

## Pharmacotherapeutic monitoring of users at the Lima Barreto Psycho-Social Care Centre (CAPS): a strategy in health promotion

Acompanhamento farmacoterapêutico de usuários do centro de atenção psicossocial Lima Barreto (CAPS): uma estratégia de promoção em saúde

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### Abstract

Mental disorders are a relevant public health issue nowadays. Pharmaceutical Care in mental health can be a viable strategy to care for users of the Brazilian Health System (SUS), effectively contributing to promote the rational use of medications and increase patient adherence to treatment. A study was carried out, therefore, at the CAPS-Lima Barreto Psycho-Social Care Centre (Centro de Atenção Psicossocial Lima Barreto, in the BrPt name) in the state of Rio de Janeiro, Brazil, aimed at using pharmaceutical care as a strategy to promote health, with the goals of identifying, assessing, and monitoring the medication-based treatment of patients with mental disorders. The work relied on the participation of 38 patients. These data were collected in a questionnaire based on the Dader methodology. Based on the results it was possible to see that 14 patients aged 31-40 years old (37%). Another parameter studied was related to the manner of administering the psychotropic drugs, where more than half of the users took their medicines with water (52%) and self-medicated themselves (79%). Apart from that, we also found that more than half the users (71%) saw an improvement in their health condition during the pharmaceutical-therapeutic monitoring.

**keywords:** Pharmaceutical care; mental health; psychotropic drugs; Health Promotion.

### Resumo

Transtornos mentais representam, atualmente, um importante problema de saúde pública. A Atenção Farmacêutica na saúde mental pode ser uma estratégia viável para o cuidado aos usuários do Sistema Único de Saúde (SUS), contribuindo de forma efetiva para a promoção do uso racional de medicamentos e aumentar a adesão do paciente ao tratamento. Portanto, realizou-se um estudo no Centro de Atenção Psicossocial Lima Barreto (CAPS), no estado do Rio de Janeiro tendo como objetivo utilizar a atenção farmacêutica como estratégia de promoção de saúde, pretendendo identificar, avaliar e acompanhar o tratamento medicamentoso de pacientes com transtornos mentais. O trabalho contou com a participação de 38 usuários. Os dados foram coletados por meio de um

questionário farmacoterapêutico de acordo com a metodologia Dáder. Com base nos resultados pode-se observar que 14 pacientes têm de 31-40 anos (37%). Outro parâmetro analisado foi em relação a forma de administração dos psicofármacos, onde mais da metade dos usuários administravam seus psicofármacos com água (52%) e realizavam automedicação (79%). Além disso, foi possível constatar que mais da metade dos usuários 71%, obtiveram melhora no seu estado de saúde durante o acompanhamento farmacoterapêutico.

**Palavras-chave:** Atenção farmacêutica; saúde mental; psicofármacos; promoção de saúde.

## **INTRODUCTION**

Mental or neural-biological disorders affect 10% of the world's adult population according to the World Health Organization - WHO (2002). It is estimated that the prevalence of these ailments will rise to 15% in 2020 (WHO, 2002). According to data provided by the Brazilian Department of Health, Brazil has 3% of the population with severe and persistent mental disorders, and some 6% have severe psychiatric disorders produced by alcohol abuse and intensive use of other drug, and 12% require some form of mental health care (BRAZIL, 2008). This high rate of people with mental disorder produces clinical and humanistic consequences as the quality of life is hampered by stigma and prejudice and, beyond that, mental disorders are an economic burden, amounting in some cases to 23.2% of the total annual health service expenditure in developed countries (MEERDING *et al.*, 1998). Therefore is estimated that economic burden is also high in Brazil, despite the fact that there are no studies on the subject made in this country or in developing ones.

The use of psychotropic medications has grown in recent years, generating repercussions about expenditure on drugs (LOBO & SERRANO, 2005). This growth is attributed to an increase in the number of diagnostics of psychiatric disorder, to the introduction of new pharmacotherapy drugs in the pharmaceuticals market, and to new therapeutic referrals for already-existing medications (RODRIGUES *et al.*, 2006).

