ORIGINAL ARTICLE

# Construction and Validation of a Questionnaire on the knowledge of pharmacists to work in Pharmaceutical Care in the Brazilian Public Health System

## Construção e Validação de um Questionário sobre conhecimentos dos farmacêuticos para trabalhar no Cuidado ao Paciente no Sistema Público de Saúde Brasileiro

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**ABSTRACT**

**Introduction:** Most Brazilian community pharmacists do not have the proper qualifications to exercise Pharmaceutical Care with patients with diabetes mellitus (DM). Thus, it is necessary to build and validate a questionnaire to measure the knowledge of pharmacists working in the Brazilian Public Health System (SUS). **Methods:** Methodological study, developed in four stages: elaboration of the questionnaire based on the literature; content validation through the Delphi technique; pre-test with SUS pharmacists; and a pilot study, in which the questionnaire was applied to SUS pharmacists who participated in the training before and after the end of a training course. To assess the pharmacist's knowledge in the course, the averages were calculated before (T0) and after (T1) the course, considering two groups: Group A (Pharmacists with ≥ 75 % participation in the course) and Group B (Pharmacists with participation < 75 %). **Results:** Using the Delphi Technique, it was necessary to execute two rounds among experts 31 and 11 respectively (Calculation for total Content Validity = 98 %, in both rounds). The final questionnaire had 13 questions, 10 of which were elaborated and validated by the authors and three questions are from a validated questionnaire. There was a difference between the averages of Group A (initial average 7.50 and final average 9.90, p <0.001), which was not observed in Group B (initial average 6.63 versus final average 6.06, p=0.120). **Conclusion:** The questionnaire on DM and associated comorbidities allowed measuring the knowledge of SUS pharmacists.

**Keywords:** Validation study, Evidence-based pharmaceutical care, Diabetes mellitus, Public health education, Education continuing.

**RESUMO**

**Introdução:** A maior parte dos farmacêuticos comunitários brasileiros não possuem a devida qualificação para exercer o Cuidado Farmacêutico junto aos pacientes com Diabetes Mellitus (DM). Assim, faz-se necessário construir e validar um questionário para medir conhecimento de farmacêuticos inseridos no Brazilian Public Health System (SUS). **Métodos:** Estudo metodoló-

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gico, desenvolvido em quatro etapas: elaboração do questionário construído com base na literatura; validação de conteúdo por meio da técnica Delphi; pré-teste com farmacêuticos SUS; e estudo piloto, em que o questionário foi aplicado aos farmacêuticos do SUS que participaram da capacitação antes e após o término de um curso de capacitação. Para avaliar o conhecimento do farmacêutico no curso, realizou-se as médias antes (T0) e após (T1) a realização do curso, considerando-se dois grupos: Grupo A (Farmacêuticos com ≥ 75% de participação no curso) e Grupo B (Farmacêuticos com participação < 75%). **Resultados:** Foi necessária apenas uma rodada entre os 31 especialistas pela Técnica de Delphi (Cálculo para Validade de Conteúdo total = 98%). O questionário final apresentou 13 questões, sendo que 10 foram elaboradas e validadas pelos autores e três questões são de um questionário validado. Houve diferença entre as médias do Grupo A (média inicial 7,50 e final 9,90, p = 0,000), o que não foi observado no grupo B (média inicial 6,63 versus final 6,06, p=0,120). **Conclusão**: O questionário sobre DM e comorbidades associadas permitiu a mensuração do conhecimento de farmacêuticos do SUS.

**Palavras-chave**: Estudo de validação, Cuidado farmacêutico baseado em evidência, Diabetes mellitus, Educação em saúde pública, Educação continuada.

## INTRODUCTION

Coping with diabetes mellitus (DM) and comorbidities in the SUS is a matter of great relevance due to the prevalence of patients with this health condition in Brazil, reaching 9.2 %, ranging from 6.3 % in the north to 12.8 % in the southeast. And even with the high prevalence, misinformation about it is still high. As the Brazilian Society of Diabetes points out, 50 % of diagnosed individuals do not even know about their health condition[1,2].

