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Perfil Farmacoepidemiológico de Benzodiazepínicos utilizados por indivíduos assistidos em Unidades de Saúde da Família em Feira de Santana, Bahia, Brasil

Pharmacoepidemiological profile of benzodiazepines in users assisted at Family Health Units in Feira de Santana, Bahia, Brazil

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RESUMO

O objetivo deste estudo foi caracterizar o perfil farmacoepidemiológico de benzodiazepínicos (BZDs) em indivíduos assistidos em Unidades de Saúde da Família (USFs). O estudo observacional, descritivo de corte transversal foi realizado em duas USFs em um município do interior da Bahia. Foram entrevistados 44 usuários por meio de um formulário estruturado. Destes participantes, 34 (77,3%) foram do sexo feminino. A faixa etária predominante entre os usuários foi a acima dos 60 anos com 36,4%. A variável presença de agravos à saúde e/ou transtornos mentais foi detectada em 90,9% dos usuários, e a depressão foi a mais frequentemente relatada (54,5%). Em relação ao questionamento sobre presença de queixas frequentes foram relatadas por todos entrevistados, sendo a insônia a mais frequentemente relatada (79,5%). Observou-se que, entre os BZDs, houve um maior percentual para o uso do Clonazepam 2 mg (52,3%). Em relação ao tempo de uso dos BZDs, constatou-se que o tempo definido entre 10 e 20 anos obteve maior percentual (27,3%). O estudo demonstrou que o consumo de BZDs é evidente na população estudada e têm crescido consideravelmente à medida que a idade avança. Evidenciou-se a inadequação do tempo de uso do BZDs, sendo considerado elevado. Medidas voltadas para a racionalização do uso de BZDs devem ser efetivadas, na tentativa de contribuir com a melhoria na qualidade de vida dos usuários.

Palavras-chave: **benzodiazepínicos; perfil farmacoepidemiológico; farmacoepidemiologia.**

ABSTRACT

This study aimed to characterize the pharmacoepidemiological profile of users of benzodiazepines (BZDs) assisted at Family Health Units (FHUs). The observational, descriptive cross-sectional study was conducted in two FHUs in a city of Bahia, Brazil. 44 users were interviewed using a structured form. 34 (77.3%) of these participants were female. 36.4% of the users were over 60 years old. The variable presence of health problems and/or mental disorders was detected in 90.9% of the users, and depression was the most frequently reported (54.5%). All users reported complaints, and insomnia was the most frequent reported one (79.5%). It was observed that, among the benzodiazepines, there was a higher percentage for using of Clonazepam 2 mg (52.3%). Regarding the length of use of benzodiazepines, it was found that the usage time between 10 and 20 years had the highest percentage (27.3%). The study showed that the consumption is evident in the studied population, and has grown considerably as age advances especially among the elderly. It was noticed the inadequacy of usage time of benzodiazepines, considered high for that population. Permanent measures should be taken to rationalize the use of benzodiazepines, thus contributing to improving the quality of life of users.

Keywords: **Benzodiazepines; pharmacoepidemiological profile; pharmacoepidemiology.**

INTRODUCTION

The Pharmacoepidemiology is characterized as a tool that can contribute to the rational use of medicines, focused on development of studies, analysis and evaluation which can reorient procedures related to registers, ways of commercialization, prescription and dispensation of products (BRASIL, 2001). Another important measure is the one that evolves educational campaigns, to reorient prescribers as well as users or consumers about the risks of self-medication, interruption of treatment, change of prescribed medicament, and the importance of the prescribed medication, regarding to drug dispensing that requires prescription retention, in which are the benzodiazepines (BRASIL, 2001).

The benzodiazepines (BZDs) emerged in the mid-1960s, after the beginning of the new era in psychiatry, with the insertion of medicaments subject to special control. So, it has been arising, a new way to attenuate the several effects of anxiety and stress of modern life. Therefore, after they were introduced in the market, they have become one of the most prescribed drugs in the world, including Brazil (STAHL, 1998; FIRMINO, 2008).

