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Evaluation of oral drug adherence in patients with oncological pain in Pernambuco reference hospital

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Abstract

Objectives: The aim of this study was to describe the profile of patients with cancer pain using oral opioids, to evaluate the therapeutic adherence of these patients and to identify the factors associated with it. **Methods:** It was a cross-sectional study carried out at the Pharmacy of the Hospital de Câncer de Pernambuco, from March to September 2019. Each patient were selected for convenience and were interviewed once, and the Medicines Evaluation Questionnaire (BMQ) was used to determine adherence and FACS for determine the socioeconomic, demographic and clinical profile. The data was analyzed using the Statistical Package for Social Sciences (SPSS) program. **Results:** In total, 46 patients were interviewed, aged between 19 and 82 years, 59% did not have complete elementary school, 74% had family income equal or less than 1 minimum wage and 71% classified as non-adherent, with the domain "recall screen" the most scored (84%). Patients using controlled-release medications ($p = 0.0000352$) and with higher levels of education ($p = 0.016$) obtain better adherence results in the BMQ questionnaire. **Conclusions:** Through the study it was possible to identify a high incidence of patients not adhering to drug therapy and their socioeconomic profile, highlighting the need for political and institutional interventions. Due to the scarcity of publications, further studies are needed to determine adherence factors in patients with cancer pain.

Keywords: medication adherence, cancer pain, health education, chronic pain, neoplasms.

Avaliação da adesão de medicamentos orais em pacientes com dor oncológica em hospital de referência de Pernambuco

Resumo

Objetivo: O objetivo deste trabalho foi descrever o perfil dos pacientes com dor oncológica em uso de opioides orais, avaliar a adesão terapêutica destes pacientes e identificar os fatores associados a ela. **Método:** Foi realizado um estudo transversal na Farmácia do Ambulatório da Dor do Hospital de Câncer de Pernambuco, durante o período de março a setembro de 2019. Os pacientes foram selecionados por conveniência e entrevistados uma única vez utilizando o Questionário de Aderência Medicamentosa *Brief Medication Questionnaire* (BMQ) para determinar a adesão e Formulário de Avaliação Clínico e Socioeconômico (FACS) para determinar o perfil socioeconômico, demográfico e clínico. Os dados foram analisados no programa SPSS. **Resultados:** No total, 46 pacientes foram entrevistados, com idade entre 19 e 82 anos, 59% não possuíam fundamental completo, 74% possuíam renda familiar menor ou igual a 1 salário mínimo e 71% classificados como não aderentes, sendo o domínio de não-adesão mais pontuado o de "recordação" (84%). Pacientes em uso de medicamentos de liberação controlada ($p=0,0000352$) e com melhores níveis de escolaridade ($p=0,016$) obtiveram melhores classificações de adesão no questionário BMQ. **Conclusão:** Através do estudo foi possível identificar uma alta incidência de pacientes não aderentes a terapia medicamentosa e seu perfil socioeconômico evidenciando a necessidade de intervenções políticas e institucionais. Devido à escassez de publicações, são necessários mais estudos para determinar fatores de adesão em pacientes com dor oncológica.

Palavras-chave: cooperação e adesão ao tratamento, dor do câncer, educação em saúde, dor crônica, neoplasias.



Introduction

Cancer is the name given to a group of diseases that are characterized by the disorderly growth of malignant cells, undifferentiated from their source tissue and that have invasive potential to other tissues.¹ One of the most common symptoms of this disease is pain, affecting at least 6 out of 10 patients, and can reach up to 9 in the more advanced stages, as cancer tends to present a chronic feature, which can be caused by tumor invasion and tissue destruction, the very treatment with chemotherapy, radiotherapy and/or surgery². For the treatment of oncologic pain, opioid is one of the most used classes, but it presents peripheral and central side effects that can compromise the patient's adherence to the treatment and consequently prevent the adequate analgesia.³ Factors such as age, medication, dose, route of administration and diseases, which can alter metabolism and excretion, can predispose or exacerbate the onset of these effects that range from nausea to cognitive symptoms.⁴

