, aged 66)
	Interest in further sessions	T.G. 1: <i>If it was possible to receive more (sessions), I would do more</i> (Male, aged 49)
		T.G. 2: <i>At the time, I said that I would like to have more because, at that time, it was only four (sessions)</i> (Female, aged 55)
Home practice	T.G. 1: <i>I started trying to do at home what I was doing here</i> (Male, aged 49)	
Improvement suggestions	T.G. 1: <i>If it (the intervention) was included in the consultation, it would help to reduce stress</i> (Male, aged 49)	
	T.G. 2: <i>Sessions should be once a week so that relaxation last longer</i> (Female, aged 55)	
Intervention effectiveness	Physical changes	T.G. 1: <i>Because, I think it started to heal a little bit more with the relaxation</i> (Male, aged 49)
		T.G. 2: <i>I will be honest, while I had the four sessions, it (the wound) improved a lot, a lot</i> (Male, aged 47)
	Behavioral changes	T.G. 1: <i>I had the wound, came here for the consultations, and since then I stopped drinking</i> (Male, aged 62)
		T.G. 2: <i>For example, in the afternoon I was sitting and, when she (her daughter) got home, she would do all the household chores</i> (Female, aged 55)
	Psychological changes	T.G. 1: <i>Psychologically, I am better and I believe the wound is going to heal</i> (Male, aged 80)
		T.G. 2: <i>After the sessions, you feel more peaceful and more confident</i> (Male, aged 47)
Interpersonal changes	T.G. 1: <i>I was not so aggressive in my daily life. I should say less demanding, and more benevolent at home</i> (Male, aged 80)	
	T.G. 2: <i>For example, I was not so nervous with the kids. I think I was more patient with the kids</i> (Female, aged 55)	
Effect duration	T.G. 1: <i>For example, when I left the session, I was calmer for two or three days</i> (Male, aged 49)	

Note. T.G. 1 = Treatment group 1 (progressive muscle relaxation with guided imagery); T.G. 2 = Treatment group 2 (hypnosis with guided imagery).

Themes	Sub-themes	Patients' Quotes
		T.G. 2: Over 15 days or three weeks, because over a 15 days or three weeks period I thought a lot about what was said in the session (Male, aged 47)
Role of psychology in the DFU treatment	Importance of psychology	T.G. 1: <i>As in all things, the psychological dimension is very important because, if we crash and lose heart, things get worse</i> (Male, aged 80)
		T.G. 2: <i>The psychological dimension is very important for things to evolve</i> (Male, aged 66)
	Psychology related bias	T.G. 1: <i>In my youth, there was this idea that "I do not need psychology, I am not crazy"</i> (Male, aged 80)
Emotions and consequences associated with the DFU	Fear	T.G. 1: <i>I was really scared. I never thought this would heal. I had a real fright</i> (Male, aged 62)
		T.G. 2: <i>I did not know if it was going to get better or worse, if they had to cut my foot. Today, I am still afraid of that because here they do not inform us of anything</i> (Male, aged 43)
	Sadness	T.G. 1: <i>Because, when I dwelt on that I was bad, I got worse. Really worse. I could not go shopping, I really could not do anything</i> (Male, aged 62)
	Revolt	T.G. 1: <i>I was revolted, anguished... I already am a revolted person</i> (Male, aged 49)
	Impossibility to work	T.G. 1: <i>And I worked, I never stopped working</i> (Male, aged 62)
T.G. 2: <i>I felt good for a long time with the sessions. Yet, I did a lot of work for a woman with a wounded foot</i> (Female, aged 55)		
<p><i>Note.</i> T.G. 1 = Treatment group 1 (progressive muscle relaxation with guided imagery); T.G. 2 = Treatment group 2 (hypnosis with guided imagery).</p>		

Insert Table 2

Perspectives regarding the intervention

Patients had no previous contact with PMR + GI and H + GI sessions. Although one patient from the T.G.1 knew generally what muscle relaxation sessions consisted of, none of the T.G.2 patients had previous knowledge regarding these sessions. All patients from both groups reported sessions were satisfying, beneficial, or important for patients with DFU. In the T.G.1, patients stressed the importance of the sessions for the "mind", and as a complement to the medical treatment, while in the T.G.2 patients emphasized the sessions' utility to calm the mind, change the way of thinking, and help to accept the complexity of the DFU healing.

