

Relax to Heal? Perspectives of Patients with Diabetic Foot Ulcers and Health Professionals on Relaxation Sessions for Wound Healing

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ABSTRACT

OBJECTIVE: To explore patients' and healthcare professionals' (HPs') perspectives on the suitability/acceptability of a relaxation intervention, its effects on patients' well-being and diabetic foot ulcer (DFU) healing, and its incorporation into the multidisciplinary management of patients with diabetic foot.

METHODS: This qualitative study was nested within a three-arm pilot randomized controlled trial. Patients with a chronic DFU received four relaxation sessions. Investigators then interviewed patients, physicians, and nurses involved with diabetic foot consultations. Interviews were audio-recorded, transcribed, and analyzed using thematic content analysis.

RESULTS: Five themes emerged from patient's interviews about the suitability/acceptability of the relaxation intervention: perceptions regarding the psychological intervention, distress, the relaxation technique, changes in the patient's life, and changes in DFU/contribution to healing. Three themes emerged from interviews with HPs: perceptions regarding relaxation, changes in the patient, and changes in DFU/healing. Regarding the feasibility of the relaxation intervention, three themes emerged for both patients and HPs: suggested modifications, stressors/difficulties, and impact of COVID-19 pandemic. The utility theme emerged only in HP interviews, with subthemes of patients' distress, psychological interventions, relaxation intervention, and integration of the psychologist in the team.

CONCLUSIONS: These findings provide evidence for the suitability/acceptability, feasibility, and utility of a relaxation intervention in diabetic foot consultations.

KEYWORDS: acceptability, diabetic foot ulcer, feasibility, healing, quality of life, relaxation intervention, suitability

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INTRODUCTION

Diabetic foot is one of the most serious complications of diabetes mellitus (DM), and it affects 40 million to 60 million people around the world;¹ every 30 seconds, a lower limb or a part of a limb is lost because of DM.² Diabetic foot ulcers (DFUs) are a source of distress that affects all areas of the patient's life—physical, psychological, social, and economic—resulting in a significant decrease in health-related quality of life (HRQoL).^{1,3-6} Patients with DFU report lower HRQoL than patients without DFU^{7,8} or patients who healed with conservative treatment.⁹

Patients with DFU report negative emotions associated with feeling a loss of control over their lives,^{10,11} difficulties in coping with becoming dependent on others to perform daily tasks,^{12,13} and fear of lower limb amputation.^{13,14} Stress, anxiety, and depression are associated with delayed wound healing, both directly through activation of the hypothalamus-pituitary-adrenal axis and the sympathetic nervous system and indirectly through the promotion of health risk behaviors.^{15,16} However, little is known about the effects of stress on the healing of chronic wounds such as DFU.^{15,17} Most studies that have assessed the effectiveness of stress reduction interventions have focused on acute wounds, in particular, surgical wounds, finding that these interventions support an improvement in healing.^{16,18}

Psychosocial interventions aimed at interrupting the physiological and behavioral pathways between stress and negative emotional symptoms may therefore impact DFU healing.¹⁹ The few existing studies have documented that relaxation reduces stress, anxiety, and depression levels; improves HRQoL in patients with type 2 DM;^{20,21} and improves wound healing in patients with chronic wounds.²² Consequently, it is important to assess

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the effects of stress reduction interventions and emotional distress on DFU healing.⁶

To address this gap in the literature, the researchers piloted an intervention of four sessions combining progressive muscle relaxation and guided imagery in patients with DFU in a randomized controlled trial (RCT). The present work is a qualitative study nested within the RCT that aimed to explore patients' and healthcare professionals' (HPs') perspectives on the suitability/acceptability of the relaxation intervention; its effects on patients' well-being, DFU healing, and HRQoL; and the integration of this adjuvant therapy into the multidisciplinary management team caring for patients with diabetic foot. The research team included HPs in this study because they have comprehensive knowledge about patients with DFU that allows triangulation of sources, and as prescribers of medical treatment, they are aware of the main barriers to and promoters of treatment success.

The specific aims of this study were:

- (1) To understand patients' and HPs' perspectives about the relaxation intervention;
- (2) To explore the contribution of the relaxation intervention to DFU healing and patients' well-being and HRQoL;
- (3) To evaluate suggestions for changes in the relaxation intervention to increase its feasibility;
- (4) To analyze the relevance of implementing a relaxation intervention in the diabetic foot multidisciplinary team; and
- (5) To determine whether the COVID-19 pandemic had an impact on the course and outcomes of the relaxation intervention.

METHODS

Design

The present qualitative study was nested within a three-arm pilot RCT of a psychological intervention.^{23,24} The protocol of the pilot RCT and its results are reported elsewhere. The pilot RCT had three assessment points: baseline, postintervention (2 months after baseline), and follow-up (6 months after baseline). The rationale behind this qualitative study focused on complementarity to enable the results of the pilot study to be better explained and understood.²⁵ According to the Medical Research Council,²⁶ this process evaluation, in addition to enabling assessment of the fidelity and quality of the implementation of a complex intervention, may also provide information about why the intervention works and how to optimize it to best benefit patients.

