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ORIGINAL PAPER

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Real world data supporting identification of the pharmacist's role in obesity and overweight treatment in Poland – a preliminary report

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ABSTRACT

Introduction. Obesity is a significant health and economic problem, both for the patient and the health care system. An essential element in the prevention and treatment of each disease is the engagement of all groups of healthcare professionals. In our study, we performed an analysis of the real world data, obtained from a survey of the medical and socioeconomic problems associated with overweight and obesity. We aimed to identify the pharmacist's role in the management of overweight and obese patients, including their individualized education in an outpatient setting.

Material and methods. The study material consisted of responses obtained from a specially designed questionnaire. Our findings indicate that the study patients had easy access to a pharmacist's professional knowledge, relevant to comprehensive treatment of obesity. In addition, our data indicates a lack of patient knowledge of a healthy lifestyle and an inability to implement such knowledge in practice.

Results. The community pharmacist should actively provide support to patients with obesity (including the primary obesity and those who want to lose excessive body mass for health-related and also for aesthetic reasons) and the management of their weight. The results of our study should be considered as an introduction to further research to facilitate the understanding of problems and expectations of patients and to prepare pharmacists to perform pharmaceutical care (PC) in this regard. Conclusion. One of the potential options to protect society against the obesity epidemic is an education about the risks inherent to obesity and promotion of a healthy lifestyle.

Keywords. overweight, obesity, pharmaceutical care, treatment, real world data

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Participation of co-authors: A – Author of the concept and objectives of paper; B – collection of data; C – implementation of research; D – elaborate, analysis and interpretation of data; E – statistical analysis; F – preparation of a manuscript; G – working out the literature; H – obtaining funds

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Introduction

The role of the pharmacist in supporting patients is increasing, especially concerning diseases related to lifestyle and those affecting a significant part of the society, e.g. related to diabetes or obesity, the last being in the focus of real world data collected in Poland.

Obesity is one of the major health problems societies are facing nowadays. According to the World Health Organization (WHO), overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health. Since 1985, obesity is considered to be a chronic disease.2 To determine the degree of obesity and overweight, most commonly Body Mass Index (BMI) has been used.3 For adults, the WHO defines a person with a BMI equal to or more than 25 is overweight and a person with a BMI 30 or more is obese4. At present, in addition to the calculation of BMI, the waist circumference (WC) measurement is important for prediction of diseases which are commonly related to overweight and obesity. Based on waist circumference and hip circumference measurements, the waist-hip ratio (WHR) is calculated. The value of WHR above 0.88 in women and above 1.1 in men is defined as abdominal or central obesity.5,6

Obesity is a systemic disease that affects people of all ages.^{7,8}. A typical feature is excessive fat tissue accumulation, due to an increased number and size of adipocytes.⁹ Nowadays, obesity is not only a single disease, but also a significant social problem, with which medicine is not able to cope. It affects more and more people and sometimes is called the epidemic of the 21st century.

Obesity appears mostly as a concomitant disease accompanying multiple diseases, e.g. central nervous system diseases, metabolic diseases, and chromosomal defects. Obesity can also be a side effect of certain drugs. Obesity created in this way is called secondary obesity.¹⁰

Obesity leads to serious negative consequences, both medical and social. The first to be mentioned is the type II diabetes mellitus (T2DM) that approximately 80% of obese patients suffer from.11 The problem of obesity and overweight is increasingly affecting children.⁷ The second major complications are cardiovascular disorders (CVD) which are a consequence of atherosclerosis. Other medical conditions that cause obesity include changes in joints, fractures, or dislocations.12 Other disorders in the organism are related to skin: fungal infections, eczema, sores, stretch marks, and furunculosis. Long-term obesity leads to disorders of the liver, cirrhosis and steatosis.11 From the reproductive system, we observe abnormalities occurring during the menstrual cycle, anovulatory cycles, decreased libido, and reduced fertility.7 It should also be mentioned that obesity can lead to sleep apnea syndrome and asthma. 11 Consequently, obesity carries serious health consequences and even leads to a shorter lifetime expectancy. 12

According to the results of IASO/IOTF (International Association for the Study of Obesity/International Obesity Task Force) from 2010, it is estimated that about 1 billion adults have an overweight (BMI 25-29.9 kg/m²) and another 475 million are obese. ¹³ The results of epidemiological studies conducted in 2003-2007, on the prevalence of obesity and overweight in among Polish adults (above 20 years) suggest that 28.4% of women and 40.3% of men suffer from being overweight and 23.8% of women and 20.8% men were obese. ¹⁴

