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A STUDY ON USAGE PATTERN OF PRESCRIPTION MEDICATIONS DISPENSED OVER THE COUNTER (OTC) IN COMMUNITY SETTINGS



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ABSTRACT

Background: Prescription medications are medications that are sold over the counter as per the prescription of a registered medical practitioner. Since there is no officially published list of Over-The-Counter (OTC) medications in India, most of the drugs are dispensed by the dispensing pharmacist.

Objective: To assess the usage pattern of prescription medicines sold OTC.

Methodology: A cross-sectional observational study was conducted at one selected pharmacy community setting in Mysore city. Research duration (4 pm to 6 pm) on daily basis carried out for a period of 9 months by research investigators to assess the prescription medications sold OTC. During the study period, the response of the customers who visited the pharmacy to purchase prescription medications without prescriptions and agreed to answer the questionnaire to assess their knowledge on the use of purchased medications were documented.

Statistical analysis used: Data was analyzed by descriptive statistics using Statistical Package for the Social Sciences (SPSS) version 20.

Results: Out of a total of 962 customers, 560 purchased prescription medications without a prescription during our research period. A total of 282 (50.36%) customers agreed to answer the questionnaire. Self-medication was highly prevalent among educated individuals aged between 21-40 years (45.71%;256). The most common purchased prescription medications OTC were analgesics (41.25%;231), followed by antibiotics (32.50%;182).

Conclusions: Overall, this research study concluded that most commonly purchased medications without prescription were analgesics and antibiotics. Drug regulatory authorities in India should enforce stringent laws to ensure control over the sale of OTC medications.

Keywords: Community Setting, Usage Pattern, OTC

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INTRODUCTION

Prescription medications are those medications which should be sold and dispensed as per the prescription of a registered medical practitioner only. Most of these medications purchased by customers in India are listed in Schedules H and X of the Drug and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 of India.^[1] Over The Counter (OTC) drugs are those medications that can be purchased without prescription. List of OTC medications in India does not exist. As a result, drugs may be sold and dispensed over the counter where customers come to purchase self-medications.^[2] This practice can end up with drug related problems when any medications dispensed over the counter. Customers approaching to community pharmacies depend more on community pharmacists due to expediency, shorter waiting time, cost reduction, availability of credit and flexible opening hours.^[3]

Incompetent community pharmacist status and lack of professional development programmers in many cities of India may be responsible for leading to following medication related problems such as incorrect self-diagnosis, delays in seeking medical advice when needed, infrequent but severe adverse reactions, dangerous drug interactions, incorrect manner of administration, incorrect dosage, incorrect choice of therapy, masking symptoms, exacerbation or prolongation of critical illness, risk of dependence and abuse and most importantly unproductive and dangerous treatment.^[4,5,6] Most often when customers approach community pharmacists for purchasing self-medications where antibiotic dispensed by community pharmacists without any valid reason may be responsible for antibiotic resistance.^[7]

Excessive consumption of following medications such as antihistamines, tramadol and morphine may be responsible for resulting drug habituation and addiction. Practising community pharmacists should be more careful while dispensing medications to specialized populations such as elderly, paediatrics, pregnant and lactating patients because of safety concern of medications which can differ from one population to another.^[8]

Most of practicing pharmacists do not have awareness on ongoing advancement in pharmacy professional which ultimately will have lack of knowledge about safety use of medicines.^[8,9] American Pharmaceutical Association research reflects that allowing dispensing of prescription products to OTC products only under the supervision of legally qualified pharmacists. According to American Pharmaceutical Association, drug which are not safer should not be labelled under OTC, as unsafe medicinal products are more dangerous to be taken without the supervision of general practitioner.^[10,11]

Carrying out this type of research work in community pharmacies located in any part of India is very difficult as most of the registered community pharmacist will not give a provision to carry out this type of research work since certain confidential business information may be leaked out. Research investigators have selected this type of research work as there were few research studies of this kind carried out in India. In the interest of making general public aware about safe use of medications by practising community pharmacists, we have chosen this research work.

MATERIALS AND METHODS

A prospective observational study was conducted in a private community pharmacy of Mysuru city, Karnataka, India over a period of nine months. Customers purchasing prescription medicines without a medical prescription were included in the study. Customers buying other than allopathic drugs or, not willing to participate in this study were excluded from the study. Data was collected by interviewing the customers and carers. Institutional Human Ethical Committee of our college approved the study.

