Development, validation and cultural adaptation of the *Compasso* protocol: Adherence to self-care in diabetes

Construção, validação e adequação cultural do protocolo *Compasso*: Adesão ao autocuidado em diabetes

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Abstract

Objective: To develop, validate the content and conduct the cultural adaptation of the *Compasso* protocol for promoting adherence to self-care practices in diabetes via telephone intervention.

Methods: Methodological research for tool development, following three stages: protocol development; content validation; and cultural adaptation. Fourteen professionals affiliated to the fields of healthcare, applied linguistics and statistics participated in the stages of development and content validation, while 341 individuals with diabetes mellitus took part in the adaptation stage. Data for validation and adaptation were collected through the *web* platform *e-Surv* and analyzed in the R environment.

Results: The *Compasso* protocol includes the following domains: behavioral and psychosocial aspects, support network, barriers, and self-care practices. The assessment of the protocol presented good agreement between the evaluators, with a mean CVI 0.96.

Conclusion: The content of the *Compasso* protocol was considered to be validated and culturally adequate to promote adherence to the practices of diabetes self-care via telephone intervention.

Resumo

Objetivo: Realizar a construção, validação de conteúdo e adequação cultural do protocolo *Compasso* para promover a adesão às práticas de autocuidado em diabetes via intervenção telefônica.

Métodos: Pesquisa metodológica de elaboração de instrumentos abrangendo as etapas: construção do protocolo; validação de conteúdo; adequação cultural. Participaram das fases de construção e validação um total de 14 profissionais das áreas da Saúde, Linguística e Estatística, e, da fase de adequação, 341 usuários com diabetes *mellitus*. Os dados para validação e adequação foram coletados através da plataforma *web* *e-Surv* e analisados no ambiente R.

Resultados: O protocolo *Compasso* aborda os seguintes domínios: aspectos comportamental e psicossocial, rede de apoio, barreiras e práticas do autocuidado. A avaliação do protocolo apresentou boa concordância entre os avaliadores, com IVC médio de 0,96.

Conclusão: Considera-se validado o conteúdo do protocolo *Compasso* e adequado culturalmente para promover a adesão às práticas de autocuidado em diabetes via intervenção telefônica.

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Introduction

Diabetes *mellitus* is a chronic condition that may lead to irreversible complications affecting daily activities and quality of life. Moreover, it requires a change in everyday behavior patterns that often entails difficulties for achieving adherence to self-care in terms of physical activity, a healthy meal plan and proper use of prescribed medicines.[3,4]

One of the challenges for health professionals is to find educational alternatives aimed at individuals with diabetes *mellitus* for building knowledge, skills and developing basic attitudes for the practice of self-care, considering autonomy, expectations and everyday life of each person.[5]

The telephone intervention is used as an innovative strategy to encourage adherence to self-care practices, as it enables effective communication between the healthcare professional and the individual with diabetes *mellitus*, when associated or compared to in-person actions.[6,7] By using a comprehensive and contextualized language, the professional is able to negotiate, motivate and promote co-responsibility for self-care, helping individuals overcome barriers. One of the potentials of telephone assistance is the individualized and systematic monitoring of individuals with diabetes *mellitus*, during the interval between the educational practice meetings, or when they are at home or outside the health service making choices and decisions related to their health.[6]

Among the tools available for the self-care approach to diabetes *mellitus* via telephone calls found in a literature review were: the Automated Telephone Disease Management (ATDM) Satisfaction Scales and Self-efficacy Psychosocial Scale - Short Version (SPS-SV), which are intended to assess the psychosocial self-efficacy and individual satisfaction with diabetes in those receiving telephone assistance.[8,9] Characteristics that facilitate the interaction between an individual and a professional via telephone call, however, are not addressed by available tools, which is a gap that needs to be filled. Indeed, as in any educational intervention, the use of an appropriate tool ensures reliable information for research quality assurance.[10,11]

In view of this situation, a protocol is necessary to promote adherence to self-care practices, with the intended purpose of educating and motivating the individual to participate effectively in the treatment regimen. The proposal is to consider the individual and his/her feelings as the core of healthcare, identifying the obstacles as well as the solutions to overcome them, in order to enable him/her to perform physical activity, follow a meal plan, and make proper use of prescribed medications.