The BZDs act in the central nervous system, and they are used in the treatment of anxiety, as well as muscle relaxant, sedatives, hypnotics and anticonvulsants. Beyond these effects, they have a safety margin that turned them the preferred drugs among the anxiolytics. Therewith, discrepancies have emerged in relation to the use and prescription of BZDs, and after that, they have become one of the most used drugs, not only in the wrong way but also illegally, causing many public health problems (SILVA, 2006; FIRMINO et al., 2011).

According to Nordon et al. (2009), the frequency of use of BZDs by people, occurs mainly among women older than 50 years, the elderly and patients with mental disorders. Still according the authors, there are factors that contributes for this use: greater permanence of women at home environment, always living the same routine and participating of the family problems, generating stress, anguish and anxiety situations, the uselessness that old people feel due to their incapacity to work which oblige them to stay at home accumulating tensions and the need of treatment by patients with mental disorders to control their crisis.

The illegal consumption of these drugs represents a risk to health, can mask a disease or complicate a symptomatic situation and consequently retard the recovery period. Thus, it is important emphasize that self-medication isolated induces a harmful and undesirable consumption by the user, which occurs due to the lack of adequate information. However, the counseling about rational use of medicaments, including the BZDs, is an important action for the population, contributing to the adequate use and less risk of dependence, complications and serious consequences.

So, this study aimed to characterize the pharmacoepidemiological profile of benzodiazepines in users assisted at a Family Healthy Unit, in Feira de Santana – BA, Brazil. With the results of this research, it was intended to enlarge the theory about BZDs and contribute with assistance to people who use these drugs, inducing the correct use.

MATERIAL AND METHODS

It was used a quantitative-descriptive methodology, beyond an investigation of social, economic and demographic factors, for the purpose of characterize the profile of benzodiazepine users assisted at Family Health Units (FHUs) in Feira de Santana - BA, Brazil. The data related to characterization of this profile were collected from October to November of 2012.

The criteria to sample selection were obtained from a survey data available in books of controlled medicaments dispensations at the FHUs. From the data, that included, name, age, medicines in use and address line, was done an active search for users, in their home as well as the ones who made any medical consultation or were found at the FHUs in the period; for data collection, it was used a structured form with the purpose to obtain information about personal data, sociodemographic variables and pharmacoepidemiological profile. The selection of the research was done by sample convenience.

The analyzed variables were categorized in: 1) independents, composed by socio-demographic data such as gender, skin color, age, marital status, schooling and family income; 2) dependents, composed by clinical variables that includes disease history, frequent complaints, medical monitoring, BZDs use, time of use of BZDs, orientation for use of BZDs, kinds of BZDs indications and adverse effects, and data associated to BZDs use, such as the use of alcohol or other drugs, if they do physical activity, operate vehicles or machinery, and BZDs indication to other people.

It was done a descriptive analysis of the variables in study, for that, statistic calculus were utilized to determine the simple and absolute

frequency to categorical variables. To quantitative variables, it was calculated an average, standard deviation with minimum and maximum values. Graphics and tables were designed to facilitate the visualization of this information. The statistical software used in this research was IBM SPSS® *Statistics* 20.0.

The study protocol was approved by Ethics committee and research in humans of the State University of Feira de Santana (number 99.900/2012). The individuals, after acceptance, signed the Free and Informed Consent Form (FICF), which enabled the research to be done.

RESULTS AND DISCUSSION

44 benzodiazepines users were interviewed, assisted at Family Health Units (FHUs) in Feira de Santana, two units were investigated: FHU X-III presenting an amount of 23 users and FHU Feira VI, presenting an amount of 21 users, corresponding to a percentage of 52.3% and 47.7% respectively.

Table 1 - Social data from benzodiazepines users assisted at Family Health Units of Feira de Santana - BA, Brazil, 2012.