Study procedure:

1. **Development of data collection form:** A suitable data collection form was designed to collect and document details from the customers related to name, age, gender, marital status, literacy status, occupation, smoking habit, alcohol consumption and details of prescription medicines purchased.
2. **Computerization of data collection form:** A computerized format of data collection form was created for the documentation of the collected data and also for easy accessibility, retrieval and analysis of collected data.
3. **Design & development of questionnaire:** A self-research questionnaire was designed and developed by research investigators. The number of questions were minimized and were made short and clear to avoid ambiguity. Initial research questionnaire was administered to few persons

and based on their feedback, perception, reliability, test-retest and inputs, the questions were modified and used in the study.

4. **Selection of customers for the study:** Customers who met study criteria were enrolled into this study.
5. **Collection of data:** Research duration (4 pm to 6 pm) on daily basis carried out for a period of 9 months by research investigators. Data collection form was used to collect details from the customers who met the study criteria. Demographic details of the customers including name and details of prescription medications purchased were documented. The customers were also allowed to fill the questionnaire to assess their knowledge on the use of prescription medications which were purchased OTC.
6. **Data Analysis:** Raw data collected using Microsoft Excel sheet, double checked for accuracy and was analysed using descriptive statistics by Statistical Package for Social Studies (SPSS) version 20.

RESULTS

I. Characteristics of the study population:

Total number of customers visited the community pharmacy were 962, among which 560 purchased prescription medications without a medical prescription during research hours. Table 1 shows demographic characteristics of participants.

Table 1: Demographic details of the study population (n = 560)

Demographic Characteristics	Categories	Total (%)
Age	≤ 20	69(12.32)
	21-40	256(45.71)
	41-60	198(35.36)
	>60	37(6.61)
Gender	Male	331(59.11)
	Female	229(40.89)
Marital Status	Married	342(61.07)
	Single	195(34.82)
	Widow	8(1.43)
	Widower	15(2.68)
	Divorced	0(0)
Smoking habit	Yes	161(28.75)
	No	399(71.25)
Alcohol Consumption	Mild	44(7.86)
	Moderate	31(5.54)
	Excess	0(0)
	No	485(86.61)
Literacy Status	Illiterate	78(13.93)
	Primary	78(13.93)
	Secondary School	138(24.64)
	High School	142(25.36)
	Degree and Above	124(22.14)
Occupation	Agriculture	8(1.43)
	Labour	83(14.82)
	Employed	137(24.46)
	Unemployed	30(5.36)
	Business	72(12.86)
	Dependent	61(10.89)
	Student	77(13.75)
	Housewife	67(11.96)
	Unknown	25(4.46)

II. Therapeutic classes of medications purchased without a medical prescription:

The average number of customers purchased prescription medications during research hours were 7.6 customers and the average number of prescription medicines sold without a prescription per customer was 1.4. The details of different medications purchased by therapeutic categories are listed in Table 2.

Table 2: Therapeutic classes of medications purchased without prescription (n = 560)

Sl. No	Therapeutic Class	Common Drugs	No.	Total (%)	
1.	Analgesics	• Aceclofenac + PCT	86	231(41.25)	
		• Acetaminophen	26		
		• Nimesulide	22		
		• Nimesulide + PCT	14		
		• Diclofenac + PCT	13		
2.	Antibiotics	• Amoxicillin	40	182(32.50)	
		• Cefixime	34		
		• Amoxiclav	30		
		• Ofloxacin + Ornidazole	28		
3.	GI medications	• Pantoprazole	52	167(29.82)	
		• Ondansetron	36		
4.	Antihypertensive	• Amlodipine + Atenolol	26	65(11.61)	
		• Telmisartan + Hydrochlorothiazide	13		
5.	Antidiabetics	• Metformin	10	31(5.54)	
		• Glimepiride + Metformin	9		
6.	Antiparasitics	• Albendazole	18	18(3.21)	
7.	Drugs for respiratory diseases	• Salbutamol + Theophylline	9	25(4.46)	
		• Salbutamol + Ipratropium	5		
		• Acebrotophylline	3		
8.	Corticosteroids	• Prednisolone	9	20(3.57)	
		• Methylprednisolone	7		
9.	Antihyperlipidemic and antiplatelet (Alone and in combination)	• Aspirin + Atorvastatin	5	13(2.32)	
		• Clopidogrel + Aspirin	3		
		• Atorvastatin	3		
10.	Selective phosphodiesterase type 5 (PDE5) inhibitor	• Sildenafil Citrate	8	8(1.43)	
11.	Others:	- Anxiolytics, sedatives and hypnotics	• Phenytoin	1	
		- Diuretics	• Lorazepam	3	
		- Antiparkinsonian medications	• Spironolactone + Furosemide	2	13(2.32)
			• Torsemide + Spironolactone	2	
			• Rosagilline	1	
			• Trihexyphenidyl	1	