DM treatment occurs according to glycemic goals, including fasting blood glucose, glycated hemoglobin, among others, which vary according to the characteristics of each patient, such as the type of diabetes, metabolism, and age. Changing one´s lifestyle is essential for reducing glycemic levels and negative health outcomes, such as physical activity, reducing alcohol intake, and dietary reeducation. Drug treatment, in contrast, is an important tool in coping with insulin resistance and other glycemic factors affected by DM[3,4].

In the context of basic health care, pharmaceutical assistance supports actions to promote, protect, and recover health, with drugs as the main means of intervention, considering their access and rational use. Several studies have already demonstrated the benefit of pharmaceutical care in glycemic control, through individualized care, avoiding the worsening of patients' health, increasing adherence to treatment, and generating clinical improvement and quality of life[5-8].

However, more than half of Brazilian community pharmacists may not be properly prepared to perform clinical activities. In addition, it was observed in these studies that about 40 % of the participants did not even know what pharmaceutical care was[9,10].

Given the above, this study is justified by the unavailability of instruments validated in Brazil that assess the knowledge of pharmacists inserted in the SUS on the treatment of DM and its comorbidities. Thus, the elaboration and validation of an instrument can contribute to the identification of knowledge gaps to be worked on in

training for the provision of pharmaceutical care to patients with DM within the scope of the SUS.

## MATERIAL AND METHODS

This is a methodological study that was developed following guidelines already described in the literature[11-13] which developed and validated a questionnaire to assess the knowledge of pharmacists to work in Pharmaceutical Care for patients with DM and the most frequent comorbidities. After validation, the questionnaire was applied before and after the training of pharmacists working in the SUS.

The training happened through eight online meetings and discussions about clinical cases that took place on the Moodle platform. Before each class, two articles and a clinical case were made available for discussion throughout the week. The discussed themes were:

- Introduction of the training and examples of real life experiences;
- Conceptual aspects and pharmacotherapeutical issues;
- Diabetes Mellitus: General aspects and evidence based actions;
- Type 2 Diabetes Mellitus (T2DM) pharmacotherapy: oral antidiabetics and insulin;
- Systemic arterial hypertension (SAH), cardiac insufficiency and dyslipidemia;
- Gestational Diabetes Mellitus and type 1 diabetes mellitus (T1DM);
- Chronic disease on kidney and DM on geriatrics;
- Non-pharmacological measures on DM and how to take care of a diabetic foot (multi-professional approach).

The study included the following stages: 1) elaboration of the questionnaire; 2) content validation; 3) pre-test; and 4) pilot study[9]. The construction and validation process of the questionnaire was carried out between December 2021 and February 2022, preceding the start of training, which took place between March and May 2022.

### Elaboration of the questionnaire

The questionnaire prepared by the authors of the present study was conceptually structured according to the eight modules that constituted the first stage of training. It was composed of questions that addressed the following topics: Pharmaceutical Care and pharmacotherapeutic problems, Evidence-Based Practice (EBP); non-pharmacological measures and lifestyle; Type 1 Diabetes Mellitus ou T1DM, Type 2 Diabetes Melllitus ou T2DM and gestational DM; DM and elderly health; dyslipidemia, systemic arterial hypertension , and heart failure. Among the questions, there were clinical cases and conceptual aspects. The questionnaire was built according to the literature, including the most current guidelines on the topics addressed[14-16].

### Content validation

The questionnaire was validated using the Delphi Technique, by pharmacists with expertise in clinical pharmacy, working in different scenarios and with different profiles[17]. The Google Forms resource was used, in which three questions were inserted about each question that

was evaluated, and the answers were organized on a Likert-type scale, as shown in Table 1:

Table 1. Question and answer options asked to the panelists to validate the questionnaire to assess the knowledge of pharmacists to work in the Pharmaceutical Care for patients with Diabetes Mellitus and its comorbidities (n=31).

| Questions for the panelists* | Answer choices | Scoring |
|---|---|---|
| Do you consider it important to keep this question in the questionnaire on pharmaceutical knowledge about Diabetes Mellitus and associated comorbidities? | Disagree<br>Indifferent<br>Partially agree<br>Agree | 0 points<br>1 point<br>2 points<br>3 points |
| Is the information contained in the question clearly expressed? | Disagree<br>Indifferent<br>Partially agree<br>Agree | 0 points<br>1 point<br>2 points<br>3 points |
| Do you consider that the information contained in the question includes important data for the training of pharmacists, in order to monitor the pharmacotherapy of patients with Diabetes Mellitus and associated comorbidities? | Disagree<br>Indifferent<br>Partially agree<br>Agree | 0 points<br>1 point<br>2 points<br>3 points |

Source: The authors.