The approach taken in the *Compasso* protocol is individualized, aiming to support the individual in conscious decision making about the guidance received, and his/her commitment to follow it. The individual is expected to have responsibility to incorporate, into his/her daily activities, the directions perceived as relevant, and shall be responsible for his/her health and control of diabetes *mellitus*.

The objective of this study was to conduct the development, content validation and cultural adaptation of the *Compasso* protocol, to promote adherence to self-care practices in diabetes *mellitus* via telephone intervention.

Methods

This was a methodological study, conducted from December 2015 to March 2016, comprising the following stages: development, content validation by an expert committee, and cultural adaptation of the protocol.

In order to map the diabetes *mellitus* domains and development of the protocol items, the main issues of adherence to self-care practices in diabetes mellitus were investigated, associated with behavioral and psychosocial aspects, based on the Guidelines of the Brazilian Society of Diabetes, in the Strategies for the Care of the Person with Chronic Disease: Diabetes *mellitus* and the Behavior Change Protocol.[2,12,13]

In order to prepare and organize the items that composed the structure of the protocol, in addition

to a literature review, discussions with experts were conducted, based on professional experiences of the participants and on the available literature. Five professionals from the fields of Healthcare, Applied Linguistics and Statistics participated in this stage. After consideration of all input from the experts, a second version was developed in order to facilitate the protocol understanding by the target population. The protcol was named *Compasso*: adherence to the self-care practices in diabetes *mellitus* via telephone intervention.

To ensure content validation and clarity, the second version was submitted for examination to an expert committee composed of nine health professionals. The selection of these professionals was carried out by convenience, as they were selected because they were actively participating in research related to the development and validation of tools, as well as being members of a research nucleus of a governmental educational institution that aims to develop educational healthcare actions. Therefore, the inclusion criteria to compose the committee were: first degree in healthcare, experience in assisting in diabetes, and conducting research in the construction and validation of tools.

An invitation was sent by e-mail to each professional providing a study explanation and requesting an analysis of the protocol content for clarity and relevance in the writing of each question, using an electronic questionnaire, administered through *web* platform *e- Surv*.

The content evaluation requested to the professionals consisted in their assigning one of the following four options to each section of the protocol: 1. One star = requires complete alteration; 2. Two stars = requires partial alteration with many modifications; 3. Three stars = requires partial alteration to improve the style of the text; 4. Four stars = No need for alteration.

After the judges' evaluation, the Content Validity Index (CVI) of the committee was calculated, obtained by adding the relative frequencies of the three and four star answers to verify the judges' level of agreement regarding the adequacy of the items evaluated. To check the validity of the second pro-tocol version, a mean of 0.90 was used to indicate a minimum.[14,15]

After each question, a form field was available for the experts' considerations and observations regarding the clarity and relevance of the proposed content, and if there was a felt need for any change, improvement or exclusion. The suggestions for improvement of the items of the *Compasso* protocol were incorporated, and the third version of the protocol was obtained.

The cultural adaptation of the protocol involved two steps of protocol testing, with administration to members of the target population linked to eight Basic Health Units, under the premises of the research project entitled "Program evaluation of empowerment in diabetes in the primary health care." The inclusion criteria for the participants of this stage were: having been diagnosed with diabetes mellitus type 2, and owning a landline or mobile phone.

The third version was first administered to 191 users with diabetes *mellitus* type 2. The main researcher contacted each individual via telephone, and was responsible for reading each question of the *Compasso* protocol and requesting the individual to answer the questions. The individual was also inquired about his/her understanding of the protocol items and wording, as well as his/her opinion on their relevance.[14] During the protocol administration, responders' answers were tape-recorded and entered on an electronic form through the *web platform e-Surv* by the researcher and,[13] being subsequently exported to a file in text format for statistical analysis in the R software and environment.