The concomitant use of many pharmacotherapy drugs is frequent practice, to leverage specific effects, or in the presence of co-morbidities and other associated medical conditions of patients. A better understanding of the metabolism of pharmacotherapy drugs provides more consistent data on medication interactions. Based on such information there are concerns on both the possibility of reducing or increasing in an exaggerated manner the action of the medications at hand and the production of toxicity (BRAZIL, 2000). Moreover, self-medication represents an additional problem in the treatment of mental disorders as the not many submit themselves to treatment. All the problems mentioned until now can be solved or mitigated with pharmaceutical care practices. Previous works demonstrate that pharmaceutical care practices boost both the quality of life of patients with mental disorder as their compliance with the treatments, re-integrating most of them in society, and reducing the damage such disorders cause (OLIVEIRA & FREITAS, 2008; BRAGA *et al.*, 2005, LUCCHETTA. & MASTROIANNI, 2012). This work aimed, therefore, at using pharmaceutical care as a strategy to promote health, with the goal of identifying, assessing, and monitoring the medication-based treatment of patients with mental disorders.

## MATERIAL AND METHODS

The preparation of the research protocol focused on following and complying with the standards set by the Brazilian Research Ethics Commission - CONEP - as well as of the Brazilian Health Council and the Brazilian Department of Health. As it is work that involves human subjects the research was carefully planned to meet the requirements set in Brazilian Health Council Resolution No. 196/96 and related elements.

The project took an exclusion criterion to remove children and adolescents aged up to 17yrs old and used an inclusion criterion for those aged 18 and over.

A document, namely a *Term of Free and Informed Consent* (TCLE), already approved by the CONEP and by the CEP of our Institution was prepared. It is a document in which every participant or one's guardian formally set on paper one's agreement with the participation in this project, after receiving an information leaflet about it (nature, goals, activities involved, type of involvement, and confidentiality, amongst others).

This is a sectional study, and the data were collected in medical records and in pharmaceuticals-oriented consultations. The pharmaceutical therapy monitoring was done pursuant to the Dader Method and to the Second Consensus of Granada (Machuca, Fernández-Llimós, Faus, 2003; DADER 2009). The Dader Method for Pharmacotherapy Follow-Up was used with the appropriate adjustments to the realities of the population at hand. It is based on the obtaining of a pharmacotherapeutic history of the patient, i.e., on the health problems one has, on the medications used, and on the assessment of the patient's condition on a given date, to identify and solve possible RNMs (possible negative outcomes related to the medication) as displayed by the subject. Pharmaceutical interventions were made after the identification, as needed to clear the RNMs and, after that, an evaluation was done of the results obtained. Pharmacotherapy Follow-Up steps, based on the Dader method, are:

- ⇒ Initial interview ⇒ Visits ⇒ Data file
- ⇒ Evaluation of information ⇒ RNM resolution cycle
- ⇒ RNM detection ⇒ Intervention plan
- ⇒ Result of pharmacotherapeutic follow-up

After the information was collected, all cases were discussed with the health team, and the interventions were proposed to the patient during the meetings.

The information provided by the patient was organised in a form adapted from the Dader Method (2009). This form was filled in at every pharmaceutical consultation, with data on patient condition, new problems reported, and interventions made, to systematise and document all the information related to the patients under monitoring. These data were studied and discussed amongst the project participants and an Action Plan was then prepared to carry out the interventions, having CEP number 161448 approval report.

## RESULTS

The work had the participation of 38 users of the Lima Barreto CAPS, located in programme area 5.1., borough of Bangu, city of Rio de Janeiro, RJ. At first, the epidemiological data of the patients was studied and showed at Table 1.