After each question, an optional field for comments and suggestions was inserted. The purpose of the evaluation was to judge the technical questions of the questionnaire, the understanding and importance of the items, and the intelligibility of the proposed answers, verifying the degree of clarity, pertinence, and the need for modifications.

Subjects were identified by active search through their electronic addresses on the Internet and contacted by email and/or telephone. The evaluation questionnaire of "Knowledge of Public Health System Pharmacists to work in Clinical Practice" was sent through a link on the Google forms platform, containing 13 questions (10 questions to be evaluated and three validated questions by Reis et. al, 2015)[9], and after agreeing to participate and signing the Free and Informed Consent Form (*Termo de Consentimento Livre e Esclarecido* - TCLE), the professionals analyzed each question, scoring them according to Table 1. The specialists in this phase had 14 days to return, from the date the e-mail was sent.

When they returned the answers, the second round was held with these same specialists, and again they had 14 days to respond.

## Pre-test

After approval by the committee of judges, a pre-test of the questionnaire was

carried out. For this, the instrument was sent to the target population (pharmacists) in order to verify that the questionnaire would be properly understood and filled out easily, in addition to possible errors, allowing the reformulation of flaws in the questionnaire[18] The sample consisted of 15 pharmacists working in the SUS, but who did not participate in the training.

The pharmacists analyzed the same items that the specialists evaluated (Table 1). The data collected through the electronic form on the Google Forms platform were analyzed and the agreement between the responses of the evaluating judges (content validation) and Primary Health Care (PHC) pharmacists (pre-test) was verified through the Content Validity Calculation (CVC).

The objective of the CVC is to measure the degree of agreement in each question present in the questionnaire[19] each item, the CVC was calculated following the steps below: (a) calculation of the average of the grades (Mx); (b) calculation of the initial CVC (CVCi), by dividing the average by the maximum value of points that the item could reach; (c) calculation of the error (Pei), from the division of the number one[19] by the total number of evaluating judges, increased by the same number of judges - the error aims to minimize possible biases of these judges; and (d) calculation of the final CVC (CVCc), from the subtraction of CVCi by Pei[12,20]. Items with CVCc greater than 0.8 were considered valid[19]. Statistical analysis was performed according to the CVC formulas implemented in Microsoft® Excel, version 10.

## Pilot study

The same questionnaire was applied through the Moodle platform, to the pharmacists who participated in the training in two different moments: before the beginning (T0) and after the end of the course (T1). Pharmacists participating in the training were given a period of five days to respond to the questionnaire, but when starting it, they had two hours to complete it. At the end of the training, which lasted eight weeks, the questionnaire was reapplied in order to assess the average number of correct answers before and after the training. In the Moodle platform it was possible to mix the questions and their alternatives. It should be noted that the participants were not informed that the content of the final questionnaire was identical to the initial questionnaire.

For the purposes of analysis, the pharmacists were divided into two groups: Group A, who had frequency and participation in training and discussion forums ≥75 %; and Group B, who were those with participation <75 %[21]. The Statistical Package for the Social Science software (SPSS - version 20.0) was used to perform the Kolmogorov Smirnov and paired T tests, with the aim of investigating whether the difference between the initial and final means were statistically significant in both groups[12].

This study was approved by the Ethics Committee for Research Involving Human Beings (CEPES), of the Federal University of São João del-Rei (UFSJ), Dona Lindu Center-West campus, under opinion 5.259.122 and CAAE 45666921.0.0000.5545.