This study fits into the CONSORT (Consolidated Standards of Reporting Trials) guidelines for pilot trials²³ and the guidelines developed by O' Cathain et al²⁷ to maximize the impact of qualitative research in pilot RCTs. It aims to provide a better understanding of how this relaxation intervention can benefit patients with DFU and HPs

who care for them through qualitative data collection and analysis.

Participants

All of the patients who participated in this study met the inclusion criteria defined for the pilot RCT: 18 years or older, diagnosis of DM, diagnosis of DFU, presence of one or two active chronic ulcers (>6 weeks) at baseline, followed at the included three multidisciplinary diabetic foot consultation centers in the north of Portugal, and presenting significant levels of stress or anxiety or depression as assessed by the Portuguese versions of the Perceived Stress Scale²⁸ and the Hospital Anxiety and Depression Scale,²⁹ respectively. Exclusion criteria comprised having an active relapsed DFU at the time of the baseline assessment, having more than two active DFUs at the baseline assessment, chronic kidney disease stage 5 (end-stage kidney disease), diagnosis of psychosis or dementia, active oncologic disease, having undergone a solid organ transplant, and receiving psychological counseling at the time of the assessment.

Only patients allocated to the RCT experimental group, who completed the four relaxation sessions, were invited to participate in the present study. Patients received a total of four, 45-minute individual sessions over 8 weeks (once every 2 weeks) on the same day as their scheduled diabetic foot consultation. During these sessions, certified and trained psychologists, following a written protocol, coached the patients into diaphragmatic breathing using the Jacobson progressive muscle relaxation for 16 muscular groups—forearm, arm, upper forehead, eye, mouth, jaw and throat, neck, shoulder, chest, stomach, thigh, leg, and foot³⁰—with the exception of the foot with the DFU. The session also included guided imagery focused on DFU healing; the patient was asked to imagine the DFU as a dark area and the relaxation as a light associated with pleasant sensations healing the DFU foot. Whenever possible, these sessions were conducted in a quiet room with a comfortable armchair or bed with an adjustable backrest so that patients were not lying down.

The authors selected four typical cases of patients with neuropathic foot. Inclusion criteria were: loss of distal sensation, presence of neuropathic pain symptoms (eg, burning, tingling, electric shock), and distal pulses present. In addition, four typical cases with neuroischemic foot were defined by the criteria: previous diagnosis of peripheral arterial disease, presence of lower limb pain, absent distal pulses, and loss of distal sensations.^{31,32} These were considered cases of interest because the type of diabetic foot may have implications for patients' levels of distress (eg, presence of neuropathic pain vs absence of neuropathic pain)^{33,34} and the degree of DFU healing (eg, peripheral arterial disease is a major prognostic factor for healing).³⁵



Physicians and nurses involved in diabetic foot consultations who had provided DFU care to the patients included in this study were also invited by the researchers to participate in this qualitative study via interview on the same day as their respective patient.

Procedure

Before the interview began, patients and HPs were informed about the aims of the study and the voluntary nature of participation. They signed an informed consent form to participate that granted investigators permission to audio-record, transcribe, and analyze the interviews while ensuring the participants' anonymity.

After completing the postintervention assessment, a trained researcher who was not involved in the intervention interviewed the patients about their experience. Interviews were audio-recorded, transcribed verbatim by one of the team's researchers, and anonymized to safeguard the participants' identity and the confidentiality of the collected data.

The project was approved by the Ethics Committees of the Centro Hospitalar do Tâmega e Sousa (Ref. 199/2018; 32/2020), Centro Hospitalar Universitário do Porto (Ref. 206-18 [181-DEFI/180-CES]), and Hospital de Braga (Ref. 99/2020; 81/2021), as well as by the Ethics Committee for Research in Life and Health Sciences of the University of Minho (Ref. CEICVS 015/2019). This study was registered in ClinicalTrials.gov (NCT04652999). The data that support the findings of this study are available from the corresponding author upon reasonable request.

Measures

Sociodemographic and clinical questionnaire for patients with DFU. The researchers designed this questionnaire for the pilot RCT. It assesses several sociodemographic (eg, sex, age, marital and professional status, years of education) and clinical variables related to DM, diabetic foot, and DFU characteristics.

Medical Term Recognition Test.³⁶ This questionnaire assesses patients' health literacy levels. Participants were asked to tick only the words they were sure really exist from a list of 40 medical terms and 30 invented nonwords that intuitively sound like medical terms. The final score is the sum of all the correct answers. The adapted and validated version for the Portuguese population includes two distinct subscales: words and nonwords. Adequate health literacy is represented by a score of 35 or greater (of 40) in words and 18 or greater (of 30) in nonwords.³⁶ For words and nonwords, respectively, Cronbach α s were .92 and .83 in the Portuguese version and .88 and .87 in the present sample.

Sociodemographic and professional questionnaire for HPs. Investigators designed this questionnaire for this study. It assesses several sociodemographic (eg, sex,

age, marital status) and professional variables related to professional activity and work with patients with diabetic foot.

