

## SHORT COMMUNICATION

### THE USE OF OTC HERBAL SEDATIVES BY PHARMACY PATIENTS – A QUESTIONNAIRES BASED SURVEY STUDY

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Self-medication, according to the World Health Organization, is the choice and use of medicines by people to treat self-recognized sicknesses or symptoms and is one part of self-care (1). It is the treatment of common health problems with products specifically designed and labeled to be used without medical supervision and approved as safe and effective for such use. Medicines for self-medication are typically known as ‘non-prescription’ or ‘over the counter’ preparations (OTC) and they are available without a doctor’s prescription through pharmacies. The term OTC (over-the-counter) should be understood as taking medicines issued without a doctor’s prescription. The decision on their use is made by the patient, possibly after consultation with the pharmacist. Products with the status of dietary supplements do not show pharmacological effect but only physiological effect. According to the official definition, they are a concentrated source of mineral components or other nutritional substances having a physiological or nutritional effect, whose task is to enrich the daily diet with components whose insufficient amount is supplied in the meals taken. Since both types of products are present in the pharmacy

market and appear in identical forms, e.g. in capsules, tablets or drops, despite the marking on the packaging, patients are not always able to assess whether they take a dietary supplement or an OTC drug. In some countries, they are also offered in supermarkets and other shops (2, 3). The increase of self-medication is due to a number of factors such as socioeconomic status, lifestyle, public health, and environmental factors as well as demographic and epidemiological factors (4). According to Ilana Levy et al. studies, approximately one in 55 hospital admissions may have been caused by adverse events associated with interactions between dietary and herbal drug supplements and drugs. To minimize the occurrence of adverse events, medical staff education should be improved (5). The main reasons for sedative disorders can be a fast pace of life, financial problems, too many work responsibilities, and the lack of sleep. Pharmacological treatment with synthetic drugs like benzodiazepines can lead to addiction, therefore patients prefer herbal sedative products that reduce stress, because of their availability and lowered risk of side-effects. Herbal sedatives are one of the most widespread products used in

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self-medication, because of contemporary lifestyle stress. They are employed in the treatment of e.g. anxiety, sleep disturbance, nervousness and distress (6, 7). Herbal remedies derived from plants and plant extracts, like leaves, flowers, roots, bark, and berries are available as individual herbal supplements, as well as herbal compounds that incorporate many herbs into formulations. They are often used separately or in combination with OTC products to support general wellbeing or to resolve symptoms like mental stress (8). Common herbal sedatives products for stress can include lemon balm, valerian root, passionflower, lavender, hops or St.John's wort. These herbs can be helpful when they are used at the correct dose after consultation with a medical practitioner or pharmacist because of possible interactions with other drugs (9).

The aim of this study was to estimate the use of herbal sedatives in self-treatment among pharmacy customers in Lower Silesia, Poland. The essence of the analysis was to work out whether or not factors such as place of residence, education, sex, age and occupation influence the purchase of these kinds of OTC products.

## EXPERIMENTAL

The study was undertaken in accordance with the principles of the Declaration of Helsinki and was approved by the Bioethical Commission of Wrocław Medical University in Poland (no KB-531/ 2013). The participants signed a consent form for the study. They were recruited from April 2015 to April 2017 in 30 pharmacies in Lower Silesia in Poland. Minimum age of 18 years was the most inclusive determining factor. Four hundred thirteen questionnaires were distributed with a request to complete them at a pharmacy or return it within two days. One hundred sixty eight completed surveys were considered for data calculations while others were rejected due to being improperly filled out.

The survey consisted of twenty questions whose purpose was to evaluate the following issues: if patients use herbal sedatives products; where they purchase them and how often; if they inform physi-

cians about their usage of these products or use them together with other medications; where they get knowledge about them; and whether or not the leaflet or information on the product package is sufficiently understandable. Figure 1 shows the questionnaire. Additionally, the demand for health education in the safe use of these kinds of products was evaluated.

All statistical analyses were made using Statistica PL® v. 13 software (StatSoft, Poland). Analyzed variables had a qualitative (nominal) character. The general correlations between variables were evaluated using Principal Component Analysis. Optimal PCA model was reduced to two components. Selected variables were subject to further statistical evaluation. The chi-square, test as well as the chi-square test with Yates correction and Fisher's exact test, were used to define the dependence between compared variables. All statistical analyses were performed at the 0.05 level of significance.