ATC Classification for the medications in the study has been shown in Table 3.

Table 3: ATC Classification of 773 prescription drugs purchased without a medical prescription. (n = 560)

ATC Classification	Common Drugs Under ATC Class	ATC Code	Total (%)
M-Musculoskeletal system M01-Anti-inflammatory and anti-rheumatic products.	Aceclofenac + PCT Diclofenac + PCT Nimesulide	M01AX M01AB55 M01AX17	229(40.89)
J-Anti-infective for systemic use J01-Antibacterials for systemic use.	Cefixime Amoxicillin Ofloxacin + Ornidazole Amoxiclav	J01DD08 J01CA04 J01RA09 J01CR02	182(32.50)
A-Alimentary tract and metabolism A02-Drugs for acid related disorders A07-Antidiarrheals, intestinal anti-inflammatory/Anti-infective agents. A10-Drugs used in diabetes	Pantoprazole Ondansetron Rabeprazole Loperamide Metformin Glimepiride + Metformin + Pioglitazone	A02BC02 A04AA01 A02BC04 A07DA03 A10BA02 -	198(35.36)
C-Cardiovascular system C07-Beta blocking agents C08-Calcium channel blockers C10-Lipid modifying agents	Amlodipine + Atenolol Metoprolol Atorvastatin	C08CA01 C07AB02 C10AA05	80(14.29)
H-Systemic hormonal preparations H02-Corticosteroids for systemic use.	Prednisolone Methylprednisolone	H02AB07 H02AB04	20(3.57)
P-Anti-parasitic products, insecticides and repellents. P02-Anthelmintics	Albendazole	P02CA03	18(3.21)
R-Respiratory system	Salbutamol + Ipratropium Br	R03AL02	25(4.46)
G-Genito-urinary system and sex hormones G04-Urologicals	Sildenafil Citrate Tamsulosin	G04BE03 G04CA02	9(1.61)
N-Nervous system N02 - Analgesics N05 - Psycholeptics	Tramadol Lorazepam Phenytoin Rasagilline	N02AX02 N05BA06 N03AB02 N04BD02	12(2.14)

III. Ailments or disease conditions on which prescription medications were used:

The most common types of ailments or disease conditions for which prescription medications were used were Gastrointestinal disorders [36.43% (204)], followed by pain disorders [27.32% (153)]. The ailments are shown in Table 4.

Table 4: Ailments or disease conditions on which prescription medications were used (n = 560)

Sl. No	Disease Condition	No.	Total (%)	
1.	GI disorders	• Gastritis	86	204(36.43)
		• Diarrhoea	37	
		• Vomiting	40	
		• Abdominal pain	28	
		• Nausea	7	
		• Others	6	
2.	Fever		47(8.39)	
3.	Respiratory system disorders	• Asthma	5	25(4.46)
		• COPD	4	
		• Rhinitis	9	
		• Breathlessness	5	
		• TB	2	
4.	Pain	• Headache/Migraine	30	153(27.32)
		• Body pain	31	
		• Knee pain	26	
		• Dental pain	35	
		• Ear pain	1	
		• Haemorrhoidal pain	3	
		• Sore throat	8	
		• Dysmenorrhea	9	
		• Others	10	
		5.	Infections: Dental infection, Urinary tract infections, Wound infections, Respiratory infections	
6.	Hypertension		62(11.07)	
7.	Diabetes mellitus		31(5.54)	
8.	Helminthiasis		18(3.21)	
9	Skin problems: Rashes		14(2.50)	
10.	Others: Depression, Epilepsy, Hyperlipidaemia, Parkinson's disease, Rheumatoid arthritis, Burning sensation in the feet, Liver failure, Maintenance of pregnancy		20(3.57)	

IV. Details of customers where prescription medications sold OTC:

Out of 560 customers, 66.43% (372) purchased prescription medications without a prescription for self-use and 33.57% (188) purchased on behalf of others (i.e. Family member, friend or neighbour).

