








CONSTRUCTION AND VALIDATION OF AN EDUCATIONAL BOOKLET TO PROMOTE ADHERENCE TO ORAL ANTIDIABETICS

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ABSTRACT

Objective: to construct and validate an educational booklet to promote adherence to oral antidiabetic agents in people with Type 2 Diabetes Mellitus. **Method:** methodological study with construction and validation by a committee of 25 judges, conducted in 2020, in Minas Gerais, Brazil. Content, language, illustrations, layout, motivation, and culture were evaluated. The Content Validity Index was used, considering valid results equal to or greater than 0.80. **Results:** The booklet entitled "Planning to take medications in the treatment of type 2 Diabetes Mellitus. Let's go?", was composed of 24 pages with information on drug adherence, glycemic control, how to use the main oral antidiabetic agents, problems of nonadherence, and behavioral strategies for the effective taking of these medications. In content validation, CVI was 0.92. **Conclusion:** the booklet proved to be a valid educational material to be used to promote adherence to oral antidiabetic drugs.

DESCRIPTORS: Diabetes Mellitus, Type 2; Medication Adherence; Hypoglycemic Agents; Educational and Promotional Materials; Validation Study.

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INTRODUCTION

Medication adherence is defined as the extent to which people follow treatment guidelines provided by a physician and/or other healthcare professionals⁽¹⁾. In the early stages of type 2 Diabetes Mellitus (DM2), adherence to oral antidiabetic drugs (OADs) is considered one of the determining factors for achieving glycemic control⁽²⁻⁵⁾. However, non-adherence to OADs has still been documented and associated with negative clinical, social, and economic impacts, especially in low- and middle-income countries⁽⁵⁻⁶⁾.

Adherence to OADs has been the object of health intervention research^(3,7-8). Among them, we highlight those based on theoretical assumptions, especially on cognitive-social theories, in which the intention or motivation is the main determinant for behavior performance. However, positive intentions are not always effective in the desired behavior⁽⁹⁻¹⁰⁾, due to a gap in the intention/behavior relationship. Some gaps related to not taking OADs are difficult behavioral beliefs, forgetfulness, costs and access to medicines, low educational level, lack of knowledge about the treatment, adverse events, taking more than twice a day, and lack of routine^(2,11).

Among the various existing theoretical references, the Implementation Intention Theory (IIT) can be used to help motivated people to transform positive intentions into effective action^(9,12). This theoretical model proposes to identify the barriers between the intention and the actual behavior and, thus, to plan strategies for its effectiveness. With IIT, it is possible to elaborate action plans ("action planning"), which specify when, where and how to perform the behavior, and coping plans ("coping planning"), which consist of anticipating barriers and listing prospective plans ("if... then") as coping strategies, that is, if a certain barrier appears, a previously planned action will be taken to overcome it.

Based on this model, a randomized controlled trial (RCT)⁽³⁾ evaluated the impact of a combination of IIT-grounded behavioral strategies to promote adherence to OAD in adults and the elderly in primary health care facilities. At the end of 15 weeks of follow-up, a significant increase in the proportion of adherence to OADs and reduction levels of glycated hemoglobin could be noted. In the literature, there are reports on the importance of exploring the quality of action and coping plans developed in intervention studies^(3,13-14).

Health communication has occurred from the use of educational technologies, among them, the booklets stand out for their practicality and feasibility of use. Primers are printed materials useful for the description of health-related issues, being possible to use them as a health promotion tool⁽¹⁵⁻¹⁶⁾. In Brazil, although a variety of educational materials are found as an educational tool in various populations and purposes⁽¹⁷⁻¹⁹⁾, there is still a need to build and validate educational materials for people with DM2 directed to the taking of OADs.

The production of educational materials, followed by the validation process, aims to direct, standardize, systematize, and streamline the guidelines for effective behavior, such as taking OADs. Validated educational materials are more likely to have correct, didactic, and understandable content, which confers a greater possibility of success in their use in educational practice. Therefore, the aim of this technology is to provide health information, strengthen autonomy and self-care, and consequently keep the disease under control by preventing its complications. Thus, the objective of this study was to construct and validate an educational booklet to promote oral antidiabetic adherence in people with Type 2 Diabetes Mellitus.

METHOD

Methodological study, conducted between January and December 2020, in

Divinópolis, Minas Gerais, Brazil, through the construction and validation of a booklet to promote adherence to OADs. The following steps were followed: 1 - narrative review on the theme; 2 - elaboration of a sequential draft of texts and illustrations with the graphic designer; 3 - validation of the material built by a committee of judges.