Different research has been performed in relation to obesity. A study by Kwagyan et al. demonstrated a high incidence of obesity and related cardiovascular (CV) events. They emphasized the need to focus on reducing obesity in a population at high risk. Associated with obesity, the incidence of hypertension, dyslipidemia and diabetes was 57%, 27% and 24%, respectively. The predicted 10-year risk of developing coronary heart disease (CHD) ranged from 4% to 17% for women and 6% to 29% for men. After six months of lifestyle changes, many of the risk factors improved, and the risk of CHD was reduced from 6% to 4% in women and from 16% to 13% in men. 15 However, no research was found in relation to the pharmacist's role in supporting obese patient treatment.

There is a need for evaluations of interventions to manage obesity and overweight in the pharmacist's community. Research in this area is warranted and trials should include the assessment of age, sex and socioeconomic status and contextual factors.¹⁶

Objective

Our research aimed to determine the role of the pharmacist in the prevention of obesity, as well as in pharmaceutical care delivered for patients with obesity or who are overweight.

On the basis of obtained real world data in order to fulfill the study objective, our project describes epidemiological characteristics of respondents with obesity, as well as those with normal body weight.

Materials and methods

We used a specially constructed questionnaire for this study. It contained 43 closed questions and 7 questions half-opened, divided into sections addressing lifestyle, including dietary habits and physical activity. We also collected data about chronic diseases, nutritional therapy, and on the participant's opinions about being assisted by a pharmacist during treatment. The questionnaire contained information about the respondent, including their data on weight, height, and the ability to calculate BMI.

The study was approved by the Ethics Committee of the Medical University of Lublin.

The survey was dedicated to the adult population of Polish people who believed that they are overweight or obese. Before conducting the study, the readability and understanding of the questionnaire was assessed and validated in a group of 10 patients. The study lasted from February 2012 to May 2012. The study was conducted using an online questionnaire. The survey was secured against being filled several times by the same person. A total of 177 completed questionnaires were collected. Information about the survey was placed on social networks.

The data obtained were analyzed using the computer software MS Excel 2007. The results were analyzed in aggregated form as descriptive statistics, showing the distribution of the quantity and a percentage of answers in each category.

Results and analysis

The study involved 177 people, including 114 women and 63 men. Analysis of the age structure of respondents revealed that the most numerous group was represented by people younger than 25 years. Demographic characteristics of the participants are presented in Table 1.

Only 22 people (12.4%) indicated physical work, including 5 women that indicated two types of work. Among the women who filled out the survey, the observed body weight was 38 kg as a minimum and 124 kg as the maximum and their height ranged from 142 to 179 cm. Body weight of men was in the range of 63 to 140 kg and the height from 168 to 192 cm. Among the respondents, 19 men (30.2%) and 37 women (32.5%) were not able to calculate their BMI. It is worth noting that only overweight and obese patients had a problem

with the correct calculation of BMI, in total it was 31.6% of respondents.

The majority of respondents (72.3%) usually consumed 3-4 meals per day, 21.5% of people consumed 5 meals and only a few individuals among respondents declared consumption of 1-2 meals (5% of respondents) or more than 5 meals per day (1.6% of respondents). 36% of women drawn attention to a number of calories in the food. 40 women (35.1%) and more than half of men (52.4%) did not pay attention to a number of calories in the meals. Following the recommendations of nutritionists, an adult should consume 5 small meals, taking into account their caloric content and to avoid frying meals. The vast majority of people filling out the questionnaire (78.5% of respondents) declared that they do not apply to these rules. However, 49.1% of respondents (87 persons) believe that they are eating healthy. While an equally large group of respondents indicated that they are eating poorly, 67 persons (37.9%) and 23 persons (13%) were not able to determine their eating habits.

