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ORIGINAL RESEARCH

Development of a customized booklet of foot-ankle exercises for people with diabetes mellitus as a management and prevention tool for musculoskeletal complications

A customized booklet of foot-ankle exercises for people with diabetes

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Diabetes mellitus;
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Health technology;
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Rehabilitation

Abstract
Background: Diabetes mellitus (DM) and diabetic peripheral neuropathy (DPN) compromises the structures of the musculoskeletal system, especially in the foot-ankle complex. Foot-related exercises can be a promising tool to be incorporated in health care programs to manage and prevent musculoskeletal complications resulting from DM and DPN progression.
Objective: To present the development, validation, and usability evaluation of a booklet that directs training and personalizes the progression of a home-based program of foot-ankle exercises.
Methods: The booklet containing a foot-ankle exercise program developed in a previous clinical trial was validated using the Delphi technique, with a multi-professional jury of experts who assessed the content of the material, language, individual education, exercise execution, exercise quality, and material implementation. The validated version was evaluated through telephone interview by a convenience sample of 10 individuals with DPN regarding its relevance, health education, comprehension, and usability.

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Results: The validation process with experts was performed in two rounds achieving 100% agreement in the second round. During the usability evaluation process the main complaint of users was that performing all the exercises was very tiring and took too much time out of their daily routine. Thus, the number of repetitions for each exercise was changed from 30 to 12.
Conclusion: The booklet is a material for prevention and management of the impacts of DM and DPN progression by improving the musculoskeletal function of the foot-ankle. This material provides an exercise regime with a personalized progression based on the perceived effort of the users.
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Introduction

In 2019, it was estimated that 9.3% of the adult world population was living with diabetes mellitus (DM) and the expectation is that the prevalence will increase to 10.2% by 2030.[1] Among the main complications of DM is diabetic peripheral neuropathy (DPN) that has a prevalence from 16% to 87% of the DM population.[2]

DPN compromises the structures of the musculoskeletal system, especially in the foot-ankle complex, leading to decreased strength of the extrinsic and intrinsic muscles,[3–7] decreased ankle range of motion,[8] and changes in the mechanical properties of the Achilles tendon.[9] These complications are responsible for some of the disabilities shown by this population, especially in mobility, due to changes in gait dynamics[10,11] and balance.[12] Additionally, loss of foot-ankle mobility is considered an important risk factor for foot ulceration.[13–15]

There is evidence of improvements in foot-ankle structure and function[16,17] and of changes in DPN symptoms[18,19] in individuals who performed foot-related exercises. Therefore, exercise can be a promising rehabilitation tool to be incorporated in health care programs to manage and prevent musculoskeletal complications resulting from DM and DPN progression. Recently, foot-ankle therapeutic exercises have become part of the international guideline recommendations to help mitigate risk factors and preventing foot ulceration in people at risk, although the quality of the evidence is still low.[20]

There are several resources that guide foot care and the importance of practicing regular physical activity.[21–24] Although feet are the most affected body segment by DM and DPN long-term complications, there are no specific material focusing on teaching foot-related exercises for deficits management and prevention. With the intention of incorporating the practice of specific foot exercises in daily lives, the development of an educational material to be used at home to motivate learning and provide guidance to people with DM is crucial.

The aim of this study was to develop, validate, and evaluate the usability of a booklet that, in addition to informing about DM and DPN, directs the training and customizes the progression of a home-based program of foot-related exercises targeting the main musculoskeletal impairments related to DM.

Methods

This study had two-phases: (i) booklet development; and (ii) validation of the booklet's content by experts and evaluation of its usability by users. All participants, both users and experts, were Brazilian and signed an informed consent form after agreeing to participate. The study was approved by the Research Ethics Committee of Universidade de São Paulo, SP, Brazil (CAAE: 90331718.4.0000.0065).

Booklet development

The booklet development included foot care recommendations and information about DM and DPN, and a customized program of foot–ankle exercises.

For the booklet layout, texts, photos, and color illustrations were included. Images and illustrations are strategies for representing and complementing textual language and are pedagogical resources that facilitate individuals' understanding.[25,26] Each exercise page has a description explaining how the exercise should be performed and contains photos to illustrate the exercise. The selection of the six foot exercises and the included progression parameters were based on a previous successful clinical trial.[18] Because the time spent to perform exercises interferes directly with the adherence to daily practice,[27] the number of exercises per session was set to be performed within 30 minutes. The exercises were selected to guarantee safety to the user while performing them at home and aimed at improving foot-ankle range of motion and strengthening the intrinsic and extrinsic foot muscles.

The progression of the exercises in the booklet was guided by the overload principle, which assumes the application of a progressive effort in the training sessions that overloads the musculoskeletal system, to cause a stress that exceeds the muscle's metabolic capacity.[28] The progression was established by increments in the training volume with increases in the number of repetitions within a set, in the number of sets, and in the load to be sustained during the exercise, i.e., exercises should first be performed sitting, then standing, and, in the last stage, standing on one foot.

Booklet validation and usability evaluation

The content validation of the Portuguese version of the booklet was performed through the Delphi technique by a jury of experts. The Portuguese validated version of the booklet was then evaluated by users with DPN to gather their opinions on its usability (**Fig. 1**).

Delphi technique and expert jury

The Delphi technique, with a jury of experts, was used to obtain consensus regarding the booklet. This technique has the advantage of keeping responses anonymous, allowing