In step 1, the content for constructing the booklet was obtained from the 2019-2020 Brazilian Diabetes Society (SBD) Guidelines⁽²⁰⁾ and previous studies^(3,11) that have used IIT to promote the taking of OADs by people with DM2.

In step 2, the booklet was built based on three aspects: language, illustration, and layout/design, which are recommended for the development of written educational materials. The texts were written with objective language directed to the target audience, in active voice and conversational style; the content was presented in a precise, updated, and evidence-based manner⁽²¹⁾. A graphic design specialist carried out the formatting and layout of the educational material in Adobe Photoshop CC2019 and Corel Draw Graphic Suite x7.

In step 3, content validation was carried out with professionals specialized in the care of people with DM2, medication adherence, and health behavior, selected by snowball sampling. The sample size was defined by the formula: $n = Z_{\alpha}^2 \cdot P(1-P)/e^2$, where Z_{α} (confidence level)=95%, P (proportion of agreement of judges)=85%, and (accepted difference from what is expected)=15%, which resulted in 22 judges⁽²²⁾. The inclusion criteria were being a health professional and having at least one year of experience (assisting or teaching/researching) with the theme; the exclusion criterion was the incomplete completion of the data collection instrument used.

The search for the judges occurred through the Lattes curriculum with the insertion of the following terms: medication adherence, Type 2 Diabetes Mellitus, health behavior, and health technology. After the identification and verification that the professionals met the established inclusion criteria, an e-mail was sent inviting them to participate in the study. Other specialists who fit the inclusion criteria were also asked to participate. Thirty-nine professionals were invited, of whom 14 did not return the contact within the deadline, which resulted in a sample of 25 judges.

For data collection, the participants received an invitation letter with the purpose of the study, the informed consent form, the booklet in PDF, the sociodemographic characterization instrument (composed of initials, age, gender, city where they work, degree, time of training, current occupation, and experience in the subject), and the instrument to evaluate the items of the booklet. This instrument, adapted from a previous study⁽¹⁸⁾, is composed of 21 items in which the judges should evaluate the booklet using a five-point Likert scale ranging from "strongly agree" to "strongly disagree". The items of the instrument were about content, language, illustrations, layout, motivation, and culture.

Data were analyzed using the software Statistical Package for the Social Science (SPSS) version 21. From the Content Validation Index (CVI), we calculated the Item-Level Content Validity Index (I-CVI), which corresponds to the raters' agreement for each item of the instrument, and the overall CVI. The I-CVI was calculated by dividing the number of judges who totally agreed or agreed with the item by the total number of judges; the overall CVI corresponds to the average of all I-CVIs. The minimum proportion of agreement for the item to be considered valid was 80%⁽²³⁾. The binomial test was used to verify the agreement, statistically, equal to or greater than 0.80 of the items separately. The significance level adopted was 5%.

The study was approved by the Research Ethics Committee of the Federal University of São João Del-Rei - CCO (opinion 3.628.173).

RESULTS

The booklet was entitled "Planning to take medications in the treatment of Type 2 Diabetes Mellitus. Let's go?" and composed of 24 pages of A5 size (148x210mm) with cover, back cover, fact sheet, summary, presentation page, information about adherence, space for notes, and references.

The booklet contains information about the importance of medication adherence and glycemic control, how to use the main OADs, and the harms of non-adherence to these medications. It then presents the action plans and coping plans available in the literature and provides a few pages for users to develop their own plans for taking their OADs.

The content was concluded with motivational phrases, such as "We understand that it is really complicated to organize your new routine, but it is possible that you will become more comfortable and be able to have a full life even if you take medicine every day", with the purpose of stimulating the reader's self-confidence to plan to take the OADs described earlier in the booklet. Figure 1 shows some illustrations of the validated version. Full access is available from the link⁽²⁴⁾.

