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Educational Interventions on Diabetic Foot Self-Care: A Study Protocol for a Pragmatic Randomized Controlled Trial

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ABSTRACT

Diabetic foot is one of the most serious complications of diabetes and foot ulcer recurrence has been associated with poor foot care. Educational programs may work as a vehicle for promoting knowledge and adequate foot self-care behaviors, reducing potential ulcerative complications in the diabetic foot, and promoting a better quality of life. This study protocol will analyze the impact of two different educational strategies – an instructive video (Experimental Group 1) compared to a foot care leaflet with real-time guided reading (Experimental Group 2) and standard care (Control Group) – on adherence and knowledge about diabetic foot care and patients' perception of their foot health. This study is a Pragmatic Randomized Controlled Trial of a non-pharmacological treatment. Participants need to have a diabetic foot diagnosis and attend a Diabetic Foot Multidisciplinary Consultation at two hospitals from the North of Portugal. Participants will be assessed at the first appointment of the diabetic foot consultation (T0), two weeks after (T1), and three months later, at follow-up (T2). Primary outcomes will be adherence and knowledge about diabetic foot care and general foot health. Secondary outcomes will be illness representations regarding diabetic foot. The results of this study will inform educational interventions to decrease diabetic foot ulcers, amputation rates, and the costs associated with both, contributing to foot care adherence and improve patient's quality of life.

Introduction

Diabetes mellitus (DM) currently affects 537 million adults worldwide and it is expected that this number will rise to 643 million by 2030 (International Diabetes Federation [IDF], 2021). In Portugal, the most recent data estimates that 13.6% of the population have DM and 28% present pre-diabetes, representing an estimated cost between 1300 to 1550 million euros, i.e., 0.6 to 0.8% of Portuguese GDP and 7 to 8% of health expenditure (Raposo, 2020).

Poor metabolic control, over long periods of time, results in complications affecting multiple organs and systems (American Diabetes Association [ADA], 2021). One of the most serious complications of DM is the diabetic foot which, in Portugal, in the year 2018, was responsible for more than 1300 hospitalizations and 928 lower limb amputations (Raposo, 2020).

Adherence to foot care behaviors has a significant impact on the prevention of Diabetic Foot Ulcer (DFU) and this should be a priority given the harmful effect on the physical and psychosocial functioning of patients with DM (Bus & Van Netten, 2016; Joseph et al., 2010; Vileikyte et al., 2005).

The literature suggests several predictors of non-adherence to foot care, such as lack of knowledge of foot complications and feet sensation loss, due to neuropathy, resulting in a lack of awareness toward the severity of their condition and importance of foot self-examination (Coffey et al., 2019; Vileikyte et al., 2004), and health literacy (Al-Kaabi et al., 2015). Although patient education may improve health literacy, it is not considered a sufficient condition to change health behaviors (Abu Abed et al., 2014). Knowledge, in turn, has been suggested as one of the factors that may mediate the relationship between health literacy and health outcomes, such as adherence and control of DM (Berkman et al., 2011).

Studies conducted with DM patients revealed that the main sources of information to manage the DM were physicians and allied health professionals, as well as information leaflets (Burke et al., 2006; Zhang et al., 2020), internet, and the family (Burke et al., 2006), being positively associated with DM knowledge (Zhao, 2014). Particularly, in type 2 DM patients, the level of formal education, duration of DM, and education about DM foot complications have been associated with foot care knowledge and foot care behaviors (Li et al., 2014). In fact, a higher level of knowledge was significantly associated with higher adherence to positive self-care behaviors (Indrayana et al., 2019; Li et al., 2014) and the latter were associated to a better quality of life (Saleh et al., 2014). Also, illness representations were predictors of adherence to foot care and survival of patients with DFU (Vedhara et al., 2014, 2016).