At the end of this stage, the difficulties of interpretation of the questions and the specific protocol vocabulary were addressed as potential problems, using an interdisciplinary perspective to solve them. The same experts who worked on the protocol development participated in interdisciplinary meetings, expressing their opinions and drawing on their expertise to solve the problems.

A semantic analysis of the items was performed in order to guarantee that all the questions were comprehensible to the target popula-

tion for which the protocol was developed.[14,16] Some items were modified according to the experts opinions, generating a fourth version of the *Compasso*. This version was entered into a new test survey via the web platform e-Surv , and administered to 150 individuals with diabetes *mellitus* type 2, using to the same methodological steps as well as the inclusion criteria as in the previous stage.

After this second stage of testing, experts identified no further problems and no individual suggested changes or indicated difficulties; thus, the fourth version was considered the final version of the *Compasso* protocol.

The methodological procedure of development, content validation and cultural adaptation of the *Compasso* Protocol is provided in figure 1.

Data were collected in a protocol developed for this purpose; containing information related to the sociodemographic and clinical variables of the individuals with diabetes: sex, age, marital status, income, and duration of diabetes, education and occupation.

All data were encoded and anonymously stored in a spreadsheet, which was exported from the *web e-Surv* platform for analysis in the R statistical programming environment.

The development of the study met national and international standards of ethics in research involving human subjects. The Research Ethics Committee of the Health Municipal Department of Belo Horizonte (Protocol No. 1,411,949) approved the project that originated this study. All participants, after due explanation about the objectives and criteria of participation, signed the Terms of Free and Informed Consent Form in duplicate and registered in *Plataforma Brasil* under *Certificado de Apresentação para Apreciação Ética* number (CAAE): 50109615.0.3001.5140.
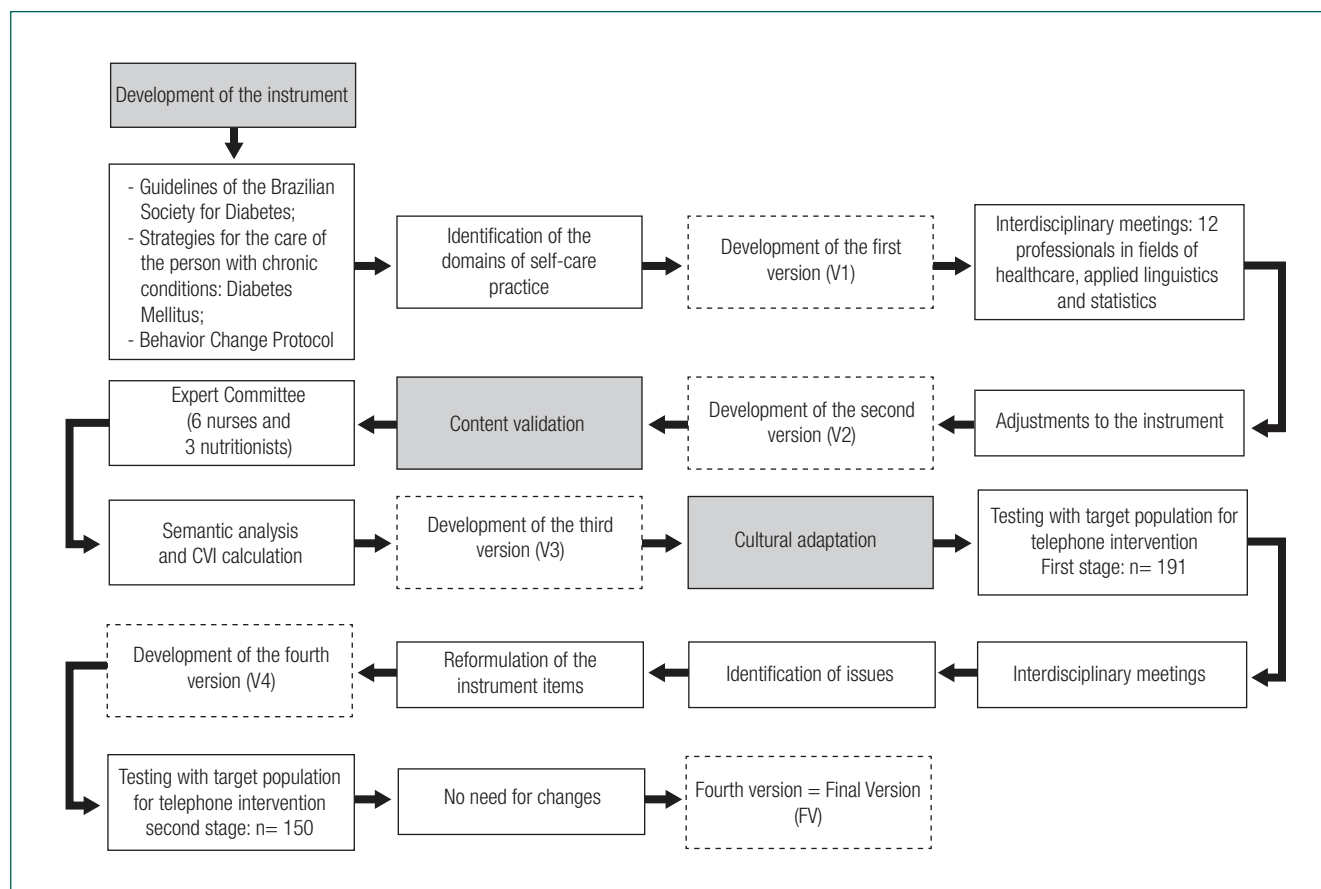