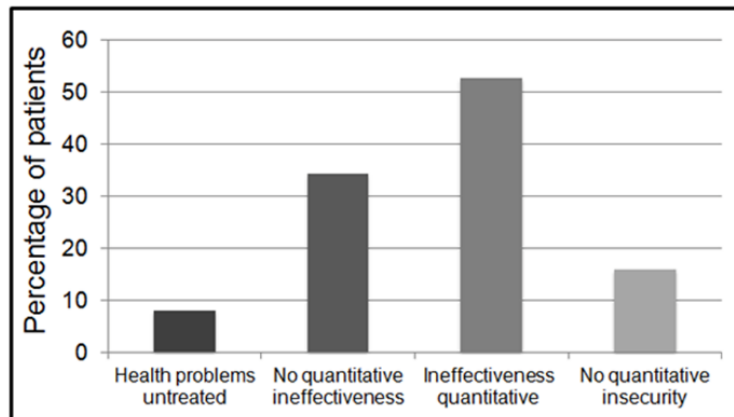
<b>Tabela 1.</b> Epidemiology data for Lima Barreto CAPS patients				
Gender	58% were male		42% were female	
Marital status	87% were single	5% were married	5% were divorced	3% were widowers
Age	26% were aged 20-30	37% were aged 31-40	13% were aged 41-50	24% were older than 50
Consumption of legal and illegal drugs		29% used alcohol	27% used tobacco	8% used illegal drugs

Having collected the epidemiology data, a study was made of the data on the forms of medicine administration. It was possible to see that the manner of administering psychotropic drugs varies a great deal amongst the patients, with 52% taking their medication with water, 11% with milk, 8% with fruit juice, and 29% reported they use other beverages or foods to take their medications. Self-medication is a very common practice, defined by the indiscriminate use of medications with no type of consultation and/or medical advice. Self-medication was considered as the use of any type of medication without a doctor's prescription and, in this context, most of the patients, namely 79% self-medicate whilst the remaining 21% do not. This way, the next step was to verify what the reasons were that led to self-medication. The most reported symptoms, that justify this behaviour, are pain (63%), fever (37%), muscle pain (18%), flu/colds (16%), and minor injuries (8%). Amongst the drugs most used in self-medication, we can mention sodium dipyron (53%), aspirin (18%), paracetamol (18%), Orphenadrine citrate (18%), and neomycin sulphate (8%).

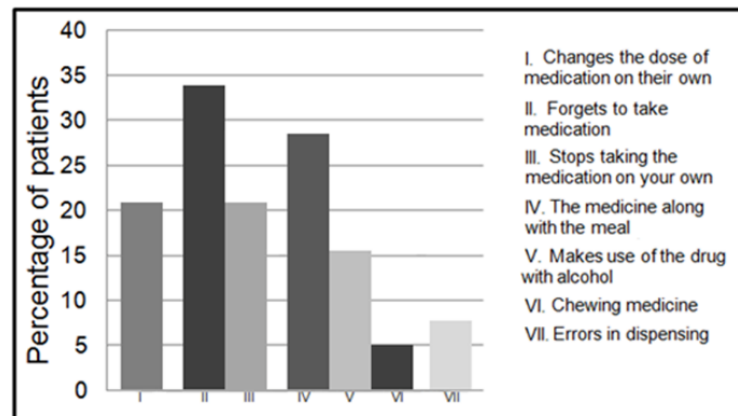
The Lima Barreto CAPS only provides SUS - Brazilian Health System - psychotropic medications. The most frequently used psychotropic medications were Haloperidol (52%), Promethazine (50%), Chlorpromazine (42%), Diazepam (39%), Clonazepam (29%), Risperidone (26%), Carbamazepine (24%), Levomepromazine (18%), Valproic acid (11%), and 8% Biperiden. Adverse effects are quite common during the drug therapy with psychotropic medications and, amongst such more common effects, as reported by the users, the most apparent ones are dry mouth (42%), trembling (13%), sleepiness (13%), fatigue (11%), insomnia (8%), polyphagia (5%), and parageusia (5%).