Interview guide. Researchers developed a semistructured interview script composed of open-ended questions for this study. The same interview script was administered both to patients with DFU who completed the relaxation sessions and to the HPs who provided medical/nursing treatment. The script was divided into five sections: The first section concerned perspectives about relaxation; the second asked about perceived changes in the patient's life and DFU as well as the contribution of intervention sessions to DFU healing; the third addressed the impact of the COVID-19 pandemic on effects/outcome; the fourth focused on potential changes to the intervention, namely, regarding the frequency, number, and length of sessions; and the last section asked about the utility of integrating this relaxation intervention into the multidisciplinary diabetic foot consultation. Each HP answered the script questions in reference to a particular patient.

Data Analysis

Descriptive statistics were performed using IBM SPSS Statistics (version 28 for Macintosh). The transcripts of the interviews were analyzed in the same order in which they were conducted, using a thematic content analysis technique³⁷ through NVivo software (QSR International; version released in March 2020).³⁸ This technique was chosen because authors adopted a post-positivist paradigm,³⁹ and thematic content analysis enables an in-depth and broad understanding of participants' perceptions about the event (ie, relaxation intervention) through a rigorous and systematic approach.³⁷ The process of coding transcripts into subthemes was inductive and performed independently by two coders who subsequently discussed the coding of subthemes and grouped them into themes. Higher-order domains were defined according to the study's aims.

RESULTS

Of the 21 patients allocated to the intervention group of the pilot RCT, 12 completed the four sessions of the relaxation program. However, data collection in the hospital was suspended because of the COVID-19 pandemic, so only eight patients were invited to be interviewed regarding their experience with the relaxation sessions. All of the invited patients agreed to participate. Thus, eight men with DFU as well as 11 HPs (six physicians and five nurses) who provided healthcare to patients with DFUs were interviewed (Tables 1 and 2).

Patients' Perspectives

Two higher-order domains that fit into the study aims were defined based on patient interviews: suitability/acceptability and feasibility (Figure 1).

Table 1. PATIENT SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS (N = 8)

Sociodemographic Variables	Postintervention Assessment		
	n (%)	Mean (SD)	Range
Sex: male ^a	8 (100.0)		
Marital status: married/cohabitating ^a	6 (75.0)		
Professional status: inactive ^{a,b}	8 (100.0)		
Monthly income: Less than minimum wage ^a	6 (75.0)		
Daily help with DFU care ^a	5 (62.5)		
Has transportation to the hospital ^a	6 (75.0)		
Means of transport used			
Personal	4 (50.0)		
Ambulance	2 (25.0)		
Public transport	2 (25.0)		
Have financial support for transportation ^a	2 (25.0)		
Inadequate health literacy ^a	4 (50.0)		
Age, y		63.63 (10.97)	48-79
Education level, y		6.63 (4.03)	4-16
Travel time between home and hospital, min		37.50 (27.52)	20-90
Distance between home and hospital, km		24.67 (16.44)	8-50
Clinical Variables			
Type 2 DM ^a	7 (87.5)		
Metabolic control: HbA _{1c} ≥ 6.5% ^a	6 (85.7)		
Comorbidities and chronic complications: n ≥ 4 ^a	7 (87.5)		
Medication: psychotropic medication ^a	0 (0.0)		
Type of diabetic foot: neuropathic ^a	4 (50.0)		
PEDIS—Sensation: 2 (loss of protective sensation) ^a	8 (100.0)		
Pain in DFU ^a	4 (50.0)		
First DFU ^a	3 (37.5)		
DFU from amputation ^a	1 (12.5)		
Previous amputation in lower limb ^a	3 (37.5)		
Healed DFU ^a	3 (37.5)		
New DFU ^a	2 (25.0)		
DM duration, y		21.38 (11.41)	7-38
DFU healing score ^{c,d}		6.50 (5.95)	0-19
PEDIS—DFU extension, ^a cm ²		0.24 (0.37)	0-10.50
No. of dressings/wk		3.88 (2.30)	0-7
No. of diabetic foot medical consultations since baseline		5.63 (2.33)	2-10

(continues)

Table 1. PATIENT SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS (N = 8), CONTINUED

Sociodemographic Variables	Postintervention Assessment		
	n (%)	Mean (SD)	Range
No. of diabetic foot nursing consultations since baseline		6.63 (1.92)	5-10

Abbreviations: DFU, diabetic foot ulcer; DM, diabetes mellitus; HbA_{1c}, glycated hemoglobin; PEDIS, perfusion, extent, depth, infection, and sensation.

^aReflects the number and percentage of “yes” answers to the respective question.

^bInactive includes unemployed and retired.

^cDFU healing score was assessed through Portuguese version of RESVECH 2.0 (Marques, 2015).

^dDFU healing score at baseline: mean, 11.38 (SD, 3.81)

^eDFU extension at baseline: mean, 4.16 (SD, 3.87)

Suitability/acceptability of relaxation intervention.

From the analysis of patients’ interviews, five themes emerged that addressed the suitability/acceptability of the relaxation intervention: perceptions regarding the psychological intervention, perception regarding distress, perceptions regarding the relaxation technique, changes in the patient’s life, and changes in DFU and contribution to healing.

Perceptions regarding the psychological intervention. Patients were aware of the importance of the psychological component in the healing process, reporting that “the psychological part is always very important, because if you let yourself go down and get discouraged, things get worse”^{*} and “When I ruminate that I was bad, I got even worse, really!” Nevertheless, patients also recognized that an associated stigma remains present in some individuals: “It is a seven-headed beast” and “I do not need psychology for anything, I am not silly, I am smart!”