Figure 1. Flow chart of the stages in the study for the development and validation of the *Compasso* Protocol

Results

From the readings and discussions of the reference materials, seven questions were elaborated for the first version of the protocol, based on the areas of self-care: 1. Feelings and barriers for caring in diabetes; 2 Dissatisfaction and readiness for change; 3- Support Network; 4 Willingness to develop a plan of goals; 5 Major complications of diabetes; 6- Follow-up meal plan 7- Physical activity.

The first protocol domain included structural, environmental and economic barriers, and those related to behavioral and psychosocial aspects. Thus, feelings such as sadness and non-acceptance of the chronic condition were considered complicating factors for the practice of self-care. The domain related to dissatisfaction and willingness to change seeks to identify behaviors that are considered priorities for change by the individuals with diabetes mellitus. The third domain is related to the support network, in which individuals identify the actors involved in the process of taking care of their health. Regarding the fourth domain, the individual is encouraged to reflect on his/her willingness to commit to the development and completion of a prospective plan of goals.

The fifth domain focus on the individual's knowledge about the potential complications caused by diabetes *mellitus*. Finally, the sixth and seventh domains, respectively, address the issues related to physical activity and follow up of a meal plan designed and agreed upon seven days prior to the phone call.

After this selection and structural organization of the protocol, the experts who worked on this stage suggested the inclusion of a domain related to prescribed medicine administration that generated the eighth question in the protocol. This inclusion is justified by the high frequency of citations pertaining this issue in national and international studies and especially in the clinical practice of experts. The eighth domain, entitled medicine administration, covers the proper use of prescribed medicine for the treatment of diabetes mellitus in the seven days prior to the phone call.

After the discussion of those seven initial questions, the second version of the *Compasso* protocol

was developed, consisting of eight questions. The experts agreed that the elaborated questions comprised important domains in diabetes mellitus in the context of educational practice, in accordance with the reviewed literature and expert experience.