## RESULTS

The results of PCA analysis which allowed selection of the most significant variables and correlations between them are presented in Figure 2. In this method, a large number of variables are converted into a smaller set of linearly uncorrelated variables – principal components. Such transformation allows finding statistically significant correlations between variables. Points on the plot situated close to each other are correlated (eg. sex – woman and herbal sedatives usage – yes), while those situated on the opposite side of the axis are negatively correlated

The summary of the analysis is shown in Table 1. P1 and P2 represent first and second principal component. R2X – explained variation (fraction of model fit), eigenvalue – value indicating variance in principal component, limit – the ratio of the degree of freedom of the component to the total model degree of freedom, Q2 – predicted variation (accuracy of prediction). The last column indicates a number of a algorithm iterations.

Table 1. Principal components analysis summary.

Component	28.9559% of the sum of squares has been explained by all the extracted components							
	R2X	R2X (Cumul.)	Eigenvalues	Q2	Limit	Q2(Cumul.)	Significance	Iterations
P1	0.16825	0.16825	4.82696	0.08121	0.04126	0.08121	S	13
P2	0.12131	0.28956	3.59264	0.05369	0.04257	0.13054	S	20

## "Estimation of the use of herbal sedatives by pharmacy patients"

Questionnaire for patients (more than one answer to questions 8-20 can be ticked)

1. Age (years)
  - a. 18-25
  - b. 26-35
  - c. 36-45
  - d. 46-65
  - e. over 65
2. Education
  - a. primary or vocational
  - b. secondary
  - c. higher
3. Gender W/M
4. Place of residence
  - a. below 20,000 inhabitants
  - b. 20-50,000 inhabitants
  - c. 50-80,000 inhabitants
  - d. 80-100,000 inhabitants
  - e. 100-500,000 inhabitants
  - f. over 500,000 inhabitants
5. I am in a stable relationship/I am not in a stable relationship (please underline correct answer)
6. Employment: student/ professionally active /does not work/retirement pension (please underline correct answer)
7. Do you use sedatives?
 

YES                      NO
8. What type of sedatives do you use?
  - a. On prescriptions
  - b. Plant original
9. Where do you buy these preparations?
  - a. Pharmacy
  - b. Herbal shop
  - c. Internet
  - d. Direct sales
  - e. Others, where?.....
10. What types of herbal preparations have you used in the last 12 months?
  - a. Herbal teas
  - b. Oral preparations (capsules, tablets, syrups, drops)
  - c. Other, what kind of?
11. How often do you buy this type of preparations?
  - a. Once a month or more often
  - b. Once every 2 months
  - c. Once every 3 months
  - d. Once every 5 months
  - e. Once every six months
  - f. Once a year
  - g. Only once
12. Does the season affect your use of sedatives?
 

YES                      NO
13. What is the most important factor in your choice of a sedative preparation?
  - a. Price
  - b. Effectiveness
  - c. Recommendation of a friend/family
  - d. Pharmacist's recommendation
  - e. Doctor's recommendation
  - f. Seller's recommendation
  - g. Composition of the preparation
  - h. Brand
  - i. Advertising (press, television, radio, Internet)
  - j. Other, what kind?.....
14. Are you familiar with the information about the preparation contained on the packaging or on the leaflet?
 

YES                      NO
15. Is the producer's information about the preparation comprehensible and readable for you?
 

YES                      NO
16. Do you take other medicines at the same time as the herbal product you are taking?
 

YES                      NO
17. Do you inform your doctor or pharmacist about taking herbal sedatives?
 

YES                      NO
18. Did your herbal sedative meet your expectations?
 

YES                      NO
19. How do you get the information about herbal sedatives?
  - a. Full-colour newspapers and magazines
  - b. Professional journals
  - c. Information on the packaging or leaflet
  - d. Books
  - e. Friends
  - f. Internet
  - g. Television
  - h. Other - what kind?.....
20. Is the source of knowledge about herbal sedatives for you?
  - a. doctor
  - b. pharmacist

Figure 1. Questionnaire for patients

**General responders' data**

The study cluster consisted of the following majorities: women (75%); patients aged 18-25 years (35.1%); patients with higher education (44.6%); and patients from cities with populations greater

than 100,000 (39.3%). Elaborated sociodemographic information is conferred in Table 2.