Self-assessment of physical fitness of respondents is quite high and both women and men chose the answer as good or rather good, which represents 142 persons (80.1%) of all responses. The most common sport among the respondents was riding a bike. That answer was provided by 61 respondents (34.5%), i.e. 40 (36.8%) women and 9 (30.2%) men), while in second place, swimming and fitness were mentioned by 45 persons (25.4%) and 42 persons (23.7%) respectively. Among men, the most popular sport is strength training (21 persons, 33.3%). Other sports activities not listed in the questionnaire were declared by 17 (14.9%) of women and 18 (28.6%) men. Respondents mentioned karate, water and winter skiing, hunting, rock climbing and

Table 1. Patient demographic characteristics

		Women (N=114)	Men (N=63)	Total (N=177)
		n (%)	n (%)	n (%)
Age group	<25 years	75 (65.8)	35 (55.5)	110 (62.1)
	26-45 years	21 (18.4)	24 (38.1)	45 (25.4)
	46-60 years	17 (14.9)	3 (4.7)	20 (11.3)
	> 60 years	1 (0.8)	1 (1.6)	2 (1.1)
Type of work	physical	16 (14.0)	6 (9.5)	22 (12.4)
	intellectual	103 (90.3)	57 (90.5)	160 (90.4)
ВМІ	<18.5	9 (7.9)	0 (0)	9 (5.1)
	18.5-24.99	82 (71.9)	37 (58.7)	119 (67.2)
	25.00-29.99	15 (13.2)	17 (27.0)	32 (18.1)
	>30.00	8 (7.0)	9 (14.3)	17 (9.6)
	mean	22.67	25.24	23.69
	median	21.70	24.19	22.86
	Min	15.43	20.34	15.43
	Max	40.48	39.44	40.48
	SD	4.15	4.13	4.39

	Women		Men		Total	
	(N=114)	mean BMI (SD)	(N=63)	mean BMI (SD)	(N=177)	mean BMI (SD)
	n (%)		n (%)		n (%)	
Yes	86 (75.4)	21.74 (3.67)	53 (84.1)	25.46 (4.38)	139 (78.5)	23.16 (4.34)
No	9 (7.9)	25.83 (2.83)	6 (9.5)	26.12 (4.12)	15 (8.5)	25.95 (3.27)
I don't know	4 (3.5)	27.09 (2.92)	1 (1.6)	24.22 (3.67)	5 (2.8)	26.52 (2.84)
I'm not interested	15 (13.2)	24.92 (5.30)	3 (4.8)	26.12 (3.90)	18 (10.2)	25.12 (5.01)

Table 2. Respondents knowledge regarding the consequences of obesity

rope parks, table tennis, tennis, squash and team games e.g. football, volleyball, basketball and paintball.

Among the respondents, very few people perform sports activities every day. It was declared by less than 14 (8%) of all respondents. 34 (53.5%) of men and 53 (46.1%) of women reported physical activity 3 times a week, indicating the activity time of 30-60 minutes among women and more than 60 minutes among men. More than 19 (11%) of respondents do not undertake any exercise.

When asked about changes in their lives influenced by physical activity, they mentioned frequently improvement in their mood (41-36.4% of women and 24-38% men), an increase of energy to work or to study (30-26.3% women and 15-23.9% of men) and improvement of their physical appearance (28-24.6% women and 17-26.8% men).

The cause of low physical activity is the lack of free time in the case of 66 (37.3%) of all respondents, lack of willingness (23–20.3% women and 13–20.2% men), lack of financial resources (19–16.9% women) and an excess of duties (16–14.3% of women and 7–1.5% men).

Another objective of the study was to test the knowledge of the respondents regarding the consequences of obesity. The results are shown in Table 2.

Most of the respondents (139, 78.5% people) claim to know the consequences of obesity. It can be noted that among the respondents, 53 (84.1%) men and 86 (75.4%) women are aware of the consequences of obe-

sity. It is interesting also the statement by 15 (13.2%) of women and 3 (4.8%) of men that the consequences of obesity are not in the scope of their interest. However, it should be noted that this response was provided in the vast majority by persons with a BMI above 25.

An important aspect of the study was to determine the health status of the respondents and the impact of obesity on that state. Obesity does not interfere with daily life in case of 54 people (30.5%), while 48 (27.1%) respondents are aware of the risks associated with this disease. In the case of 3 (2.6%) women and 4 (6.3%) men, obesity contributed to the development of diseases such as diabetes, arthritis, hypertension, elevated cholesterol and triglycerides plasma levels and cholelithiasis. One person pointed out two diseases - diabetes and osteoarthritis. From chronic diseases, 21 (11.9%) suffer out of 177 respondents. Diseases mentioned by the respondents were: hormonal disorders (7 people, 4.0% of the studied population), circulatory disorders (5 people, 2.8% of the studied population), diabetes mellitus (3 people, 1.7% of the studied population), respiratory diseases (2 people, 1.1% of the studied population), arthritis and chronic allergy (2 people respectively, 1.1% of the studied population and glaucoma (1 person, 0.6% of the studied population).