Education programs are an important vehicle for promoting knowledge and self-care behaviors, potentially reducing diabetes complications and promoting a better quality of life (Bonner et al., 2016; Saltar & Sahar, 2020). Indeed, patient education is defined by the American Family Physician (2000) as "the process of influencing patient behavior and

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producing the changes in knowledge, attitudes and skills necessary to maintain or improve health (. . .) Effective patient education also ensures that patients have sufficient information and understanding to make informed decisions regarding their care."

Educational interventions concerning foot health have been conducted in several formats (e.g., face-to-face, lectures, booklets, video) and modalities (e.g., individual, family, group), with positive effects, namely in terms of foot health outcomes, knowledge about foot care, foot care activities and lower limb function (Saltar & Sahar, 2020; Stolt et al., 2020); but not all have the same level of effectiveness and few studies have assessed their real effectiveness. Some studies showed that the combination of audio-visual methods with leaflets regarding foot care (Rahaman et al., 2018), or face-to-face sessions with leaflets (Fan et al., 2014; Vatankhah et al., 2009) were effective. For example, a study with a single 20-minute individual face-to-face education session combined with a leaflet on foot care behaviors showed improvements in knowledge and the practice of diabetic foot care, in patients with type 2 DM (Vatankhah et al., 2009). Also, the visualization of how to perform foot care was significantly associated with increased frequency of foot care behaviors (Bell et al., 2005) and the video visualization was shown to be more effective than individual instructions (Anilvince & Rao, 2015) or written materials/leaflets in patients with DFU (Gravely et al., 2011; Wilson et al., 2010), suggesting that video-based education might be particularly advantaged when the content is procedural. Nonetheless, take home written materials the patient may review, as needed, may also promote long-term retention of new information and improve later recall, resulting in better adherence to self-care behaviors (Wilson et al., 2010).

Literature on health communication proposes the adoption of a patient-centered communication style by health professionals (Epstein, 2000), where care is provided considering patients' individuality, information needs, and emotions (Epstein & Street, 2007). Clinical information should be given according to patients' level of understanding and, thus, a "one size fits all" approach is not adequate (Carrard et al., 2016; Epstein & Street, 2007; Joseph et al., 2010). In this case, face-to-face communication, potentiating patients' participation in their own care and a better relationship with health professionals (Epstein & Street, 2007) has been associated with patients' higher satisfaction (Peltola & Isotalus, 2020; Wanzer et al., 2004). In type 2 DM patients, proximal outcomes such as agreement, trust, and motivation were mediators in the relationship between patient-centered communication and adherence behaviors/health outcomes (Brown & Venetis, 2022).

Health communication, using leaflets and/or video, proposes the presentation of standardized content regarding health messages. Meppelink et al. (2015) found that the adoption of non-difficult messages and illustrations led to the best-informed decisions, in older adults with low health literacy. Moreover, given the need for effective messages to promote healthy behaviors adoption in DM patients, Gardner and Leshner (2016) suggested that the narrative delivery style and the referencing of patient's family members or caregivers are mechanisms that increase persuasion by decreasing patients' reactance. These mechanisms can be incorporated in videos that also encompasses several stimuli such as images, text, and sound, and may be particularly useful in patients with low health literacy (Claros Gómez & Cobos Pérez, 2015; Tuong et al., 2014), which might explain their effectiveness. In fact, delivering health messages through a video is considered a beneficial intervention that help patients make informed decisions about screening and treatment promoting adherence to medical recommendations (Winston et al., 2018). Interventions that use at least a technology tool (e.g., video, phone, smartwatch, mobile app, online portal), for several purposes including educational information or a follow-up education reinforcement were shown to be effective in reducing the recurrence of DFU and improving self-care behaviors (Obilor et al., 2022). Therefore, video-based information tools should be integrated into healthcare delivery.

