

## THE USE OF NUTRITIONAL SUPPLEMENT IN ROMANIAN PATIENTS – ATTITUDES AND BELIEFS

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### Abstract

Taking into account that an increasing number of patients ask for nutritional supplement to support their chronic treatment, consisting into products made of plants or vitamins and minerals and starting from the premise that they do not induce side effects, so their administration is well tolerated, this paper aims to assess: the factors that make the patient use nutritional supplements, the main categories of nutritional supplements that are used by the patient, the patients knowledge about the legislative regulations on food supplements and the patients' trust in the efficacy and safety of these products. The population included in the study consisted of 372 patients living in the urban area of Bucharest, Romania, who answered a questionnaire related to the subject presented previously, taking into account variables such as age, gender, income level, educational level. Following the responses obtained, we report that the use of nutritional supplements faces many problems such as the abuse of these products without the recommendation of a health specialist (physician or pharmacist), the possibility of online purchase from unsafe sources, the lack of information regarding the indications of the food supplement, efficacy and safety of these products, the poorly known legislative regulations of food supplements.

### Rezumat

Există un număr din ce în ce mai mare de pacienți care cer suplimente nutriționale pentru a sprijini tratamentul lor cronic, constând în produse obținute din plante sau suplimente cu vitamine și minerale, plecând de la premisa că nu provoacă efecte secundare și tratamentul cu acestea este bine tolerat. Lucrarea are scopul de a evalua factorii care determină pacienții să utilizeze suplimente nutriționale, principalele categorii de suplimente alimentare care sunt utilizate de pacient, cunoștințele pacienților cu privire la reglementările legislative privind suplimentele alimentare și încrederea pacienților în eficacitatea și siguranța acestor produse. Studiul a inclus 372 pacienți care trăiesc în mediul urban din București, care au răspuns la un chestionar referitor la subiectul prezentat anterior, luând în considerare variabile precum vârsta, sexul, nivelul veniturilor, nivelul de educație. În urma răspunsurilor primite, utilizarea suplimentelor nutriționale se confruntă cu multe probleme, cum ar fi consumul acestor produse fără recomandarea unui medic specialist (medic sau farmacist), posibilitatea achiziționării *online* din surse nesigure, lipsa informațiilor privind indicațiile suplimentului alimentar, eficacitatea și siguranța acestor produse, reglementările legislative puțin cunoscute ale suplimentelor alimentare.

**Keywords:** nutritional supplements, patients, legislative regulations, food supplements, health specialists

### Introduction

Although the allopathic medicine is still the primary treatment recommended both by physicians and pharmacists, the increased interest in the alternative therapies causes the patient to take into account more and more the option of using nutritional supplements. The European Food Safety Authority defines food supplements as concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement a normal diet. These are made as pills, capsules or liquids and are similar to formulations typical for medicines. They

contain concentrated vitamins, minerals, or other substances in specific dosages [20].

In Europe, products containing vitamins and minerals represent 50% of total sales of food supplements; those containing other substances have 43% market sales [20]. The use of nutritional supplements is steadily raising in Europe, especially in the North - West area, mostly by women. For example, in Denmark women buy ten times more food supplements (65.8%) than in Greece (6.7%) [2, 21].

The situation of dietary supplementation is similar in the United States where in the recent national surveys, 52% of US adults reported the use of at

least one such product and the most popular are vitamins and minerals [15].

Based on the definition of food supplement, the decision of using such products should be taken carefully and justified by an increased physiological demand or insufficient intake of nutrients from dietary sources. So, there is a high risk that the amount of specific nutrients exceeds the dietary reference intake due to unjustified supplementation. According to earlier performed studies, about 9% of the consumers in the EU develop adverse effect like diarrhoea, constipation, gastric pain, headache, nausea or vomiting, and also more severe adverse effects such as neurological disturbances, liver toxicity and interference with other drugs used for chronic disease. Therefore, unregulated consumption of food supplements and without a recommendation from a health specialist could represent a risk, rather than a benefit for the population [20].

The main reason for using food supplements is to prevent diseases, enhance mental and general health, to protect the function of vital organs, and to compensate for dietary deficiencies [9, 17, 20].

The increasing availability of food supplements in pharmacies, online shops, supermarkets and the aggressive advertising in the media, and also the belief that these substances have only positive effects determine the patient to buy a high amount of these products and encourage self-medication. This fact also indicates that the medical community needs a continuous monitoring of this phenomenon and moreover sufficient knowledge to be able to inform the patient about the risks of using nutritional supplements.