Therapeutic adherence is the term used to define the patient's acceptance and cooperation in an appropriate way to the treatment, and this collaboration may be affected by the health team, the therapy itself, and by the patient's socioeconomic and individual characteristics^{5,6}. According to a Brazilian study, the prevalence of non-adherence in patients with chronic diseases is 31%, while for the World Health Organization (WHO) it was around 50%.⁷ Individuals with chronic diseases and older adults have a great predisposition to non-adherence and this reflects in a great impact on the health system since it is associated with the increase in the number of hospitalizations, prescriptions, and purchase of medications leading to limitations that will impact on the quality of life of these patients.⁸

The Pharmacy of Pain, partner of the Pharmacy of Pernambuco, is located in the Outpatient Clinic of Pain of the *Hospital do Câncer of Pernambuco*. Approximately 150 patients are treated monthly in the pharmacy, which provides oral medications free of charge to those who are included in the eligibility criteria defined in the Clinical Protocol and Therapeutic Guideline (*Protocolo Clínico e Diretriz Terapêutica*, PCDT) of chronic pain of the Ministry of Health and/or Technical Standard 15/2013 of Neuropathic Pain from the Health Secretariat of State of Pernambuco. Given the above, this work aims to describe the profile of the patients with oncologic pain using oral opioids, to evaluate the therapeutic compliance of these patients, and to identify the factors associated or not with it.

Methods

A prospective, cross-sectional and quantitative study was conducted. The sample was collected by means of an individual interview for data collection. The research was approved by the Research Ethics Committee (REC) of the *Sociedade Pernambucana de Combate ao Câncer - Hospital de Câncer of Pernambuco*, under CAAE number 04336518.0.0000.5205. Patients over 18 years of age were selected from March to September 2019, diagnosed with chronic intractable pain (CID 52) using opioids and/or adjuvants provided by the Pharmacy of Pain of the Outpatient Clinic of the *Hospital de Câncer of Pernambuco* in Recife/PE/BR and who were duly enrolled in the Chronic Pain Program of the Specialized Pharmaceutical Assistance Component (*Componente Especializado de Assistência Farmacêutica*, CEAF). Carriers and

accompanying persons, minors and patients with difficulty or impossibility of verbal and written communication were excluded. Patients with less than 1 month of treatment for chronic pain were also excluded from the study because it was impossible to evaluate adherence.

The patients were selected by convenience, where all the patients who met the inclusion criteria and attended the outpatient clinic on the days of consultation with the pain physician were invited to an individual interview. Two questionnaires were used in the interview: A Drug Adherence Questionnaire, the Brief Medication Questionnaire (BMQ) and the Clinical and Socioeconomic Assessment Form (*Formulário de Avaliação Clínico e Socioeconômico*, FACS). The FACS is based on the work by Tavares e colaboradores (2016) and has questions about socio-demographic information, clinical data and about the health team, with the objective of trying to describe the existence of adherence determining factors that have no direct correlation with the drug, having a mean duration of 15 (fifteen) minutes of application. The second questionnaire was validated and translated into Portuguese by Bem, Neumann, and Mengue (2012) and aims to estimate the therapeutic adherence, with a mean duration of 10 minutes. This questionnaire analyzes the patients' responses and categorizes them into the domains of reminder, belief, and regimen, in which patients who answer more than three questions are classified as non-adherent, two as probably non-adherent, one as probably adherent and patients who have no positive response to the questionnaire are classified as adherent. The sensitivity and specificity of the BMQ questionnaire for the evaluation of adherence has been estimated at 85.5% and 69.8% respectively.¹¹ The patient's medical record was consulted in cases where the patient could not provide the diagnosis or the site of the disease.

The results were tabulated in the Microsoft Excel 2016 for Windows software (Microsoft Corporation; Albuquerque, NM, USA) and later analyzed in the Statistical Package for Social Sciences (SPSS) for Windows software (SPSS Inc; Chicago, IL, USA). The associations between categorical variables were performed by Pearson's Chi-square test, and the associations between categorical and continuous variables by means of the ANOVA One-Way test. The normality of continuous variables was verified by the Kolmogorov-Sminorv test. The significance level was determined at 5%; therefore, p values < 0.05 were considered statistically significant.