Regarding the specific characteristics of informational videos, systematic reviews suggest that those videos that only present verbal or graphical health information are commonly considered inadequate to change patient behavior; while videos that present real people performing specific behaviors are more effective (Abu Abed et al., 2014). In fact, this perspective of patient education through a video in which an individual executes the appropriate behaviors fits into the Social Cognitive Theory of Bandura (also known as behavioral modeling), which suggests that learning takes place by observing or imitating the behaviors of others (Bandura, 1978). One of the key points of this theory emphasizes the need for the models to be as similar as possible to the individual regarding sex, age or race, as well as belonging to a high power status (Sarafino & Smith, 2017). Also, the consequences regarding the individual behavior of the models are important for the observer to adopt or not the target behavior (Sarafino & Smith, 2017). Thus, when the individual model is reinforced for its behavior, it is more likely that the observer also adopts the same target behavior (Bandura et al., 1963b).

Symbolic modeling, such as watching a film or videotape, is almost as effective as watching, *in vivo*, a real-life model (Bandura & Mischel, 1965; Bandura et al., 1963a; Bandura, 1973), and as effective when several symbolic models are used (Bandura & Menlove, 1968). Video modeling has been associated with an increase in self-care behaviors facilitating the learning of new behaviors and should, therefore, be considered in the development of health-related education tools (Tuong et al., 2014).

Social Cognitive Theory will provide the framework for this study that will analyze the impact of an educational video in which patients and health professionals will show how to perform the appropriate diabetic foot care behaviors, comparing it with a leaflet with real-time guided reading versus standard care for diabetic foot. These two strategies were chosen as experimental groups, based on previous studies that found clear benefits in the promotion of foot care behaviors (Abrar et al., 2020), and also because these distinct educational strategies were already being implemented at the hospitals where data collection took place.

Considering that about 15–25% of patients with DM will develop a DFU in their lifetime (Vas & Edmonds, 2020); that DFU recurrence rates, even after successful cure, are around 40% within one year and 65% within three years (Boyko &

Monteiro-Soares, 2020; Schaper et al., 2020); and that a history of previous DFU is associated with a higher risk of DFU incidence, amputation, and mortality (Martins-Mendes et al., 2014); it is necessary to prevent DFU through the implementation of effective interventions that promote foot care. Such interventions will allow patients with DM and diabetic foot to acquire knowledge and adopt and/or change their foot care behaviors, in order to reduce the likelihood of DFU development and/or DFU recurrence and, consequently, reduce amputation rates. As a result, physical, psychological, family, social, and economic costs will decrease contributing to a better quality of life in patients with a DFU.

Objective and hypothesis

The aim of this Randomized Controlled Trial (RCT) is to analyze the impact of different educational strategies – an instructive video (Video Watching Group – experimental group 1) compared with a leaflet with real-time guided reading (Real-time Leaflet Reading Group – experimental group 2) and with standard care about diabetic foot (Standard Care Group – control group) – on adherence and knowledge about diabetic foot care, as well as on patients' perception of their general foot health, over time.

Due to the behavioral modeling and the characteristics of the video, particularly the models involved – patients and health professionals – who will demonstrate how to perform foot care behaviors with future positive consequences (e.g., plow the fields, play on the playground with grandchildren, etc.), it is expected that participants from the *video watching* group will show better adherence to diabetic foot care, higher levels of knowledge, and the perception of poor foot health than those from the *real-time leaflet reading* group, and both will present better health outcomes than the *standard care group*, over time.

Trial design

This study used an experimental design – Pragmatic Randomized Controlled Trial (RCT) of a non-pharmacological treatment (Boutron et al., 2017; Zwarenstein et al., 2008), since the aim is to find out whether, under routine care conditions, an educational intervention is able to change behavior. Concerning the intervention, it is a non-pharmacological treatment since the effectiveness of two educational strategies will be tested i.e. instructive video watching versus leaflet with real-time guided reading compared to standard care (Boutron et al., 2017).

This is a two-center RCT with three study arms and blocked stratified randomization. Participants will be randomized at a ratio of 1:1 for the two conditions – Video Watching Group or Real-time Leaflet Reading Group versus Standard Care Group – into blocks of variable size, multiples of two. This randomization will be stratified according to the hospital (hospital 1 versus hospital 2) and the presence or absence of active DFU.