Two patients from T.G.1 and three from the T.G.2 expressed their interest in receiving more sessions. In the T.G.1, patients also reported to practice PMR + GI exercises at home, at their own initiative. Most patients suggested that both interventions should include more sessions, and that the number of sessions should be defined according to an initial personalized evaluation. In the T.G.2, it was also suggested that the room

where the sessions took place should have been more private, with no interruptions, and that H + GI should be included in the hospital standard DFU treatment.

Intervention effectiveness

As a result of both treatment groups, patients reported physical, psychological, behavioral, and interpersonal changes. All participants, except one from the T.G.1 saw improvements in the DFU evolution, associated with stress reduction interventions. Other physical improvements were identified in the T.G.1, such as better blood circulation, ability to walk, and body balance, as well as in the T.G.2, such as better glycemic control, less pain, and breathing control.

Psychological changes included feeling calm, weightless or relaxed, and more positive thinking, as reported by most patients of T.G.1 and the totality of T.G.2. In both groups, patients also mentioned improvements regarding the acceptance of the disease and sleep quality.

Participants from both groups noticed behavioral improvements related to interventions, specifically regarding adherence to self-care. One patient from T.G.1 also identified a significant positive progress in his alcohol addition problem. All patients from T.G.2, and most from the T.G.1, reported changes in their interpersonal relationships as they felt they were more patient and less offensive at home and with other close persons.

One patient from the T.G.1 told that sessions impact on him lasted about two or three days, and then started disappearing. Other patient from T.G.2 also expressed that the effect only lasted during the intervention sessions. Two patients, one from each group, referred that the sessions had a prolonged effect after the complete treatment. Finally, two other participants from the T.G.2 reported that the effect lasted from one session to another (three weeks) and that, even today, they feel a part of those effects.

Role of psychology in the DFU treatment

Most patients from the T.G.1, and half patients from the T.G.2, stressed the importance of psychological interventions for the DFU treatment, and mentioned the patient psychological condition as essential for the DFU healing process. The majority of patients from T.G.1 also referred that many patients may decline, psychological support due to some psychology related bias or prejudice.

Emotions and consequences associated with the DFU

Patients expressed some negative feelings associated with DFU. In the T.G.1, feelings such as sadness, revolt, and fear of amputation were identified, while, in the T.G.2, fear of amputation, distress, or trauma was mentioned. In both groups, most patients described their life when they were actively working and socially productive, emphasizing how important the professional dimension was to them, and how that changed after the emergence of a DFU.

Caregivers' themes and sub-themes

Interviews with family caregivers resulted in four main themes shared by both groups, although with some differences in the fourth time. Caregivers' first four themes were similar to the ones found with patients,

described above. T.G.1 yielded an additional theme designated promotion of self-care behaviors. Themes, sub-themes, and sample extracts are presented in Table 3.

Table 3
Caregiver's Themes, Sub-Themes, and Extracts

Themes	Sub-themes	Caregiver's Quotes
Perspectives regarding the intervention	Knowledge about the intervention	T.G. 1: <i>In the context of the diabetic foot, I was told by my father</i> (Caregiver 2, aged 43)
		T.G. 2: <i>I know very little</i> (Caregiver 1, aged 36)
	Usefulness	T.G. 1: <i>These sessions made him good. He got better, although I did not noticed a big difference</i> (Caregiver 1, aged 49)
		T.G. 2: <i>I think that it is very helpful because we have here a difficult patient that has improved</i> (Caregiver 2, aged 50)
	Need to have more sessions	T.G. 1: <i>I thought that the sessions made him feel good and that he needed more</i> (Caregiver 3, aged 55)
T.G. 2: <i>If he continued (the sessions), I think he would improve his health because he has a lot of pain</i> (Caregiver 2, aged 50)		
Improvement suggestions	T.G. 1: <i>It was four sessions, they were not many</i> (Caregiver 1, aged 48)	
	T.G. 2: <i>But I think that these sessions should be offered to him and other patients at the beginning (of treatment)</i> (Caregiver 2, aged 50)	
Intervention effectiveness	Physical changes	T.G. 1: <i>He told me that he noticed his blood pressure was lower</i> (Caregiver 2, aged 43)
		T.G. 2: <i>Now, the wound is healing a little bit, but it has been really worse</i> (Caregiver 1, aged 36)
	Behavioral changes	T.G. 1: <i>For example, he used to smoke and eat everything and now he does not. He used to eat cakes and drink coffees</i> (Caregiver 4, aged 60)
		T.G. 2: <i>Now, she does not do many of the things she did before. For example, we have a field and since this heel wound appeared she did not work there anymore</i> (Caregiver 1, aged 36)
	Psychological changes	T.G. 1: <i>I felt he was calmer, patient, more receptive</i> (Caregiver 1, aged 49)
		T.G. 2: <i>He is calmer! He has more patience. When he leaves this place, he goes more relaxed, and he is not always muttering</i> (Caregiver 2, aged 50)
Interpersonal changes	T.G. 1: <i>He is much better. Even with the children. My kids tell me "He is so much changed!"</i> (Caregiver 4, aged 60)	
<p><i>Note.</i> T.G. 1 = Treatment group 1 (progressive muscle relaxation with guided imagery); T.G. 2 = Treatment group 2 (hypnosis with guided imagery).</p>		