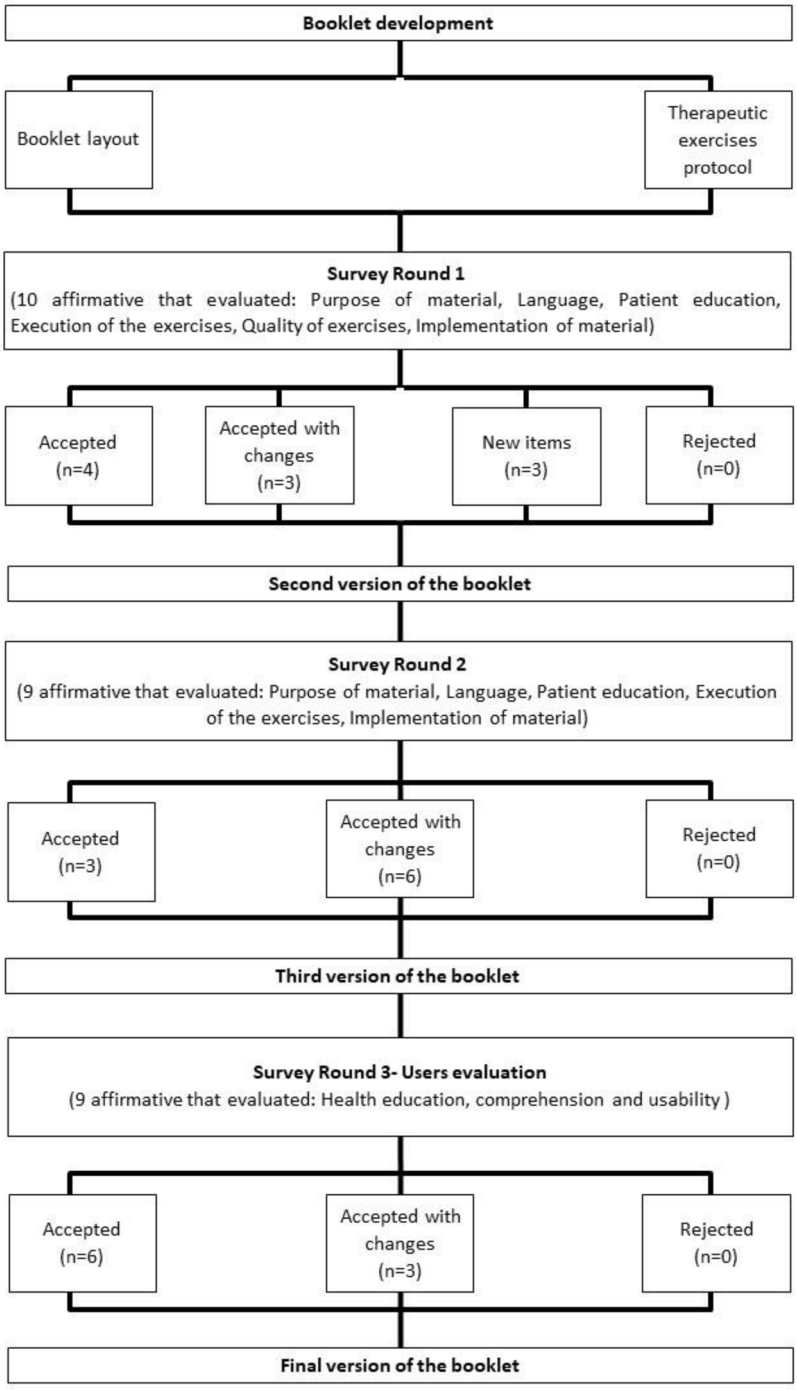


Fig. 1 Flowchart of the booklet development, validation process by specialists (first and second rounds) and evaluation process with users (third round).

experts' opinions to be heard and analyzed in several rounds, to improve the refinement process.[29] A broad analysis of the material required a multidisciplinary team of experts with clinical experience in the care of individuals with DM and/or practice in health education.

There is no established number of experts on the jury,[30] but studies indicate between 15 and 60 experts.[31] Fifteen experts, all Brazilian, were invited, but seven were not available to participate in all necessary stages of the study. Thus, eight experts (30—55 years) accepted the invitation and were included: an educator, a nurse, three physical therapists, a physical education professional, and two occupational therapists. For the experts selection, curricula were evaluated using an adaptation of the Fehring criteria (Fig. 2).[32,33] The experts were recruited with a minimum score of five out of 14 in the experts adapted scoring system.

The Delphi process was performed in two rounds. In the first round, the jury presented suggestions on the booklet layout and the exercise protocol. The suggestions were then analyzed and incorporated into the second version of the

Fehring criteria (1994)	Score	Adapted criteria	Adapted Score
Master's in nursing	4	**A.** Master's, courses or experience in continuous education related to diabetes	2
Masters in nursing: dissertation with supplementary material content relevant in the area	1	**B.** Dissertation with relevant content in the area	1
Research (published articles in the area of diagnostics)	2	**C.** Studies published on diabetes and/or its complications or relevant content	2
Article published in the area of diagnostics in a reference journal	2	**D.** Article published on diabetes and/or its complications in an indexed journal	1
Doctorate in diagnostics	2	**E.** Doctorate related to the issue or medical area	2
Clinical practice of at least one year in the field of clinical nursing	1	**F.** Experience of at least 1 year in caring for patients with diabetes and/or with a focus on prevention or foot care	4
Certified in clinical medicine with proven clinical experience	2	**G.** Experience (clinical, teaching or research) with a focus on rehabilitation, exclusive or not, of diabetes	2
Maximum Score	14		14

Experts	Age (Years)	Sex	Profession	Adapted criteria applied to the jury							Total
				A	B	C	D	E	F	G	
1	33	F	Physical therapist	2	1	2	1	2	4	2	14
2	55	F	Educator	2	0	2	0	0	4	2	10
3	41	F	Physical education professional	2	1	2	1	2	4	2	14
4	35	F	Physical therapist	2	0	2	1	2	4	2	13
5	30	F	Physical therapist	1	0	2	0	0	4	2	9
6	33	F	Nurse	2	0	0	0	0	4	2	8
7	52	F	Occupational therapist	1	1	2	1	2	4	2	13
8	42	F	Occupational therapist	1	0	2	0	0	4	2	9
MEAN	40.12	----------		11.25							

Fig. 2 Adaptation of the Fehring's content validation model applied to the expert jury and the scores of the eight experts. *F = Female*.

booklet. In the second round, the second version of the booklet was submitted to the same jury, and they were asked to inform if the material was approved or not.

Survey round 1 and 2 - validation by experts

In the first submission of the booklet, we prepared a structured questionnaire according to the Delphi technique.[34–36] The first round was performed between March to May 2015, when the specialists answered individually about statements related to: purpose of the booklet, language suitability to the target population, quantity and quality of the information, contribution of the foot-exercises to improve DM and DPN deficits, and motivation for daily exercise practice (Table 2). The experts gave each statement a score on a five-point Likert scale: strongly agree; agree; neither agree nor disagree; disagree; strongly disagree.

Experts opinions and comments regarding each item were grouped, and the ratings of each item were analyzed. The items were classified as accepted, accepted with changes, or rejected, using the consensus criteria based on previous

studies.[37] Items that at least 70% of experts indicated "strongly agree" and "agree" were accepted; items that this same percentage of experts indicated "neither agree nor disagree" were accepted with changes, and items that at least 70% indicated "disagree" or "strongly disagree" were rejected.[32,36,38] We also strongly recommended the experts to give suggestions and/or justifications for their answers. In this exploratory stage, all suggestions that were considered pertinent to the purposes of the booklet were incorporated, generating a second version of the booklet.

In the second round, performed between May to July 2015, we submitted a new structured questionnaire to the same experts explaining all changes and inclusions made, and we asked them to reassess the booklet, indicating whether they agreed (YES) or disagreed (NO) with the statement, in addition of asking for more comments and suggestions. For the second round, items that rated at least 70% in the jury's general opinion as "agreed (YES)" were accepted.