Perception regarding distress. Patients experienced distress associated with their DFU, saying, “This is not a flu, it is not, it is not like breaking a foot.” Fear was very present in their discourse: “I was really scared.” Patients also showed distress regarding amputation: “I see one without his fingers, I see another without his foot, I see another without his leg... If I came here and they told me that I was going to have to cut my finger... I would leave here... I do not know what I would do!” After amputation, patients reported “We are a little bit discouraged with these things, and it is not easy.”

Perceptions regarding the relaxation technique. Patients did not have prior knowledge about relaxation. “It is a new thing for me, as it probably is for a lot of people.” However, they perceived positive effects such as feeling “relaxed,” “calm,” and “anesthetized” and stated “It feels like I was in heaven,” “more relieved in my head...more at ease,” and after the session, “I am laughing

^{*}Patient comments were translated by the authors from Portuguese into English and lightly edited by a third party for grammar and readability, making all efforts to preserve the original meaning.



Table 2. HEALTH PROFESSIONAL SOCIODEMOGRAPHIC CHARACTERISTICS (N = 11)

Sociodemographic Variables	n (%)	Mean (SD)	Range
Age, y		46.55 (10.41)	32-65
Sex: female ^a	8 (72.7)		
Marital status: married/cohabitating ^a	9 (81.8)		
Children ^a	7 (63.6)		
Have a chronic disease ^a	3 (27.3)		
Professional Variables			
Academic qualifications			
Master's/bachelor's degree	7 (63.6)		
Specialty	3 (27.3)		
PhD	1 (9.1)		
Professional activity			
Physician	6 (54.5)		
Nurse	5 (45.5)		
Medical specialty			
Endocrinology	3 (27.3)		
General medicine	1 (9.1)		
General surgery	1 (9.1)		
Orthopedics	1 (9.1)		
Medical-surgical nursing	1 (9.1)		
Community/public health nursing	1 (9.1)		
Working hours			
Fixed schedule	9 (81.8)		
Shift work	2 (18.2)		
Time since graduation, y		23.73 (10.58)	8-44
Professional experience, y		23.45 (10.58)	7-43
Duration of work at diabetic foot consultations, y		13.45 (8.80)	3-30

^aReflects the number and percentage of "yes" answers to the respective question.

and singing... I was in the clouds," "the day flows better." One patient reported that relaxation helped his blood circulation and increased foot sensation "because

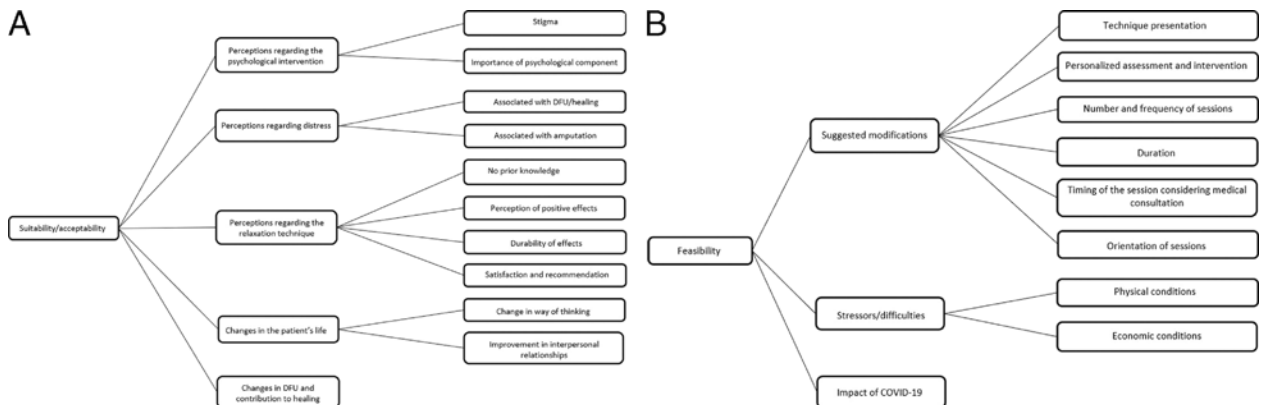
I had a leg catheterization [revascularization] and it did not turn out 100%, there was a vein [artery] here that was really all clogged up, even so I did not do anything else and [the wound] does not seem to be any worse, but now my foot feels more sensitive than before [the sessions]." Regarding the durability of the effects, "I have been feeling its impact over time" and started to attenuate "(2 days after the session) and then I started to relapse."

In general, patients were satisfied, saying, "I liked it, I liked it, I liked it a lot... I would do it again right now! I would do it today!" and "I am just satisfied, because I see that people and institutions are trying to innovate in order to give better conditions to patients." Some thought it was an "added value for the patient" and recommended this relaxation program to other patients with DFU: "For me, all patients should do this... they should go through these sessions."

Changes in the patient's life. Because of the relaxation intervention, patients were aware of changes in their way of thinking: "And one thinks positive... and I always thought about the wound. I thought because I wanted to get better... always. Always on the positive side, never on the negative side" and "I've forgotten a lot of that. You already lose the idea that it is going to be cut more this, cut more that." Some also reported an improvement in interpersonal relationships: "It improved a lot too [the relationship with his wife]."