This RCT has a superiority framework (Piaggio et al., 2012), since we expected that participants from the Video Watching group will show better adherence to diabetic foot care and higher levels of knowledge than those of the Real-time Leaflet Reading group, and both will present better outcomes than the Standard Care group, over time.

The development of the study protocol followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for pragmatic trials (Zwarenstein et al., 2008) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013). This protocol is described following the SPIRIT guidelines, and the SPIRIT schedule of the study is also presented in Figure 1. This study was registered at ClinicalTrials.gov (NCT04811989) on March 23 2021.

Materials and methods

Participants, interventions and outcomes

Study setting

Participants will be patients followed at two Diabetic Foot Outpatient Clinics from the North of Portugal. The diabetic foot consultations are performed by a multidisciplinary team that included physicians (endocrinology, general and vascular surgery, orthopedics), nurses, and podiatrists. In one of the Diabetic Foot Outpatient Clinic, patients attending the first diabetic foot consultation watch an instructive video about diabetic foot care behaviors and receive face-to-face education on diabetic foot care during the medical consultation provided by both the physician and the nurse. At the other Diabetic Foot Outpatient Clinic, patients attending the first diabetic foot consultation receive face-to-face education on diabetic foot care during the medical consultation provided both by the physician and the nurse, and take home also a leaflet on diabetic foot care to read (standard care).

Eligibility criteria

To ensure the applicability of the intervention to the largest number of usual health care settings, a pragmatic RCT should, as far as possible, include participants to whom this intervention will be administered in the real world (Zwarenstein et al., 2008). The inclusion criteria are: being over 18 years old; diabetes mellitus diagnosis and presence of diabetic foot defined as "infection, ulceration, or destruction of tissues of the foot of a person with currently or previously diagnosed diabetes mellitus, usually accompanied by neuropathy and/or peripheral artery disease in the lower extremity" (Van Netten et al., 2020, p. 2); being assessed and followed in the Multidisciplinary Diabetic Foot Outpatient Clinic of the respective hospitals. Exclusion criteria will include illiterate patients, those with clinical dementia described in the patient's clinical record or cognitive disability that precludes patients from answering the questionnaires, as well as those with severe visual and/or hearing impairment.

The physician or nurse will recruit eligible participants prior to the medical consultation according to the medical records and referral to this consultation. The researcher will invite patients to participate and will administer the questionnaires, in an interview format, in the hospital consultation office, considering the age range of the sample, the level of education, and the presence of visual problems associated with

	STUDY PERIOD					
	Enrolment	Baseline Assessment	Allocation	Interven-tion	Post-interven-tion	3-month follow-up
TIMEPOINT	$-t_1$	t_0			t_1	t_2
ENROLMENT:						
Eligibility screen	X					
Invitation	X					
Informed consent	X					
RANDOMISATION:						
Allocation			X			
INTERVENTIONS:						
Video watching				X		
Leaflet with real-time guided reading				X		
Face-to-face teaching				X		
ASSESSMENTS:						
Adherence to the diabetic foot care behaviors		X			X	X
Knowledge of foot care		X			X	X
General foot health		X			X	X
Representations of diabetic foot		X			X	X
Foot pain		X			X	X
Foot function		X			X	X
Footwear		X			X	X
Clinical data		X				
Health literacy		X				
Sociodemographic data		X				

Figure 1. Standard protocol items: recommendations for interventional trials (SPIRIT) schedule.

DM. This will occur before patients watch the instructional video/real-time guided leaflet reading and before the first medical consultation where they will receive standard education on diabetic foot (T0 – first Multidisciplinary Diabetic Foot Consultation).

Participants will be allocated to Video Watching Group (Experimental Group 1)/Real-time Leaflet Reading Group (Experimental Group 2) or to Standard Care Group (Control Group; Figure 2).

The clinical information will be collected during the medical consultation.

Interventions

The educational strategies that will be implemented in each group are presented in Table 1.