Survey round 3 - users' usability evaluation

The booklet was evaluated by a convenience sample of 10 Brazilian users from a larger randomized controlled trial,[39] all diagnosed with DM (average (range) time of diagnosis 17.7 years (2−37 years)) with a mean ± standard deviation DPN degree of 3.9 ± 2.9 (range 2.2−9.3). The DPN degree was determined based on the Decision Support System for the Classification of Diabetic Polyneuropathy (http://www.usp.br/labimph/fuzzy/), a software that uses a fuzzy linguistic model that considers three input domains: symptoms and tactile and vibratory sensitivities.[40,41] The software gives a score from zero to 10, with higher scores indicating more severe DPN. All the users presented low risk of ulceration according to IWGDF Guidelines on the prevention and management of diabetic foot disease.[42] The participants used the booklet for eight weeks, three times a week, and were interviewed by telephone between February to April 2020. The users scored, using a five-point Likert scale, nine affirmative sentences about: health education, comprehension, and usability (Table 2). Because round 3 is an evaluation step, and not a validation one as the previous rounds, the items that rated less than 70% approval (sum of "agree" and "strongly agree") were revised but not submitted to a new evaluation round.

Data analysis

Data were analyzed using descriptive statistics and the content validation index (CVI) for the first round.[43−45] A criterion of 70% consensus approval was used for all the changes implemented in the booklet.

Results

First version of the booklet

In the first version of the booklet, we included two characters to facilitate the communication with the reader through dialog balloons, to guide them about foot self-care and to clarify how the booklet works. In addition to the selected exercises, we included an introduction of the booklet content, explanations about how to use the booklet, important information about the disease, and recommendations for foot care.

A warm-up exercise through a self-massage was also included to prepare the user to perform the exercises (Table 1). Each exercise had six sublevels of progression (Fig. 3). This progression corresponded to an increase in the difficulty due to a change in the adopted posture (sitting, standing, standing on one foot), and within each posture, the volume of the exercise could be increased (one to two sets of 30 repetitions). The control and progression of the exercises was performed through the completion of a table, where the user, after performing an exercise, would qualify the exercise as "easy", "difficult / tired", or "hurt". Each category had a specific definition to guide the user in their choice and the table used a color feature to facilitate the identification of each criterion (Fig. 2). For each exercise and according to the user's performance, the most appropriate progression was indicated, which includes increasing, maintaining, or decreasing the training volume. For example, if the answer was "easy" to perform a certain exercise, then there was a recommendation to increase the training volume. If the exercise was classified as "difficult", the last sets of repetitions should be maintained, but if "hurt" was chosen, the advice was to stop doing this exercise for a day, but if pain persists, the user should seek a health service.

Validation and evaluation processes

Survey round 1- validation by experts

The general results for the first round showed that the experts agreed with 82.5% of the statements, they neither agreed nor disagreed with 11.25%, and disagreed with 6.25% (Table 2).

The average CVI of the first round was 0.82, which indicates that the first version of the booklet achieved satisfactory validation content.[46] However, for the 4th affirmative statement *("The material prepares the user with enough information to perform the exercises without the assistance of a professional"*) and for the 7th statement *("The explanation of how to use and complete the tables when performing the exercises guides the progression of the exercises sufficiently")* the CVI was 0.50 and 0.37, respectively. The remaining eight statements obtained CVI values above 0.80.

In general, there was a high approval rate for the first round, but as the jury made several suggestions, a second version of the booklet was developed. The exercise illustrations and guidance for recording practice and personalized progression were reviewed.

Experts considered that completing the progression tables was complex, so they suggested to transform the two tables into a single table. Also, the experts considered that the terms suggested for the user to define the feeling of performing the exercises (easy, difficult / tired, or hurt) should be changed because the expression "hurt" refers to a condition that suggests other complications that require medical attention and does not belong to the category of perceived exertion. They also suggested the inclusion of a Visual Analogue Scale (VAS). So, the VAS was included, with the words "easy", "difficult", or "very difficult", the numbers from 0 to 10, and the facial expressions that symbolize the degree of effort felt when performing the exercise (Fig. 3).

Table 1 Booklet validation - Therapeutic exercise protocol.

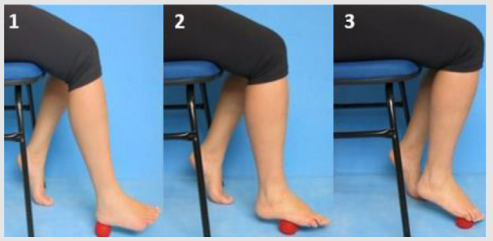
Name			Evolution	Execution	Aim
Warming Up	**Part 1**		-	**Part 1:** While sitting, cross one leg over the other and massage the sole of your foot with both hands **for 1 min**, sliding your fingers along your feet in circular movements. Repeat on the other foot.	Relaxation of the plantar muscles
	Part 2		-	**Part 2:** Place the ball on the floor and slowly roll your foot over it from the heel to the tips of your toes **for 1 min on each foot.** Make sure you can feel the ball pressing against your skin.	
	Part 3		-	**Part 3:** While sitting, cross one leg over the other and carefully twist one toe at a time from side to side like a screw, **10 times for each toe.** Repeat on the other foot.	Mobilization with accessory movements
Exercise 1			1.a. Sitting, 1 set of 30 repetitions. b. Sitting, 2 sets of 30 repetitions. 2.a. Standing, 1 set of 30 repetitions b. Standing, 2 sets of 30 repetitions. 3.a. On one leg, 1 set of 30 repetitions . b. On one leg, 2 sets of 30 repetitions.	**While sitting, with your feet flat on the floor**, raise the inner edge of your left foot without lifting your little toe off the floor and then the outer edge of your right foot without lifting your big toe. Now do both feet at the same time, but in the other direction, without lifting your little toe on the right foot and your big toe on your left foot. Once you have mastered this, do the same exercise **standing up** with your hands resting on a sturdy table or chair for support, and then progress to standing on one foot.	Improve foot-ankle mobility. Strengthening of foot inver-tors and evertors

Table 1 (*Continued*)

