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Selected Socio-demographic Factors Influencing the Development of Occupational Burnout Syndrome in Polish Psychiatric Nurses Working in Locked Wards in the Vicinity of Warsaw

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Abstract

Introduction: *A nurse is a member of a therapeutic team who has the closest and most frequent contact with the patient. Being exposed to high levels of prolonged stress caused by the unpredictable behaviour of their patients, nurses working in mental health hospitals are under particular pressure.*

Research objectives: *The aim of the following research is to analyse how selected socio-demographic variables influence the development of the general level of work-related burnout and its single components among psychiatric nurses.*

Research material and methods: *The research was conducted on a group of 76 psychiatric nurses (N=76) from two hospitals in the vicinity of Warsaw. For the purposes of the research, a survey has been used with a two-part standardised questionnaire: the Maslach Burnout Inventory (MBI) and the General Health Questionnaire – 28 (GHQ-28) developed by David Goldberg for mental health evaluation – both adapted into Polish.*

Findings: *An analysis of variables based on the MBI questionnaire reveals that the educational background statistically differentiates the levels of two aspects of occupational burnout syndrome: emotional exhaustion and the assessment of personal accomplishment as well as influencing the general level of work-related burnout. An analysis of a correlation between different aspects of health and the number of years worked in nursing, which has been conducted using the questionnaire GHQ-28, shows that the latter correlates positively with some aspects of the former.*

Conclusions: *Higher educational background of the nurses taking part in the survey has an impact on the general level of work-related burnout. With the increase of work experience in a given workplace, rises the level of mental health problems and emotional exhaustion.*

Key words: *occupational burnout syndrome, psychiatric nursing staff, exhaustion, educational background*

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Background

Work-related burnout syndrome has been one of the most researched topics in the field of health and occupational psychology in recent years. According to the World Health Organisation (WHO), around three hundred million employees worldwide are affected by various health problems as a result of chronic stress at work [1]. Occupational burnout is one of the negative consequences of unmodified work-related stress [2]. This phenomenon has been examined worldwide for the last forty years, in particular among social workers and health care professionals [3]. The subject of *emotional labour* is part of a broader problem of social values where the distinction between work and private life becomes increasingly blurred [4]. Today, the importance of nursing personnel in the Polish health care system is growing. The group constitutes an essential element of the system. It plays a vital role in health promotion and prevention of diseases in various aspects of people's lives. In terms of staffing levels, the situation of Polish nurses proves to be difficult. As stated in the report of the Nurses and Midwifery Council (Naczelna Izba Pielęgniarek I Położnych, NIPiP), there will be 4.7 nurses per 1000 people in 2020 and in the largest Masovian district – 5.44 nurses per 1000 people. Nevertheless, it is the largest group of medical professionals working in health care [5,6].

Nursing professionals are required to demonstrate good organisational skills, patience and compassion for another person, which clearly differentiates this profession from the others. In addition, psychological stress, low salary, lack of close cooperation within the medical team and difficult communication with patients and their families have a considerable impact on the development of occupational burnout syndrome. Being exposed to high levels of prolonged stress caused by the unpredictable behaviour of their patients, nurses working in mental health hospitals are under particular pressure [7,8]. The necessity to employ coercive measures towards aggressive patients intensifies nurses' fear for their own safety thus contributing to the development of work-related burnout

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syndrome [9]. The need for safety is a fundamental human need. It enhances the confidence and developmental opportunities of a person and it implies a lack of danger of losing important values such as life, health, job or respect [10]. Mental health patients often refuse to take medicine or to give consent to medical treatment and they are usually admitted to hospital on a court order which, in turn, escalates their aggression. The hospitalisation period in a psychiatric clinic in Poland is long and it takes 30.3 days on average [10,12,13].

Prolonged emotional pressure and tiredness of mental health nurses can cause automatism as well as a tendency to perceive the reality in a stereotypical way [13]. For that reason it appears to be vital to take preventive steps with regards to the impact on the health and productivity of nursing staff but also the quality of care of their patients [13,14].