Themes	Sub-themes	Caregiver's Quotes
		T.G. 2: In the ambulance, he does not grumble anymore with the firemen (Caregiver 2, aged 50)
	Effect duration	T.G. 1: <i>Since he had no more sessions, I think his mood got worse</i> (Caregiver 3, aged 55)
		T.G. 2: <i>In the next days he was good. Even today, I notice some changes</i> (Caregiver 2, aged 50)
Importance of psychology in the DFU Treatment		T.G. 1: <i>I believe that people's psychological state helps in all aspects for their recovery</i> (Caregiver 2, aged 43)
		T.G. 2: <i>Because if I cut one finger, even if my family tries to support me, it is not the same thing as having a psychologist</i> (Caregiver 2, aged 50)
Emotions and consequences associated with the DFU	Fear and suffering	T.G. 1: <i>He is afraid of having to cut his foot. I told him they will cut it only as a last resort</i> (Caregiver 3, aged 55)
		T.G. 2: <i>At times, she went to the consultation and she was told that things were not going well. They scared her</i> (Caregiver 1, aged 36)
	Patient's routine	T.G. 1: <i>He is all day watching TV or in Facebook</i> (Caregiver 4, aged 60)
	Patient's unemployment	T.G. 1: <i>He is off work due to sick leave and he was used to work every day, even on Saturdays</i> (Caregiver 3, aged 55)
		T.G. 2: <i>Because a lot of patients have a work and have to support their families, and they start to think how will they support their families, right?</i> (Caregiver 2, aged 50)
	Caregiver's social activities	T.G. 1: <i>I have to stay at home all day. On weekends, who does not want to take a walk?</i> (Caregiver 4, aged 60)
		T.G. 2: <i>It is just me and him, and we cannot go out, right? (...) We do not have much interaction with others</i> (Caregiver 2, aged 50)
Promotion of self-care behaviors		T.G. 1: <i>I take my medication in front of him on purpose. Do you understand? To encourage him to do it</i> (Caregiver 3, aged 55)
<i>Note.</i> T.G. 1 = Treatment group 1 (progressive muscle relaxation with guided imagery); T.G. 2 = Treatment group 2 (hypnosis with guided imagery).		

Insert Table 3

Perspectives regarding the intervention

One caregiver from the T.G.1 said she knew muscle relaxation sessions, but none of the remaining caregivers had previous knowledge about the interventions. All caregivers considered that sessions were very useful and an important complement to the medical intervention, especially because they notice some differences in their family member.

Two caregivers from the T.G.1 and one from the T.G.2 told that their relatives needed between further sessions. Caregivers from the T.G.1 suggested that if sessions were implemented in a non-hospital setting, and the protocol included more sessions, the intervention would be more effective. On the other hand, one caregiver of the T.G.2 referred that if sessions were offered before the patient's first amputation, the intervention would be more useful.

Intervention effectiveness

As in both patients' treatment groups, caregivers described physical, psychological, behavioral, and interpersonal changes. All caregivers, except one from the T.G.2, detected improvements in the DFU healing. One caregiver from the T.G.1 also referred improvements in the blood pressure, while other caregiver from the T.G.2 said she noticed improvements in the patient's foot pain.

Most caregivers from the relaxation group told their family member was calmer, relaxed, and pacific. One of the caregivers from the hypnosis group also noticed their partner was calm, patient, happy, and less demanding or grumbler. Regarding behavioral changes, one caregiver from T.G.1 told that her husband stopped drinking, started smoking less, and was having a healthier diet while receiving sessions. Similarly, another caregiver said that, after completing the hypnosis sessions, her mother adopted more self-care behaviors such as resting her feet, and avoiding work on the field. Most caregivers from T.G.1 noticed the patient became more tolerant and considerate with them, while one caregiver from the T.G.2 stated her partner was much calmer when he had to wait for consultations, the ambulance, or even in the supermarket line.