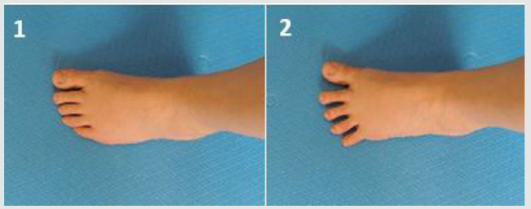
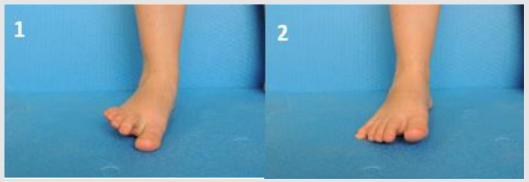
Name		Evolution	Execution	Aim
Exercise 2		1.a. Sitting, 1 set of 30 repetitions. b. Sitting, 2 sets of 30 repetitions. 2.a. Standing, 1 set of 30 repetitions b. Standing, 2 sets of 30 repetitions. 3.a. On one leg, 1 set of 30 repetitions, b. On one leg, 2 sets of 30 repetitions.	**With your feet flat on the floor**, slowly spread your toes as far apart as possible without lifting your heel off the floor. **Start off sitting down** and do one foot at a time, progressing to both feet at the same time once you feel confident. As your ability improves, progress to doing it standing up and then standing on one leg.	Improve foot mobility (metatarsophalangeal joints). Strengthening of the foot intrinsic muscles.
Exercise 3		1.a. Sitting, 1 set of 30 repetitions, b. Sitting, 2 sets of 30 repetitions. 2.a. Standing, 1 set of 30 repetitions, b. Standing, 2 sets of 30 repetitions. 3.a. On one leg, 1 set of 30 repetitions, b. On one leg, 2 sets of 30 repetitions.	With your heel on the floor and your toes raised, touch the ground first with your big toe and then your little toe in a slow controlled movement. **Start off sitting down** and do one foot at a time, progressing to both feet at the same time once you feel confident. As your ability improves, progress to doing it standing up and then standing on one leg.	Strengthening of the foot intrinsic muscles. Coordination training
Exercise 4		1.a. Cotton Wool, 1 set of 30 repetitions, b. Cotton Wool, 2 sets of 30 repetitions. 2.a. Ball, 1 set of 30 repetitions, b. Ball, 2 sets of 30 repetitions. 3.a. Pencil, 1 set of 30 repetitions, b. Pencil, 2 sets of 30 repetitions.	While sitting, grip the object with your toes, lift it off the floor and then release it. Do one foot at a time, keeping your heel on the floor throughout.	Improve toes mobility Strengthening of the foot intrinsic muscles.

Table 1 (*Continued*)

Name		Evolution	Execution	Aim
Exercise 5		1.a. Sitting, 1 set of 30 repetitions, b. Sitting, 2 sets of 30 repetitions. 2.a. Standing, 1 set of 30 repetitions, b. Standing, 2 sets of 30 repetitions. 3.a. On one leg, 1 set of 30 repetitions, b. On one leg, 2 sets of 30 repetitions.	Stamp your heel on the floor as fast as possible, as if you're impatient. **Start off sitting down** and do one foot at a time, then progress to doing the exercise standing up.	Improve ankle mobility Strengthening and endurance of the ankle muscles.
Exercise 6		1.a. Sitting, 1 set of 30 repetitions, b. Sitting, 2 sets of 30 repetitions. 2.a. Standing, 1 set of 30 repetitions, b. Standing, 2 sets of 30 repetitions. 3.a. On one leg, 1 set of 30 repetitions, b. On one leg, 2 sets of 30 repetitions.	**Start off sitting down,** with both feet flat on the floor, rise up and down on the tips of your toes. As your ability improves, progress to doing it standing up and then standing on one leg.	Improve ankle mobility Strengthening of the ankle muscles.

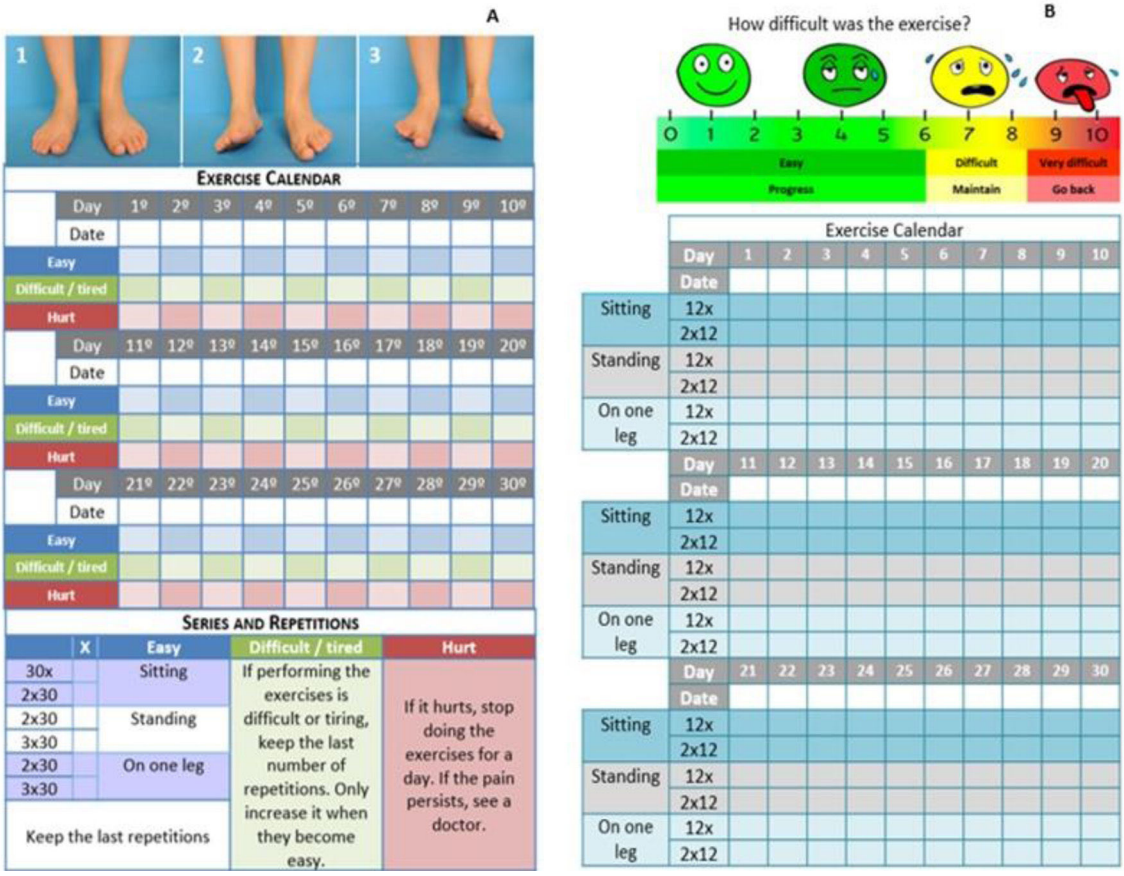


Fig. 3 Booklet table versions for exercise progression control. *A - First version (in the left) and B - final version (in the right).*

For the statements *"The language used to present the content that makes up the booklet is appropriate for the diabetes mellitus population"* and *"The way the exercises are described allows the users to properly understand how it should be performed"* the jury pointed out spelling and agreement errors, suggesting corrections and the inversion of the order of some information. The experts considered the language adequate, but because some words or phrases, such as "overload", "glycemia", "injury to the peripheral nerves", could lead to difficulties in the content's understanding by the user, changes were made.

Survey round 2- validation by experts

In the second round, 100% of the experts agreed with all the statements, meaning that they agreed with all the items and content of the booklet. As some suggestions were again made by the experts, even with a full consensus, these suggestions were incorporated. The jury suggested reversing the order of some information and replacing some words to improve the language and exercises descriptions.