Changes in DFU and contribution to healing. Patients perceived changes in their DFU: "The size has reduced almost, come on, 80%." However, some were cautious about the contribution of relaxation to DFU healing, saying, "It is logical that I do not know how long this wound would last if I did not have the relaxation... From what I did, I think there was a certain improvement...." One patient shared "I do not believe it is the session that will heal the wound.... It is [doctors and nurses] in there and the treatments.... What the sessions will help is going to

Figure 1. PATIENT INTERVIEW ANALYSIS RESULTS



be... almost a complement... That will ease our head, won't it? And we will, our body... will be more... open to healing...."

Feasibility of relaxation intervention. Three themes emerged regarding the feasibility of the relaxation intervention: suggested modifications, stressors/difficulties, and the impact of the COVID-19 pandemic.

Suggested modifications. Patients thought they should receive "more detailed information" regarding the technique, particularly by the HP who knows them better than the research team. Patients suggested that assessment and intervention should be personalized to patients' symptoms and profile, because this "depends from person to person."

Regarding the number, frequency, and length of sessions, opinions diverged. Some participants thought the number of sessions was enough, but some wanted more: "At least two, three times a week... But, if it was once a week, I think it would already be very good!" and "if it were a little longer it would not be bad." Regarding the timing for the relaxation sessions, patients reported that they would go to the hospital to receive the sessions even if they had no medical consultation. However, they preferred the sessions to occur the same day as their medical appointment "because it is two in one." The session should take place before the medical consultation.

Participants felt that the psychologists adequately guided the sessions face-to-face: "Things were always done well, I think." However, one patient claimed that he could not relax alone at home because "my head turns all over the place," suggesting an alternative format may be beneficial: "Maybe online would work, by video call or even by phone."

Stressors/difficulties. Patients commented on the physical conditions during relaxation. For example, "the place is not suitable... Sometimes you are concentrating, but you hear the noise passing by... and you get distracted." Another suggested that "a room in dim light with very quiet music will be awesome!" Participants also noted that the chair was uncomfortable and "a comfortable armchair or bed" would be better. One patient was worried about getting a parking ticket, and another said, "I come by taxi and the driver would sometimes get angry for waiting longer... and it would also cost me more."

Impact of COVID-19. The sessions were conducted in a post-COVID pandemic period, and most patients thought that COVID did not interfere with the way sessions were conducted. Some patients reported that these sessions helped them more during COVID.

Health Professionals' Perspectives

Researchers defined three higher-order domains that fit the study aims: suitability/acceptability, feasibility, and utility (Figure 2).

Suitability/acceptability of relaxation intervention.

From the analysis of HP interviews, three themes emerged that regarded the suitability/acceptability of the relaxation intervention: perceptions of relaxation, changes in the patient, and changes in DFU/healing.

Perceptions of relaxation. Some HPs had prior knowledge of relaxation techniques, including negative experiences, whereas others had no prior knowledge or experience. This study has a theoretical-empirical rationale that was mentioned by some HPs: "If we reduce the levels of anxiety, of cortisol, of adrenaline, I think for sure that will have an influence on the healing process, eventually." Moreover, "by being more relaxed they will also... be more receptive to the teachings that we give them, and they will assimilate this information better... when they receive the information, they can modify their behavior so that the wound has a good evolution."

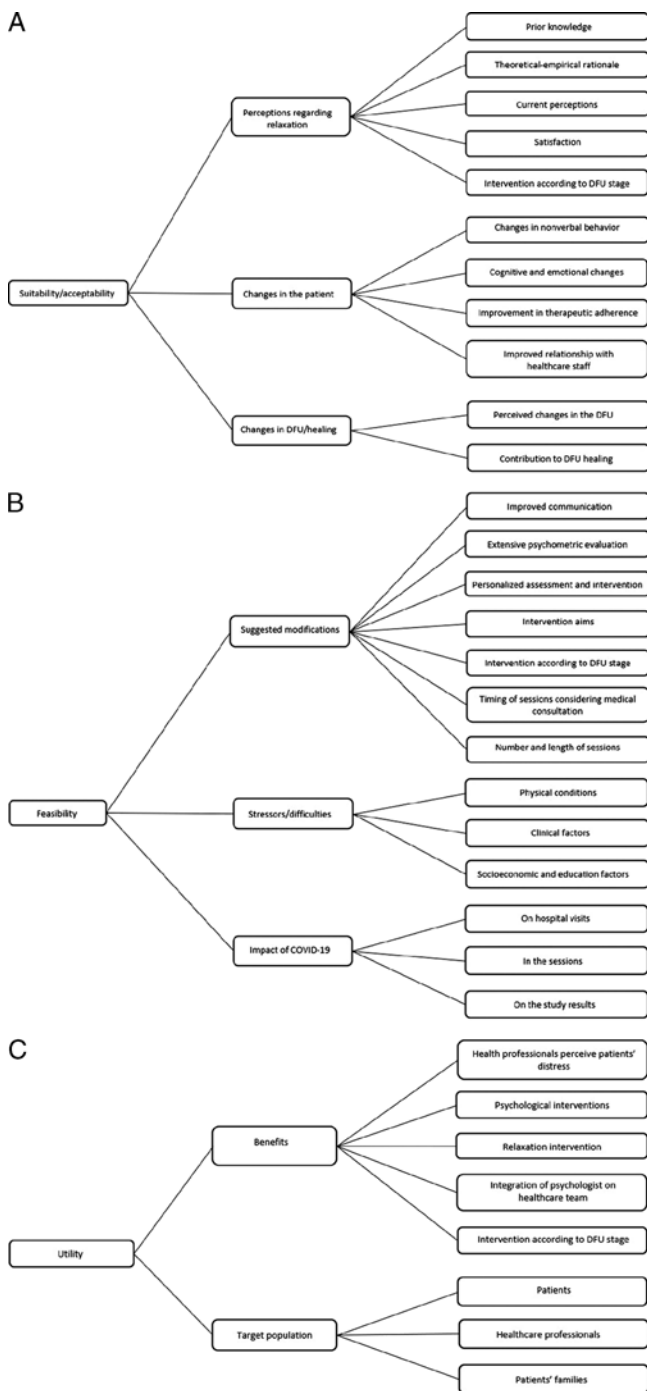
The HPs perceived the relaxation intervention as important, "an added value." Also, HPs reported that patients were satisfied with the intervention: "Those who did participate were grateful for the intervention and I think, at least some of them, actively told me that it was something they would like to continue." They also perceived satisfaction in patients' families: "The wife I think noticed and was really pleased with all the care that was being given to her husband."