Regarding the duration effects, two accounts from the T.G.1 indicated that the effect stayed over time, however, after the end of the intervention, the sessions effect started to disappear. Nevertheless, one caregiver from the T.G.2 reported that the effects were still visible at the present time.

Importance of psychology in the DFU treatment

Caregivers from both groups considered that the patients' psychological state was determinant to the treatment success. In the T.G.1, caregivers stressed determination and positive thinking, while one caregiver from the T.G.2 highlighted the importance of psychology to help the patient to accept the disease.

Emotion and consequences associated with the DFU

In both groups, caregivers mentioned the fear of amputation patients felt every time they went to a consultation, in part due to a lack of information shared by the medical team. According to the T.G.1 caregivers, the DFU had a significant impact on patients' routine, resulting in patients' inactivity, isolation, and depression. In both groups, caregivers reported that patients' unemployment and lack of social activities was a consequence of the DFU.

Promotion of self-care behaviors

Caregivers from the T.G.1 expressed that a major concern related to their role was ensuring patients attended their consultations or took the prescribed medicine on time. However, this category did not emerge in caregivers from the hypnosis group.

Discussion

Thematic analysis of participants' experiences revealed that all patients and caregivers who accepted to collaborate in this study, were satisfied and showed a positive opinion about the effectiveness of the two stress reduction interventions for psychological well being and DFU healing progression.

Interviews with patients yielded four key themes common and caregivers: (1) perspectives on the intervention, (2) intervention effectiveness, (3) the role of psychology in the DFU treatment, and (4) emotions and consequences associated with the DFU. Regarding the perspectives on the intervention, patients had never experienced relaxation or hypnosis sessions, but they reported that the sessions were satisfactory, beneficial, and important because they were good for their minds as a complement to medical treatment (T.G.1), and helped them to accept the complexity of DFU (T.G.2). Overall, caregivers had no previous knowledge about the interventions, considering sessions as very useful and an important complement to the medical intervention, especially because they notice differences in their family members. Interventions were well received by patients and perceived as effective by caregivers, indicating a high level of acceptability that will promote adherence to the psychological intervention if available in clinical settings/contexts.

Patients and caregivers reported some suggestions to improve the implementation of this type of intervention complementing medical treatment. All patients suggested a greater number of sessions defined according to an initial personalized assessment, and defend the existence of a private space for the sessions or, according to caregivers, that the intervention should be implemented in a non-hospital setting and should include more sessions. Importantly, this intervention should be available in an initial phase of treatment, essentially before the patient's amputation (T.G.2). These suggestions are extremely useful for informing decision-makers and hospital administrators.

Patients that received PMR + GI also reported practicing the intervention exercises at home, on their own initiative, thus denoting greater adherence to the sessions. Also, patients that received H + GI claimed that those sessions should be included in standard treatment for DFU, supporting its evidence-based beneficial clinical impact. [36] A substantial body of research has demonstrated the efficacy of hypnosis as part of the integrative treatment of many conditions that traditional medicine has found difficult to treat. [37] In fact, hypnosis has shown not only to reduce anxiety in medical conditions but also change physiological parameters, [38] being effective in the management of diabetes, including regulation of blood sugar. [23] Regarding wounds, hypnosis has been shown to be effective in reducing pain in children with burns, but not in reducing pain intensity or accelerating wound healing; [39] and was also effective in accelerating the healing of postoperative wounds. [40] Although, so far, no studies have shown the effectiveness of hypnosis in accelerating DFU healing, the opinion of patients and caregivers from the H + GI and PMR + GI groups shows that the sessions have been helpful at various levels of functioning in DFU patients.

Regarding the intervention effectiveness, patients and caregivers from both groups reported physical, behavioral, psychological, and interpersonal changes, associated with the two interventions. In addition to the evolution of the DFU, physical changes such as better blood circulation, ability to walk and body balance (T.G.1), better glycemic control, less pain, and breathing control (T.G. 2) were reported highlighting the benefits of these two types of psychological intervention in this population. [22, 25, 41, 24]

In terms of psychological changes, patients reported a feeling of calm, lightness or relaxation, more positive thinking, better sleep quality, and acceptance of the disease. These changes/ improvements in the mood state were also noticed by caregivers who felt their relative was calmer, relaxed, and peaceful (T.G.1), patient/tolerant, happy, and less demanding or grumpy (T.G.2). Psychological interventions don't only have positive effects in reducing negative emotions, but also may promote the development of a cognitive and emotional process of diabetes acceptance as a chronic disease, thus helping patients to cope with it.