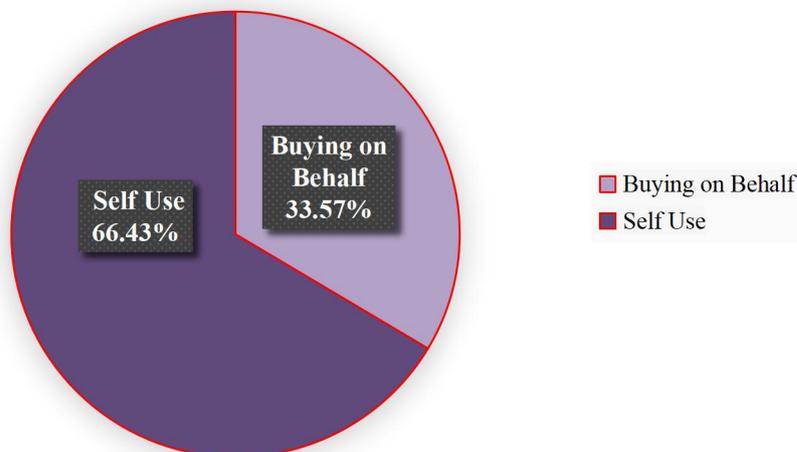


Figure 1: Details of customers where prescription medications sold OTC

V. Methods of obtaining prescription medications in the study population:

Prescription medications sold without a prescription were done so by the following: 54.46% (305) of the customers purchased medications by describing symptoms to the pharmacist and 45.54% (255) purchased medications by providing a used container or tablet strip, medication name written on a piece of paper (not a medical prescription) or by asking for medications verbally, as shown in Table 5.

Table 5: Methods of obtaining prescription medications in the study population (n = 560)

SI. No	Method	Total (%)
1.	Describing symptoms and asking for medications	305(54.46)
2.	Providing a used container/tablet strips, medication name written on a piece of paper (not a medical prescription) asking for drug verbally	255(45.54)

VI. Prescription medications purchased over the counter without a medical prescription:

The total number of prescription medications which were purchased without a prescription during research hours were 773. Fixed dose combinations were accountable for 46.44% (359), of which 53.56% (414) were purchased as single drugs as shown in Figure 2.

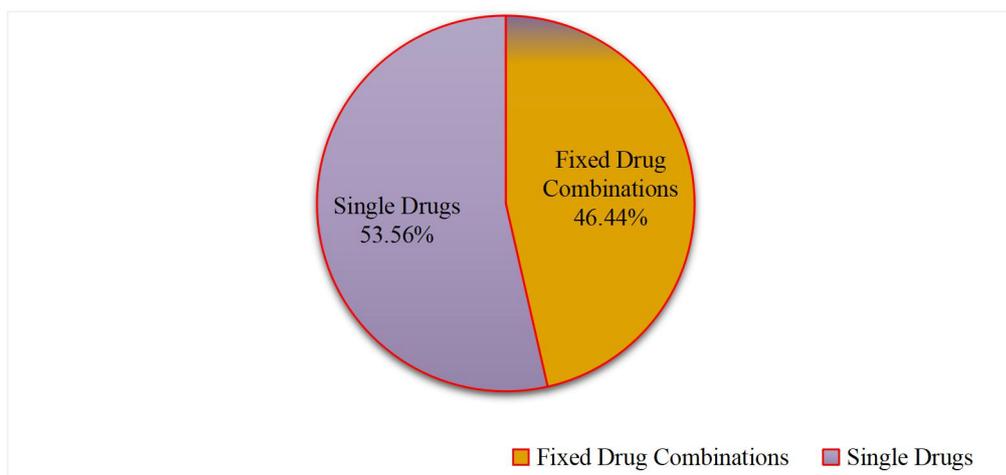


Figure 2: Prescription medications purchased without a medical prescription

The common purchased fixed dose combinations are outlined in Table 6. Aceclofenac + acetaminophen was the most purchased fixed drug combination.