The experts reached a consensus that the *Compasso* protocol was meant to promote adherence to self-care practices within the context of diabetes via telephone intervention and not serve as a measuring instrument. Thus, scales or scores related to the protocol questions were not considered, as well as the calculation of internal consistency.

The second version was submitted for examination by an expert committee made up by six nurses and three nutritionists with experience in treatment of diabetes *mellitus* type 2 and conducting research in the construction and evaluation of instruments. Table 1 shows the results of their responses and the Content Validity Index (CVI) calculated for each question of the protocol.

Table 1. Content Validity Index of each question of the *Compasso* protocol according to the evaluation of health professionals

Question	Judges' scores									
	1	2	3	4	5	6	7	8	9	CVI
1	3	4	4	3	4	4	4	4	4	1.0
2	4	4	4	4	4	4	4	4	4	1.0
3	4	4	4	3	4	4	2	3	2	0.75
4	4	3	4	3	4	4	4	4	4	1.0
5	4	3	4	4	4	4	4	4	4	1.0
6	4	4	4	4	4	4	4	4	4	1.0
7	4	4	4	4	4	4	4	4	4	1.0
8	4	3	4	3	4	4	4	4	4	1.0
Mean CVI										0.96

CVI- Content Validity Index

The higher the value of the CVI, the lower the number of changes needed to improve each evaluated question. Only one question obtained a score less than 0.90, calling for debate and improvement. Question number three "Do you think there is someone you can resort to who can help you?" was reworded as " Sir/Ma'am, do you think there is someone you can resort to who can help you?" This adjustment was deemed appropriate to add greater politeness and promote the individual's understanding of the question.

The other questions were considered clear by the judges, so no changes were deemed necessary.

The third version was tested with the target population, using a methodology that prioritized the overall understanding of the items by the individuals, and included interdisciplinary meetings for resolution of the problems found in the test phase.

A total of 341 individuals with diabetes mellitus 2 responded to *Compasso* by telephone call. The majority were women (66.6%), unemployed (80.9%) and lived with a partner (69.5%). Regarding education, 26 (7.6%) individuals were illiterate, and 245 (71.9%) had complete or incomplete elementary education. The mean age was 64.3±8.8 years and numbers of years of diagnosed diabetes was 13.5±10.6 years. The length of time spent on answering the *Compasso* protocol ranged from five to ten minutes.

Initially, 191 individuals answered the third version of the *Compasso*, and those questions that revealed difficulties in understanding were discussed by the experts in the interdisciplinary encounters, where improvements were proposed, such as the use of more colloquial words and more easily understood. Words such as "own", "barrier", "achieve-ment", "practice" and "self-care" were the focus of changes and resulted in the fourth version of the protocol.

After these alterations, more than 150 individuals were contacted via telephone intervention to answer the fourth version of *Compasso*. The purpose of this re-administration was to determine whether the improvements suggested by the experts were consistent with the particular profile of the target population, and its level of understanding with respect to the protocol questions.

In general, in this second administration, when asked about the understanding of the items and the words, the individuals did not express any difficulty in understanding the questions of the instrument, which led to the final version of the protocol, which was culturally appropriate for the Brazilian population with diabetes *mellitus* type 2 (Quadro 1).

Finishing this stage, the responses to the eight questions were grouped according to the frequency of citation by individuals and, later, categorized, to facilitate and standardize the completion of the *Compasso* protocol.

Quadro 1. Final version of *Compasso* protocol: follow up of self-care practices in diabetes via telephone intervention