The educational level of the respondents was statistically significant. The majority of respondents had a higher or secondary (88.7%) education and

11.3% had primary and vocational education. Three fourths (75%) of respondents below the age of 25 had secondary education. Of respondents between the ages of 26 and 35, 87% had higher education. Among respondents over 60 years old, 75% had an elementary, and 27% had a vocational education ( $\chi^2 = 56.819$ ,  $p < 0.001$ ). Of respondents below the age of 20, 80% were students. Among people above age 60, 95% were pensioners. Among people aged 46-60, 97% were professionally active ( $\chi^2 = 259.829$ ,  $p < 0.001$ ). The majority of respondents with higher education, 87%, were women, while 50% of respondents with elementary education and 47% with a vocational education were men ( $\chi^2 = 10.301$ ,  $p < 0.001$ ). Among respondents, 81% with higher education and 67% with a vocational education were professionally active ( $\chi^2 = 64.842$ ,  $p < 0.001$ ).

#### Place of residence

About half of respondents (54%) living in cities with a population under 20.000 were below the age of 25. In the cities above five hundred thousand inhabitants, 50% of respondents were between the ages of 46-60 and 41% were above age 60 ( $\chi^2 = 34.215$ ,  $p < 0.001$ ). About half of respondents (56%) living in cities with more than 500.000 inhabitants, and 64% of respondents living in cities with between 100.000 to 500.000 inhabitants had a higher education, while 67% of respondents living in cities below 20.000 inhabitants had a secondary education ( $\chi^2 = 29.524$ ,  $p < 0.001$ ). The majority

(69%) of respondents living in cities with a population above 500.000 were professionally active, while 55% of respondents living in cities from 100.000 to 500.000 inhabitants and 74% living in cities from 20.000 to 50.000 inhabitants were professionally active ( $\chi^2 = 32.294$ ,  $p < 0.001$ ).

#### Age, education, employment status

The application of sedative preparations depended considerably on the age of the people examined ( $p < 0.001$ ). Principally the youngest respondents below age 25 and the oldest above 60 declared using these products. The application of sedative preparations depended on the employment status of respondents ( $p < 0.001$ ). The largest percentage (42%) of people who didn't use sedative preparations was found in the group of professionally active people. The education of respondents had a significant impact on whether or not to purchase the preparations ( $p < 0.001$ ). Respondents with a secondary and elementary education mainly followed the recommendation of the doctor concerning the purchase of a preparation ( $p < 0.001$ ). Respondents with an average or higher education, when choosing a sedatives preparation, take into account their composition and are disposed to seek information about medicines on the internet.

#### Gender

The sex of the respondents had a significant influence on the application of sedative products and natural sedative preparations. Mainly men (88%)

Table 2. Socio-demographic characteristics of the study population.

Characteristics	Total completed surveys number N = 168	Number of cases	Percentage %
Gender	Women	126	75
	Men	42	25
Age (years)	18-25	59	35.1
	26-35	26	15.5
	36-45	31	18.5
	46-65	30	17.8
	Above 65	22	13.1
Place of residence	Below 20.000	54	32.1
	20.000 - 100.000	48	28.6
	Over 100.000	66	39.3
Education	Primary and vocational	19	11.3
	Secondary	74	44.1
	Higher	75	44.6