The Dader methodology (2009) rates the RNMs on a basis of need (the need for a health problem to exist, that justifies the use of a medication), of effectiveness (efficacy in attaining the desired therapeutic goals) and safety (neither leading to other health problems, nor worsening existing ones). The RNMs most frequently found were quantitative ineffectiveness, at 53%, non-quantitative ineffectiveness, at 34%, non-quantitative insecurity, at 16%, and non-treated health problems, with 8% (Figure 1).

No RNM was found due to the use of unnecessary medications, nor due to a quantitative lack of safety. The most common cause related to the quantitative ineffectiveness RNM came from a change in dosage of the medication (21%), while the non-quantitative ineffectiveness had, as main causes, forgetting to take the medication (34%) and failing to take the medication on one's own account (21%); the non-quantitative insecurity had, as causes for RNM the taking of the medication with alcoholic beverages (16%), taking the medication at meal times (29%) and chewing the medicine (5%). Finally, the RNM related to untreated health problems was produced by dispensing errors (8%) (Figure 2).



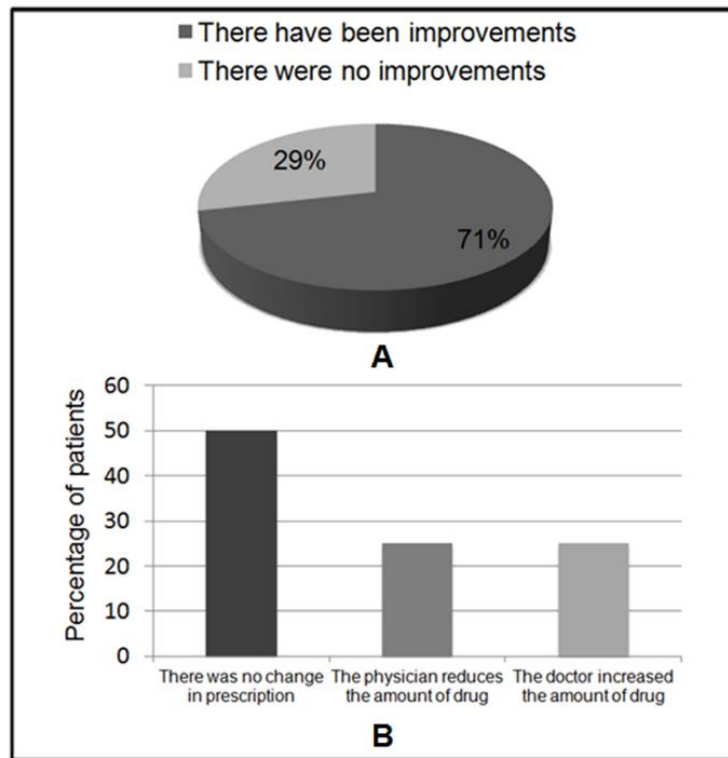
**Figure 1.** Most frequent RNMs (Negative Results related to Medication) as found in patients of the CPAS (Psycho-Social Care Centre).



**Figure 2.** Most frequent causes for RNMs (Negative Results related to Medication) as found in patients of the CPAS (Psycho-Social Care Centre).

The next stage in the process of pharmaceutical care after the detection of an RNM is that of intervention, which can be successful or not. It was found that 71% of the patients saw an improvement of their health condition with 29% having no improvement (Figure 3 A). Several actions were taken to intervene and solve the RNMs, such as the use of posters, guidance booklets on the rational use of the medications, work groups on medication to advise users on their correct usage, and the distribution of medication storage boxes.

The pharmaceutical care provided to patients with mental disorders is pivotal in the effort to see them comply with the requirements of treatment, as the pharmacology-therapeutic follow-up helps solve possible RNMs, apart from assisting the patient on the correct administering of the medications and on possible medicament interactions that might happen with drugs that are freely available in the market, that may hamper the treatment made with pharmacotherapy drugs, even leading to intoxication. In another parameter studied, related to medical prescription, it was seen that 25% of the patients had an increase in the volume of their medication, 25% saw a reduction in the volume of their medication, while 50% had no change in that (Figure 3 B).



