


ORIGINAL ARTICLE

## CONSTRUCTION AND VALIDATION OF AN EDUCATIONAL BOOKLET ON THE USE OF IMMUNOSUPPRESSIVE DRUGS AFTER KIDNEY TRANSPLANTATION

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### ABSTRACT

**Objective:** Construct and validate by agreement an educational booklet on the use of immunosuppressive drugs after kidney transplantation. **Method:** Methodological study carried out in an outpatient follow-up clinic for post-transplant patients, from December 2019 to August 2020. It was developed in two phases: construction of the booklet and validation by agreement of the material by expert judges. A minimum level of agreement of 80% was necessary for the validation of the material. **Results:** Of the 30 items evaluated in the booklet, in the first phase, 15 were modified. After the modifications in the material performed in the second phase, only one item had an agreement value lower than 80%. **Conclusion:** The booklet was validated in content and appearance. Thus, the material could be used to assist health professionals in the health education process and support the care provided to kidney transplant patients.

**DESCRIPTORS:** Kidney Transplantation; Immunosuppressants; Teaching Materials; Validation Studies; Nursing.

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## INTRODUCTION

Rate of non-adherence (NA) to immunosuppressants in kidney transplantation (KTx) is higher than non-adherence rates in other types of solid transplants<sup>(1)</sup>. Studies highlight multidimensional interventions that involve educational, behavioral, and psychological activities that effectively increase the rate of adherence to immunosuppressive drugs after kidney transplantation. Educational interventions, in particular, are the most clearly documented in the literature and are characterized by providing information, to individuals or groups, by correspondence or through information and communication technologies<sup>(2-3)</sup>.

To ensure that educational interventions are successful, health professionals must consider the characteristics of the patients and the routine of care, selecting the best way to make the material available, i.e. in written, verbal or visual form. The use of telephone follow-ups and mobile phone applications for patient monitoring and education has also greatly increased<sup>(2-3)</sup>.

Thus, printed educational material supports treatment, expanding patients' knowledge and, consequently, their self-care and adherence to treatment. It should be stressed that the materials prepared by health professionals complement the educational process and the verbal guidelines provided in the consultations<sup>(4-6)</sup>.

A systematic review that evaluated promising interventions in treatment adherence for the referred population emphasizes that the use of customized educational material is an important factor for educational and behavioral interventions<sup>(7)</sup>. Thus, the present study aimed to construct and validate by agreement an educational booklet on the use of immunosuppressive drugs after kidney transplantation.

## METHOD

Methodological study developed in two phases: construction of the educational booklet for kidney transplant patients, and validation of the educational material by judges. The booklet was constructed according to the recommendations for the design and effectiveness of educational materials, according to the following characteristics: content, language, organization, layout, illustration, learning and motivation<sup>(8)</sup>.

The study was carried out in an outpatient clinic for post- KTx patients, in a city located in Minas Gerais, Brazil. The material was constructed and validated from December 2019 to August 2020.

The construction of the booklet involved surveying the profile of post-kidney transplant patients and bibliographic research of the main publications related to the use of immunosuppressants in post KTx. The booklet was based on the following theoretical references: Recommendations of the Brazilian Association of Organ Transplantation (ABTO) and scientific articles on adherence to immunosuppressants in post KTx.

Therefore, this educational booklet was developed to disseminate information on the new post kidney transplant routine and promote health education on the correct use of immunosuppressive drugs in the post-transplant stage. Design, diagramming and illustration were performed by professionals trained on communication, advertising and art, respectively. Validation of content and appearance was applied in the evaluation of the booklet, that is, an instrument based on judgment that seeks to measure the adequacy of content items, as well as agreement among expert judges<sup>(8)</sup>.

Data was collected from May to August 2020. The judges were previously selected

and invited to participate in the study and the following materials were made available to them: full text of the educational material (booklet), the questionnaire on the professional profile and the procedure for judgment of the educational material.