Social Data	Total	
	n	%
Gender		
Female	34	77.3
Male	10	22.7
Total	44	100.0
Skin Color		
White	11	25.0
Brown	29	65.9
Black	04	9.1
Total	44	100.0

Source: Authors

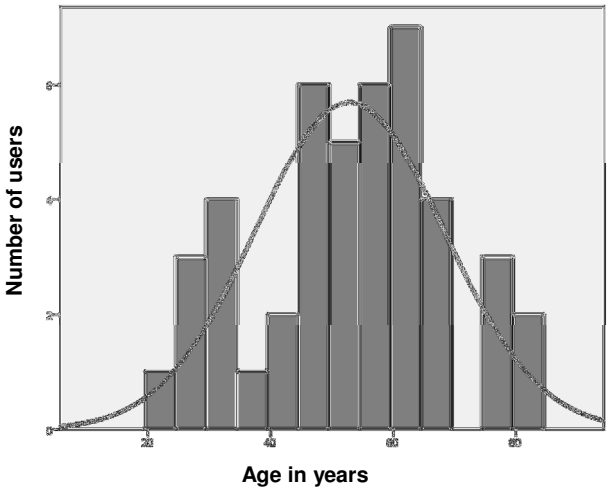
According to the data presented in Table 1, from 44 individuals interviewed, 34 were women (77.3%), corresponding the majority, and men totaled 10 individuals (22.7%).

The prevalence of women indentified in this study is compared to others studies that say that women has the biggest indication of BZDs consumption, such as Nogueira Filho (2011), who conducted his study about profile of old people who use BZDs, in a Primary Health Care in Belo Horizonte (MG), brings that among the 44 users of his research, the majority were women, representing 29 users (72.5%). Firmino et al. (2011) in his study done in the city of Coronel Fabriciano, Minas Gerais, also presents the female gender as the majority, corresponding to approximately 75% of the patients. Aspect also confirmed by Medeiros (2004) when reports a predominance of women (72.6% in an amount of 1732 patients) in study developed in Florianopolis - SC.

Regarding to skin color, the Brown category corresponded to majority, declared by 29 users (65.9%). Table 1 also presents data about the frequency of users per skin color category evaluated.

The age average of the sample, calculated in years, was 52.9 with standard deviation of ±15.4, and distribution range between 22 and 81 years old (presented in Figure 1). And, in relation to age group, the biggest prevalence was in the age group equal or superior to 60 years old (36.4%), corresponding to the biggest percentage of users.

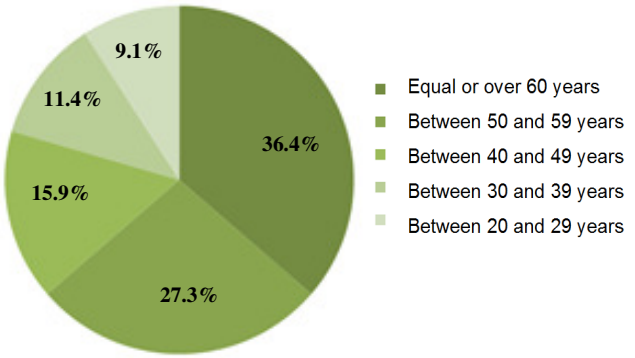
Figure 1 - Frequency distribution per age of the benzodiazepines users assisted at Family Health Unit in Feira de Santana - BA, Brazil 2012.



Source: Authors

The comparison between the age distribution observed and the normal distribution expected reveals that there is not a normal distribution regarding to age (Figure 1) to this analyzed sample. Another aspect that deserves to be considered is the most prevalent age group, it was observed that as the age advances, the index of use of BZDs increases. This aspect can be compared to others studies, where the prevalence of BZDs use occurs in the age group over 60 years old. (ALVARENGA et al., 2007; ALVARENGA et al., 2009). However, it is different in another studies, that shows the majority of users corresponding to age group over 40 and less than 60 years old (MEDEIROS, 2004; FIRMINO, 2008; CASALI, 2010). Figure 2 shows a graphical distribution in percentage of users in relation to age group.