Among the respondents, 24 (21.1%) women and 14 (22.2%) men answered that they are slimming contin-

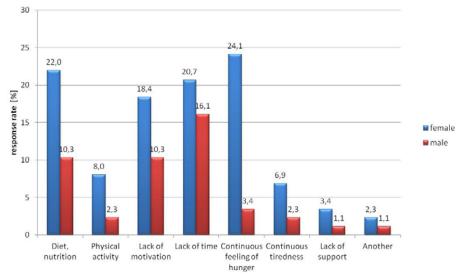


Figure 1. Most difficult situations during weight loss

supplement mengine loss				
		Female	Male	Total
		n (%)	n (%)	n (%)
Effectiveness of treat-	Effective	7 (14.3)	5 (41.7)	12 (19.7)
ment with drugs and	Not effective	13 (26.5)	4 (33.3)	17 (27.9)
dietary supplements	Difficult to say	29 (59.2)	3 (25.0)	32 (53.5)
	Yes	8 (16.3)	2 (15.4)	10 (16.1)
Adverse events	No	33 (67.3)	8 (61.5)	41 (66.1)
	I don't know	8 (16.3)	3 (23.1)	11 (17.7)

Table 3. Effectiveness of treatment and occurrence of adverse events assessed by respondents using drugs and dietary supplement weight loss

uously. The answer that sometimes was chosen only by 44 (38.6%) women and 13 (20.6%) men. Among those group, they were asked what are the most difficult situations and the biggest problems during the weight loss process. Figure 1 shows the results.

Respondents were asked whether they use dietary supplements or drugs for weight loss. 119 (67.2%) responded that they do not, while 44 (24.8%) of people answered that they use supplements or drugs and 19 (10.7%) only occasionally. Among the used products the most frequently mentioned (by 100 respondents, 56.5%) were plant preparations. Three patients indicated sibutramine, as a product they used. That is a very worrying information since sibutramine was withdrawn from trading on the Polish pharmaceutical market in 2010.

Analysis of the answers has shown that 78 (43.9%) of persons treated with drugs or food supplements use them irregularly, only when necessary and 12 (7%) are using them for longer than six months.

Respondents also determined the effectiveness of treatment and occurrence of adverse events. The results are summarized in Table 3.

The effectiveness of medications or dietary supplements used by 95 respondents in order to lose weight

was assessed rather negatively as 53.5% replied difficult to say and (49) 27.9% as ineffective. This is essential information for the pharmacist as an advisor in the self-treatment process. 117 respondents in the vast majority (66.1%) stated that there were no side effects observed by them when they were using drugs and dietary supplements. Particular attention must be paid to those who responded affirmatively to this question since it is important their response after the diagnosis of the adverse event (10 people - 5.6%).

Those who responded do not know (11 persons - 6.2%) require a detailed education on the occurrence of adverse drug reactions. Regarding this, necessary information should be given by a pharmacist during the dispensing of medicines and diet supplements. The collected data should be an indication for the pharmacists that patients must be informed about the possibility of the occurrence and character adverse events during any pharmaceutical advice-giving situation, especially in the process of self-medication.

Seeing the need to involve the pharmacist into the process of pharmacotherapy of patients with obesity and overweight the respondents were asked whether they expect such assistance from pharmacists. The results are shown in Figure 2.

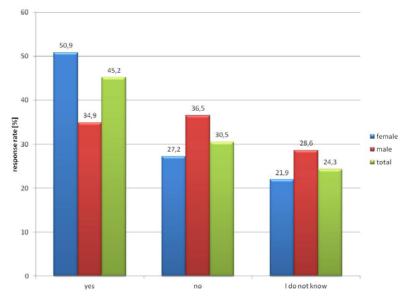


Figure 2. Respondent opinions regarding availability of Pharmaceutical Care (PC) services aimed at weight loss

More than 80 (45%) of respondents see the possibility and the need to be assisted by a pharmacist in their fight against obesity. Among the study group, 54 (30.5%) of respondents do not want to use the knowledge and experience of the pharmacists. However, among the selected answers in the questionnaires, a significant percentage of the patients do not know how to evaluate the possibility of using pharmacist support.