Behavioral improvements were associated with adherence to self-care behaviors such as a foot rest and avoidance of farm work/gardening. One patient, even reported a reduction in alcohol and tobacco consumption, and a healthier diet – evidenced by the caregiver's statement. Changes in interpersonal relationships were also perceived by patients and caregivers, as patients reported feeling more patient and less offensive, and caregivers corroborated those changes. Foot ulcers in people with diabetes are associated with high levels of morbidity, with symptoms of anxiety and depression being the most prevalent. [8–9, 42–43] Therefore, understandably, psychological interventions had almost a direct, immediate positive effect and an indirect impact on medication adherence, empowering patients to engage in self-care behaviors, and boosting overall mood. [42]

Regarding the duration of the changes resulting from interventions, participants' opinions differed in both groups, ranging from effects that only lasted during the session to long-term effects after the end of the intervention. However, T.G.2 patients and caregivers reported longer effects, as most of them expressed that the effect remained over time, and was visible till the present moment. In fact, the use of hypnosis for the DFU treatment has been found to promote positive behavioral changes, with longer lasting effects. According to Kohen [44] 85% of patients that received hypnosis years ago reported prolonged feelings of pain relief as a result of self-hypnosis techniques. Wood and colleagues [45] demonstrated that the hypnotic intervention altered T-cell activity what may explain the longer effects hypnosis may have, regarding healing.

Most patients were aware of the importance of psychological interventions for the DFU treatment - reflecting a belief in the mind-body connection – although some patients may feel reluctant to participate in psychological interventions due to prejudice or shame, or even because they feel emotionally overwhelmed by the emotional consequences of the disease. Therefore, the moment when the intervention is made available is extremely important [42] Caregivers also highlighted the role of psychological status for successful treatments, determination, positive thinking (T.G.1), and acceptance of the disease (T.G.2), highlighting caregivers' awareness of the importance of psychological intervention to help the patient accept the disease. [46]

Patients, especially those from T.G.1, reported that DFU was a source of negative emotions and consequences, such as sadness, anger, revolt, and anguish, living with the fear of amputation and trauma, [8–9, 43] and dealing with the impossibility to work. Caregivers from both groups stressed the fear of amputation felt by patients. As previously suggested in the literature, [47] people with diabetes fear amputation worse than death. Thus, in the face of this negative emotionality, the role of psychological intervention is even more useful and relevant to improve the patient's general wellbeing, reduce symptoms of anxiety and depression, and stimulate emotional regulation [42] particularly when patients are unemployed, inactive, with their QoL compromised due the DFU. [43]

Regarding consequences associated with the DFU, caregivers highlighted the impact on the patient's daily life, resulting in inactivity, isolation, depression (T.G.1), unemployment and lack of social activities for the caregiver (T.G. 1 and T.G. 2), as shown by previous research [14–15]. This whole burden scenario is exacerbated when the patient is amputated, [48] which is probably why a caregiver suggested that the intervention should be provided to patients before the amputation surgery.

In addition to the four themes identical to patients, one more theme emerged from the caregivers' interviews, particularly (5) promotion of self-care behaviors, that refers to the demands of assuring patients' self-care behaviors, such as the concern to warrant patients attend appointments or take the prescribed medication at the appropriate time (T.G.1). However, this category was not visible in the caregivers of patients from T.G.2.

Overall, psychological interventions aimed to reduce levels of suffering, such as depression, anxiety, and stress, higher in patients with DFU, [8–9, 43] since these psychological factors negatively affecting wound healing [49–50]. In addition to the various positive and beneficial changes found in the behavioral, emotional, and interpersonal functioning of patients, psychological interventions had effects in improving ulcer healing in some patients, and in reducing symptoms of psychological morbidity in all patients. These results highlight the positive effects of both interventions (relaxation or hypnosis) on the patients' general emotional state, ulcer healing and general wellbeing.