Table 6: Common purchased fixed dose combinations (n = 359)

Sl. No	Fixed dose combination	Total (%)
1.	Aceclofenac + Acetaminophen	86(23.96)
2.	Amoxicillin + Clavulanic acid	30(8.36)
3.	Ofloxacin + Ornidazole	28(7.80)
4.	Amlodipine + Atenolol	26(7.24)
5.	Glimepiride + Metformin	9(2.51)

VII. Some of prescription medications purchased together with non-prescription medications:

Some of prescription medications purchased without prescription together with non-prescription medications has been shown in Table 7.

Table 7: Some of prescription medications purchased together with non-prescription Medications

Sl. No.	Prescription Medication	Non-prescription Medications	Uses
1.	Sildenafil citrate	Multivitamins and multimineral	Erectile dysfunction
2.	Most of antibiotics - Amoxiclav - Amoxicillin - Azithromycin	- Cough syrups (Ambroxol, Diphenhydramine, Dextromethorphan or other drugs (in combinations)) - Antihistamines (Cyproheptadine, Cetirizine)	- Cough - Cold and Flu - Allergic Rhinitis
3.	Diclofenac tablet	Diclofenac gel	Knee pain, Joint pain
4.	Domperidone alone or in combination with PPIs	ORS	Vomiting
5.	Loperamide	ORS	Diarrhoea

VIII. Assessment of customer's knowledge on the use of prescription medications purchased over the counter without a medical prescription:

Of the total of 560 customers visited the pharmacy to purchase prescription medicines without a prescription, 282 customers agreed to fill up the questionnaires, which gives a response rate of 50.36%. It has been presented in Table 8.

Table 8: Source of information before purchasing prescription medications over the counter. (n = 282)

Source	Total (%)
Healthcare professional	157(55.67)
Friend/Family member	112(39.72)
Internet	2(0.71)
Advertisement	11(3.90)

Alternatively, customers purchased prescription medications without a prescription because (n =122, 43.26%) said disease is simple, (n = 68, 24.11%) familiar with the disease and treatment, (n = 41, 14.54%) there was a previous experience with similar problems, (n = 31, 10.99%) time saving, (n = 18, 6.38%) treatment cost is high in hospitals and (n = 2, 0.71%) said it is easy and convenience.

It was found that, 55.32% (156) rarely visited the pharmacy to purchase medications over the counter. Customers reading the labelled information were accountable only for 56.03% (158), 90.43% (255) said they would consult a pharmacist before purchasing any medications from the pharmacy and 62.06% (175) said they will stop using the drug and go to the doctor if the drug did not work for their problems. Results are depicted in Table 9.

Table 9: Practice and attitude of customers on the use of prescription medications (n = 282)

Questions	Category	Total (%)
How often do you take medications purchased over the counter?	Often	20(7.09)
	Sometimes	106(37.59)
	Rarely	156(55.32)
	Never	0(0)
Do you read product information leaflet?	Yes	124(43.97)
	No	158(56.03)
Would you consult a pharmacist before buying any medication from the pharmacy?	Yes	255(90.43)
	No	27(9.57)
What step will you take if a drug did not work for your problem?	Stop and go to the doctor	175(62.06)
	Stop and return to the pharmacy	68(24.11)
	Decrease the dose	1(0.35)
	Increase the dose	31(10.99)
	Use the drug more often	7(2.48)

DISCUSSION

Easy availability of wide range of medications has resulted in increased proportions of prescription medications use without a medical prescription as shown in previous research studies in India and other research studies conducted in different parts of the world such as Saudi Arabia, Egypt, Iran and Tanzania which shows the same.^[11-14] Of those surveyed requesting drugs without a prescription, more than fifty percent were literate. This might indicate that educated individuals play an active role on their health and carers initiatives. In our study, prescription medications use was found to be more among males than females. Lack of time to go to doctors may be responsible for higher prevalence among males than females and may be due to the fact that the study was conducted in a thinly populated area. This study is similar to studies conducted by Nagaraj *et al.*^[15] and Al-Mohamadi *et al.*^[11] who also found significantly higher proportion of males. Majority of customers belonged to the age group of 21-40 years. Marak *et al.*^[20] also found that self-medication practices were more common among young adults aged between 18–35 years. About 45% of medications purchased without a prescription were done so by providing a used container or tablet strips, drug name written on a piece of paper (not a medical prescription) or asking for the drug verbally.