In Romania, like in other countries, the legislation on nutritional supplements still needs some improvements taking into account that the approval to market supplements containing vitamins and minerals is given by Ministry of Health and the National Public Health Institute, but for products containing medicinal and aromatic herbs as well as products of the hive, it is given by the Ministry of Agriculture and Rural Development [13, 14]. A very important aspect regarding nutritional supplements is the way of labelling. The label should contain on it the name of the nutrients, the recommended daily dose amount and 4 warnings: do not exceed the dose, the product does not replace a varied and adequate diet, do not leave the product to children and if it is forbidden for athletes. However, as a result of evaluations carried out by the National Consumer Protection Authority and Ministry of Health, some problems were identified such as labels that did not contain the information in Romanian language, the lack of daily dosage, the lack of some ingredients that were mentioned on the label, the role in preventing, treat and also cure some disease [14].

Another worrying aspect is the lack of quality, efficacy and safety studies as there are made for medicines,

to demonstrate the therapeutic indications mentioned on the label, and to demonstrate the absence of side effects or to mention them [13, 15]. Moreover, in countries like Spain and Italy, there has been demonstrated that some food supplements were contaminated with pathogenic microorganisms [7, 24]. Thus, the assessment of the risk of consuming nutritional supplements is hard to be made because nutritional supplements are products given without medical prescription. Thus, the patient should inform the physician or the pharmacist about the products they are using in order to prevent the interaction with their chronic treatment or some adverse reactions that can occur.

This paper aims to assess the factors that make the patient use nutritional supplements, the main categories of nutritional supplements, the patient's knowledge about the legislative regulations on food supplements and the patients trust in the efficacy and safety of these products.

## Materials and Methods

The study was conducted between March 2018 and October 2018 in Bucharest, Romania, by giving questionnaires to the general population.

The population included in the study was represented by 372 patients aged between 18 and 84 years. The inclusion criteria were age over 18, Romanian citizen, people willing to participate to the study. The exclusion criteria were psychiatric disorders, illiteracy, people who did not want to take part in this research.

The instrument used in the current research was the questionnaire consisting of specific inquiries related to this subject.

There were taken into account variables such as age, gender, income level, education level.

Thus, the patients were assessed using the items below: (1) The definition of food supplement; (2) The primary source of information to be taken into account when purchasing such a product; (3) The main reasons for buying nutritional supplements; (4) The observed differences in health status after using a nutritional supplement; (5) The assessment of health status after using the nutritional supplement is done by evaluating specific clinical parameters, such as laboratory tests; (6) The importance of medical advice when buying food supplements; (7) The influence of the price of a food supplement; (8) How many food supplements do they use; (9) What are the main categories of nutritional supplements that they use; (10) Where do they purchase these products; (11) Their knowledge about the legislative framework of nutritional supplements.

## Results and Discussion

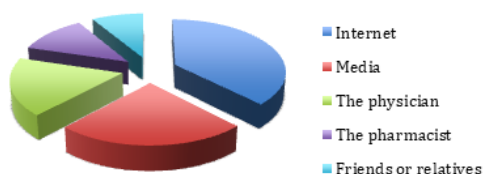
The patients who answered the questionnaire were aged between 18 to 84 years old (with an average of

56 years), and living in the urban area of Bucharest, with a monthly income of 300 - 500 euro. 73.7% were women and 26.3% were men, 54.8% of them were university graduates, 29.7% high school graduates and 15.5% post graduate degree holders.

From the subjects evaluated, 28% were able to give an approximate definition of food supplements taking into account that an important percentage are university graduates this fact is normal, where as a worrying percent of 72% have different knowledge about what a food supplement is, most of them considering these products medicines.

The primary source of information about nutritional supplements is the internet for 37.7% of the subjects evaluated, 24.2% take into account the media, 17.8% ask for information from their physician, 11.7% of the population request an advice about nutritional supplement from the pharmacist, and 8.6% find information from their friends or relatives. This result is relevant because the population included in this study is well trained, most of them university graduates and the fact that they live in the urban area of Bucharest facilitate their easy access to information.