The aim of the following study is to analyse how selected socio-demographicsuch as the level of education, job seniority, and age of the respondents variables influence the development of the general level of work-related burnout and its single components among psychiatric nurses.

Material and methods

The research was conducted on a group of (N=76) mental health professionals in March 2019 with 93.4% of female and 6.6% of male respondents involved. The average age of the examined group was 40 years old. 28.9% were people under 40 years of age. 52.6% of respondents were between 41 and 50 years of age. 18.4% of respondents were over 50 years old. The average work experience among studied nurses was 21 years and 6 months, however the average work experience in the same place of work was 16 years and 1 month. The respondents work in two psychiatric clinics in the vicinity of Warsaw. 40% of all mental health patients in Poland are hospitalised in the Masovian district [11].

The research is based on a method of diagnostic survey with two standardised questionnaires serving as a research tool. One of them is a Polish version of the Maslach Burnout Inventory (MBI) adapted by Tomasz

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Pasikowski in the form of a self-test with two answer options: 'yes' and 'no'. It consists of 22 items related to three aspects of occupational burnout: emotional exhaustion (EE), depersonalisation (DEP) and a low sense of personal accomplishment (PA). There are separate results for each of the subscales. It is possible, however, to establish a general level of occupational burnout [16].

The second test used in the survey was a standardised questionnaire translated by Dorota Merecz. It is a four-scale test which includes somatic symptoms, anxiety and insomnia, symptoms of depression and other mental health problems. The results of each separate scale constitute a general score [17]. Apart from the questionnaires, the survey includes questions about respondents' salary and personal information.

The group taking part in the survey consisted of both nurses who completed psychiatric courses or had a psychiatric specialisation (N=20) and nurses without a specialisation (N=56). 17.1% of the respondents finished secondary education, 42.1% completed higher vocational education, 35.5% of which held a bachelor's degree in nursing, while the rest of 6.6% had a bachelor's degree in a field other than nursing. 40.8% of nurses had an MA degree with 39.5% with an MA in nursing and 1.3% with an MA in a different field of study. In terms of marital status, 76.3% of nurses were married, 9.2% – divorced, 13.2% – singles and 1.3% – widowed.

A statistical analysis has been carried out by means of an IBM SPSS Statistics 25 pack. Here, the descriptive statistics for each of the measured variables have been calculated and the consistency of the distribution of variables with the normal distribution has been tested. For that purpose, the Shapiro-Wilk test has been used and a number of correlations with Spearman's rank correlation coefficient (Spearman's rho) have been tested. Additionally, the Kruskal-Wallis testing method has been employed – a non-parametric equivalence of a one-way analysis of variance for independent samples. Statistically significant results of the Kruskal-Wallis test have been complemented using post hoc tests. The data has been then analysed with a chi-squared test where a significance threshold of $\alpha=0.05$ has been set. The p-values from 0.05 to 0.1 have been interpre-

ted as significant on the level of statistical tendency. Furthermore, the basic descriptive statistics of the analysed variables have been calculated and a normality distribution tests have been performed. According to the results, the distribution of all analysed variables deviates indeed from the normal distribution. Considering the results of the test, the non-equipotency of the test group and their small number, a contrastive analysis with non-parametric tests has been carried out – a non-parametric equivalence of a one-way analysis of variance and Spearman's rank correlation coefficient.

Results

An analysis of variables with an MBI questionnaire reveals that educational background differentiates statistically the level of two aspects of occupational burnout: emotional exhaustion and the assessment of personal accomplishment but also the overall value of work-related burnout. As for depersonalisation, no significant statistical differentiation has been confirmed. Table 1 shows the results of the variance analysis. The results obtained in a paired comparison of the assessment of personal accomplishment indicate that the respondents with secondary education achieve lower results than those with an MA degree in nursing (p=0.008), a bachelor's degree in nursing (p=0.005) and a bachelor's degree in a different subject field (p=0.018). A paired comparison of the overall value of occupational burnout shows a statistical difference between nurses who completed secondary education and those with a bachelor's degree in nursing (p=0.008, Figure 1).