The information provided in the video and leaflet includes general diabetes care, diabetic foot care, and footwear care. The information in the video is the same as in the leaflet. Face-to-face education is based on this same information. Both the video and the leaflet aim to improve adherence to diabetic foot care behaviors, reduce the relapse rate and prevent DFU.

Video watching group. Participants allocated to this group will watch, individually, in the presence of the researcher (in a hospital room), an instructive video on diabetic foot care and will receive face-to-face education on diabetic foot care during their consultation provided both by the physician and the nurse, according to the guidelines from Portuguese General Direction for Health (Portuguese General Direction for Health, 2010) and International Working Group on the

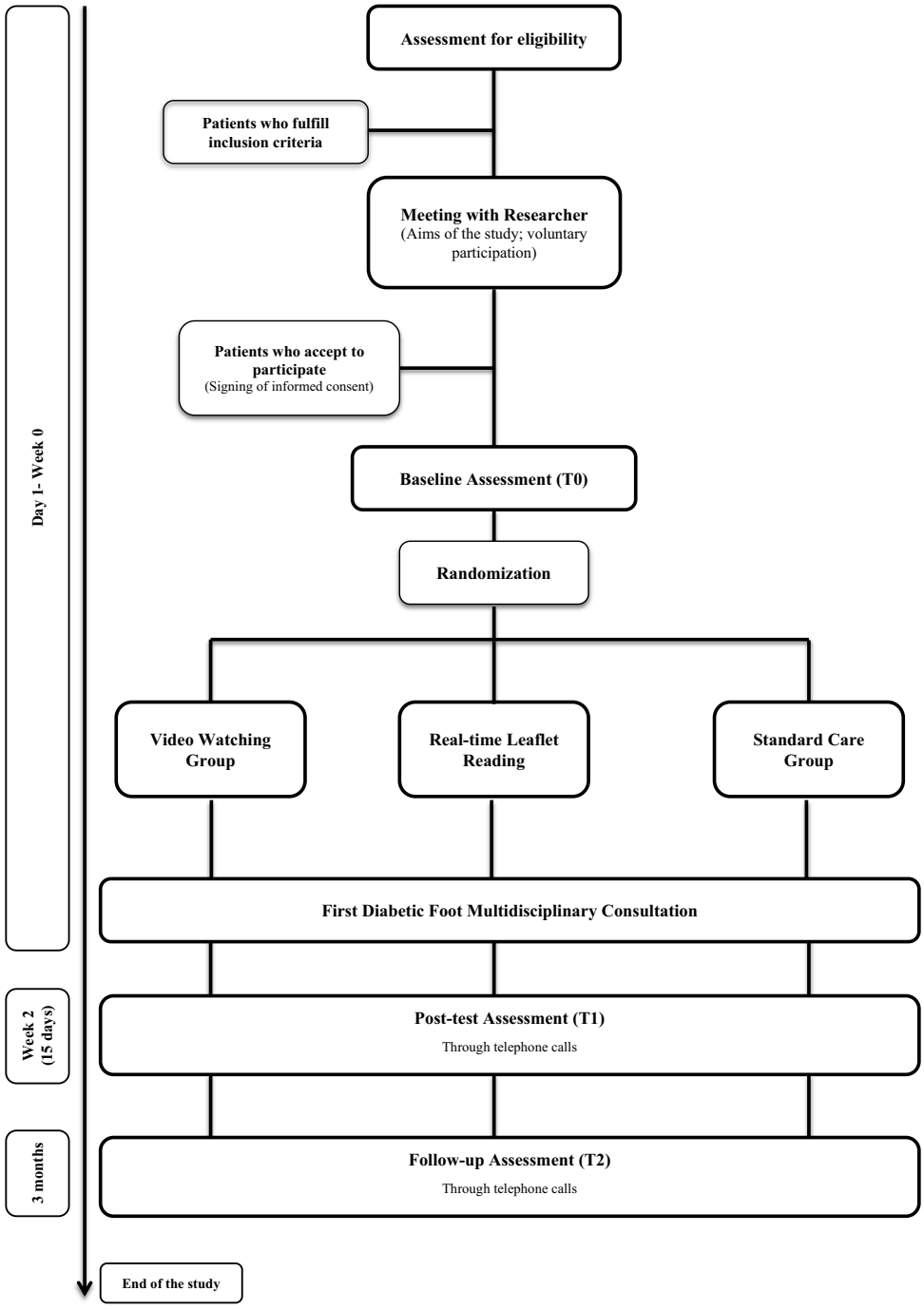

Figure 2. Diagram of the study plan.