Results

46 patients were interviewed with similar proportions for both genders (48% male and 52% female), aged between 19 and 82 years old, most of whom (37%) were over 58 years old and self-declared brown-skinned (61%). Regarding the educational level, 3 out of 5 patients (59%) did not have complete elementary school and about 74% had an income less than or equal to 1 minimum wage. About 57% of the patients used the Out-of-Home Transport (*Transporte Fora do Domicílio*, TFD) benefit to move to and from their homes and the outpatient clinic (Table 1). TFD is characterized by a right, guaranteed by the Ministry of Health, which allows the SUS to pay expenses related to the displacement of patients living outside the metropolitan area to the municipality where the treatment will be performed.



Table 1. Demographic and socioeconomic characteristics of patients with oncologic pain stratified according to the BMQ drug adherence classification

Characteristics	All	Drug Adherence				p-value
		Adherent	Probably Adherent	Probably Non-Adherent	Non-adherent	
Sociodemographic data						
Female gender n (%)	24 (52.0)	1 (4.2)	3 (12.5)	4 (16.7)	16 (66.7)	0.400
Age in years old n (%)						
18 – 27	1 (2.0)	-	-	-	1 (100.0)	0.981
28 – 37	6 (13.0)	-	-	1 (16.7)	5 (83.3)	
38 – 47	14 (30.0)	1 (7.1)	2 (14.3)	2 (14.3)	9 (64.3)	
48 – 57	8 (17.0)	-	-	2 (25.0)	6 (75.0)	
> 58	17 (37.0)	1 (5.9)	1 (5.9)	3 (17.6)	12 (70.5)	
Ethnicity n (%)						
White	12 (26.0)	-	3 (25.0)	-	9 (75.0)	0.013*
Mixed	28 (61.0)	1 (3.6)	-	5 (17.9)	22 (78.6)	
Black	5 (11.0)	1 (20.0)	-	2 (40.0)	2 (40.0)	
Marital status with partner n (%)						
Marital status with partner n (%)	28 (61.0)	-	2 (7.1)	7 (25.0)	19 (67.9)	0.128
Schooling n (%)						
No studies or less than 1 year of study	5 (11.0)	-	-	-	5 (100.0)	0.016*
1-8 years of study	6 (13.0)	1 (16.7)	-	-	5 (83.3)	
9 years of study	27 (59.0)	1 (3.7)	1 (3.7.0)	5 (18.5)	20 (74.1)	
10-12 years of study	7 (15.0)	-	1 (14.3)	3 (42.9)	3 (42.9)	
Over 12 years	1 (2.0)	-	1 (100.0)	-	-	
Family income n (%)¹						
< 1 or 1 minimum wage	34 (74.0)	2 (5.9)	1 (2.9)	6 (17.6)	25 (73.5)	0.425
2-3 minimum wages	10 (22.0)	-	2 (20.0)	1 (10.0)	7 (70.0)	
>3 minimum wages	2 (4.0)	-	-	1 (50.0)	1 (50.0)	
Locomotion used n (%)						
On foot/Asking for a ride/Bicycle	3 (7.0)	-	1 (33.3)	1 (33.3)	1 (33.3)	0.599
Public transportation	8 (17.0)	-	-	2 (25.0)	6 (75.0)	
Own vehicle	3 (7.0)	-	-	1 (33.3)	2 (66.7)	
TFD	26 (57.0)	1 (3.8)	2 (7.7)	4 (15.4)	19 (73.1)	
Others (Urban mobility application)	6 (13.0)	1 (16.7)	-	-	5 (83.3)	
Clinical data						
Patients with comorbidities n (%)	15 (32.6)	1 (6.7)	1 (6.7)	3 (20.0)	10 (67.0)	0.931
Cases of patients with comorbidities	18 (100.0)	-	1 (5.5)	3 (16.7)	14 (77.8)	
Diabetes Mellitus	3 (17.0)	-	-	-	3 (100.0)	
Arterial hypertension	9 (50.0)	-	1 (11)	1 (11.0)	7 (78.0)	
Chronic Obstructive Pulmonary Disease	1 (5.5)	-	-	-	1 (100.0)	
Chronic Heart Failure	1 (5.5)	-	-	1 (100.0)	-	
Chronic Renal Failure	1 (5.5)	-	-	-	1 (100.0)	
Pulmonary emphysema	1 (5.5)	-	-	-	1 (100.0)	
Rheumatism	1 (5.5)	-	-	1 (100.0)	-	
Glaucoma	1 (5.5)	-	-	-	1 (100.0)	
Medications (cases) n (%)						
Methadone	76 (100.0)	4 (5.2)	7 (9.2)	14 (18.4)	51 (67.1)	
Methadone	18 (23.6)	-	1 (5.6)	4 (22.2)	13 (72.2)	
Dipyron	12 (15.7)	-	2 (16.7)	3 (25.0)	7 (58.3)	
Morphine	12 (15.7)	1 (8.3)	-	3 (25.0)	8 (66.7)	
Gabapentin	11 (14.4)	-	1 (9)	1 (9.0)	9 (82.0)	
Codeine	7 (9.3)	-	-	2 (28.5)	5 (71.4)	
Morphine LC	6 (7.9)	1 (16.7)	3 (50)	-	2 (33.3)	
Amitriptyline	4 (5.2)	2 (50.0)	-	1 (25.0)	1 (25.0)	
Paracetamol	2 (2.7)	-	-	-	2 (100.0)	
Pregabalin	2 (2.7)	-	-	-	2 (100.0)	
Curcuma longa	1 (1.3)	-	-	-	1 (100.0)	
Duloxetine	1 (1.3)	-	-	-	1 (100.0)	