In this study, the categories of medications most frequently requested without a prescription were analgesics, antibiotics and medications used to treat gastrointestinal conditions. These findings are similar with previous study conducted by Keshari *et al.*^[16] where 46.44% of medications were purchased as fixed dose combinations. Antibiotics were mainly used for cough,

dental infection, throat infection and wound infections. However, ofloxacin + ornidazole was dispensed to customers in most cases of diarrhoea. The common purchased fixed dose combination was aceclofenac + acetaminophen. Similar results were seen by studies conducted by Nagaraj M *et al.*^[15] in Bangalore city and Loharkar *et al.*^[17] in Pune, India showed 45% of self-mediations were fixed drug combinations and only 15% of them were rational according to 'WHO Model List' for Essential Drugs.

Prescription medications for chronic diseases such as amlodipine and atenolol, aspirin and clopidogrel, metoprolol and atorvastatin were easily obtained from the community pharmacy in this study. In contrast, a study conducted in Saudi Arabia by Al-Mohamadi *et al.*^[11] indicate that any drug despite its class could be easily purchased in community pharmacies without a prescription. Gastrointestinal disorders, pain disorders, empirically or prophylactically treatment of infections were the most common conditions for which people used prescription medications which were consistent with studies carried out by Nagaraj M *et al.*^[15] and Bertoldi *et al.*^[4]

Some of the frequently purchased prescription medications which were purchased together with non-prescription medications were mostly antibiotics with cough syrups, sildenafil citrate with multivitamins and multimineral. All these medications were purchased without any valid reason. In the present research study, pharmacists and doctors were found to be the most common source of drug information followed by friend or family member. Customers intended the use of prescription medications

OTC as some diseases were simple, familiar with the disease and treatment. Only 14.54% purchased prescription medications as they had previous experience with similar problems. The difference we found in other research studies such as a study conducted by Al-Motassem *et al.*^[18] and Albalawi *et al.*^[19] due to research designs. The medications purchased by the customers who said that they would consult a pharmacist before purchasing any prescription medications were accountable for 90.43% (255). These findings were similar with the study conducted by Hassali *et al.*^[20] done in Malaysia.

Maximum of the practicing community pharmacists in India were diploma in pharmacy holders where they lack knowledge about the safe use of medications. In most circumstances, it has been observed that people purchasing medications in community pharmacies have wrong perceptions about the use of trade names, where they prefer to purchase only reputed pharmaceutical products without looking into the appropriate ingredients present on the labeling of the medicinal product. The consumption of drugs by patients is often influenced by the dispensing practices and the type of information given during dispensing by dispensing pharmacists. Pharmacists can contribute to positive health-care outcomes about medications by educating about the safe use of medications to the customers.

Drug regulatory authorities have to enforce stringent laws on practicing community pharmacists so that violation of Pharmaceutical Code and Ethics may be minimized wherever possible in future and must insist prescription medications to be dispensed by legally qualified pharmacists on a medical prescription. Continuing

professional development programs should be conducted to the practicing community pharmacists to improve knowledge in our community pharmacy practice, so that we can create more awareness to the general public about safe use of medicines. OTC drug list in India should be generated and implemented.

CONCLUSIONS

This study concluded that most commonly purchased medications without prescription were analgesics such as aceclofenac + acetaminophen and antibiotics such as amoxicillin. Customers depended more on pharmacists and it reflects that pharmacists are not meant only in dispensing medications but also have knowledge about safe use of medications, where we can create more awareness to the public about safe use of medications. Drug regulatory authorities in India should enforce stringent policies in respective states so that practicing community pharmacists should only dispense safe medications as OTC drugs.

LIMITATIONS

- Time duration of our research study per day was very less and the total number of customers visiting the community pharmacy during the research work vary without any reason which has resulted to a small sample size.
- Lack of time from customers in filling up the questionnaire lead to less number of complete questionnaires.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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INFORMED CONSENT

Informed consent was obtained from all individual participants enrolled in the study.

ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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