## RESULTS

Out of the 51 pharmacists with expertise in clinical pharmacy invited, 31 agreed to participate in the first round and 11 in the second round. Among the three points

analyzed in each question, none of them obtained CVCc < 0.8 and the CVCt was 98 % in the first round. The same happened with the validation with the target audience, all of them obtained CVCc > 0.80 and CVCt = 91 %. Table 2 shows the CVCc of the two groups that validated the questionnaire:

Table 2. Final content validity coefficient (CVCc) of the specialists' and target audiences' assessments of the questionnaire "Knowledge of Public Health System Pharmacists to work in Clinical Practice".

| Points addressed | CVCc content validation (n=31) | CVCc second round of content validation (n=11) | CVCc pre-test (n=15) |
|---|---|---|---|
| Pertinence in keeping the question | 0.99 | 0.97 | 0.92 |
| Clarity of information | 0.97 | 0.99 | 0.87 |
| Importance of the question for the training course | 0.99 | 0.99 | 0.93 |

Source: The authors.

Even with CVCc greater than 0.80, some changes were made to the questionnaire after suggestions from the judges, in order to improve the quality of the questionnaire (Table 3). In addition, it was suggested that all acronyms be preceded by their respective meaning, starting with capital letters, such as Evidence-Based Clinical Practice (EBP). This suggestion was accepted.

Table 3. Changes made to the questionnaire "Knowledge of Public Health System Pharmacists to work in Clinical Practice" after suggestions from the technical judges (n=31)

| **Change location** | **Questions sent to technical judges** | **Suggested changes** |
|---|---|---|
| Statement | 1. Diabetes mellitus (DM) is an important public health problem, as it is associated with complications that compromise the productivity, quality of life and survival of affected individuals. Regarding DM and its pharmacotherapy, judge statements 1 as true or false. | 1. Diabetes mellitus (DM) is an important public health problem, as it is associated with complications that compromise the productivity, quality of life and survival of affected individuals. **Thus, a multidisciplinary approach is essential, in which a clinical pharmacist is inserted in order to optimize the treatment of patients with this morbidity. In the context of pharmaceutical care,** DM and its pharmacotherapy, judge the statements below as true or false: |

| | | |
|---|---|---|
| Answer option | 2. ( ) De-intensification of glycemic control is recommended, avoiding HbA1c rates lower than 6.5 % for all elderly people, due to the increase in global and cardiovascular mortality, in addition to the risk of hypoglycemia. | 2. ( ) **In clinical practice, de-intensification (reduction of excessive treatment) of glycemic control should be recommended, avoiding HbA1c rates lower than 6.5 % for the elderly (60 years or older), due to the increase in overall mortality and cardiovascular disease, in addition to the risk of hypoglycemia.** |
| Statement | 3. What do you understand by "Evidence-based clinical practice"? | **Evidence-Based Clinical Practice (EBP) is an important component for decision-making in health, including Pharmaceutical Care. Regarding EBP, we can understand it as:** |
| Answer option | 6. c) If the patient was in phase 2, with decreased insulin secretion, the use of Glibenclamide 5 mg would be correct, and the combination with insulin secretagogues may be necessary, such as GLP-1 analogues (Liraglutide), DPP-4 inhibitors (Linagliptin) or SGLT-2 analogues (Dapagliflozin). | 6. c) If the patient was in phase 2, with a decrease in insulin secretion, the use of Glibenclamide 5 mg would be correct, and it may be necessary to combine it with **incretin mimetics**, such as GLP-1 analogues (Liraglutide), DPP-4 inhibitors (Linagliptin) **or agents that promote glycosuria, such as SGLT-2 inhibitors** (Dapagliflozin). |
| Statement | 8. Patient L.C.S, 15 years old, 1.75 m, 66 kg, does not consume alcohol and tobacco, sedentary lifestyle (does not play sports for fear of glycemic control). Diagnosed with Type 1 Diabetes Mellitus (DM 1). Uses insulin according to the prescription: | 8. Patient L.C.S, 15 years old, 1.75 m, 66 kg, does not consume alcohol and tobacco, sedentary lifestyle (does not play sports for fear of glycemic imbalance). Diagnosed with Type 1 Diabetes Mellitus (DM 1). Uses insulin as prescribed: |
| Answer option | 9. V - The treatment of gestational diabetes includes nutritional education, physical activity, and when indicated, the use of drugs such as metformin and insulin. | 9. V - The treatment of gestational diabetes includes nutritional education, physical activity, and when indicated, the use of drugs such as: metformin **(assessing the risk x benefit)** and insulin. |

Source: The authors.