The professionals invited to participate in the validation (17 judges) were physicians, nurses and pharmacists, who had at least one year of experience in kidney transplantation. The recruitment of the judges was made by convenience, using snowball sampling. Thus, professionals specialized in nephrology/ kidney transplant recommended additional participants. This is a type of non-probabilistic sampling that uses reference chains<sup>(8)</sup>. Nurses, physicians and pharmacists who have been actively involved in the area of kidney transplantation for at least one year were included and professionals specialized in nephrology not involved in transplantation, as well as retired professionals were excluded.

The judges assessed the booklet through a judgment instrument developed by the authors themselves. The instrument is supposed to assess the content and appearance from thirty sub-items, divided into six sessions.

The first session was based on questions about the general objectives of the booklet; the second was related to the structure and general organization of the material, which involves formatting, illustrations, size, font and font size; the third, fourth and fifth sessions were related to the structure, organization and content of the topics – kidney transplantation, immunosuppressants and tips for the correct use of immunosuppressants, respectively; and, finally, the sixth session concerned the relevance of the educational material.

The judges analyzed the agreement and relevance of each item. The items were evaluated and considered adequate, partially inadequate and inadequate. If necessary, adjustments in the instrument could be suggested. At the end of the period of evaluation by the expert judges, the recommendations were accepted and incorporated into the educational material. Subsequently, the new version of the booklet was submitted to the same 17 judges for a new round of evaluations, as well as a new editing and diagramming process.

The data obtained were analyzed using the Statistical Package for the Social Sciences version 21 and R program version 3.6.3. Agreement was achieved through the adequacy of the adjustment of the percentages of the judges who agreed with the relevance of the educational booklet. Items with an agreement level lower than 80% were changed. Internal consistency was assessed with Cronbach's alpha coefficient, and the following cutoff points: 0.6 – Minimum; 0.7 Acceptable; 0.8 – Good and 0.9 – Excellent<sup>(9)</sup>. A reliability coefficient greater than or equal to 0.7 was considered desirable in this study.

The present study was submitted to and approved by the Research Ethics Committee of Universidade Federal de Juiz de Fora, under protocol number 3,605,805.

## RESULTS

The present booklet contains three topics: kidney transplantation, immunosuppressants and guidelines for the proper use of immunosuppressants, and a section for notes. The former version of the booklet was 10 cm wide and 15 cm long, with 22 pages (counting back and front). It has front cover, back cover, summary and three pages for notes. The concept of kidney transplantation, followed by the definition of immunosuppressants and finally the guidelines for the correct use of these drugs were addressed from page 6 of the booklet.

In the first round, the form was sent to 17 professionals. Of these, eight answered the questions and participated in the study. Of the eight judges, six were female (75%),

with a mean age of 40.3 years, five were nurses (62.5%) and three were physicians (37.5%). They had graduated 20 years ago (50%), and had been active in kidney transplantation for a period of 10 to 20 years (50%).

Of the 30 subitems evaluated in the educational material, six were classified as 100% adequate (20%), nine were classified as having more than 80% of adequacy (30%) and 15 were classified as having less than 80% of adequacy (50%). The subitems classified as having less than 80% of adequacy (Table 1) were revised, and the judges' suggestions for changes were considered.

Table 1 - Description of the booklet's items modified because of their level of adequacy evaluated by judges. Juiz de Fora, MG, Brazil, 2020