**Figure 3. A.** Evaluation of the solution for RNMs found in patients that attended more than two meetings at the CAPS (Psycho-Social Care Centre). **A.** Percentage of improvement/no improvement in RNMs. **B.** Percentage of any change in medical prescription.

These results show that, in the majority of the cases, the patients had no problem related to the type or quantity of medication, but problems related to the guidance received on the correct use of such medications.

## DISCUSSION

We found that more than half of the patients seen at the Lima Barreto CAPS are male (Table 1). Many studies in the domain of mental health try to understand the differences that exist in the manners of illness and their relation with gender (BORREL *et al.*, 2008, DOYAL, 2001 ANDRADE *et al.* (2006). In general, men have a higher prevalence of disorders associated too psycho-active substances, including alcohol, and disorders related to impulse control, attention deficit, hyperactivity, personality disorders of an anti-social and schizo-type nature. Women, in their turn, have higher rates of prevalence for anxiety and humour disorders than men. Studies conducted in psychiatric or admission in-patient services have shown a predominance of male patients (COUTINHO *et al.*, 2002; MEDEIROS, 2005; RABELO *et al.*, 2005; MIRANDA *et al.*2008).

The results obtained in this study are in line with previous works that demonstrate a higher prevalence of single males with mental disorders (Table 1). A study on the epidemiological profile of users of a CAPS in the city of Recife, in Brazil, showed that 53.3% of them are single and only 1.1% are divorced (OSINAGA; FUREGATO & SANTOS, 2007).



The data shows that the age bracket of those patients was of 31-40 years of age. According to studies made by Freitas and collaborators (2012), patients with psycho-social disorders seen at the CAPS-AD in the city of Picos, state of Piauí, in Brazil, were, in most of the cases, aged over 40, although the CAPS-AD works mainly with users that have mental disorders produced from alcohol and drug abuse. Another study made at a CAPS in the city of Parobé, state of Rio Grande do Sul, southern Brazil, showed that a significant part of the users was aged 31-55 (55,1%) (TERGOLINA & PINHEIRO, 2009).

There is no CAPS-AD in the region where the Lima Barreto CAPS is located, and we found that most of their patients were alcohol, tobacco and illegal drug users (Table 1). The most common drug reported by the users was alcohol (29%). According to data by the Brazilian Department of Health, more than 6% of the population have severe psychiatric disorders produced by the use of alcohol and other drugs (BRAZIL, 2008). According to a Global Report by the United Nations Office for Drug Control and Crime Prevention - UNODCCP of 2006 it is estimated that 5% of the world's population aged 15-64 uses, on a regular basis, some kind of illegal substance, that is, approximately 200 million people. Alcohol is the legal substance that is most consumed, followed by tobacco. The National Epidemiologic Survey on Alcohol and Related Conditions (Nesarc) produced by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) interviewed individuals aged 18 years or more between years 2001 and 2002 and found that 30.3% of them had some form of psychiatric disorder produced by the use of alcohol, with 17.8% through abuse and 12.5% in dependence, throughout their lives. (HASIN, STINSON, *et al.*, 2007). A difficulty in the start of treatment of a population lies precisely in the difference that exists between previously-existing disorders and disorders that are peripheral to their chemical dependence, due to the fact that their symptoms of depression, anxiety and mania prevail in the period of drug abstinence (ALVES & COLS., 2004).

The data of this work shows that more than half of the users seen at the Lima Barreto CAPS took their psychotropic medication with water (53%). Freitas and collaborators (2012) carried out the monitoring of the users then seen at the CAPS-AD in the city of Picos, Piauí and also found that most of them took their psychotropic medication preferably with water (83.9%).

This study also found that self-medication is a very frequent practice amongst users. Self-medication is common practice in Brazil, a country placed in fifth place in the consumption of medications list, first place in Latin America, and place ninth in financial volume in that domain (SOUZA *et al.* 2008). This fact may be associated to the 24,000 deaths per year in Brazil, produced by medicament intoxication. The reasons that lead people to use medication without a doctor's prescription are many, amongst which the main ones are the advertising made for some drugs, the difficulty and cost associated to having a doctor's opinion, the limitations in prescribing power, the despair and anguish triggered by symptoms or the likelihood of contracting a disease, information on medications as found in the Web or in other media.