After these changes, the questionnaire was sent back to the specialists for a new evaluation, and again, the CVCt was 98 %. After the validation of the 15 pharmacists (target audience), no further changes were made to the questionnaire. The questionnaire consisted of 10 questions prepared by the authors, all multiple choice, with five response options and only one correct. In the final version of the questionnaire, three more questions were added that were previously validated by Reis et. al. (2017) totaling 13 questions, which were answered at the beginning and at the end of the training "Implementation of Clinical Pharmacy in the SUS – ImplanFarSUS".

In the pilot study, 45 pharmacists started training and of these, 41 answered the sociodemographic questionnaire, 82.2 % female (n=34), with a median age of 37.2 years (IQ 33.95 - 46.7) (minimum = 25.2 years; maximum = 70.3 years) with a median training time of 14.0 years (IQ 7.5 – 20.0), and working time in the SUS of 8 years (IQ 3-14 years). Among them, 51.2 % (n=21) studied at private universities and 70.7 % (n=29) have some type of graduate degree: 58.5 % (n=24) attended *Lato Sensu* graduate courses, 9.8 % (n=4) had a master's degree and 2.4 % (n=1) had a doctorate. Twenty-six pharmacists completed the training. The initial and final questionnaire scores for both groups are described in Table 4.

Table 4: Descriptive statistics of the questionnaire "Knowledge of pharmacists to work in the Pharmaceutical Care of patients with Diabetes Mellitus and its comorbidities" at T0 (n=41) and T1 (n=26).

| Group | | Evaluation average | Standard deviation | P value* |
|---|---|---|---|---|
| A**(17 pharmacists) | Initial | 7.50 | 1.27 | <0.001 |
| | Final | 9.90 | 0.74 | |
| B*** (9 pharmacists) | Initial | 6.63 | 1.50 | |
| | Final | 6.06 | 1.34 | 0.120 |

*The p value refers to the difference between the means, according to the paired t-test.

** Pharmacists with ≥75 % share. *** Pharmacists with participation below 75 %.

There was a significant difference between the initial and final means of Group A ($p<0.05$), which was not observed in Group B ($p=0.120$). In T0, the question with the highest number of correct answers was question number 8 (33 correct answers/80.5 %), which concerns guidelines on insulin mixtures. Question 4 was that with the lowest correct answer rate (4 correct answers/9.8 %) in T0, showing that the management of SAH is a gap to be filled. In T1, the question with the highest number of correct answers was number 3 (26 correct answers/100 %), which explains the understanding of pharmacists about evidence-based clinical practice; while questions 4 (arterial hypertension management) and 13 (Pharmaceutical Assistance cycle) had the lowest number

of correct answers, with 7 (26.9 %) and 3 (11.5 %) respectively.

It should be noted that question number 13 refers to question number 21 of the questionnaire already validated by Reis et al. (2017). The questionnaire is available at the link (in English and Portuguese): https://ufsj.edu.br/nepefac/instrumentos_guias_e_pareceres_.php

## DISCUSSION

The information clarity index achieved by professionals with expertise in Clinical Pharmacy and by the target audience, as well as the pertinence and importance of each question, evaluated by the CVC (>0.8), showed that the instrument is adequate for the population to which it is intended (pharmacists working in the Public Health System)[19]. The CVC calculation has been used in the same way in the validation of several instruments in the health area[22-25].

In addition, the questionnaire proved to be feasible to be applied to the target population, measuring the effect of a training course and showing better results in the group that effectively participated in the course.

The feasibility and applicability of the instrument is due to several reasons, including the number of questions in the instrument. The use of smaller questionnaires has proven to be a good alternative when compared to larger questionnaires[26] so much so that abbreviated versions have been widely used worldwide, including by the World Health Organization[27-30]. The option for a questionnaire in multiple choice format allows the collection of more information about the individuals' knowledge, which would not be so effective if the model adopted presented alternatives of the true/false type[31,32].