104 respondents (58.8%) believe that pharmaceutical care delivered by pharmacists would help them in the management of overweight and obesity. Unfortunately, 51 (28.8%) of respondents believe the contrary, while 22 (12.4%) did not know anything about the service of pharmaceutical care. Taking advantage of the easy access offered by pharmacies to the possibility of using the services of a pharmacist, an important issue for pharmacists is to show the advantages, opportunities and benefits of implemented pharmaceutical care, particularly to those who do not know anything about the pharmaceutical care or are against it.

Discussion

Numerous studies have indicated the impact of obesity on patient health as well as the presence of concomitant diseases. Among data available in the literature, a similar relationship to our findings was described by A. Abramczyk. The authors emphasized that among patients with diabetes, normal body weight was declared only by 12.8% of patients.¹⁷ Other patients were overweight or obese.¹⁷ Within the responses on the self-assessment of their health and knowledge about the impact of obesity on their health, every third person could see the risks associated with this disease. Obesity in the case of 7 (4%) respondents contributed to the development of diseases such as diabetes, arthritis, hypertension, gallbladder stones and abnormal diagnostic tests in particular, elevated cholesterol and triglycerides. Due to the number of analyzed persons, this analysis cannot confirm the epidemiological data about diabetes in the obese population. Chronic diseases indicated by 21 of the respondents (11.9%) certainly require the use of medicinal products and compliance with dietary recommendations. In this regard it should be noted a possible solution that has been discussed for years concerning the ability to use the knowledge and skills of pharmacists in ensuring safe pharmacotherapy. One of the proposed activities of pharmacists is the implementation of medical use review (MUR) in the area of drugs used in chronic diseases. These actions undertaken by pharmacists in other countries produce tangible therapeutic effects and improve the quality of life of patients. The task for the pharmacist in the process of delivering the drug or diet supplement used for weight loss is to provide the patient with detailed information about the duration of treatment.

Undoubtedly, the causes of overweight and obesity should be sought in the cultural conditions and habits. Assessing the lifestyles of Polish people based on a survey, we can conclude that it deviates from the desired standards such as planning five balanced meals and physical activity for at least 30 minutes per day seven days a week. In the study group, most patients consumed up to four meals a day and had a good self-esteem in their physical fitness. These results confirm the need to implement healthy eating habits, physical activity from an early age. Wojtyla-Bucior et al., when analyzing the situation of Polish children and adolescents, found that the dietary habits of these groups are unsatisfactory. 18 They consume an insufficient amount of fruits, vegetables and fishes and a lot of snacks, meals and sweet beverages. Knowledge, beliefs, skills and attitudes towards healthy diets and lifestyles acquired during puberty determine lifestyle in adulthood. S. H. Babey et al. indicated positive patterns of social and cultural activities and the support of schools as protective social factors that promote health and well-being of young people. The positive action in the area of health of children and adolescents should include the elimination of the junk food from school shops. These actions are the result of recent changes to the law on food safety and nutrition.¹⁹ Promoting a healthy lifestyle among the population should also be a priority task for the pharmacists. Every third person interviewed confirmed the need to include pharmacists in solving the problems of overweight and obesity. The motivation for a healthy lifestyle, education in the area of calculating calories content of meals or selection of supplementation supporting proper nutrition are just some of the tasks that permanently should be part of the daily life of pharmacists. The consequences of receiving inadequate nutrition are especially severe in the period of growth and development and at old age. A characteristic feature of these periods is the lack of an energy balance. The process of aging is associated with a reduction in body weight associated with a reduction in organ weight, skeletal muscles and bones. According to some researchers, the optimal BMI for persons over 65 years of age should be in the range of 24 to 29 kg/m². However due to the necessity to verify the latest data on BMI it is still considered to be optimal for this age group a BMI between 18 to 24.9kg/m².²⁰⁻²²

Dietz et al. believe that the treatment of obesity needs changes including clinical management and improving the training of health care workers with the skills necessary for the treatment of patients with obesity. The authors pay particular attention to behavioral skills and ability to work in a team of specialists which include the most elementary skills such as reasonable conversations with patients about their weight and the ability to assess their readiness for change. Therefore, authors propose to redefine the professional competen-

cies of the specialists in health care.²³ The need for these changes is confirmed by the fact that in our survey conducted, every eighth respondent was able to determine their expectations for pharmacists.