Figure 2 - Frequency Distribution per age group of benzodiazepines users assisted at Family Health Units in Feira de Santana - BA, Brazil, 2012



Source: Authors

Regarding to marital status presented in Table 2, the number of single users was 16 (36.4%) that corresponded to the major percentage compared to the other categories. Considering the schooling level of the users, the major percentage was 40.8% (n=18), who have not completed elementary school. The total distribution of the users, according to their schooling level is also presented in Table 2.

The predominance of users who have not completed elementary school was identified and has basis in literature, as Nogueira Filho (2011) and Nordon et al. (2009) said in their studies that the majority of the users just achieved elementary school.

The investigation about family income in minimum salaries, received for each member of the family revealed that in the family of 18 users (40.9%) the average of family income monthly was one or less than two minimum salaries, representing the major percentage of the interviewed users. The Table 2 also presents the frequencies of users according to family income.

Table 2 - Socio-demographic data of benzodiazepines users assisted at Family Health Unit in Feira de Santana - BA, Brazil, 2012.

Socio-demographic data	Total	
	n	%
Marital status		
Single	16	36.4
Married	14	31.8
Widower	09	20.4
Divorced	05	11.4
Total	44	100.0
Schooling		
Illiterate	07	15.9
Incomplete Elementary School	18	40.9
Complete Elementary School	05	11.4
Incomplete High School	03	6.8
Complete High School	09	20.5
Complete Higher Education	02	4.5
Total	44	100.0
Family Income in minimum salaries		
Less than 1/2	02	4.5
Between 1/2 and less than 1	05	11.4
Between 1 and less than 2	18	40.9
Between 2 and less than 3	12	27.3
Between 3 and less than 5	03	6.8
Over than 5	04	9.1
Total	44	100.0

Source: Authors

Another aspect identified was in relation to marital status. It can be noticed that single individuals are taking more BZDs, what disagrees with another studies, such as Nordon et al. (2009), that evidenced that married people were predominant in the use of BZDs.

Considering family income, as lower is the income higher is the consumption of BZDs, fact also confirmed by Nordon et al. (2010) and Nogueira Filho (2011), that revealed that the majority of the users receive less than three minimum salaries.

The presence of health problems and/or mental disorders was detected in 40 (90.9%) individuals of the research, who assigned at least one of the alternatives in the form. Depression was the most frequently reported (n=24; 54.5%). Table 3 shows the distribution of users frequency according to presence of health problems and/or mental disorders.

The prevalence of Insomnia, among the most frequently complaints evidenced in the study is confirmed by Nordon et al. (2010) in his study in Sorocaba (SP). But, it disagrees with studies, which brings the anxiety as the most predominant followed by insomnia (MEDEIROS, 2004; NOGUEIRA FILHO, 2011). Regarding to frequency of complaints, all the users have reported at least one of the alternatives in the form. Insomnia was the most frequently reported (n=35; 79.5%) Table 4 shows the frequency distribution of users per complaints presence.

Table 4 – Frequency of Complaints Occurrence in benzodiazepines users assisted at Family Health Unit in Feira de Santana - BA, Brazil, 2012.

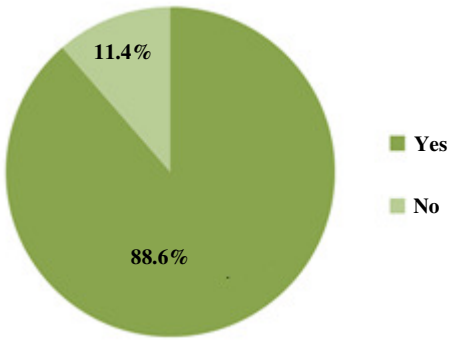
Complaints	Frequency	
	N	%
Anxiety		

Yes	34	77.3
No	10	22.7
Total	44	100.0
Insomnia		
Yes	35	79.5
No	09	20.5
Total	44	100.0
Fear		
Yes	17	38.6
No	27	61.4
Total	44	100.0
Irritability		
Yes	20	45.5
No	24	54.5
Total	44	100.0
Unrest		
Yes	17	38.6
No	27	61.4
Total	44	100.0
Others		
Yes	25	56.8
No	19	43.2
Total	44	100.0