1 Brazilian minimum wage corresponding to approximately US\$ 250.00 in the research period from March to September 2019.

Table 2. Characteristics of clinical history, health care and adherence of patients with oncologic pain

Characteristics	All	Drug Adherence				p-value ¹
		Adherent	Probably Adherent	Probably Non-Adherent	Non-adherent	
Oncological data						
Type of neoplasm by specialty n (%)						
Head and neck	13 (28.3)	1 (7.7)	-	3 (23.1)	9 (69.2)	
Orthopedic	6 (13.0)	-	-	1 (16.7)	5 (83.3)	
Gastrointestinal	3 (6.5)	-	-	2 (66.7)	1 (33.3)	
Hematologic	4 (8.7)	-	1 (25.0)	-	3 (75.0)	
Urologic/Pelvic	8 (17.4)	-	-	2 (25.0)	6 (75.0)	
Breast	7 (15.2)	1 (14.3)	1 (14.3)	-	5 (71.4)	
Skin	3 (6.5)	-	1 (33.3)	-	2 (66.7)	
Neurological	2 (4.3)	-	-	-	2 (100.0)	
Procedures						
Chemotherapy n (%)	35 (76.1)	2 (5.7)	3 (8.6)	6 (17.1)	24 (68.6)	0.619
Radiotherapy n (%)	33 (71.7)	2 (6.1)	3 (9.1)	7 (21.2)	21 (63.6)	0.668
Surgeries n (%)	28 (60.9)	2 (7.1)	1 (1.8)	5 (4.9)	20 (71.4)	0.239
Emergency services in 1 year n (%)	33 (71.7)	1 (3.0)	2 (0.1)	5 (15.2)	25 (75.8)	0.776
Hospitalizations in 1 year n (%)	19 (41.3)	1 (5.3)	2 (10.5)	3 (15.8)	13 (68.4)	0.812
Health conditions						
Limitation in daily activities n (%)	36 (78.3)	1 (2.8)	3 (8.3)	5 (6.3)	27 (25.8)	0.364
Health self-perception n (%)						
Very good	2 (4.3)	-	-	1 (50.0)	1 (50.0)	
Good	7 (15.2)	-	1 (14.3)	1 (14.3)	5 (71.4)	
Regular	17 (37.0)	1 (5.9)	2 (11.8)	4 (23.5)	10 (58.8)	0.819
Poor	15 (32.6)	1 (6.7)	-	2 (13.3)	12 (80.0)	
Very poor	5 (10.9)	-	-	-	5 (100.0)	
Visual Analog Pain Scale – VAP n (%)						
Mild	2 (4.3)	-	-	1 (50.0)	1 (50.0)	
Moderate	23 (50.0)	1 (4.3)	2 (8.7)	4 (17.4)	16 (69.6)	0.916
Severe	21 (45.7)	1 (4.8)	1 (4.8)	3 (14.3)	16 (76.2)	
Data about use of medications						
Patients using non-prescription drugs n (%)	18 (39.1)	1 (5.6)	2 (11.1)	2 (11.1)	13 (72.2)	0.631
Number of non-prescription drug use cases	20 (100.0)	1 (5.0)	3 (15.0)	2 (10.0)	14 (70.0)	
Dipyron	13 (65.0)	1 (7.7)	2 (15.4)	2 (15.4)	8 (61.5)	
Paracetamol	3 (15.0)	-	1 (33.3)	-	2 (66.7)	
Acetylsalicylic acid + associations	1 (5.0)	-	-	-	1 (100.0)	
Dipyron + associations	1 (5.0)	-	-	-	1 (100.0)	
Diclofenac + associations	1 (5.0)	-	-	-	1 (100.0)	
Ibuprofen	1 (5.0)	-	-	-	1 (100.0)	
Patients with Adverse Drug Reactions – ADRs n (%)	26 (56.5)	1 (3.8)	2 (7.7)	4 (15.4)	19 (73.1)	0.957
Number of ADR cases	38 (100.0)	1 (2.6)	2 (5.2)	5 (13.1)	30 (78.9)	
Xerostomia	2 (5.2)	-	-	-	2 (100.0)	
Xerosis	1 (2.6)	-	-	-	1 (100.0)	
Tremors	1 (2.6)	-	-	-	1 (100.0)	
Dizziness	3 (7.8)	-	1 (33.3)	1 (33.3)	1 (33.3)	
Sweating	1 (2.6)	-	-	-	1 (100.0)	
Sleepiness	1 (2.6)	-	-	-	1 (100.0)	
Hiccup	1 (2.6)	-	-	-	1 (100.0)	
Allergic reactions	1 (2.6)	-	-	1 (100.0)	-	
Nausea/Vomits	8 (21.0)	1 (12.5)	-	1 (12.5)	6 (75.0)	
Inappetence	1 (2.6)	-	-	-	1 (100.0)	
Dyspnea	1 (2.6)	-	-	-	1 (100.0)	
Dermatitis	1 (2.6)	-	-	-	1 (100.0)	
Constipation	8 (21)	-	1 (12.5)	2 (25.0)	5 (62.5)	
Confusion	1 (2.6)	-	-	-	1 (100.0)	
Chronic headache	2 (5.2)	-	-	-	2 (100.0)	
Shivering	1 (2.6)	-	-	-	1 (100.0)	
Anxiety	1 (2.6)	-	-	-	1 (100.0)	
Aggressiveness	1 (2.6)	-	-	-	1 (100.0)	