*1. O que o(a) senhor(a) acha mais difícil para cuidar da sua saúde?	*5. O senhor(a) imagina o que pode acontecer com o(a) senhor(a) se o(a) senhor(a) não se cuidar?
a) Seguir o plano alimentar b) Não possui nenhuma dificuldade c) Tomar os medicamentos d) Marcar consulta e) Falta de dinheiro f) Fazer atividade física g) Outros	a) Complicações cardiovasculares b) Amputação c) Hipoglicemia ou hiperglicemia d) Morte e) Problema na visão f) Outros
*2. O que o(a) senhor(a) acha que poderá fazer primeiro para cuidar da sua saúde?	6. Nesta última semana que passou, quantas vezes o(a) senhor(a) conseguiu seguir o plano alimentar?
a) Seguir o plano alimentar b) Fazer atividade física c) Tomar medicamentos d) Marcar consulta e) Organizar o tempo f) Outros	a) Nenhuma vez na semana b) 1 - 2 vezes por semana c) 3 - 4 vezes por semana d) 5 - 6 vezes por semana e) Todos os dias f) Não se lembra
*3. O(a) senhor(a) acha que tem alguém que possa ajudar o(a) senhor(a)?	7. Na última semana, quantas vezes o(a) senhor(a) fez pelo menos 30 minutos de atividade física?
a) Amigo b) Cônjuge c) Família (pais, filhos) d) Não tem ninguém e) Profissional de saúde f) Outros	a) Nenhuma vez na semana b) 1 - 2 vezes por semana c) 3 - 4 vezes por semana d) 5 - 6 vezes por semana e) Todos os dias f) Não se lembra
4. O (a) senhor(a) está disposto a fazer alguma coisa para enfrentar essas barreiras que o(a) senhor(a) me falou?	8. Nos últimos sete dias o(a) senhor(a) tomou as injeções de insulina e/ou o número de comprimidos do diabetes indicado pelo médico do(a) senhor(a)?
a) Se sente disposto b) Não se sente disposto	a) Nenhuma vez na semana b) 1 - 2 vezes por semana c) 3 - 4 vezes por semana d) 5 - 6 vezes por semana e) Todos os dias f) Não se lembra

*Questions that allow more than one choice.

Quadro 2. Modifications made in accordance with each version and stage of development of the *Compasso*: development, validation and cultural adaptation.

Item	Versions V1 and V2 Stage: Protocol development (Portuguese version)	Version - V3 Stage: Content validation (Portuguese version)	Version - V4 (Final version) Stage: Cultural adaptation (Portuguese version)	Justification
Q1	O que o (a) senhor (a) acha mais difícil para cuidar da sua própria saúde?	No changes	O que o (a) senhor(a) acha mais difícil para cuidar da sua saúde?	The word "own" was unusual for the target population, which caused difficulties in understanding.
Q2	O que o(a) senhor(a) acha que poderá fazer primeiro para cuidar da sua saúde?	No changes	No changes	
Q3	O(a) senhor(a) acha que tem alguém que possa te ajudar?	O(a) senhor(a) acha que tem alguém que possa ajudar o(a) senhor(a)?	No changes	Adjustment in the form of treatment for greater politeness and understanding of the question.
Q4	O (a) senhor(a) está disposto a fazer alguma coisa para enfrentar essas barreiras que o(a) senhor(a) me falou?	No changes	O(a) senhor(a) está disposto a fazer alguma coisa para enfrentar essas dificuldades que o senhor(a) me falou?	Replacement of a lexical item by another with greater frequency of use
Q5	O(a) senhor(a) imagina o que poderá acontecer com o(a) senhor(a) se o(a) senhor(a) não realizar as práticas de autocuidado?	No changes	O senhor(a) imagina o que pode acontecer com o(a) senhor(a) se o(a) senhor(a) não se cuidar?	Replacement of one expression by another one more close to everyday language
Q6	Nesta última semana que passou, quantas vezes o (a) senhor(a) conseguiu seguir o plano alimentar?	No changes	No changes	
Q7	Na última semana, quantas vezes o (a) senhor(a) fez pelo menos 30 minutos de atividade física?	No changes	No changes	
Q8	Nos últimos sete dias o (a) senhor (a) tomou as injeções de insulina e/ou o número de comprimidos do diabetes indicado pelo médico do(a) senhor (a)?	No changes	No changes	

The final version of the protocol, with the changes made in accordance with each stage, and their justification can be found in the quadro 2.