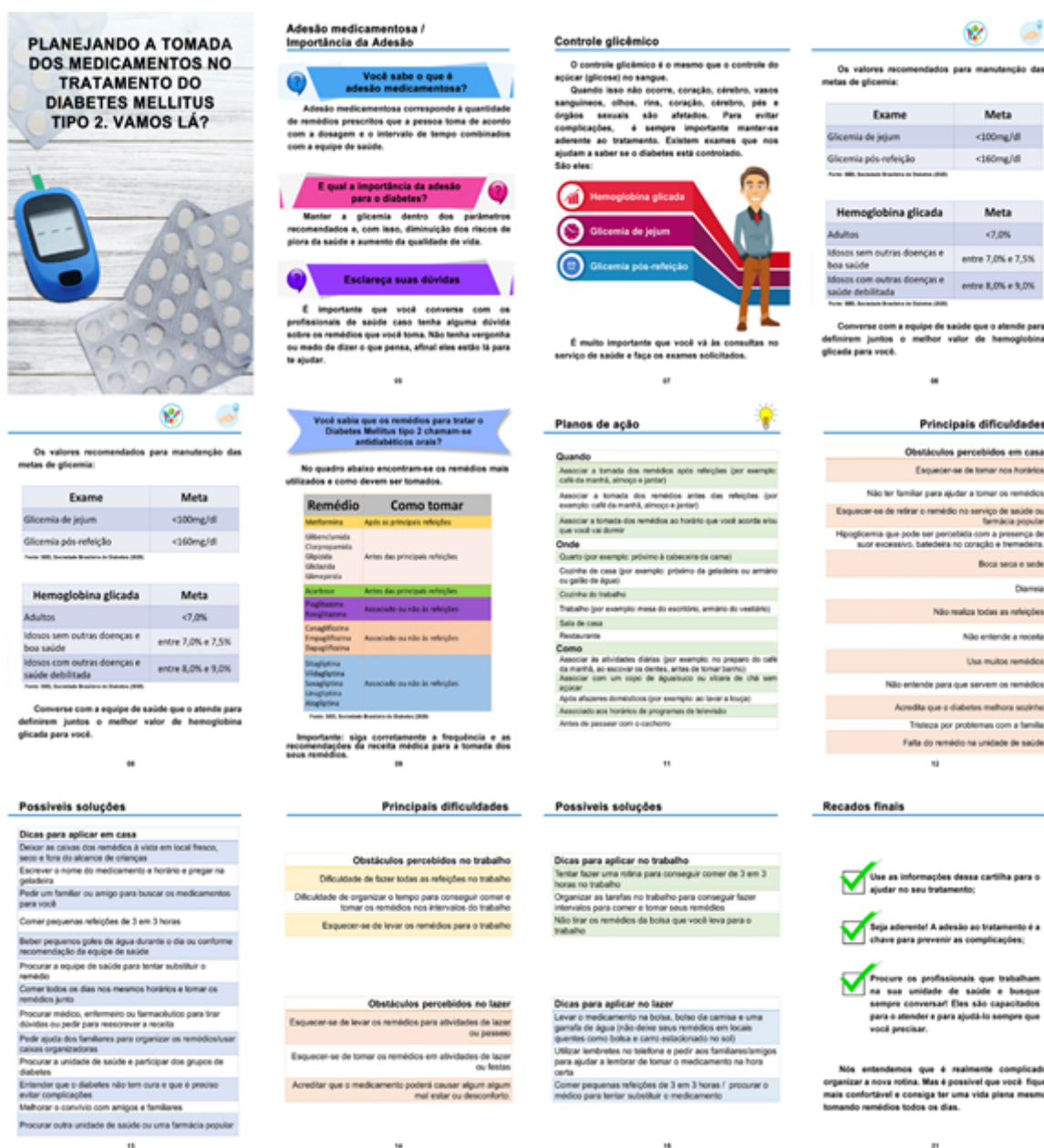


Figure 1 - Illustrations of the educational booklet "Planning the taking of medications in the treatment of Type 2 Diabetes Mellitus. Let's go?". Divinópolis, MG, Brazil, 2020. Source: Authors (2020)

Content validation was performed by 25 judges. Most participants were nurses, PhDs, professors, with extensive professional experience and publications involving the theme, distributed in three Brazilian regions and abroad (Table 1).

Table 1 - Characterization of the judges. Divinópolis, MG, Brazil, 2020

Characterization of the judges (n=25)	n (%)
Age (years), mean (SD)	37,4 (5,3)
Education time (years), mean (SD)	13,7 (5,8)
Publication involving the theme	20 (80)
Professional categories	
Nurse	20 (80)
Physician	3 (12)
Pharmacist	2 (8)
Titration	
Doctorate degree	13 (53)
Master's Degree	9 (36)
Specialization	3 (12)
Current occupation	
Professor - nursing undergraduate	11 (44)
Professor - medicine undergraduate	3 (12)
Professor - Pharmacy undergraduate	2 (8)
Professional assistants in ambulatory/primary care	9 (36)
Region of operation	
Southeast	19 (76)
Northeast	3 (12)
North	1 (4)
Abroad (Portugal)	2 (8)

Source: Authors (2020)

The 21 items evaluated with their respective CVI values are detailed in Table 2. The binomial test showed statistical significance ($p < 0.001$) in the agreement equal to or greater than 0.80 between the judges in all items evaluated.