Survey round 3 - users' usability evaluation

Ten users evaluated the booklet usability in the third round (90% women, 58.7 $\pm$ 3.9 years old), and they had different educational levels: 30% incomplete elementary school, 50% high school, and 20% higher education.

The target population used the booklet for eight weeks and concluded that the material explains in a simple way the complications of DM and DPN and the importance of self-care. However, all of them reported that they already had previous knowledge about the theme and that the booklet reinforced important information received from the health professional. They did not report any complaints of pain and stated that it was easy to understand how the exercises should be performed, and that the illustrations facilitated the adherence to the training. But the users also reported that performing all the exercises was very tiring and took a lot of time from their daily routine.

Among the 9 items evaluated, three had a rating approval below 70%. These were related to performance and exercise progression. Sixty percent of the users reported having difficulty performing 30 repetitions of the six exercises, being unable to finish the repetitions, and feeling very tired during the execution. To solve this issue, either they performed less repetitions, or fractionated the set in different days, and completed the total number in more days. To further improve the material, the number of repetitions was changed from 30 to 12.

The final version of the booklet was entitled "Foot and Ankle Exercises for People with Diabetes Mellitus" and presents 36 pages, including sessions that introduce the characters that present all the content to the users, sessions

Table 2 Overall results (in percentage) of the Likert scale applied to the two Survey Round: 1 - Validation by experts and 3 - Users' usability evaluation.

	Affirmative statements *Survey Round: 1 - Validation by experts*	**Agree**	**Strongly Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly Disagree**
1	The material is in accordance with the research objective.	50%	50%	0%	0%	0%
2	The language used to present the content of the booklet is suitable for the population with diabetes mellitus.	12.5%	75%	12.5%	0%	0%
3	The explanation for diabetic neuropathy and its deleterious consequences for the functionality of the feet provides all the information necessary for users to become aware of the importance of daily exercise.	50%	50%	0%	0%	0%
4	The material provides enough information for the user to perform the exercises without the assistance of a professional.	0%	50%	12.5%	25%	0%
5	The exercises contained in the booklet contribute to the reduction of the deficits caused by diabetic neuropathy in the function of the feet.	50%	37.5%	25%	0%	0%
6	The booklet provides the necessary information to carry out personalized training.	25%	62.5%	0%	12.5%	0%
7	The explanation of how to use and complete the tables when performing the exercises guides the progression of the exercises sufficiently.	0%	37.5%	37.5%	25%	0%
8	The material encourages the daily practice of the proposed exercises.	50%	50%	0%	0%	0%
9	The booklet favors the dialog between the person with diabetes and the health service that accompanies him/her.	75%	12.5%	12.5%	0%	0%
10	The booklet can be adopted by health services and offered as a frequent guide to the population.	62.5%	25%	12.5%	0%	0%

	Affirmative statements *Survey Round: 3 - Users' usability evaluation*	**Agree**	**Strongly Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly Disagree**
1	The information in the booklet allowed me to improve self-care strategies with my feet.	70%	20%	0%	10%	0%
2	The booklet motivated my daily practice of foot exercises.	40%	40%	20%	0%	0%
3	The explanations about how diabetes mellitus affects my feet are easy to understand.	70%	20%	10%	0%	0%
4	During reading, I could understand how to use the booklet.	70%	30%	0%	0%	0%
5	In general, the booklet layout is adequate.	80%	10%	10%	0%	0%
6	The guidelines and images are sufficient to carry out the exercises independently.	90%	10%	0%	0%	0%
7	The guidelines for filling out the exercise progression table are clear.	10%	50%	20%	10%	10%
8	I was capable of performing the required number of repetitions of each exercise.	20%	40%	20%	20%	0%
9	I was able to fill out the exercise progression table properly.	10%	40%	30%	20%	0%

with information about self-care and about DM and DPN, frequently asked questions, and the exercise session. The validated version of the booklet is available in Portuguese in the online supplementary material A. A translated version in English is also available as online supplementary material B but was not used in this study.

Discussion

The aim of this study was to develop, validate, and evaluate the usability of an educational booklet containing home-based foot-ankle exercises designed for people with DM and DPN that allows the customization of the training

progression according to individual effort perception. To achieve this, the developed booklet had its material content validated with a Delphi technique consensus by experts, and had its usability evaluated by users with DPN.

The booklet was developed and validated with a high degree of agreement between the experts, that also suggested changes that further improved the booklet. Among the main contributions were changes in the vocabulary to make the text simpler and understandable by the target population, and improvements in the table to control the exercise progression. The suggestions resulted in the reduction of the amount of text and in the use of images that made the material more attractive, strategies that have been used with success for people with low health education.[25,47] Studies point out that language could be a barrier to self-management of people with DM, because the lack of understanding about the disease and its complications brings adverse results in the control of the disease and its comorbidities.[48,49] The jury also suggested incorporating an informative session for health professionals, expanding the use of the booklet, that can be used as a guide for groups of people with diabetes in primary care, home-based treatment, or even individual sessions.

In the evaluation round, users did not complain about the language, however, they suggested changes in the number of repetitions of the exercises. In addition to comments by the users that the exercises were tiring, it was also pointed out that the time to complete all exercises was excessive, which became an obstacle for its inclusion in their daily routine. Because exercise protocols with eight to 12 repetitions are reported as sufficient to produce increases in both muscle strength and endurance,[50] the number of repetitions was decreased from 30 to 12.

Considering all the implemented improvements, we can conclude that the booklet is a didactic and intuitive tool that favors the daily practice of foot-ankle exercises. The use of the educational material by health professionals is also a way to remember the verbalized guidelines. It is not intended to replace professional activity, but rather serve as a resource that helps and complements their action.[51,52]

There is evidence that home exercises are effective.[53–55] On the other hand, to maintain the effects of home exercise programs, users must maintain exercise practice for a long time, and the adherence of older adults to home exercise interventions decreases over time.[56] Literature shows that patients who used educational materials changed their lifestyle,[57] improved their knowledge about DM, improved self-management, and improved their quality of life.[58] In addition, receiving written guidance on DM care made people improve their adherence to treatment, even six months after receiving the material.[59] Thus, it is possible to affirm that the use of the booklet is a continuous care strategy.