Changes in the patient. The HPs noticed changes in patients' nonverbal behavior: "He came in smiling... could look professionals in the eye;" "facial expression less contracted, no fear, more uninhibited;" and "more at ease." In terms of cognitive and emotional aspects, HPs felt patients improved, expressing views such as "he was more accepting of his health condition," "improvements in their self-esteem even and in how they understand their illness," and "I think it gave him hope toward a positive evolution... and even in terms of motivation for the future." Further, HPs perceived improvement in therapeutic adherence, saying, "He started to be calmer, he started to be more still, more rested, he ended up resting his feet more, he ended up following our guidelines more." The HPs felt that patients' relationships with healthcare staff also improved: "It was noticeable that he found it easier to communicate with us."

Changes in DFU/healing. The HPs noted changes in patients' DFUs, saying, "A great decrease of the... of the areas... with improvement also of the signs of infection." In terms of the contribution of the intervention to DFU healing, the HPs were almost unanimous: "I cannot say it was directly [from the sessions], but indirectly I am sure it was" and "I cannot tell you 'this was directly responsible for.' Now, as a whole, I think that yes, it was a very positive element."

Feasibility of relaxation intervention. Three themes emerged regarding the feasibility of the relaxation

Figure 2. HEALTHCARE PROFESSIONAL INTERVIEW ANALYSIS RESULTS



intervention: suggested modifications, stressors/difficulties, and impact of the COVID-19 pandemic.

Suggested modifications. Some HPs suggested improving communication, saying, “I feel the need for feedback, both on the screening diagnosis you [psychologists] make and feedback regarding the response in terms of the

patient’s perception.” Others complained about extensive psychometric assessment: “The questionnaire was very long, lots of questions... they stayed here for a long time and wanted to leave.”

The HPs further commented that assessment and intervention should be personalized: “Should be on a case-by-case basis, considering patients’ needs, attitude, DFU severity, and frequency of hospital visits.” Moreover, HPs proposed that intervention aims should include “maintenance” and “prevention” and that education should “try to clarify what it means to be chronic, what a problem of this type of condition is, and how [patients] are going to face it.” Interventions according to the DFU stage were also proposed and are depicted in Figure 3.

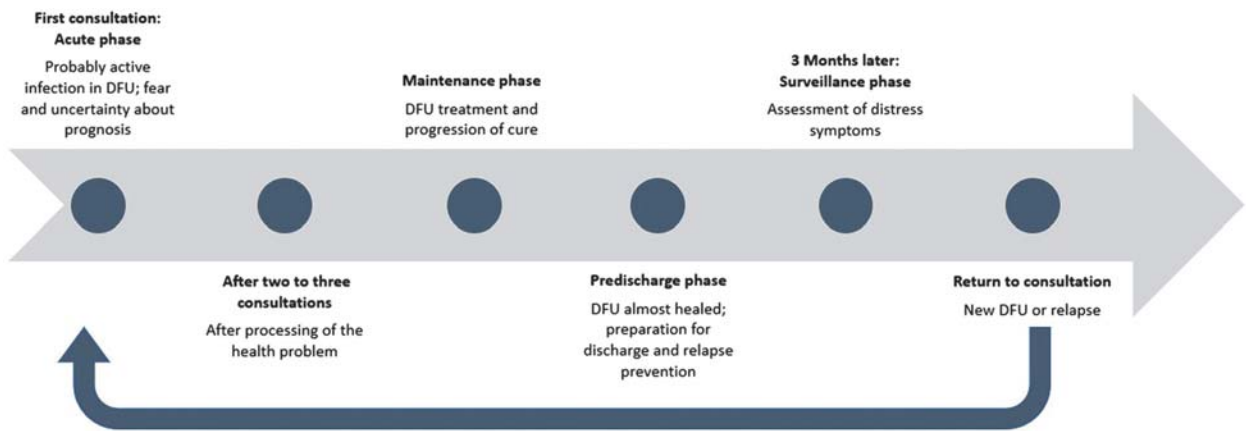
Regarding the timing of the relaxation sessions with respect to medical consultation, HPs were divided, saying, “I think it would be useful if the sessions were pre-consultation so that they [patients] go in there already with an adequate level of relaxation” and “I think the relaxation session needs to be after the consultation.” Finally, some HPs had no specific suggestions about the number or length of sessions but expected a dose-response effect: “We would probably expect that interventions offered more often with shorter time periods will have better outcomes.”