Table 2 - Judges' agreement regarding the items of the educational booklet. Divinópolis, MG, Brazil, 2020 (continues)

Variables	n (%)*	I-CVI**
1. Content		

1.1 Content covers care for adherence to OADs ^{&}	24 (96)	0,96
1.2 Headings and subheadings are coherently divided	24 (96)	0,96
1.3 Highlighted excerpts are worth highlighting	24 (96)	0,96
1.4 Content meets the needs of the target audience	21 (84)	0,84
1.5 Text sequence is logical	23 (92)	0,92
1.6 Content is relevant to inform people with DM2 [§]	25 (100)	1
1.7 Content is correct from a scientific point of view	23 (92)	0,92
2. Language		
2.1 Language is compatible with the target audience	21 (84)	0,84
2.2 Sentence formation is attractive and not tiresome	25 (100)	1
2.3 There is clarity and objectivity in the text	23 (92)	0,92
3. Illustrations		
3.1 Illustrations match the content	22 (88)	0,88
3.2 Illustrations are understandable	25 (100)	1
3.3 Captions help the reader understand the image	21 (84)	0,84
3.4 Number of images is sufficient to address the content	23 (92)	0,92
4. Layout		
4.1 Font size and font favor reading	22 (88)	0,88
4.2 Colors used in the text make it easy to read	25 (100)	1
4.3 The arrangement of items on the page is organized	22 (88)	0,88
4.4 Number of pages and size of the material are coherent	23 (92)	0,92
5. Motivation		
5.1 Reader is encouraged to continue reading by the content	23 (92)	0,92
5.2 Primer is enlightening	24 (96)	0,96
6. Cultural fit		
6.1 It meets the profiles of people with DM2 [§] taking OADs ^{&}	22 (88)	0,88

* Percent item agreement; **Item-Level Content Validity Index; & Oral Antidiabetics; § Type 2 Diabetes Mellitus.

Source: Authors (2020)

All items were rated as adequate, with a level of agreement greater than 80% in all domains of assessment. The overall CVI in the validation with judges was equal to 0.92. Given this result, only one round of validation was required. However, even with high levels of agreement and a global CVI of 0.92, some judges made suggestions for improving the booklet, both in terms of appearance and content, such as: reformulation of the booklet title; replacement or exclusion of technical terms; reformulation of illustrations; and simplification and redrafting of sentences. The proposals were analyzed and accepted (Chart 1). At the end of this process, the designer was asked to make the changes, under the direct supervision of the researcher.

Chart 1 - Modifications made to the booklet based on the suggestions of the judges. Divinópolis, MG, Brazil, 2020

Suggestions from the judges	Modifications made
Content	
Reformulation of the title	Reformulated to: "Planning for taking medications in the treatment of Type 2 Diabetes Mellitus. "Let's go?".
Simplification of sentences	Sentences modified to: "Drink small sips of water during the day or as recommended by the health care team", "Seek the health care team to try to replace the medicine", "Eat every three hours in small amounts".
Insertion of information	Inserted the following information: "Remember that your medication should not be kept in hot (such as the kitchen) or humid places (such as bathrooms), and should also be kept away from the height of children (above 1.5 meters)"; "If you are going to carry your medication, do not leave it in hot places, such as inside a bag exposed to the sun, or inside a car parked in the sun. This can compromise the quality of the medicine"; "It is very important that you attend your appointments at the health service and perform the requested tests".
Language	
Replacement, exclusion, or definition of technical terms	Substituted "medicines" and "pharmaceuticals" for " medicines".
	Substituted "your adherence is not good" for "your blood glucose is outside the recommended parameter for you".
	Defined the terms "adverse events" and "hypoglycemia" to "unwanted complications from the drug" and "drop in blood sugar", respectively.
	Defined the term "medication adherence" to "participation and involvement in the appropriate use of medicines".
	Defined the term "glycemic control" to "(...) when we say glycemic control it is the same as saying blood sugar (glucose) control".
	Replaced the phrase "reasons leading to non-engagement" with "reasons leading to non-engagement".
Illustrations	
Cover image redesign	Redesigned the picture of pills on the homepage, showing only medications inside the primary package and glucometer.
Layout	
Enlarge font	Increased the font size to make it easier to read, especially in the "main difficulties" and "possible solutions" boxes.
Motivation	
Add motivation message	Inserted the following message: "We understand that it is really complicated to organize the new routine. But it is possible that it will become more comfortable and that you will be able to have a full life even though you take medication every day."
Culture	
No notes at all.	