¹ The authors was defined the variable “types of neoplasia” as not suitable for the Chi-square test

As for the clinical aspects, the most prevalent neoplasms were head and neck (28.3%) and urologic/pelvic (17.4%); the mean time elapsed until diagnosis was 4 years, with a minimum of 7 months and a maximum of 22 years. During the interview, the number of emergency care and hospitalizations resulting from the lack of pain control in the last year was questioned, when a positive response was observed in 72% and 41%, respectively. Regarding health perception, 78% reported limitations in daily life due to pain and 44% described it as bad or very bad even when using medications, according to Table 2.

About the analysis of the Pain Outpatient service, the patients had on average 15 months of follow-up with the pain physician, ranging from 1 to 72 months. About 85% of the patients reported having received some kind of guidance on the use of the drug and, of these, 82% were guided exclusively by the physician. Only 07 (seven) patients reported having done some kind of research to get more information about analgesics treatment. As for self-medication, more than a third claimed to be using medicines not prescribed by any attending physician.

Still talking about the therapy, it was possible to observe that 7 out of 10 patients were classified as non-adherent by the BMQ questionnaire, the reminder domain being the most scored. The regimen domain was the second most scored (70%), among which 43% of the patients reported dose failures and 22% dose reduction or omission. By the questionnaire, 7% of the patients were classified as probably adherent, 18% as probably non-adherent and only 4% as adherents. The most prescribed drugs for pain treatment were methadone (23.7%), dipyron (15.8%), morphine (15.8%) and gabapentin (14.5%), respectively. It is also possible to identify that the drugs amitriptyline, dipyron, paracetamol, pregabalin, duloxetine, and *Curcuma longa* were mentioned, but they are not part of the list of substances made available by the outpatient pharmacy. More than half of the patients had some type of adverse drug reaction during use (57%), of which the most cited were constipation, nausea, and vomiting.