Stressors/difficulties. This theme had three aspects: physical conditions, because “we do not have an appropriate physical space for [this purpose];” clinical factors such as neuropathy, DFU recurrence, and other comorbidities; and socioeconomic and educational factors such as illiteracy, socioeconomic disadvantages, and concerns that the patients operate “without family support,” and “they have to come by ambulance, they depend on the help of others, it takes a long time to get here.”

Impact of COVID-19. The impact on hospital visits was mentioned, with HPs noting that at the beginning of the pandemic patients missed appointments: “If it was a wound that they considered small or not serious they missed the appointment.” However, “When it was a serious wound, they came, with COVID or without COVID... they were not afraid because they were very distressed, because they could lose their foot.” However, the HPs felt that the pandemic did not interfere with the course of the relaxation sessions, considering “I think that these sessions helped also with that [pandemic] because there was an additional stress.”

The HPs’ opinions regarding the potential impact of the COVID-19 pandemic on the results of the study also diverged. Some argued that “the potential could have been much more positive if it was not for this whole pandemic” and “obviously put a great deal of stress to the situation, a great deal of anxiety that probably exceeds the gradient [in which] we were trying to intervene.” Another considered “the anxiety levels may have gone

Figure 3. HEALTHCARE PROFESSIONALS' PROPOSED OPPORTUNITIES FOR STRESS REDUCTION INTERVENTIONS FOR PATIENTS WITH DIABETIC FOOT ULCERS



way up and skyrocketed... the results may even be better than what would be expected."

Utility of Relaxation Intervention. Two themes emerged from HPs' comments regarding the utility of the relaxation intervention: benefits and target population.

Benefits. Four aspects of this theme were defined: patients' distress perceived by HPs, psychological interventions, relaxation intervention, and integration of psychologists in the team.

The HPs perceived great levels of distress in patients with DFU: "A diabetic's fear is losing his legs, losing his feet," "they are all immensely depressed, overwhelmed, withdrawn, sad, full of medication, full of hospital appointments and with very little life of their own. And with a lot of abandonment and loneliness too... with a negative psychological burden, depressed, handicapped, full of fear of dying! In fact, a cloud accompanies them, a black cloud!"

Considering this distress, HPs argued that psychological intervention is "very important" to help these patients: "They are people with a huge burden of disease, with a huge adversity and they need someone to listen to them." They emphasized that relaxation, in particular, is an "added value" because "he is more relaxed, he listens to us better... We can carry out the treatment in better conditions," "This intervention and the possibility of having someone to help at the end or the beginning of the DFU treatment, to reduce anxiety and stress, I think is important, both for therapeutic adherence... and even for the physiological piece, perhaps, that is wound healing," and therefore, "I think that it should be a protocol, if possible, that should be implemented as a medium-term plan." For this purpose, it would be pertinent to include a psychologist in the multidisciplinary teams of diabetic foot consultations. The HPs commented, for example, "I think that integrating the psychologist in the consultations, a clinical health psychologist, would be extremely

important" and "it would greatly improve the care we give to these patients."

Target population. The HPs felt that the target population for the stress reduction intervention should be patients with high stress levels: "Patients who have more pain, the ischemic patients, and those who are on hemodialysis," "more serious cases, whose prognosis could be worse," and "the first consultations." The HPs also asked for relaxation for themselves, because "we have more stress than most patients" and noting "professionals have to be included, because if we are well, we help others better." Finally, they noted that patient's family members could be another target for this intervention: "We have very stressed family relatives."

DISCUSSION

Patients with DFU found the relaxation intervention to be acceptable and felt the psychological component was important. They reported being very distressed about having the DFU and having great fear of lower limb amputation. Previous research exploring the experience of living with DFU has found several symptoms of distress^{10,40} and reported that patients often fear amputation more than death.¹⁴ These factors might have contributed to a perceived need for psychological intervention. Patients accepted the sessions and reported several positive effects, such as greater well-being and easier performance of daily tasks. They stated that these effects were prolonged after sessions but attenuated with the passage of time. The literature suggests that although relaxation may provide immediate effects, practice will improve these outcomes in a dose-response effect,^{30,41} as some HPs mentioned. In general, patients were satisfied with the sessions and recommended them to other patients.

The HPs also considered the relaxation intervention acceptable/suitable and an important adjuvant to medical treatment based in a theoretical-empirical background.

Norman et al¹⁹ also noted the need for studies to evaluate theoretical informed psychosocial interventions in healing.