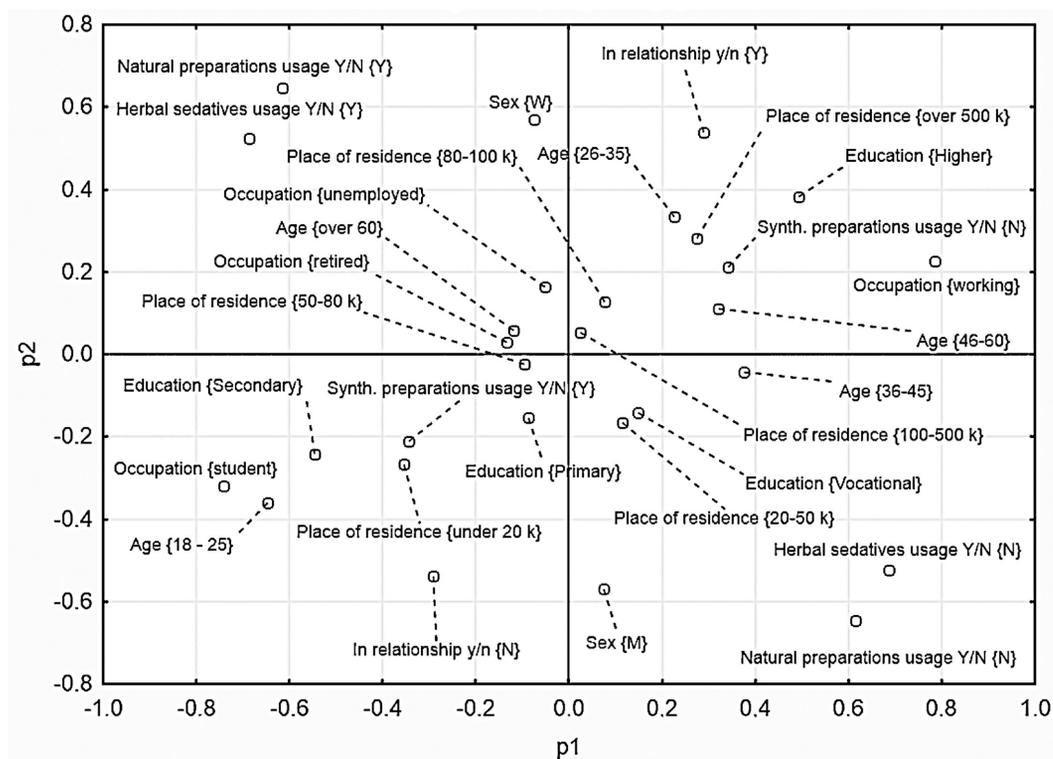


Figure 2. Loading scatterplot (p1 vs. p2)

used synthetic products while only 12% of surveyed women did. Respondents using synthetic preparations indicated that they did not use natural preparations at the same time ( $p < 0.001$ ) and vice versa. Almost all (91%) of the examined women declared purchasing of natural preparations while only 68% of men did. The majority (88%) of respondents taking natural preparations declared at the same time that they did not approve of synthetic drugs and also declared that they had taken oral preparations within the last 12 months ( $p < 0.001$ ).

#### Sources of information about herbal products

The main criteria for choosing an herbal product among 70% of people using synthetic drugs was doctor's recommendation ( $p < 0.001$ ). Respondents using synthetic medications (73%) declared taking other medicines at the same time ( $p < 0.001$ ). The majority (69%) of respondents not taking synthetic medicines also did not take other medicines. The majority of respondents bought sedative preparations in the pharmacy (66%), while 17% bought them in herbal shops. Seventeen percent did not answer this question. Respondents, for whom a doc-

tor was the source of information, bought medicines at a pharmacy (100%,  $\text{Chi}^2 = 4.481$ ,  $p < 0.001$ ), used oral preparations within the last 12 months (87%,  $\text{chi}^2 = 6.805$ ,  $p < 0.001$ ) and declared that they had read the leaflet (95%,  $\text{chi}^2 = 8.270$ ,  $p < 0.001$ ). Respondents for whom the main source of information was television bought preparations mostly in herbal shops (53%,  $\text{chi}^2 = 9.758$ ,  $p < 0.001$ ) and the price of products was important for them (55%,  $\text{chi}^2 = 8.047$ ,  $p < 0.001$ ). They read the leaflet (95%,  $\text{chi}^2 = 5.387$ ,  $p < 0.001$ ), declared that they searched for information about medicines through the internet (71%,  $\text{chi}^2 = 4.099$ ), and read the information on the packaging or the leaflet (55%,  $\text{chi}^2 = 10.229$ ,  $p < 0.001$ ). Respondents who declared that the source of information about preparations was found in books were also interested in the composition of the preparation (88%,  $\text{chi}^2 = 10.295$ ,  $p < 0.001$ ). They declared getting information about medicines from the internet (100%,  $\text{chi}^2 = 10.328$ ,  $p < 0.001$ ) and from specialist journals (86%,  $\text{chi}^2 = 24.878$ ,  $p < 0.001$ ). The majority (80%) of respondents declared that books are not a source of information about the medicine and also

did not get information from the packaging or the leaflet ( $\chi^2 = 9.068$ ,  $p < 0.001$ ).