Among the factors analyzed, higher levels of education were associated with fewer positive responses in the BMQ questionnaire ($p = 0.016$). Similarly, the use of controlled-release medications was related to better treatment adherence ratings ($p = 0.000035$). No statistically significant associations were observed between therapeutic adherence and other socioeconomic and clinical factors, although it is possible to observe a predominance of some values in relation to these variables.

Discussion

Few studies are published when the subject is chronic oncologic pain and adherence, but it is known that there are multiple factors that can interfere with the involvement of this type of patient and consequently with the relief of symptoms.

The association with socioeconomic and demographic characteristics is often cited in adherence studies. Although not observed in this study, the literature also shows that female gender, younger age, and black ethnicity may be associated with less commitment to the drug treatment, the latter mainly due to demographic and access differences to the drug.^{7,12,13} In parallel, in other studies, a lower financial condition seems to be a negative factor for continuing treatment.^{12,14}

Non-adherence is known to have a high economic impact on the health systems due to the spending on disease progression, lack of symptoms' control and number of hospitalizations.^{15,16} In the present study, it is possible to observe a high incidence of emergency care that leads to questionings about the duly use of home therapy, even considering oncologic pain as subjective and difficult to control, given also the high proportion of non-adherent patients. In another study conducted in an oncologic emergency unit, also in Recife - PE, 46.6% of the care was due to pain treatment, reaffirming the importance of appropriate therapy for this symptom.¹⁷

In fact, patients can benefit from educational interventions by the health care team to improve adherence. Patients who were engaged in drug therapy by the health care team and were informed about the occurrence and management of adverse events were better suited to treatment and improved in therapeutic adherence.^{18,19} Even with the high number of positive reports regarding instructions on the correct use of the drug in this work, the engagement of other professionals and the understanding of the importance of the treatment by the patient could provide considerable gains for both parties.

Regarding the drug, other researches show that adherence can vary even among active principles, given the occurrence of posological variations and adverse reactions, which are frequent with the use of opioids and which tend to predispose to non-adherence.^{5,12,13} In this study, besides the large number of patients who scored in the reminder domain, a significant association was noted between patients who used a controlled-release (CR) drug and the adherence, a fact that may be correlated with better ease in administering this type of pharmaceutical form, information also observed by Meghani *et al.*²⁰ Furthermore, as seen by Zhu and *et al*, patients with better educational levels presented a positive association with therapeutic adherence.¹⁴

Believing in the therapy is a great facilitator for adherence, but the presence of symptoms and adverse effects can affect it negatively.²¹ In a study by Jacobs *et al*, the presentation of adverse drug reactions (ADRs) had a strong association with non-adherence.²² In the present study, no associations between the previous variables were observed, but a high incidence of self-reported ADRs (48%) and a high level of non-adherent patients (71%) were demonstrated. In other studies, with different evaluation methods in patients with oncologic pain, the adherence levels ranged from 33% to 73%.^{5,14} These differences may be related both to the profile of the population and to differences in the instruments for collecting and targeting the research.

The limitations of this study are the very design of the study, cross-sectional, due to the inexistence of a temporal sequence; the self-reporting, which suffers from the bias of reminder and measurement; the collection instrument, where there is variability of questionnaires available; and the very subjectivity of the evaluation of pain since it is a multi-factorial symptom and also involves physical, psychic, spiritual, emotional, and social issues, of which not all were contemplated. The small number of patients can also be considered a limitation, justified by their return to the outpatient clinic to continue the treatment.

Conclusion

Through this study it was possible to identify a low adherence in patients using opioids to the treatment of oncologic pain, apart from a high incidence of emergency care. From the profile



of these patients, it is possible to identify the need for political interventions in order to minimize social risk factors related to non-adherence. Better levels of education and the use of controlled-release drugs have had a positive association with better therapeutic adherence, which may direct the institution and health professionals to better ways of guiding these patients, with the use of instruments to promote health education or even the use of drugs with a lower dosage regimen. Due to the scarcity of work in this type of population, further studies are needed to determine factors and behaviors that minimize this scenario and promote a better quality of life for patients with oncologic pain.

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Collaborators

DLBS conducted the research, conducted the interviews and performed the statistical analysis. JRC and NCOS participated in the design and coordination of the study and helped to write it. All the authors have read and approved the final manuscript.

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Conflict of interest statement

The authors declare that there are no conflicts of interest regarding this article.

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