Section	Item	Inadequate n (%)	Partially Inadequate n (%)	Adequate n (%)
1.2 Objectives	Change in behavior	0(0)	5(62,50)	3(37,50)
1.3 Objectives	Circulation of the booklet	0(0)	3(37,50)	5(62,50)
2.1 General Structure	Sociocultural adequacy	0(0)	3(37,50)	5(62,50)
2. 4 General Structure	Number of pages	1(12,50)	2(25)	5(62,50)
2.5 General Structure	Title adequacy	0(0)	3 (37,50)	5(62,50)
3.2 KTx. Structure	Information structuring	0(0)	3(37,50)	5(62,50)
3.4 KTx Structure	Writing and spelling	0(0)	2(25)	6(75)
4.1 Immunosup. Structure	Clear and objective messages	0(0)	2(25)	6 (75)
4.2 Immunosup. Structure	Information structuring	0(0)	3(37,50)	5(62,50)
4.4 Immunosup. Structure	Writing and spelling	0(0)	2(25)	6(75)
5.1 Tips for use	Clear and objective messages	0(0)	3(37,50)	5(62,50)
5.2 Tips for use	scientifically correct information	0(0)	3(37,50)	5(62,50)
5.4 Tips for use	Information structuring	0(0)	3(37,50)	4(50)
5.5 Tips for use	Writing	0(0)	3(37,50)	5(62,50)
6.3 Relevance	Prevention of complications	0(0)	2(25)	5(62,50)

KTx: Kidney Transplant

Source: The authors (2020).

According to the judges' suggestions, changes were made, as follows: grammar check, adapting text to the target audience, standardization of the use of the term adherence in the entire booklet, change of the font, size of font and images, construction of tables. Chart 1 (below) presents the qualitative synthesis of the recommendations made by the judges and accepted by the authors up to the final version of the booklet.

Chart 1 - Synthesis of the qualitative analysis of the suggestions made by the judges. Juiz de Fora, MG, Brazil, 2020

Judges' suggestions	
Cover	Replace the term patients with receivers.
Immunosuppressants Section	Insert pictures of the pills and create an organization table for the use of immunosuppressants. Add more drug trade names.
Immunosuppressants Section Correct use of immunosuppressants	Emphasize the importance of not missing appointments. Talking about the importance of patients organizing themselves to get their medicines at the pharmacy. Guidelines to help patients remember to take the medication. Standardization of the use of the word "adherence".
General Structure	Reduce the number of pages. Change the font for better viewing and reading.

Source: The authors (2020).

In the first phase, Cronbach's alpha was 0.76, indicating adequate internal consistency for the items analyzed. The modifications were implemented, and the new version of the booklet maintained the topics on kidney transplantation, immunosuppressants and guidelines for the proper use of immunosuppressants, and included a final section for notes. The booklet has 19 pages, which are 10 cm wide and 15 cm long. The new version was then returned to the judges.

Six judges participated in the second round. Of these, four (66.6%) were women, four nurses (66.6%), four had graduated 10 to 15 years ago (66.6%), all had completed specializations, three of them had worked in the field for less than 10 years (50%) and three for 10-20 years (50%).

The evaluation form was the same one used in the first round. Of the subitems evaluated, 23 were classified as 100% adequate (76.6%), six subitems had more than 80% adequacy (20.0%) and one (3.3%) had an adequacy value lower than 80%. Table 2 shows the seven items that were not evaluated as 100% adequate.

Table 2 – Description of items of the booklet not evaluated with 100% adequacy. Juiz de Fora, MG, Brazil, 2020

Section	Item	Inadequate n (%)	Partially Inadequate n (%)	Adequate n (%)
Structure – KTx	Clear and objective messages	0 (0)	1 (16,67)	5 (83,33)
Structure – KTx	Information structuring	0 (0)	1 (16,67)	5 (83,33)
Structure - KTx	Writing and spelling	0 (0)	1 (16,67)	5 (83,33)
Immunossup Structure.	Information Structuring	0 (0)	1 (16,67)	5 (83,33)
Immunossup Structure.	Writing and spelling	0 (0)	1 (16,67)	5 (83,33)
Tips for use	Information Structuring	0 (0)	2 (33,33)	4 (66,67)
Tips for use	Writing and spelling	0 (0)	1 (16,67)	5 (83,33)

KTx: Kidney Transplant; Immunossup: Immunossuppressing drugs

Source: The authors (2020).