Based on the analysis of the data gathered, it was found that pain (63.1%) was the most common symptom reported by the patients to justify their self-medication. According to Braga (2005), the main complaint to justify self-medication is pain (33%). Other studies on the care provided to patients with psychiatric disorders have show that the chief justification that leads patients to self-medication is the headache (58%) (OLIVEIRA *et al.*, 2008).

The data obtained show that some of the drugs most used in self-medication are sodium dipyrone (52.6%) and aspirin (18.4%). Other studies have shown that the drugs most used in self-medication were dipyrone (35%), followed by paracetamol (25%). (FREITAS *et al.*, 2006).

According to statistical data released every year by the Brazilian Toxicology Data System (SINITOX), medications are the main class of agents that cause human intoxication in Brazil (BITTENCOURT *et al.*, 2008; BRICKS, 1998). According to Lucchetti and collaborators, dipyrrone is the main pain killer used in Brazilian therapeutics, with a 38% market share, followed by paracetamol (29,7%), and aspirin (27.1%) (2010). Paracetamol is pain-killer and antipyretic drug derived from p-amine-phenol, of the AINES class and with low anti-inflammatory action (HE *et al.*, 2011). The easy access to paracetamol and the lack of knowledge of the population of its harmful effects in the body have significantly increased the number of cases of intoxication caused by this drug (SEBBEN *et al.*, 2010). Its toxicity can be boosted by the simultaneous use of enzyme-inducing medicaments such as phenytoin, phenobarbital, and carbamazepine, which increase CYP3A4 activity, raising NAPQI levels (ALBERTO *et al.*, 2009). It was also observed that the users of the Lima Barreto CAPS simultaneously made use of psychotropic drugs with paracetamol, increasing the risk of toxicity during the pharmacotherapeutic treatment. Dipyrrone, in its turn, is a non-opioid painkiller that is widely used in to treat pain, acute and chronic (EDWARDS, *et al.* 2002) that interacts with Chlorpromazine which is an anti-psychotic drug used in some states of dementia and schizophrenia. This type of medicament interaction was also seen in the patients of the Lima Barreto CAPS. Dipyrrone works to block the impulses produced by dopamine in the synapses (Medication Guide, 2006). The simultaneous use of chlorpromazine with sodium dipyrrone can cause an increase of adverse reactions of the chlorpromazine, such as severe hypothermia, pseudo-parkinsonism, blurred vision or other alterations in sight, hypotension, intestine constipation, sickness, lack of appetite, sleepiness, dry mouth, and nasal congestion, amongst others. (Medication Guide, 2006; BERGAMASHI *et al.*, 2007).

The medications most frequently used by patients of study were haloperidol (anti-psychotic drug) at 52.2%, and promethazine (anti-histaminic) 50%. Haloperidol is an anti-psychotic drug of the butyrophenone class, recommended for the treatment of several conditions, including schizophrenia, behavioural disorders, mania, severe anxiety crises, and Tourette's syndrome (MARTINDALE, 1999) and, due to its wide action, is a neuroleptic drug widely prescribed in the world (BALDESSARINI, 1996). Despite its wide prescription, the literature describes several undesirable effects of it during the drug therapy with it such as sedation, hypotension, and antimuscarinic effects, although the extra-pyramidal effects are the ones that most frequently take place (OLIVEIRA, 2002). As for promethazine, it is a phenothiazine-derived drug that acts as an anti-histaminic, anti-emetic, sedative and anti-cholinergic, through competitive antagonism, but that does not block the release of histamine. The association of haloperidol with promethazine is usually employed to reduce restlessness, sedation and extra-pyramidal symptoms (trembling, rigidity, and bradykinesia). (FALKAI *et al.*, 2006). Anti-psychotic drugs are amongst the psycho medications that are used the most, after antidepressant drugs (CARDOSO *et al.*, 2010, MOORE *et. al.*, 2002).