Self-management of diabetes aspects is a complex activity that requires the person with diabetes continuous attention and updates about psychological, social, economic, and behavioral factors interfering in their control of diabetes.[60,61] Thus, education for self-management is a key element as it provides guidance for people when making their health care decisions and carrying out their activities.[62,63] Contemporary educational resources, such as websites, apps, and digital platforms, have transformed the self-management process by using technology to facilitate care coordination and promote patient health literacy.[63,64] However, the use of such technological resources presents some barriers for those who are not comfortable with digital technology[65–67] or have social and economic limitations. Internet access also interferes in the technological tools' consumption, affecting those who are already vulnerable such as older adults, racial/ethnic minorities, and people with low income and education. Therefore, printed materials, such as the developed booklet, can be a safe option for self-management processes and education as they are more accessible to people of all ages and any income level, and do not require additional technological resources.[68,69] Health professionals can decide which is the best tool for the patient's treatment based on their level of adherence and preferences for a booklet or a software/app for self-care and personalized foot-ankle exercises.[32]

The booklet is a tool to complement the care provided by the health team and is not intended to replace the care provided by health professionals. It can be used in clinics, home care, and primary care, acting as a resource to raise awareness of the need for continuous foot-ankle care in people with diabetes. It is recommended that at the distribution sites the user should be trained and guided by a health care provider to fully understand the content of the booklet and perform the exercises properly.

Limitations of the study

The inclusion of the visual analogue scale, the language adaptation, and the inclusion of the session with foot care recommendations increased the number of pages of the booklet (18 front and back pages), making it an extensive material. It should be printed in colors, but color printing further increases the costs, which can make it more difficult to be distributed. Furthermore, new studies could expand the consultation to a greater number of users. The booklet was produced, validated, and evaluated in Portuguese only by Brazilians, so while an English version is provided, it was not assessed by the experts and users for the features related to language. Therefore, future studies are necessary for validation of the booklet for other countries and languages, including English.

Conclusion

The booklet was validated with a high rate of agreement among experts, and the usability assessment step performed by the users was essential for the improvement of the material. The developed booklet is an educational material for continuous health care, for improving foot-ankle musculoskeletal function, and intends to be a useful tool to prevent and manage the impacts of DM progression. The unique contribution of this material comparing to others available for this population is a regime of exercises with a customized progression based on the users' effort targeting the reduction of the primary musculoskeletal deficits in the foot-ankle region.

Conflicts of interest

The authors affirm that this study has not received any funding/assistance from a commercial organization that may lead to a conflict of interests.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.bjpt.2022.100402.

References

1. Saeedi P, Petersohn I, Salpea P, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: results from the International Diabetes Federation Diabetes Atlas, 9th edition. *Diabetes Res Clin Pract*. 2019;157:107843. https://doi.org/10.1016/j.diabres.2019.107843.
2. Sobhani S, Asayesh H, Sharifi F, et al. Prevalence of diabetic peripheral neuropathy in Iran: a systematic review and meta-analysis. *J Diabetes Metab Disord*. 2014;13(1):97. https://doi.org/10.1186/s40200-014-0097-y. Published 2014 Oct 15.
3. Bus SA, Yang QX, Wang JH, Smith MB, Wunderlich R, Cavanagh PR. Intrinsic muscle atrophy and toe deformity in the diabetic neuropathic foot: a magnetic resonance imaging study. *Diabetes Care*. 2002;25(8):1444–1450. https://doi.org/10.2337/diacare.25.8.1444.
4. Andersen H, Nielsen S, Mogensen CE, Jakobsen J. Muscle strength in type 2 diabetes. *Diabetes*. 2004;53(6):1543–1548. https://doi.org/10.2337/diabetes.53.6.1543.
5. Leenders M, Verdijk LB, van der Hoeven L, et al. Patients with type 2 diabetes show a greater decline in muscle mass, muscle strength, and functional capacity with aging. *J Am Med Dir Assoc*. 2013;14(8):585–592. https://doi.org/10.1016/j.jamda.2013.02.006.
6. Martinelli AR, Mantovani AM, Nozabieli AJ, et al. Muscle strength and ankle mobility for the gait parameters in diabetic neuropathies. *Foot (Edinb)*. 2013;23(1):17–21. https://doi.org/10.1016/j.foot.2012.11.001.
7. Henderson AD, Johnson AW, Rasmussen LG, et al. Early-stage diabetic neuropathy reduces foot strength and intrinsic but not extrinsic foot muscle size. *J Diabetes Res*. 2020;2020: 9536362. https://doi.org/10.1155/2020/9536362. Published 2020 Mar 12.
8. Giacomozzi C, D'Ambrogi E, Cesinaro S, Macellari V, Uccioli L. Muscle performance and ankle joint mobility in long-term patients with diabetes. *BMC Musculoskelet Disord*. 2008;9:99. https://doi.org/10.1186/1471-2474-9-99. Published 2008 Jul 4.
9. Guney A, Vatansever F, Karaman I, Kafadar IH, Oner M, Turk CY. Biomechanical properties of Achilles tendon in diabetic vs. non-diabetic patients. *Exp Clin Endocrinol Diabetes*. 2015;123(7):428–432. https://doi.org/10.1055/s-0035-1549889.
10. Allet L, Armand S, Golay A, Monnin D, de Bie RA, de Bruin ED. Gait characteristics of diabetic patients: a systematic review. *Diabetes Metab Res Rev*. 2008;24(3):173–191. https://doi.org/10.1002/dmrr.809.
11. Yi LC, Sartor CD, Souza FT, Sacco IC. Intralimb coordination patterns in absent, mild, and severe stages of diabetic neuropathy: looking beyond kinematic analysis of gait cycle. *PLoS ONE*. 2016;11(1): e0147300. https://doi.org/10.1371/journal.pone.0147300. Published 2016 Jan 25.
12. Brown SJ, Handsaker JC, Bowling FL, Boulton AJ, Reeves ND. Diabetic peripheral neuropathy compromises balance during daily activities. *Diabetes Care*. 2015;38(6):1116–1122. https://doi.org/10.2337/dc14-1982.
13. Monteiro-Soares M, Boyko EJ, Ribeiro J, Ribeiro I, Dinis-Ribeiro M. Predictive factors for diabetic foot ulceration: a systematic review. *Diabetes Metab Res Rev*. 2012;28(7):574–600. https://doi.org/10.1002/dmrr.2319.
14. Crawford F, Cezard G, Chappell FM, et al. A systematic review and individual patient data meta-analysis of prognostic factors for foot ulceration in people with diabetes: the international research collaboration for the prediction of diabetic foot ulcerations (PODUS). *Health Technol Assess*. 2015;19(57):1–210. https://doi.org/10.3310/hta19570.
15. Bus SA, Lavery LA, Monteiro-Soares M, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update). *Diabetes Metab Res Rev*. 2020;36(Suppl 1):e3269. https://doi.org/10.1002/dmrr.3269.
16. Allet L, Armand S, de Bie RA, et al. The gait and balance of patients with diabetes can be improved: a randomised controlled trial. *Diabetologia*. 2010;53(3):458–466. https://doi.org/10.1007/s00125-009-1592-4.
17. Cerrahoglu L, Koşan U, Sirin TC, Ulusoy A. Range of motion and plantar pressure evaluation for the effects of self-care foot exercises on diabetic patients with and without neuropathy. *J Am Podiatr Med Assoc*. 2016;106(3):189–200. https://doi.org/10.7547/14-095.
18. Sartor CD, Hasue RH, Cacciari LP, et al. Effects of strengthening, stretching and functional training on foot function in patients with diabetic neuropathy: results of a randomized controlled trial. *BMC Musculoskelet Disord*. 2014;15:137. https://doi.org/10.1186/1471-2474-15-137. Published 2014 Apr 27.
19. Kanchanasamut W, Pensri P. Effects of weight-bearing exercise on a mini-trampoline on foot mobility, plantar pressure and sensation of diabetic neuropathic feet; a preliminary study. *Diabet Foot Ankle*. 2017;8:(1) 1287239. https://doi.org/10.1080/2000625X.2017.1287239. Published 2017 Feb 20.
20. van Netten JJ, Sacco ICN, Lavery LA, et al. Treatment of modifiable risk factors for foot ulceration in persons with diabetes: a systematic review. *Diabetes Metab Res Rev*. 2020;36(Suppl 1): e3271. https://doi.org/10.1002/dmrr.3271.
21. Evans A, Phillips PJ. Patient Handout: diabetic Foot Care. *Med Today*. 2006;7:63–64. Accessed June 16, 2020; https://medicinetoday.com.au/sites/default/files/pdf/medicine_today/article/MT2006-06-063-EVANS-PH.pdf.
22. National Diabetes Education Program. *Take Care of Your Feet for a Lifetime: a Booklet for People with Diabetes*. 1st ed. National Institute of Diabetes and Digestive and Kidney Diseases; 2014.
23. Canada Wounds. *Brochure Clinician diabetes Healthy Feet and Your patients: How healthy are YOUR patients' feet?* 2017. Published. Accessed June 16, 2020; https://www.woundscanada.ca/docman/public/diabetes-healthy-feet-and-you/dhf-brochures/933-brochure-diabetes-healthy-feet-and-your-patients-en/file.
24. *NHS. North West Coast Strategic Clinical Network. Diabetes Footcare Pathway Blueprint*. 2017. Published online 2017:1-30; https://www.england.nhs.uk/north/wp-content/uploads/sites/5/2018/05/NWCSN_Diabetes_Footcare_Final_-Report_2017-1.pdf.