### Satisfaction

Respondents declaring that the preparation met their expectations had also used oral preparations within the last 12 months (83%,  $\chi^2 = 7.155$ ,  $p < 0.001$ ). About 93% of people declaring that the preparations met their expectations also took the recommendation of a pharmacist under consideration ( $\chi^2 = 4.278$ ,  $p = 0.03861$ ).

## DISCUSSION AND CONCLUSION

Herbal remedies that are non-prescription products are often used by pharmacy customers separately or in combination with other products to resolve the symptoms of various kinds of stress (7). This survey was the first study in Lower Silesia (Poland) to assess self-medication with herbal sedatives among pharmacy patients and it demonstrated that self-medication practices involving these products were widespread within the surveyed sample of the Polish population. The research was focused on factors that influence customers' behavior (10, 11). Sedative disorders are preponderantly self-diagnosed and self-treated with herbal sedatives products (12). In our study, a majority (64%) of respondents use herbal sedatives for self-treatment and buy them in a pharmacy. Age and gender are significant determinants of the consumption of herbal products and dietary supplements generally. Previous studies have shown a higher consumption among women than men and also among older than younger adults (13-15). The present study found an identical pattern of consumption when compared to Swedish studies in that women bought more herbal products (16). In the study by Plichta et al. no significant gender differences in the study population were found (17). The vast majority (91%) of our respondents had secondary or higher education and only 9% had an elementary or vocational education. This data was similar to the Barrenberg and Garbe outcomes in the German population, also to the Calamusa outcomes in Italy, and to the Bochenek outcomes in Poland (18-20). Different results were obtained in Sweden by Hakonsen where no differences in the educational level were observed (16). The majority of our interviewees declared that they did not consider a doctor's recommendation when choosing an herbal preparation. In Italy, the most frequently cited sources of information were doctors and pharmacists (18). Also in Italy, written and mass-media sources of information about products were less

commonly mentioned, in particular, the internet – 8.5%, while in our study more than 70% of respondents got information from the internet. Most of the Italian respondents were aware of the risks related to herbal preparation side effects, while Polish patients did not have that kind of knowledge and even did not inform their doctors about taking such products (18). Half of the respondents read the information on the leaflet (51%). Also in the Bochenek and Wozniak-Holecka studies, a majority of patients interviewed found information about products on the leaflet (20, 21). Most respondents, as reported by Calamusa, read the leaflet every time they bought an herbal medication (18). The majority of respondents buy them in pharmacies, a finding which is similar to the Swedish data (16). The main criteria for buying herbal products in pharmacies was the product range, pharmaceutical care of trained staff, and the availability of less expensive OTC substitutes. This finding is not consistent with the results of a survey in Estonia, where the general consumption of medicinal plant products increased with age (22). Older people usually suffer from chronic diseases and have more time to look for OTC products, while younger people look for fast treatment options (22).

The survey was undertaken in one region of Poland, and, even though an acceptable sample of pharmacy customers was used, the conferred results do not seem to be generalizable across the whole country or for various demographic groups, because there is no data with which obtained results can be compared. The low range of male respondents who participated in the survey may be related to the lower frequency of their visits to community pharmacies. In the future, the survey setting may be modified also about the impact of participants' income on the use of herbal preparations, which was not taken into account in this study.

Herbal sedative products are usually used by the employed or students who are vocationally busy and possibly want to return to professional activity as soon as possible. Respondents using herbal sedative preparations also often use more than one medication. This group of people, being at an increased risk of adverse effects resulting from polypharmacological interactions, should be a target group for the health education programs. Therefore, pharmacists, especially in local pharmacies, play an important role in safe and effective therapy and in reducing the risk for serious adverse events. From a marketing point of view, the most important target groups for natural sedative products in the analyzed population are women and customers younger than 25.

**Conflicts of interest**

The authors declare no conflict of interest.

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