Discussion

Profiling the management of self-care practices of individuals with diabetes, covering the psychosocial and behavioral factors related to health, are the main antecedents of an educational intervention. Knowledge of the context of the life of those in the target population on whom the practice will be used is an effective manner to bring the health professional close to the main complicating factors of adherence to self-care practices of individuals with diabetes, which should be carefully cultivated.[8,9]

The School of Nursing, the Laboratory for Experimentation in Translation at the Faculty of Arts, and the Biostatistics Laboratory of the *Universidade Federal de Minas Gerais*, sought to develop the *Compasso* protocol with the main objective of assisting the health area of work to assess the self-care management of individuals with diabetes. The aim was to develop and validate an adequate protocol that could be administered via telephone, given the ease

afforded by this type of contact, the potential of promoting the satisfaction of the individual receiving this type of intervention, and the need to monitor individuals with diabetes between the intervals of conventional educational practices.[11]

The steps for development of instruments recommended by the literature were followed in order to ensure the construction of a reliable tool. [14] The participation of professionals in the fields of healthcare, applied linguistics and statistics at this stage was important to assure proper selection and organization of items and domains, in addition to the analysis of the potential data in the test phase.[14,17,18]

As a result of the validation performed by the health professionals, the *Compasso* was considered a protocol with relevant and valuable content regarding the promotion of adherence to self-care practices in diabetes *mellitus* type 2, a factor that was evidenced by the mean CVI of 0.96, recommended as an acceptable value in the literature.[14,15]

The content of *Compasso* questions include findings from other studies in which the individuals reported that the barriers for the practice of self-care are related to psychosocial, economic and behavioral factors.[3] Since these obstacles can explain the fact that a considerable number of individuals

are unable to follow a meal plan, do not practice phsical activity, and do not adhere to medication treatment, educational interventions addressing these issues are necessary in the planning of interventions.[3,19]

The selection of the *web e-Surv* platform proved to be effective to improve and facilitate the methods of data collection and storage for the content validation and cultural adaptation stages of the *Compasso* protocol.[20] *e-Surv* is a free online tool, with ease of accessibility and use, whose applicability for data collection in the health area context is well described in the literature.[13,21]

The stage of cultural adaptation had the participation of attentive experts who discussed the problems of the target population by means of interdisciplinary meetings, and allowed the exploitation of the problems at their root, ensuring an approximation with the local vocabulary, colloquialisms and simple words.[16] The participation of individuals with diabetes, at this stage, also contributed to obtaining a functional protocol to be administered via telephone.

Compasso was easily understood, even for individuals of low level of education, predominant in the test groups, including those without literacy, and shown to be useful to apply via telephone, because it is a short protocol and of rapid implementation. In populations with low level of education, it is necessary to adopt methodologies that address these specificities and integrate the different contexts, as performed in the cultural adaptation.[16,20]

As such, the use of *Compasso* can provide information to the healthcare professional planning and implementing contextualized telephone interventions and encouraging the adherence to the self-care practices. In addition, the *Compasso* may provide a monitoring of the individual with diabetes *mellitus* in a systematic manner, in order to reduce the demand for highly complex health services, facilitating the longevity of care.

The study limitation is the fact that was not possible to compare the *Compasso* with other existing tools with similar purpose, since they were not found in the available literature. Thus, the use of other validation testing was not possible.

Conclusion

The *Compasso* protocol was validated regarding content and clarity and was culturally adapted, thus being available to be used by professionals working in the healthcare area for education practices in diabetes *mellitus* via telephone intervention.

Collaborations
Fernandes BSM, Reis IA e Torres HC contributed with the study design, analysis, data interpretation, paper writing, relevant critical review of the intellectual content and final approval of the version to be published. Pagano AS contributed with the study design, analysis, data interpretation, paper writing, relevant critical review of the intellectual content Cecilio SG contributed with the article writing, relevant critical review of the intellectual content and final approval of the version to be published.

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