Limitations

This study has some limitations that need to be acknowledged such as the number of patients and caregivers involved. Although the analysis of the interviews indicated a level of coherence regarding the emerging themes, the inclusion of more participants could provide more in-depth information. All psychologists who performed the stress reduction techniques were highly trained, but there might have been bias regarding the person of the therapist and therapist's gender that was not controlled for. Also, only patients from two hospitals in the north of Portugal were involved. Therefore, more studies involving more patients and caregivers from other hospitals are needed, in order to better understand the impact of stress reduction techniques on DFU healing and emotional wellbeing.

Implications for clinical practice

Psychological interventions should be included as standard treatment for DFU patients in addition to clinical/medical treatment. Both patients and caregivers reported a positive evolution and improvements in DFU healing during and after sessions. Patients and caregivers also reported psychological improvements after treatment. Thus, in addition to previous positive results from both relaxation and hypnosis training techniques in patients with DFU, [25] this study shows promising and encouraging results for decision-makers to implement a specialized psychological support/consulting service for DFU patients in multidisciplinary diabetic foot clinics.

As for the characteristics of the stress reduction interventions, future interventions should include more than four sessions, tailored to the patient's psychological assessment. In order to increase the benefits of such interventions, stress reduction techniques may also be taught so that patients may learn to practice self-relaxation and auto-hypnosis exercises, at home. To promote home practice on a daily basis, sessions could

be recorded and made available to patients who should be coached in self-relaxation and self-hypnosis, using a taped script or a smartphone application. Further research should assess the effectiveness of included post-hypnotic suggestions as an important part of scripts for self-hypnosis and self-relaxation.

Distressed caregivers may also be offered a support group to help reduce overload, especially among caregivers who care for patients who suffered an amputation, have a chronic illness, report physical symptoms and have been caregivers for several years. [48]

Future studies should address the dyad patient-caregiver, over time, and better understand how muscle relaxation and hypnosis promote QoL, adherence to medical treatment, and self-care behaviors so that a psychological intervention protocol may be created to answer patients' needs, as well the needs of informal caregivers, the medical team, and psychologists when caring for patients with a DFU.

Conclusion

The objectives of the stress reduction interventions were to reduce stress and increase psychological wellbeing and, consequently, promote the conditions that facilitate DFU healing. Overall, patients and caregivers were satisfied with both types of psychological interventions (progressive muscle relaxation and hypnosis) but reported lasting effects with hypnosis. A future goal will be to increase the number of sessions and analyze the impact of the number of sessions on patients with DFU. Four sessions were considered not enough for both patients and caregivers, but no information is available regarding the minimum number of sessions needed to see changes in the DFU healing process.

According to the results, both interventions were perceived by patients and caregivers as having a positive effect on patients' emotional wellbeing and DFU progression. Participants also suggested that psychological interventions could be included in the standard treatment for DFU, as a complement to medical/clinical protocol for DFU treatment, although they should be available early on, when the patient begins treatment in the first diabetic foot consultation. One possibility would be a stress reduction protocol that would include a careful psychological evaluation, as is common practice in other chronic diseases/ conditions, where patients with clinical stress should be referred to an individual/ group stress reduction intervention.

The deeper understanding of patients and caregiver's perspective on stress reduction interventions as adjuvant to standard medical treatment may also shed light on the mechanisms that are involved in the relationship between psychological stress, physiological stress, and DFU healing.

Abbreviations

DFU - Diabetic Foot Ulcer.

DM - Diabetes Mellitus.

H+GI - Hypnosis with guided intervention.

HADS - Hospital Anxiety and Depression Scale.

PMR+GI - Progressive muscle relaxation with guided imagery intervention.

PSS - Perceived Stress Scale.

QoL - Quality of Life.

RCT - Randomized Control Trial.

T.G.1 - Treatment group 1.

T.G.2 - Treatment group 2.

Declarations

Ethics approval and consent to participate

This study is in accordance with the Declaration of Helsinki and it was approved by the two hospitals where data collection took place [198/2018; 2018-205 (180-DEFI/179-CES)]. All participants signed an informed consent to participate in the study.

Consent for publication

The consent for publication was obtained by all participants.

Availability of data and materials

Requests for further details on the datasets can be submitted to the corresponding author (gracep@psi.uminho.pt).

Competing interests

The authors declare that they have no competing interests.

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Authors' Contributions

M.Graça Pereira was responsible for the study design, data interpretation and revising the paper critically for important intellectual content.

Susana Pedras was involved in the literature review and data interpretation.

André Louro and Alberto Lopes were responsible for data acquisition and data interpretation.

Margarida Vilaça was responsible for literature review, data acquisition, and data interpretation.

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