As for the possible changes resulting from an adequacy value lower than 80%, after the second round, only one item was rated less than 80%, and only one judge expressed such opinion. In the second round, Cronbach's Alpha value was 0.86, showing adequate internal consistency for the analyzed items.

Figure 1 shows the graphical representation of the final version of the booklet.

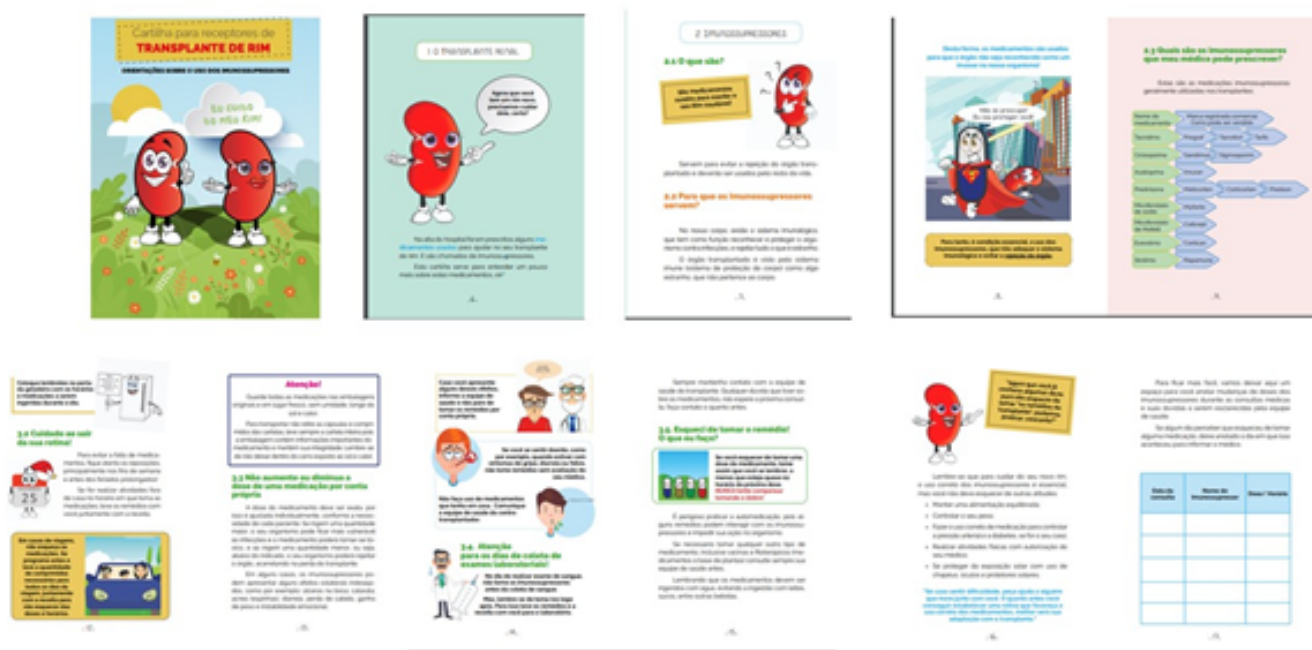


Figure 1 – Illustrative representation of the final version of the educational booklet. Juiz de Fora, Minas Gerais, Brazil, 2020. Source: The authors (2020).

## DISCUSSION

The booklet was developed to implement interventions to improve patients' adherence to the use of immunosuppressive drugs in the scenario investigated. A level of agreement greater than 80% of the booklet items was obtained after the second round of evaluation by the judges and a Cronbach's Alpha value of 0.86. Thus, its validity is consistent with the findings obtained in other studies on the construction and validation of educational materials<sup>(8,10)</sup>.

The process of validation and adaptation of educational material by experts is important, as it ensures the verification of the consistency of information, contributing to the development of information technology with greater scientific rigor. Health professionals and researchers should be aware of validation procedures of educational materials, as they favor the proper use of reliable and appropriate instruments in their professional practice<sup>(8,10)</sup>. In addition, the construction of a validated booklet targeted to a specific audience can increase adherence to the use of technology.