25. Meppelink CS, Smit EG, Buurman BM, van Weert JC. Should we be afraid of simple messages? The effects of text difficulty and illustrations in people with low or high health literacy. *Health Commun*. 2015;30(12):1181–1189. https://doi.org/10.1080/10410236.2015.1037425.
26. Ooms JA, Jansen CJ, Hoeks JC. The story against smoking: an exploratory study into the processing and perceived effectiveness of narrative visual smoking warnings. *Health Educ J*. 2020;79(2):166–179. https://doi.org/10.1177/0017896919867436.
27. Hancox JE, van der Wardt V, Pollock K, Booth V, Vedhara K, Harwood RH. Factors influencing adherence to home-based strength and balance exercises among older adults with mild cognitive impairment and early dementia: promoting Activity, Independence and Stability in Early Dementia (PrAISED). *PLoS ONE*. 2019;14:(5) e0217387. https://doi.org/10.1371/journal.pone.0217387. Published 2019 May 23.
28. HELLEBRANDT FA, HOUTZ SJ. Mechanisms of muscle training in man: experimental demonstration of the overload principle. *Phys Ther Rev*. 1956;36(6):371–383. https://doi.org/10.1093/ptj/36.6.371.
29. Dutt A, Tan M, Alagumalai S, Nair R. Development and validation of the ability in behavior assessment and interventions for teachers using Delphi technique and rasch analysis. *J Autism Dev Disord*. 2019;49(5):1976–1987. https://doi.org/10.1007/s10803-019-03887-4.
30. Powell C. The Delphi technique: myths and realities. *J Adv Nurs*. 2003;41(4):376–382. https://doi.org/10.1046/j.1365-2648.2003.02537.x.
31. Grisham T. The Delphi technique: a method for testing complex and multifaceted topics. *Int J Manag Proj Bus*. 2009;2(1):112–130. https://doi.org/10.1108/17538370910930545.
32. Ferreira JSSP, Sacco ICN, Siqueira AA, Almeida MHM, Sartor CD. Rehabilitation technology for self-care: customised foot and ankle exercise software for people with diabetes. Najafi B, ed. *PLoS ONE*. 2019;14:(6): e0218560. https://doi.org/10.1371/journal.pone.0218560.
33. Fehring RJ. Methods to validate nursing diagnoses. *Heart Lung*. 1987;16(6 Pt 1):625–629.
34. Paschoal LN, Souza PN, Buchalla CM, Brito CMM, Battistella LR. Identification of relevant categories for inpatient physical therapy care using the International Classification of Functioning, Disability and Health: a Brazilian survey. *Braz J Phys Ther*. 2019;23(3):212–220. https://doi.org/10.1016/j.bjpt.2018.08.006.
35. Chiarotto A, Ostelo RW, Turk DC, Buchbinder R, Boers M. Core outcome sets for research and clinical practice. *Braz J Phys Ther*. 2017;21(2):77–84. https://doi.org/10.1016/j.bjpt.2017.03.001.
36. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *J Adv Nurs*. 2000;32(4):1008–1015.
37. Paziana K, Timpano E, Stolbach A. Designing and implementing emergency department pain management curriculum: a Delphi approach. *AEM Educ Train*. 2018;2(2):121–129. https://doi.org/10.1002/aet2.10092. Published 2018 Apr 2.
38. Sumsion T. The Delphi technique: an adaptive research tool. *Br J Occup Ther*. 1998;61(4):153–156. https://doi.org/10.1177/030802269806100403.
39. Silva EQ, Suda EY, Santos DP, et al. Effect of an educational booklet for prevention and treatment of foot musculoskeletal dysfunctions in people with diabetic neuropathy: the FOotCAre (FOCA) trial II, a study protocol of a randomized controlled trial. *Trials*. 2020;21(1):180. https://doi.org/10.1186/s13063-020-4115-8. Published 2020 Feb 13.
40. Picon AP, Ortega NR, Watari R, Sartor C, Sacco IC. Classification of the severity of diabetic neuropathy: a new approach taking uncertainties into account using fuzzy logic. *Clinics (Sao Paulo)*. 2012;67(2):151–156. https://doi.org/10.6061/clinics/2012(02)10.
41. Watari R, Sartor CD, Picon AP, et al. Effect of diabetic neuropathy severity classified by a fuzzy model in muscle dynamics during gait. *J Neuroeng Rehabil*. 2014;11:11. https://doi.org/10.1186/1743-0003-11-11. Published 2014 Feb 8.
42. Schaper NC, van Netten JJ, Apelqvist J, et al. Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). *Diabetes Metab Res Rev*. 2020;36(Suppl 1):e3266. https://doi.org/10.1002/dmrr.3266.
43. Lynn MR. Determination and quantification of content validity. *Nurs Res*. 1986;35(6):382–385.
44. Alexandre NM, Coluci MZ. Validade de conteúdo nos processos de construção e adaptação de instrumentos de medidas [Content validity in the development and adaptation processes of measurement instruments]. *Cien Saude Colet*. 2011;16(7):3061–3068. https://doi.org/10.1590/s1413-81232011000800006.
45. Almanasreh E, Moles R, Chen TF. Evaluation of methods used for estimating content validity. *Res Soc Adm Pharm*. 2019;15(2):214–221. https://doi.org/10.1016/j.sapharm.2018.03.066.
46. Yusoff MSB. ABC of content validation and content validity index calculation. *Educ Med J*. 2019;11(2):49–54. https://doi.org/10.21315/eimj2019.11.2.6.
47. Murugesu L, Hopman ME, Van Voorst SF, Rosman AN, Fransen MP. Systematic development of materials for inviting low health-literate individuals to participate in preconception counseling. *Int J Environ Res Public Health*. 2019;16(21):4223. https://doi.org/10.3390/ijerph16214223. Published 2019 Oct 31.
48. Kitching JB. Patient information leaflets—the state of the art. *J R Soc Med*. 1990;83(5):298–300.
49. Holt RIG. Diabetes education, education and education. *Diabet Med*. 2017;34(8):1023–1024. https://doi.org/10.1111/dme.13399.
50. Medicine American College of Sports. American College of Sports Medicine position stand. Progression models in resistance training for healthy adults. *Med Sci Sports Exerc*. 2009;41(3):687–708. https://doi.org/10.1249/MSS.0b013e3181915670.
51. Clauson KA, Zeng-Treitler Q, Kandula S. Readability of patient and health care professional targeted dietary supplement leaflets used for diabetes and chronic fatigue syndrome. *J Altern Complement Med*. 2010;16(1):119–124. https://doi.org/10.1089/acm.2008.0611.
52. Moura DJ, Moura ND, Menezes LC, Barros AA, Guedes MV. Development of a booklet on insulin therapy for children with diabetes mellitus type 1. Construção de cartilha sobre insulinoterapia para crianças com diabetes mellitus tipo 1. *Rev Bras Enferm*. 2017;70(1):7–14. https://doi.org/10.1590/0034-7167-2016-0183.
53. Kim JY, Lee MK, Lee DH, et al. Effects of a 12-week home-based exercise program on quality of life, psychological health, and the level of physical activity in colorectal cancer survivors: a randomized controlled trial. *Support Care Cancer*. 2019;27(8):2933–2940. https://doi.org/10.1007/s00520-018-4588-0.
54. Hill KD, Hunter SW, Batchelor FA, Cavalheri V, Burton E. Individualized home-based exercise programs for older people to reduce falls and improve physical performance: a systematic review and meta-analysis. *Maturitas*. 2015;82(1):72–84. https://doi.org/10.1016/j.maturitas.2015.04.005.
55. Cyarto EV, Brown WJ, Marshall AL, Trost SG. Comparative effects of home- and group-based exercise on balance confidence and balance ability in older adults: cluster randomized trial. *Gerontology*. 2008;54(5):272–280. https://doi.org/10.1159/000155653.
56. Forkan R, Pumper B, Smyth N, Wirkkala H, Ciol MA, Shumway-Cook A. Exercise adherence following physical therapy intervention in older adults with impaired balance. *Phys Ther*. 2006;86(3):401–410.
57. Linton DN, Porteous J, Eatson H, et al. Educational booklet reinforces knowledge of osteoporosis and influences intentions to improve bone health in previously diagnosed and treated