Source: Authors

About medical monitoring, for users of BZDs, it was observed that 39 users looked for medical consultation (88.6%) and 5 users (11.4%) did not. Figure 3 shows the distribution of frequency of users according medical monitoring.

Figure 3 - Occurrence of Medical monitoring accomplished by benzodiazepines users assisted at Family Health Unit in Feira de Santana – BA, Brazil, 2012.



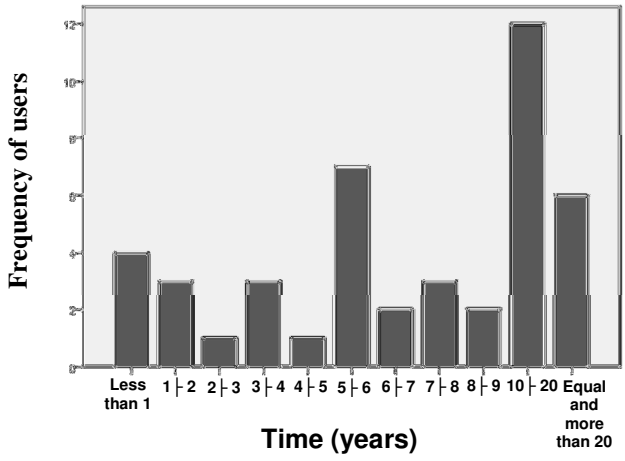
Source: Authors

It was detected that all users were doing use of some kind of drugs of the BZD class. There was a major percentage of use of Clonazepam 2 mg (n=23; 52.3%). Table 5 presents the frequency distribution of users according to BZD used.

It was also noticed, the prevalence of use of Clonazepam 2mg, followed by Diazepam 10mg, and it was detected that the acquisition of these drugs, majoritively, happened at Family Health Units (FHUs), considering that in these institutions there is free distribution of diazepam and clonazepam, which are the BZDs standardized at FHUs. When compared to another studies, It was noticed that there were divergences, Mendonça and Carvalho (2005) in their study accomplished in a Health Mental Nucleus from the School Health Center of one college in São Paulo, shows diazepam being the most utilized BZD for the majority of their sample because it has free distribution in that School Health Center. Nogueira Filho (2011) also reinforced this evidence in his study done with a Team of Primary Health in Belo Horizonte (MG), where diazepam was the BZD with higher prevalence. As well as Nordon *et al*. (2009), who also brings diazepam as the most utilized between the studied population. However, there are data that evidence clonazepam as the most consumed in Brazil, about 10 million boxes sold only in 2010 (PIMENTEL, 2012).

It was observed that the time of use of BZD was between 10 and less than 20 years obtained the higher percentage, in 12 (27,3%) of the users. Figure 4 presents the frequency distribution of users according to time of use of BZDs.

Figure 4 - Frequency distribution per period of consumption of benzodiazepines by users assisted at Family Health Unit in Feira de Santa - BA, Brazil, 2012.