The inclusion of experts from different areas supports the construction of an educational material, as it values the different opinions and views of each professional on the same topic. It should be noted that the construction of educational technologies is also a way to standardize the care provided to patients<sup>(11)</sup>.

In the context of KTx, performing immunosuppressive therapy after transplantation is essential to prevent graft rejection and increase transplant success. It is important to measure immunosuppressive adherence and identify the factors that contribute to it, as this can contribute to planning interventions that are more consistent with the reality<sup>(12-13)</sup>.

Thus, interventions that can increase immunosuppressive drug adherence are necessary for the maintenance of organ grafting, especially after hospital discharge. It is well established in the literature that main changes in life habits occur in the first month after KTx. Thus, emphasizing the importance of teaching the proper use of immunosuppressive drugs may contribute to a greater success of the treatment<sup>(12)</sup>.

Among the possible interventions to guide patients, the delivery of printed educational material has been a strategy used in the health area with the aim of improving satisfaction, knowledge and adherence to treatment by patients. The use of written materials developed by healthcare professionals is recommended to support verbal guidance<sup>(5)</sup>. Moreover, the guidelines must be adapted to the target audience, regarding language, content and illustrations.

People in the post-transplantation phase who have poor health education may show low adherence to treatment, which makes recovery difficult and may delay their social reintegration and return to daily activities<sup>(7,10)</sup>. Thus, the educational booklet has a key role, given the poor availability of educational materials to assist in the verbal guidance provided during outpatient follow-up, both for patients and for caregivers/family members<sup>(7,10)</sup>.

The use of booklets with information on chronic kidney disease and studies that recommend educational materials with guidelines on general care in the postoperative period of KTx, involving topics such as food, use of medicines, risks of infection, hygiene and quality of life, were identified in the national literature<sup>(4,14)</sup>. Therefore, we decided to develop a specific educational material for the use of immunosuppressing drugs post KTx.

The process of health education has been characterized mainly by stimulating the promotion and improvement of knowledge to ensure a better quality of life for the individuals. It is based on practices that encourage autonomy and more control over their health, through the exchange of information. In this process, health professionals are supposed to mediate knowledge to achieve desirable health standards<sup>(15)</sup>.

In this context, the role of nursing, which is directly associated with guidance to patients, both at hospital discharge and in outpatient consultation, was highlighted. According to the Nursing Practice Act, nurses can carry out nursing consultations and are also prepared to engage in educational activities, in order to promote health improvement<sup>(16)</sup>.

One limitation of this study is the small sample size (less than 20 experts participated in the study). Thus, the sample was not sufficiently large and heterogeneous. Another limiting factor for the process of validation of the booklet is the fact that the material was not assessed by kidney transplant patients, since during the COVID-19 pandemic many appointments were conducted remotely. However, the evaluation of the booklet by patients is expected to occur in the near future.

## CONCLUSION

The study promoted the development of the educational booklet "Guidelines on the use of immunosuppressive drugs". The content and appearance of the educational material were validated by experts (physicians and nurses) actively involved in kidney transplantation, and the booklet was considered instructive, adequate and viable for health education activities with kidney transplant patients regarding the proper use of

immunosuppressive drugs in post-KTx.

The booklet can be useful for health professionals in the health education process. It also assists in their daily care activities, in addition to providing guidelines that encourage self-care for kidney transplant recipients.

The present study collaborated with the process of nursing care for kidney transplant recipients, improving guidance and follow-up of patients. This favored a better adaptation to the treatment and, consequently, an improvement in the patients' quality of life.

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Drafting the work or revising it critically for important intellectual content - Carbogim F da C, Poveda V de B; Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved - Fonseca CC, Santos KB dos. All authors approved the final version of the text.

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