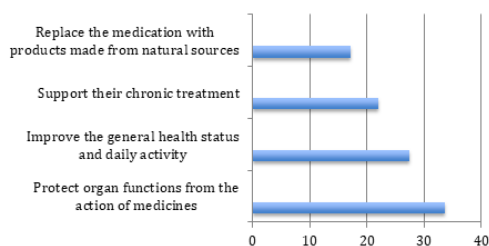
**The primary source of information about dietary supplement**



**Figure 1.**

The primary source of information about dietary supplement

When they were asked which are the factors reasons that determined them to buy nutritional supplements, 27.3% answered that they want to improve their general health status and daily activity, 21.9% want to support their chronic treatment, 33.6% think that using nutritional supplement will help them to protect organ functions from the action of medicines, where as an increased percentage of 17.2% use them to replace the medication with products made from natural sources.



**Figure 2.**

The main reason why people use nutritional supplements

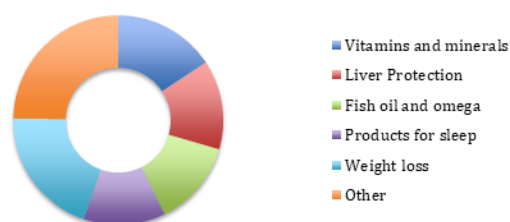
52.6% of the evaluated population considered that an improvement appeared after using nutritional supplements, but they never considered necessary to make some laboratory tests to quantify this improvement, 27.7% did not observe any changes and 19.7% do not know to tell about any improvement. Even though the population in this study is well trained considering their education level, their answers regarding this item are surprising.

When asked if they request any medical advice before buying nutritional supplement 68.9% answered that they ask their physician or pharmacist, whereas an alarming 31.3% do not take into account the opinion of any healthcare specialist. 87.4% consider that is important to consult a healthcare specialist before purchasing a nutritional supplement, but for 12.6% of the evaluated population, this aspect is less important. The evaluated patients consider that the price is an essential aspect when purchasing such a product (62.6%).

From the population evaluated, 48.8% use between 1 to 3 nutritional supplements, 31.4% use 3 to 5 nutritional supplements, 11.7% more than five, and 8.1% less than one, maybe because they have easy access to information as they live in an urban area and their age determine the population to read more about this category of products.

When they were asked what are the main categories of dietary supplements that they use 15.7% of them answered vitamins and minerals, 13.8% products for the liver protection, 13.2% fish oil and omega, 12.7% products for sleep and relaxation, 19.9% products for weight loss, 24.7% other (Figure 3).

**The main categories of dietary supplements**



**Figure 3.**

The main categories of dietary supplements the assessed population uses

A very important aspect was the place from where they purchase these products, thus 44.6% buy nutritional supplement from the pharmacy, 34.1% from online shops, and 21.3% from supermarkets.

The legislative framework for nutritional supplements is the same as for the medicine for 94.6% of the subjects evaluated, whereas 5.4% do not know anything about this aspect.

Analysing the responses received, the questioned patients live in the urban area, predominantly women

and most of them are university graduates, a fact that reflects their easier access to information about alternatives to the chronic treatment. However, a significant number of patients do not know what a nutritional supplement is, and its role in supplementing a normal diet. Most of them consider the nutritional supplement a medicine. This lack of information is very dangerous because the patient may consider the supplement is as safe and efficient as a medicine, and also they may think that the studies conducted over the years before a medicine is marketed are the same for a nutritional supplement. Moreover, they may think that the authorities that give the approval to market a supplement are the same as for medicines. A very important aspect of this questionnaire was the primary source of information people use before purchasing a nutritional supplement, and the fact that most of them consult the internet and media should be an alarm first of all for health specialists because this can lead to wrong information that is not adapted to the patients need and that can result in the failure of a chronic treatment. As mentioned in other studies regarding the advertising of food supplements, there are aspects that fail to comply with the health claims rules. The competent authorities do not always manage to monitor food supplements advertising according to current legal standards [5, 7]. In another recent survey, only 50% of food supplements users were advised by a health professional, while others were often influenced by sport coaches, friends, or the internet and other media [20]. That is why the physician and also the pharmacist should initiate discussions on this subject before the patient mention the use of such a product in order to prevent the wrong usage or the interaction with their treatment, and more over to identify the adverse reactions that can occur and if the patient really needs to take a nutritional supplement.