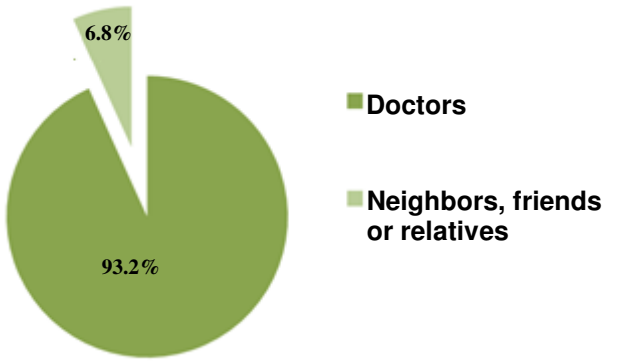
Regarding the time of use of BZDs, it was found that the time of use between 10 and less than 20 years obtained the major percentage. So, the use of BZDs has happened in an inadequate and abusive way for long time, considering that the use of BZDs must be shorter as possible (SILVA et al., 2003). Thus, when compared to others studies, there was equivalence regarding the time of use as Mendonça and Carvalho (2005) said that the average time of use of BZDs was 16 years in their studied population, and Nordon et al. (2010) affirmed that the predominant time of use was

more than 36 months. Different from other studies that said the more prevalent time of use is between 6 to 12 months (HUF; LOPES & ROZENFELD, 2000; CASALI, 2010), and between one to five years (NOGUEIRA FILHO, 2011).

The BZDs obtainment must occur under medical orientation and with prescription, this way, it is noticed, in this investigation, the use of BZDs still is done by medical orientation, following the pharmacological criteria, although there are still people who use these medicaments following non-medical orientation.

When asked about who oriented the users about the use of BZDs, the majority (n=41; 93.2%) answered that received medical orientation. Figure 5 shows the frequency distribution of users according who gave orientation about the use of BZDs.

Figure 5 - Frequency distribution according to who guided the use of benzodiazepines to users assisted at Family Health Unit in Feira de Santana - BA, Brazil, 2012.



Source: Authors

The indications for use of BZDs referred for users, who affirmed presenting at least one of the proposed alternatives in the form, and insomnia was the most reported (n=37; 84.1%). Table 6 shows the frequency distribution of users according the indications.

As well as the most frequent complaints, the kinds of indications obtained similar results, which insomnia is the most reported. Thus, it is according Nordon et al. (2009) who affirmed, in his study, the predominance of insomnia in relation to the others indications. Different of Nogueira Filho (2011) who brings anxiety as the major prevalence as initial indication.

The adverse effects caused by the use of BZDs reported by the users, who affirmed present at least one of the proposed alternatives in the form, dependence was the most reported (n=31; 70.5%). Table 7 shows the frequency distribution of users according adverse effects.

Table 7 - Frequency of the adverse effects reported by users of benzodiazepines assisted at Family Health Unit in Feira de Santana - BA, Brazil, 2012.

Adverse effects	Total	
	N	%
Dependence		
Yes	31	70.4
No	04	9.1
Not applicable	09	20.5
Total	44	100.0
Somnolence		
Yes	11	25.0
No	24	54.5
Not applicable	09	20.5
Total	44	100.0
Forgetfulness		
Yes	07	15.9
No	28	63.6
Not applicable	09	20.5
Total	44	100.0
Others		
Yes	02	4.5
No	33	75.0
Not applicable	09	20.5
Total	44	100.0

Source: Authors

Life habits and use of BZDs refer to the use of alcohol or another drug, to realization of physical activity, operating vehicles or machinery and the indication of BZDs to another people. Table 8 shows the frequency of the users according life habits.

Therefore, it was observed that the majority of the users (n=28; 63.6%) reported that do not use alcohol or other drugs. In relation to physical activities, 32 users (72.7%) reported that do not do any physical activity. Regarding the operation of machines and vehicles it was observed that 38 users (86.4%) said that do not drive vehicles or operate machines, what corresponded the majority of the interviewed. And, in accordance to the interviewed, 40 of them (90.9%) affirmed that do not indicate the BZD to others.

CONCLUSIONS

It is observed that the consumption of BZDs is evident between the interviewed subjects, and has grown considerably as age advances, specially between elderly. Furthermore, the inadequate time of use of BZDs, which was considered elevated to the studied population. Therewith it is important emphasize that this

consumption growth is due to the great number of prescriptions, and the fact that BZDs are between the drugs of choice against the pressures of modern life, which causes emotional and physiological disturbs. However, measures should be taken to rationalization of the use of BZDs, contributing to education and improving life quality of the patients who use these medicaments.