Table 1. Educational strategies planned in each group of the RCT.

	RCT group		
Educational strategies	EG1	EG2	SCG
	Video Watching Group	*Real-time Leaflet Reading Group*	*Standard Care Group*
Face-to-face teaching	✓	✓	✓
Instructive video on diabetic foot care	✓		
Informative leaflet with real-time guided reading		✓	
Informative leaflet to read at home			✓

EG1 = Experimental Group 1; EG2 = Experimental Group 2; SCG = Standard Care Group.

Diabetic Foot (Schaper et al., 2020). The researcher will not answer the patient's questions after the video (the patient's questions will be addressed during the medical consultation). In the video, the information is presented verbally and appropriately captioned, as well as exemplified by real patients and health professionals from the hospital where data collection will take place (Dantas, 2018). The video lasts approximately six minutes.

Real-time leaflet reading group. The participants allocated to this group will receive a leaflet with diabetes foot care information. The researcher will guide the reading, individually with each patient, and patients will be allowed to ask questions and get answers in real-time. During the medical consultation, patients will also receive face-to-face education on diabetic foot care provided by the physician and the nurse. The leaflet includes foot care information in visible writing and some images on how to perform self-care behaviors.

Standard care group. This group will only receive the standard care that includes face-to-face education about diabetic foot care according to the guidelines from the Portuguese General Direction for Health (Portuguese General Direction for Health, 2010) and the International Working Group on the Diabetic Foot (Schaper et al., 2020), during the consultation that includes the physician and nurse and, at the end, will receive the take home leaflet on diabetic foot care to read. The researcher is not included in standard care.

Outcomes

Primary outcome measures. *Adherence to diabetic foot care* behaviors. Adherence to foot care behaviors will be assessed through the Nottingham Assessment of Functional Foot Care ((GISEF, 2020c; Lincoln et al., 2007). Composed of 29 items whose answers are given on a Likert scale ranging from 0 to 3. Higher scores correspond to a higher frequency of foot care behaviors. The original version showed a Cronbach's alpha of 0.53 (Lincoln et al., 2007) and 0.61 (Senussi et al., 2011), which was considered acceptable (Lincoln et al., 2007).

Foot self-care (an indirect measure of adherence) will be assessed through the subscale of the Foot Care of the Summary Diabetes Self-Care Activities Questionnaire (Bastos et al., 2007; Toobert et al., 2000). The subscale includes three items in which patients are asked how many of the last seven days did they perform the respective foot care behavior. Answers are given on a scale between 0 and 7, and its score is calculated through the mean number of days. Higher scores indicate higher levels of foot self-care. A Cronbach's alpha of 0.61 was found in the Portuguese version.

Knowledge on foot care. Knowledge on foot care will be assessed through the Questionnaire on Knowledge of Foot Care (GISEF), 2020b; Hasnain & Sheikh, 2009). Each correct answer is scored with 1 and higher scores indicate better knowledge about foot care. Data on the validity and reliability of the original instrument is not available (Hasnain & Sheikh, 2009).

General foot health. General foot health will be assessed through the respective subscale of the Foot Health Status Questionnaire (FHSQ; Bennett et al., 1998; (GISEF), 2020a). Scores are transformed into a scale of 0 to 100, where 0 corresponds to the perception of poor foot health state/condition and 100 to the perception of excellent foot health. In the original version, Cronbach's alpha was 0.88.