patients. *Osteoporos Int*. 2020;31(9):1703—1711. https://doi.org/10.1007/s00198-020-05392-2.
58. Mohammadi S, Karim NA, Talib RA, Amani R. The impact of self-efficacy education based on the health belief model in Iranian patients with type 2 diabetes: a randomised controlled intervention study. *Asia Pac J Clin Nutr*. 2018;27(3):546—555. https://doi.org/10.6133/apjcn.072017.07.
59. Caetano IRCES, Santiago LM, Marques M. Impact of written information on control and adherence in type 2 diabetes. *Rev Assoc Med Bras (1992)*. 2018;64(2):140—147. https://doi.org/10.1590/1806-9282.64.02.140.
60. Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. *Diabet Med*. 2005;22(10):1379—1385. https://doi.org/10.1111/j.1464-5491.2005.01644.x.
61. Gonzalez-Zacarias AA, Mavarez-Martinez A, Arias-Morales CE, Stoicea N, Rogers B. Impact of demographic, socioeconomic, and psychological factors on glycemic self-management in adults with type 2 diabetes mellitus. *Front Public Health*. 2016;4:195. https://doi.org/10.3389/fpubh.2016.00195. Published 2016 Sep 12.
62. Powers MA, Bardsley J, Cypress M, et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *J Acad Nutr Diet*. 2015;115(8):1323—1334. https://doi.org/10.1016/j.jand.2015.05.012.
63. Beck J, Greenwood DA, Blanton L, et al. 2017 National standards for diabetes self-management education and support. *Sci Diabetes Self Manag Care*. 2021;47(1):14—29. https://doi.org/10.1177/0145721720987926.
64. Fatehi F, Menon A, Bird D. Diabetes care in the digital era: a synoptic overview. *Curr Diab Rep*. 2018;18(7):38. https://doi.org/10.1007/s11892-018-1013-5. Published 2018 May 10.
65. Jain SR, Sui Y, Ng CH, Chen ZX, Goh LH, Shorey S. Patients' and healthcare professionals' perspectives towards technology-assisted diabetes self-management education. A qualitative systematic review. *PLoS ONE*. 2020;15(8): e0237647. https://doi.org/10.1371/journal.pone.0237647. Published 2020 Aug 17.
66. Smith B, Magnani JW. New technologies, new disparities: the intersection of electronic health and digital health literacy. *Int J Cardiol*. 2019;292:280—282. https://doi.org/10.1016/j.ijcard.2019.05.066.
67. Benda NC, Veinot TC, Sieck CJ, Ancker JS. Broadband internet access is a social determinant of health!. *Am J Public Health*. 2020;110(8):1123—1125. https://doi.org/10.2105/AJPH.2020.305784.
68. de Oliveira SC, Lopes MV, Fernandes AF. Development and validation of an educational booklet for healthy eating during pregnancy. *Rev Lat Am Enfermagem*. 2014;22(4):611—620. https://doi.org/10.1590/0104-1169.3313.2459.
69. Sium A, Giuliani M, Papadakos J. The persistence of the pamphlet: on the continued relevance of the health information pamphlet in the digital age. *J Cancer Educ*. 2017;32(3):483—486. https://doi.org/10.1007/s13187-015-0948-3.