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Table 3 – Disease Occurrence in individuals in use of benzodiazepines assisted by Family Health Units in Feira de Santana (BA), Brazil, 2012.

Kind of Disease and mental disorders	Frequency	
	n	%
Hypertension		
Yes	22	50.0
No	18	40.9
Not applicable	04	9.1
Total	44	100.0
Respiratory Diseases		
Yes	03	6.8
No	37	84.1
Not applicable	04	9.1
Total	44	100.0
Diabetes		
Yes	07	15.9
No	33	75.0
Not applicable	04	9.1
Total	44	100.0
Epilepsy		
Yes	02	4.5
No	38	86.4
Not applicable	04	9.1
Total	44	100.0
Schizophrenia		
Yes	06	13.6
No	34	77.3
Not applicable	04	9.1
Total	44	100.0
Depression		
Yes	24	54.5
No	16	36.4
Not applicable	04	9.1
Total	44	100.0
Mood disorders		
Yes	09	20.5
No	31	70.4
Not applicable	04	9.1
Total	44	100.0
Panic Disorders		
Yes	06	13.6
No	34	77.3
Not applicable	04	9.1
Total	44	100.0
Heart Diseases		
Yes	08	18.2
No	32	72.7
Not applicable	04	9.1
Total	44	100.0

Source: Authors

Table 5 - Benzodiazepines used for users assisted at Family Health Units in Feira de Santana - BA, Brazil, 2012.

Kind of Benzodiazepines	Frequency	
	N	**%**
Diazepam 5mg		
Yes	04	9.1
No	40	90.9
Total	44	100.0
Diazepam 10mg		
Yes	13	29.5
No	31	70.5
Total	44	100.0
Clonazepam 0.5mg		
Yes	03	6.8
No	41	93.2
Total	44	100.0
Clonazepam 2mg		
Yes	23	52.3
No	21	47.7
Total	44	100.0
Clonazepam 2.5mg/ml		
Yes	01	2.3
No	43	97.7
Total	44	100.0
Bromazepam 6mg		
Yes	01	2.3
No	43	97.7
Total	44	100.0
Flurazepam 30mg		
Yes	01	2.3
No	43	97.7
Total	44	100.0
Cloxazolam 1mg		
Yes	01	2.3
No	43	97.7
Total	44	100.0

Source: Authors

Table 6 – Frequency of indications for use of benzodiazepines to users assisted at Family Health Units in Feira de Santana - BA, Brazil, 2012.

Indications	Frequency	
	N	%
Anxiety		
Yes	23	52.3
No	21	47.7
Total	44	100.0
Insomnia		
Yes	37	84.1
No	07	15.9
Total	44	100.0
Depression		
Yes	16	36.4
No	28	63.6
Total	44	100.0
Unrest		
Yes	09	20.5
No	35	79.5
Total	44	100.0
Fear		
Yes	03	6.8
No	41	93.2
Total	44	100.0
Nervousness		
Yes	08	18.2
No	36	81.8
Total	44	100.0
Irritability		
Yes	03	6.8
No	41	93.2
Total	44	100.0
Tachycardia		
Yes	01	2.3
No	43	97.7
Total	44	100.0
Others		
Yes	03	6.8
No	41	93.2
Total	44	100.0

Source: Authors

Table 8 - Life habits of users assisted at Family Health Units in Feira de Santa - BA, Brazil, 2012.

Life habits	Total	
	N	%
Use of alcohol and other drugs		
Yes	16	36.4
No	28	63.6
Total	44	100.0
Physical activity		
Yes	12	27.3
No	32	72.7
Total	44	100.0
Vehicles or machinery		
Yes	06	13.6
No	38	86.4
Total	44	100.0
Indication to other people		
Yes	04	9.1
No	40	90.9
Total	44	100.0

Source: Authors