On the question concerning the application of medicines and diet supplements for weight loss, 100 respondents most often (56.5%) mentioned plant preparations For weight-reduction drugs, three respondents mentioned sibutramine. This response causes concern since sibutramine was withdrawn from the market in the European Union in 2010. Respondents may be indicating this product due to its use in the past. However, the option of purchase via the Internet cannot be excluded. Also, in this situation, the pharmacist can educate the patient indicating the risks associated with the use of products purchased outside the regular circulation of questionable quality and threatening health or the patient's life. This way of distribution is often related to falsified products. It is evident that also these issues that should be explained to the patient by a professional pharmacy team. Another issue in choosing dietary supplements for the treatment of overweight or obesity is the need to correct the information obtained from unreliable advertisements. Advice provided by a pharmacist in the course of issuing to the patient medication or diet supplement used for weight loss should also contain information about the time of the treatment duration.²⁴

The majority of respondents (104 - 58.8%) believe that pharmaceutical care would help in recovery from the consequences of overweight and obesity. As M. Panas and J. Brandys note, the problem of obesity is a medical problem and obesity prevention and treatment is a process that requires constant motivation of the patient.²⁵

To our knowledge, the present study is one of the very few studies that explore the importance of the role of pharmaceutical services in a daily management of obese patients.

Taking into account the results and expectations of patients, it seems that the community pharmacy, due to easy access to the use of services of a pharmacist, should serve as the primary connection between the patient and all healthcare professions involved in the treatment of overweight and obesity.

Brown et al. conducted a systematic study review of community pharmacy intervention for Public Health. Five studies evaluated the effectiveness of community pharmacy-based weight-loss interventions and did not demonstrate significant differences in weight between groups. However, the majority of these studies were comparing a pharmacy-based intervention with another active intervention either within the pharmacy or in another setting. Five studies evaluated the effectiveness of community pharmacy-based weight-loss interventions that did not demonstrate significant differences in weight between analyzed groups. 16

In one study participants had significant weight loss compared with the control group after 1 year. Two weightloss trials reported for cost-effectiveness. The pharmacy-based trial was not cost-effective when compared to the commercial programs. Another study reported costs for two primary care-based weight-loss services (GP and pharmacy) and the costs were broadly similar to that of the pharmacy-based. ¹⁶ The overall lack of information in this area supports the need for more research regarding the attitudes of pharmacy staff towards members of the public who are overweight and obese. This work must build and be extended beyond descriptive statistical representations of this phenomenon by including information on the behaviours of pharmacists and other pharmacy staff members and the impact on outcomes for the public. ²⁶

Conclusion

The community pharmacist should play an active role in facilitating weight loss and maintenance among patients with overweight and obesity (including primarily those, who want to lose the excessive body mass for health-related reasons and also for aesthetic reasons). Potential options to protect society from the obesity epidemic are education about the cardio-metabolic risks (which are inherent to obesity) and promotion of a healthy lifestyle. Regarding this, the pharmacist's expertise, aimed at prevention of potential problems, related to the medications (e.g.: adverse effects, interactions with food, or drug-drug interactions) used for multiple comorbidities of obesity (e.g., CVD), combined with ongoing patient support and improving their quality of life should be utilized by healthcare teams, including collaborating physicians and nurses in the community.

However, further research, focused on a deeper understanding of the psychosomatic problems and expectations of patients with obesity, as well as on designing novel methods to prepare pharmacists to perform pharmaceutical care (PC) in this high-risk patient population is merited.

Study limitations

In the present study, we reported that the conducted research was addressed especially to people who are overweight and obese. However, a significant number of individuals who responded to the questionnaire did not report a BMI over 25. Perhaps this is because the respondents were people under 25 years of age. Respondents with overweight and obesity accounted for a quarter of the studied group. The decision to analyze all questionnaires was taken on the basis that people who filled the questionnaires perceived themselves as obese or overweight. The analysis of the results confirmed that in this group are included respondents who reported chronic diseases such as diabetes or hypertension inseparably associated with overweight and obesity.

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