The occurrence of adverse effects is all too common during the pharmacological therapy with psychotropic drugs (BRUNTON *et al.*, 2010), and the adverse effects most frequently reported by users include: dry mouth, at 42.1 %, trembling, at 13.2 %, and sleepiness, at 13.2 %. According to Abreu and collaborators (2000), the adverse effects produced by the use of psychotropic drugs are the main factors responsible for the discontinuation of treatments, worsening of the quality of life, low adherence, medication interactions, and poor social adaptation of patients.



According to a study done on anti-depressant and anti-psychotic medications prescribed at the CAPS of the city of Porciúncula – state of Rio de Janeiro, it was demonstrated that the main undesirable reactions displayed by patients included insomnia (27.1%), aggressiveness (21.9%), apathy and sleepiness (16.7%), anxiety (14.6%), restlessness and hallucinations (10.4%), psychomotor agitation (9.5%), trembling and deliriums (7.3%). Another study showed that the main adverse reaction during treatment is the headache (30%). Following the occurrence of adverse reactions, 42% of the patients suspend their treatment (Braga *et al.*, 2005). According to this study and to all the other related ones, it is possible to see that the adverse reactions are widely variable.

According to the data studied, the RNMs most frequently seen were untreated health problems, at 7.9%, non-quantitative ineffectiveness, at 34.2%, quantitative ineffectiveness, at 52.6%, and non-quantitative insecurity, at 15.8% (Figure 1). The main causes for RNMs were forgetting to take the medication (34%), followed by not using the medication taken on one's own account (29%) (Figure 2). Some patients reported that the difficulty in taking their psychotropic drugs was a result of their forgetting to take them. The main reasons that led the patients not to take the medication on their own account were: adverse effects, inefficacy of the therapeutic course and a dissatisfaction with the pharmacological treatment. Other studies also indicated that side effects were the reason to discontinue treatment with 80.0% of the patients that decided did not follow it (NICOLINO *et al.*, 2011). It was found that the patients may consider the discomfort produced by the symptoms of the disease as strongly as those produced by the adverse effects of the treatment with anti-psychotic drugs (LENERT *et al.*, 2000).

As regards the solution of the RNMs it was found that most of the patients that took part in this work (71%) had their RNMs solved (Figure 3 A). According to the evaluation of change in medical prescription, it was found that there was no change in the medical prescription for most of the users (50%). Especially, in some cases there was a decrease in the volume of medications prescribed (25%) (Figure 3 B). The results show that in most of the cases the patients had no issues related to the type or quantity of medication, but had problems related to the guidance on the correct use of their medication.

## CONCLUSIONS

The results of this study show the importance of the pharmacotherapeutic monitoring of patients with mental disorders, as it provides guidance in the treatment, producing better adherence and compliance, knowledge of the medications used, as well as of the disease, and especially the prevention. The identification and resolution of issues related to drug use, in addition to reducing the costs of pharmacological treatment, reducing toxicity risks, enabling the early detection of adverse reactions and drug interactions, and monitoring patients' clinical evolution, promotes rational use of the drugs involved.

According to Brazilian Ordinance No. 336/GM of February 19<sup>th</sup>, 2002 the presence of a Pharmacy professional in the multi-disciplinary team of a CAPS (Psycho-Social care Centre) is no longer mandatory. This ordinance does not strengthen the need of a pharmacist in the health team of the CAPS.

Considering a multi-professional approach, the pharmacist can carry out activities to support the health team, in the guidance of patients and their health providers on the correct and safe use of the medications, according to criteria of therapeutic rationality (SILVA *et al.*, 2009).

Despite the map of the distribution of mental disorders in the world (WHO, 2002) showing rather high figures, it is also possible to see that the pharmaceutical practice offered to the population is extremely small or little publicised (LUCCHETTA & MASTROIANNI, 2012).

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