Secondary outcome measures. *Diabetic foot representations*. Representations about diabetic foot will be assessed through the Illness Perception Questionnaire – Brief (IPQ-B; Figueiras et al., 2010). The response scale ranges from 0 to 10. Higher scores indicate more threatening representations about diabetic foot.

Other measures. *Foot pain-* will be assessed through the respective subscale of the FHSQ (Bennett et al., 1998). Scores are transformed into a scale of 0 to 100, where 0 corresponds to significant or extreme foot pain and 100 to no foot pain or discomfort. In the original version, Cronbach's alpha was 0.88.

Foot function- will be assessed through the respective subscale of the FHSQ (Bennett et al., 1998). Scores are transformed into a scale of 0 to 100, where 0 corresponds to a severe limitation in the performance of physical activities because of feet limitations and 100 indicates no limitation. In the original version, Cronbach's alpha was 0.86.

Footwear- will be assessed through the respective subscale of the FHSQ (Bennett et al., 1998). Scores are transformed into a scale of 0 to 100, where 0 corresponds to severe problems with access to appropriate footwear and 100 indicates no problems. In the original version, Cronbach's alpha was 0.85.

Health literacy will be assessed through the Medical Term Recognition Test (METER; Paiva et al., 2014). The Portuguese version suggested that items are organized into two subscales: words and nonwords, whose Cronbach's alphas were 0.92 and 0.83, respectively. The Portuguese version also proposes a cut-off point of adequate health literacy for scores ≥35/40 in words and ≥18/30 in nonwords (Paiva et al., 2014).

Clinical data (e.g., HbA1c levels, presence/absence of active ulcer and duration of DFU, the recommendation to use therapeutic footwear) will be assessed through a clinical questionnaire developed for this study.

Sociodemographic data will be used to characterize the sample (e.g., age, marital status, gender, socio-economic level) based on a sociodemographic questionnaire developed for this study.

Participant timeline

The participants will be assessed before the first multidisciplinary diabetic foot evaluation (T0), about two weeks after the first assessment (T1), and three months after T0 in a follow-up assessment (T2). The T1 and T2 assessments will be carried out through the phone after the patients' consent.

The SPIRIT diagram of participant timeline was presented in Figure 1.

Sample size

A sample of 54 patients, 18 in each arm is sufficient to detect a clinically important 2-point difference in foot care adherence and foot health between groups (video watching/real-time leaflet reading/standard care), a standard deviation of 3.5 for each of the variables, using a test for bi-flow

differences between means with the power set at 80% and the significance level at 5%. Considering a dropout rate of 10%, the sample size required will be 60 patients (20 per group) (Sakpal, 2010).

Assignment of interventions

Allocation

After the T0 evaluation, participants will be randomized for the two conditions – Video Watching Group or Real-time Leaflet Reading Group versus Standard Care Group (Figure 1) – into blocks of variable size, multiples of two. This randomization will be stratified according to the hospital and the presence or absence of active DFU. This randomization procedure will be carried out using an online random number generator, by a researcher external to the team involved, in order to ensure the concealment of participants' allocation s in the several groups (Pandis, 2012). After this procedure, it will not be possible to conceal the group to which a patient was allocated to the medical and nursing team, since they must administer the standard care intervention and to the researcher in charge of informing the respective team and administering the Real-time Leaflet Reading Intervention Group. Only the participants will be blind to allocation, i.e., they will not be aware of the education formats that are being provided.

According to the group where the patient was allocated, the researcher will inform the patient that, he/she will watch a video about diabetic foot care or will be with a researcher that will read a diabetic foot care leaflet to him/her.

Statistical analysis

To characterize the sample regarding the sociodemographic and clinical characteristics, frequencies in percentage for nominal/ordinal variables; while the means and standard deviations for scalar variables will be presented, using SPSS (version 27).

Intention-to-treat analyses will be performed. For primary outcome measures, changes in adherence, knowledge, and general foot health mean scores, from T0 to T1 and to T2, between the three groups, will be analyzed. For secondary outcomes, changes in diabetic foot representations mean scores, from T0 to T1 and to T2, between groups, will be performed.