The difference in means observed in Group A at T0 and T1 was not observed in Group B. This explains two important points, namely: the instrument was able to measure the effect of the intervention, evidencing the internal validity of the questionnaire, since it was able to measure what was proposed, attributing quality to the construct[21,33]. The other point is that the course was effective in relation to the acquisition of knowledge by pharmacists. In this sense, it is important to note that the positive effect observed in Group A may be related to the commitment of the student/professional[33,34].

When evaluating the contents of the questions with more and less correct answers, the high rate of correct answers in question number 8 (both in T0 and in T1) shows that SUS pharmacists already have some practice with guidelines on mixing insulins, especially those that are available from the SUS. However, the limited knowledge about the management of SAH, both in T0 and in T1, shows that pharmacists should delve deeper into the subject, mainly because it is a chronic disease with a high prevalence in Brazil[1].

Finally, the profile of pharmacists working in the SUS identified in the present study does not differ much from the profile found by other researchers: young adults, predominantly female[35,36] predominance of women not only in the Pharmacy course, but in the area of health as a whole is well documented in the literature[37]. The fact that a minority of pharmacists who attended postgraduate courses opted for *Lato Sensu* (specialization) can be explained by the wide variety of this type of course on

the market, in addition to the shorter time and flexible schedules, which is not seen in the *Stricto Sensu* category (master's/doctorate), since they demand more time and often, exclusive dedication[38].

It is important to point out that the study was carried out online, which is an environment where it is not possible to control some variables, such as the distraction of the participants (panel of specialists and pharmacists) and the fatigue in analyzing each proposed item, as well as a less control of the pilot study, in the application of the initial and final questionnaires. Additionally, the evaluation in a "test" format may not be the best strategy to verify if pharmacists are prepared for this practice. However, it is pertinent to point out that the purpose of the questionnaire was to measure the pharmacist's knowledge before and after a training course, which is one reason that allows its recognition as a sufficient indicator to consider the purpose for which it was created. Furthermore, no tool was found in the literature that could be used to measure the knowledge of pharmacists working in the SUS about DM and associated comorbidities. In this regard. it`s envisioned for the instrument to be utilized in the context of implementing a pharmaceutical care service in the field of attention primary to health, since it can identify potential weaknesses of the professional`s knowledge .

## CONCLUSION

The constructed and validated questionnaire allowed measuring the knowledge of SUS pharmacists on Pharmaceutical Care in DM and associated comorbidities. It was still possible to explain the effectiveness and importance of training aimed at this public, as long as there is commitment, to increase knowledge on the subject and subsequently exercise their clinical duties in the public health system.

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- SRS: Contribuição substancial no esboço do estudo e na interpretação dos dados; 2- Participação na redação da versão preliminar; 3- Participação na revisão e aprovação da versão final; 4- Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo.
- MST: Contribuição substancial no esboço do estudo e na interpretação dos dados; 2- Participação na redação da versão preliminar; 3- Participação na revisão e aprovação da versão final; 4- Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo.
- MRF: Contribuição substancial no esboço do estudo e na interpretação dos dados; 2- Participação na redação da versão preliminar; 3- Participação na revisão e aprovação da versão final; 4- Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo.
- WNO: Contribuição substancial no esboço do estudo e na interpretação dos dados; 2- Participação na redação da versão preliminar; 3- Participação na revisão e aprovação da versão final; 4- Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo.
- PRON: Contribuição substancial no esboço do estudo e na interpretação dos dados; 2- Participação na redação da versão preliminar; 3- Participação na revisão e aprovação da versão final; 4- Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo.
- VSB: Contribuição substancial no esboço do estudo e na interpretação dos dados; 2- Participação na redação da versão preliminar; 3- Participação na revisão e aprovação da versão final; 4- Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo.
- MLP: Contribuição substancial no esboço do estudo e na interpretação dos dados; 2- Participação na redação da versão preliminar; 3- Participação na revisão e aprovação da versão final; 4- Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo.
- AOB: Contribuição substancial no esboço do estudo e na interpretação dos dados; 2- Participação na redação da versão preliminar; 3- Participação na revisão e aprovação da versão final; 4- Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo.

**CONFLICTS OF INTEREST**
The authors declare that they have no conflicts of interest.

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