Source: Authors (2020)

DISCUSSION

The organization of information in the booklet occurred from an educational and behavioral perspective, with the purpose of contributing to the correct intake of OADs by people with DM2. The educational material presents information on the relationship between glycemic control and drug adherence to OADs, besides providing content related to behavioral strategies and support for the effectiveness of this health behavior, based on the experiences of each person.

The booklet was considered a validated material by health professionals regarding the items content, language, illustrations, layout, motivation and culture, aspects that were proven by the overall CVI, whose average was 0.92, above the acceptable by the literature⁽²³⁻²⁵⁾. However, some expressions and terms were reformulated and standardized to simplify the text and encourage the understanding of the target audience, in order to maintain the order and convergence of the readers' understanding, besides making the material more accessible to audiences with lower educational levels.

People with DM2 commonly experience several barriers to taking OADs such as forgetfulness, absence of routine, presence of adverse events, unfamiliarity with the treatment, and problems with prescriptions, as raised in a previous study⁽¹¹⁾. With this, a systematic assessment by professionals from different practice areas, including nurses, physicians, pharmacists, and psychologists, is important to specifically understand these factors and identify their influences on adherence to OADs. This approach consists of the process of measuring adherence, raising barriers to overcoming them, establishing follow-up plans that confirm the planned treatment change, followed by evaluation of progress in achieving goals⁽²⁶⁾.

The available booklet can be considered an effective tool in these steps, meeting the recommendations of international and national diabetes societies^(20,27). The ability to perform a health behavior involves, in some way, the ability to read and understand targeted information. The use of a validated booklet can enrich the process of knowledge construction, making it simpler and more effective, both for the target audience and for professional educators, especially because it deals with reliable and consistent materials that ensure the consolidation of quality guidelines⁽²⁸⁾.

In research reports and scientific articles, it is noted that few studies have set out to measure the impact of interventions using the assumptions of IIT. In Iran, an RCT was conducted to design and evaluate a theory-based intervention to promote medication adherence among people with rheumatoid arthritis. The study found that action plans and coping plans significantly collaborated to increase adherence measure scores in the intervention group at three ($p < 0.001$) and six ($p < 0.001$) months of follow-up⁽¹⁵⁾.

In Brazil, another RCT, which specifically evaluated the impact of the development of action plans and coping plans involving people with DM2 using OADs, identified a significant increase ($p = 0.003$) in the global assessment of adherence and effective behavior ($p < 0.0239$) in the intervention group compared to the control group at the end of 105 days. In addition, a significant 0.5% reduction in glycated hemoglobin levels was observed in the intervention group between baseline and the end of the study ($p < 0.0001$)⁽³⁾. The UK Prospective Diabetes Study (UKPDS) describes that a 1% decrease in A1c levels was related to a 21% reduction in the risks of diabetes-related deaths, 14% in myocardial infarctions, and 37% in microvascular complications⁽²⁹⁾.

It is expected that, with the dissemination of this booklet, it will become an instrument to be used by professionals, professors, and students of the health area in the teaching-research-extension tripod and for the community in general, to contribute to the dissemination of behavioral strategies that can promote adherence to OADs and, therefore, impact the quality of life and health of people with DM2. Thus, several paths are open to be followed through other investigations, seeking to broaden the horizons of knowledge about adherence to OADs and designing intervention studies to prove the effectiveness of the material.

Although this study provides innovative technology to promote adherence to OADs, it has some limitations. First, other aspects involving glycemic control, such as diet and physical activity, were not addressed in the booklet, because the central focus was on adherence to OADs; the insertion of this other information could make the educational material extensive, besides not working specifically on a health behavior. Second, the validation process occurred only with judges, without evaluation of the target audience; however, throughout the booklet, clear language and absence of technical terms were used.

Due to the covid-19 pandemic and social isolation measures, the research group was unable to validate the booklet with target audiences in health care facilities. Therefore, we chose to refine the content, language, and illustrations of the booklet in a future study, as well as investigate its effectiveness for promoting OADs adherence and reducing glycemic levels in people with DM2.

CONCLUSION

The booklet was considered valid by the specialists regarding content, language, illustrations, layout, motivation, and culture. This educational material can enable the promotion of OADs in people with DM2 followed-up in primary or secondary care and, thus, consist in a viable technological resource to be used by nursing and other health professionals, with the purpose of enabling the access of users to the knowledge of important strategies and care.

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