For all the hypotheses, statistical analyses will be carried out using the Generalized Mixed Models (SEM), which allow examining changes in the groups, over time, through the R statistical software.

Ethics and dissemination

Research ethics approval

The project has already been submitted and approved by the Ethics Committees of the Centro Hospitalar do Tâmega e Sousa (Ref. 47/2020) and Centro Hospitalar Universitário do Porto (Ref. 2020.230(182-DEFI/183-CE)); as well as by the Ethics Committee for Research in Life and Health Sciences from University of Minho (Ref. CEICVS 134/2020).

Consent

The researcher will inform patients about the aims of the study and the voluntary nature of their participation, inviting them to participate, and to sign an informed consent form. Participants are free to withdraw from the study at any time. In that case, all data collected will be destroyed (paper records) or deleted (database records).

Confidentiality

The data collected will be submitted to a pseudonymization process – the participant's name or identification will be transformed into a unique code assigned at the time of inclusion in the study, under the responsibility of the researcher, in order to make participants non-identifiable while data are being processed, with anonymization being fully guaranteed until the end of the study.

Dissemination policy

When the study is over, results will be presented to the ethics committees, as well as to all health professionals involved. In order to disseminate results to patients and health professionals, posters with the main results will be posted in the consultation wall as well as on the waiting room. The results will be published and presented in national and international journals and conferences.

Discussion

"Which educational strategy has the greatest impact on patient adherence and knowledge regarding diabetic foot care: An instructive video or a leaflet on foot care with real-time guided reading when compared to standard care of diabetic foot?." This is the question this study aims to answer and the results will guide health professionals about educational strategies required for foot care adherence in patients with diabetic foot.

Given the need for effective messages for DM self-care education (Gardner & Leshner, 2016) and based on the current strategies being implemented in diabetic foot outpatient clinics, this study was designed to assess their effectiveness. Grounded on behavioral modeling from the Social Cognitive Theory of Bandura, we expect that watching a video with real patients and health professionals from the patients' hospital, explaining and demonstrating the performance of foot care behaviors will have a more positive impact on patients' knowledge and adherence to these recommendations, than the other two strategies. In patients with low health literacy and when health behaviors implementation is concerned, a video intervention is considered more efficient than intervention modalities not focused on showing patients how to perform the appropriate behavior (Abu Abed et al., 2014; Anilvince & Rao, 2015; Tuong et al., 2014). However, there are few studies assessing the effectiveness of videos with the features of the one that will be

implemented in this RCT and, particularly, in patients with diabetic foot whose profile has very specific characteristics and is well established in the literature: a male patient, aged over 60 years, living alone, with poor education and not being professionally active, diagnosed with diabetes mellitus usually more than ten years ago and history of poor metabolic control (Neves & Penedo, 2015; Pedras et al., 2016; Ribu et al., 2007). The video in the experimental group 1 combines real models (patients, caregivers, health professionals) showing how to perform the adequate foot care, with a positive message at the end to motivate patients to adhere. Moreover, this study will test the video presentation against other two strategies: a more personalized patient-centered approach and standard care in order to help to clarify what is the best strategy to educate patients with diabetic foot.

As such, the implementation of this study will be very important for patients with diabetic foot, since all the target strategies will enable patients with DM and diabetic foot, as well as their caregivers, to acquire knowledge and foot care behaviors. At a broader level, a decrease in the likelihood of developing first or relapse DFU is expected and, consequently, reduced lower limb amputation rates and associated physical, psychological, family, social, and economic costs, culminating in better quality of life (Saltar & Sahar, 2020). Besides, the results will inform about the best strategy for health professionals to educate diabetic foot patients.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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Authors' contributions

All the authors participated in the concept and design of the trial, and data analysis plan. GF participated in drafting the manuscript. All the authors read, critically revised, and approved the final manuscript.

Trial Registration

ClinicalTrials.gov, ID: NCT04811989.

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