Both patients and HPs considered relaxation to be an “added value” that promoted positive change (both self-perceived and perceived by others). Patients confirmed that they changed their way of thinking: they began to have a more positive outlook regarding their DFU and to think about amputation less. It is possible that the guided imagery being focused on DFU healing, with patients imagining the DFU decreasing in size as the healing was taking place during the relaxation, may have fostered a sense of personal control over the DFU and hope for future healing. This is in accordance with HPs’ perceptions of patients who received the intervention. Some authors have suggested that, as a more cognitive approach to relaxation, imagery can benefit patients who are feeling a loss of control over their lives or hopelessness,^{10,11} helping to decrease those symptoms and promote patients’ HRQoL.⁴² Also, patients’ interpersonal relationships improved, particularly at home, and patients reported feeling calmer and less aggressive toward their family and friends.

The HPs, in turn, perceived changes in patients’ behaviors, emotions, and cognitions associated with relaxation, including positive impacts on patient adherence and their relationship with the healthcare team. As a result of the intervention, patients seemed to listen more to the HP, rested their feet more, and followed off-loading advice more frequently. Thus, the likelihood of engaging in health risk behaviors decreased, contributing indirectly to DFU healing, in line with previous literature.^{15,16} Both patients and HPs reasoned that the pathway from relaxation to healing is indirect; therefore, the relaxation intervention functioned as an adjuvant, helping to improve patient adherence and DFU healing.

Concerning feasibility, the same themes emerged from patients and HPs. Both groups thought that the assessment and intervention should be personalized, with an initial assessment preceding the sessions (as in this study) but that the number, frequency, and length of sessions should be based on assessment results and tailored to patients’ needs, attitudes, DFU severity, and hospital visits. Another study conducted in patients with DFU also found that patients expect HPs to be empathic and treat them as an individual and not as “another patient with DFU,”¹³ corroborating the results of the present study.

Although the patients in this study could visit the hospital for relaxation sessions in addition to their scheduled medical appointments, they recommended that scheduling sessions on the same days of the medical consultations was a good option, especially for those patients who live far away from the hospital. One patient proposed an alternative to overcome scheduling difficulties due to COVID, namely, conducting sessions through a

video call or telephone call. This option may also be implemented to overcome patient difficulties in traveling to the hospital and the noisy hospital conditions, which both patients and HPs reported being a barrier to relaxation. Some studies found that telephone interventions are effective in promoting foot care adherence because they offer flexibility with patients’ schedules and are inexpensive.^{43,44} This treatment option could be tested in a future pilot study.

In the HP interviews, participants offered interesting proposals, such as the suggestion to time the stress intervention according to patients’ DFU stage. The authors recommend that when treating patients with DFU, providers consider both these potential opportunities for intervention, as well as the aims of intervention (ie, stress reduction; relapse prevention; education about diabetic foot, chronicity, DFU, and coping skills). Because HPs reported that most patients had low educational attainment and showed health illiteracy, a psychoeducational approach⁴⁵ tailored to patients’ level of comprehension⁴⁶ and socioeconomic constraints would be pertinent to improve adherence and outcomes.

The COVID-19 pandemic did not appear to have interfered with the course of sessions, but the sessions may have helped patients cope with the additional stress from COVID-19. Some HPs conjectured that COVID-19 may have led to worse results in this study, whereas others thought it may have improved the results.

The theme regarding the utility of the stress intervention emerged only in HP interviews. It is possible to conclude that HPs appreciate the importance of psychological interventions and, in particular, relaxation sessions for patients with DFU to help them to accept and cope with DFU-related distress and treatment setbacks. For this purpose, it is necessary to integrate psychologists in the multidisciplinary management of diabetic foot and DFUs.⁴⁵ Not only should patients be targeted for relaxation intervention (especially patients with severe pain or stress levels), but also HPs and patients’ family members to help prevent burnout and burden, respectively.

Limitations

The small sample size of this study requires caution when interpreting the findings. Patients in this study were treated at only three hospitals in the north of Portugal (although these are currently the most important hospitals with multidisciplinary foot consultations in this area), limiting generalizability. In addition, the COVID-19 pandemic emerged during the RCT data collection, which limited the number of patients included in the study. Finally, the relaxation intervention was not always conducted in the best physical conditions: it was difficult to control noise levels and room availability in a busy hospital setting. However, this is a qualitative study nested in a

pilot RCT study, and all the participants who completed the four relaxation sessions and were invited to participate provided relevant information to guide the performance of a future definitive RCT.

CONCLUSIONS

The findings of this study provide evidence of the acceptability/suitability, feasibility, and utility of the relaxation intervention. Therefore, a future definitive RCT should consider the suggested modifications provided by patients and HPs to test the effectiveness of the relaxation intervention on DFU healing. Future studies should also consider the reported stressors/difficulties and plan alternative ways to overcome them and test other formats of delivering the intervention such as video or telephone calls.

Psychological support and relaxation interventions should be included in the DFU care provided to patients, considering their reported distress and its influence on therapeutic adherence and, indirectly, on DFU healing. The authors recommend that healthcare institutions prioritize the integration of psychologists in multidisciplinary DFU care teams. ●

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