Considering the responses received, people use dietary supplements to improve the general health status, or to support their chronic treatment based on the belief that these products do not interact with the medication and they are free of adverse reactions. This aspect is similar in other countries like USA where almost half of adults' report using  $\geq 1$  dietary supplements to "improve" and "maintain" the overall health [6]. They also think that using a supplement will help them to protect their organs, even though they never investigated if they had such problems before using nutritional supplements. The most alarming aspect is that an important percentage uses nutritional supplements to replace the treatment initiated by a specialist, for example they use supplements with fish oil instead of statins to lower the LDL Cholesterol. The gravity of this fact can result in the therapeutic failure and the worsening of the disease. They also consider that an improvement appeared after using nutritional supplements, but this fact is impossible

to be quantified as long as there are no laboratory tests to confirm that. The evaluated patients do not consider an important aspect the evaluation of their health status using clinical parameters before and after using such products although this can demonstrate the efficacy of a nutritional supplement in a certain disease or certain patient. It is important to emphasize that there were patients that did not observe any changes or that do not know to tell anything about this aspect and they still use nutritional supplements. This can lead to over medication without a rational purpose.

A positive aspect in the evaluated population was that most of the patients ask their pharmacist or physician about the products that they want to use and this thing can lower the possibility of ingesting products that interfere with the chronic treatment and also of products that are not necessary for them. However, an alarming percentage of people do not take into account the opinion of a healthcare specialist and more over they do not consider necessary to tell the pharmacist or physician about this aspect because in their opinion what is made of natural source is safe and efficient. For example, in USA less than a quarter of supplements used by adults were recommended by a physician or health care provider [2].

Even though the price is an important aspect for the population evaluated the sales of nutritional supplements are increasing, people being willing to spend as much money as they consider for the improvement of their healthcare status. This aspect correlated with the lack of information from a specialist can result in an irrational use of nutritional supplements.

The abuse of these products can be quantified by the large number of supplements used by the evaluated people. If we also consider a chronic treatment with 3 different medicines, a person ingests daily at least 6 different types of products. Increasing the number of pills taken daily, the incidence of interactions and adverse reactions is also increased, and is very difficult to identify which of the products used caused the unpleasant events. If we consider the aspect that dietary supplements for different indications can contain the same herbal extract, this aspect is even more difficult to quantify, as presented before [6, 10-12, 16, 19, 22].

Most of the people evaluated the use of supplements for losing weight, fact that can affect their physical activity, expecting that a product will solve their problem. The questioned people also use vitamins and minerals and this aspect can exceed the dietary reference intake. Products for protecting the liver are used in high percentage by the evaluated people, sometimes without a demonstrated liver dysfunction, this also being a case of over medication. The use of fish oil products and omega can lead, without monitoring the clinical parameters of a patient with high values of cholesterol, to therapeutic failure and can also aggravate the current disease. Nutritional supplements

for sleep can determine the sudden discontinuation of treatment with benzodiazepines, for example, which can cause a rebound effect and withdrawal. The increased risks on adverse events when combining the prescribed drugs with medicinal products are also mentioned in previous studies that emphasize the dietary supplement interactions with medication for cardiovascular diseases or psychiatric, anticoagulant medication, because of their content in garlic, ginkgo, ginseng [6, 11, 12, 16, 19]. Achieving nutritional supplements from online shops or even supermarkets can lead to unjustified use of these products because there is no healthcare specialist to consult in these places and more over the untrusted source of purchasing can result in contaminated products with microorganisms or undeclared substances as presented before in similar studies [1, 4, 7, 18, 22, 23].

The fact that people consider the legislation for nutritional supplement is the same as for the medicines results in a higher unjustified confidence level people have in these products considering that the same kind of studies are conducted for dietary supplements and the safety and efficacy are similar as for medicines. The problem regarding the legislation of food supplement is also an alarming aspect in the countries near Romania, like Moldova, where it is incomplete and unsatisfactory formulated which could be a prerequisite for the irrational use of food supplements [7].

## Conclusions

In conclusion, this study presents some of the main aspects that the Romanian patients confront with when it comes to the use of nutritional supplements. This paper can conclude that the beliefs of the evaluated people regarding nutritional supplements are rarely based on medical evidence and that the professional figures, like physicians and pharmacists should be more involved in this subject in order to avoid the abuse of supplements and interactions and potential adverse reactions of this products. Moreover, the authority regulations on this subject should be more complete to demonstrate the safety and efficacy of these products.

## Conflict of Interest

The authors declare no conflict of interest.

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