There is a cause-effect relationship between occupational burnout and work experience in general as well as work experience in a given workplace. Furthermore, a positive correlation between emotional exhaustion and work experience in a given workplace has been established. This means that emotional exhaustion increases proportionally with the years of work experience in a given workplace. Also, there is a weak negative correlation between work experience and the asses-

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sment of personal accomplishment. In other words, the longer the experience, the lower the evaluation of personal accomplishment (Table 2).

A GHQ-28 analysis of the correlation between different aspects of health (somatic symptoms, anxiety and insomnia, symptoms of depression and other mental health problems) and work experience shows that work experience in a given workplace correlates positively with some of the aspects of health. In the case of mental health problems, the correlation is statistically positively significant. The longer work experience in a given workplace, the higher the level of mental health problems. The remaining correlations have not reached the level of statistical significance but merely the level of statistical tendency. This is the correlation between work experience in a given workplace and somatic symptoms, anxiety and insomnia and general health (Table 3).

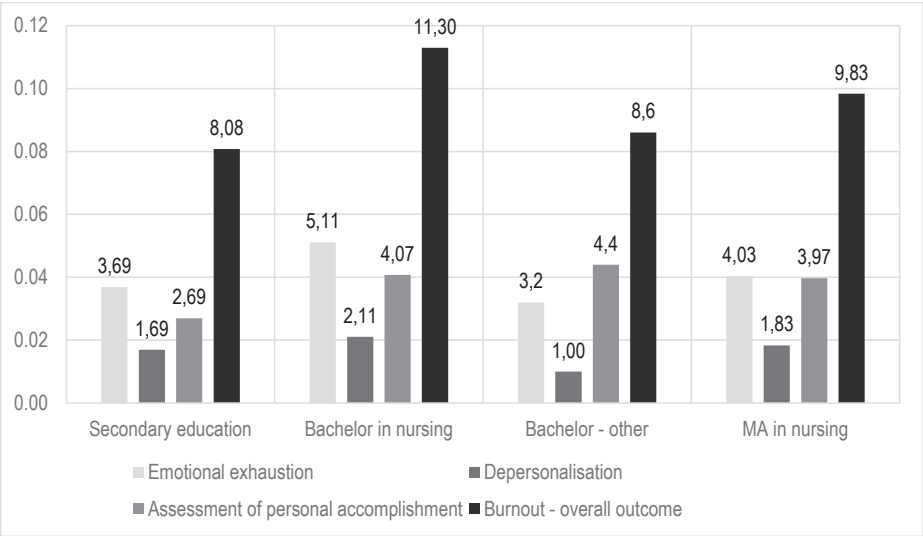

Figure 1. An average value of occupational burnout depending on educational background

Table 1. Occupational burnout depending on educational background – a comparison

		M	H	p
Emotional exhaustion	Secondary education	3.00	10.59	0.014
	Bachelor in nursing	5.00		
	Bachelor – other	2.00		
	MA in nursing	3.00		
Depersonalisation	Secondary education	1.00	4.86	0.182
	Bachelor in nursing	2.00		
	Bachelor – other	1.00		
	MA in nursing	2.00		
Assessment of personal accomplishment	Secondary education	3.00	14.89	0.002
	Bachelor in nursing	4.00		
	Bachelor – other	4.00		
	MA in nursing	4.00		
Burnout – overall value	Secondary education	8.00	11.46	0.010
	Bachelor in nursing	11.00		
	Bachelor – other	8.00		
	MA in nursing	9.00		

M – average value, H – statistics of the Kruskal-Wallis test, p – significance

Table 2. Correlation between work experience and occupational burnout

		Work experience in nursing	Work experience in a given workplace
Emotional exhaustion	Spearman's rho	0.05	0.23
	p	0.648	0.048
Depersonalisation	Spearman's rho	-0.14	0.03
	p	0.235	0.777
Assessment of personal accomplishment	Spearman's rho	-0.20	-0.06
	p	0.083	0.619
Burnout – overall value	Spearman's rho	-0.11	0.12
	p	0.364	0.300

Spearman's rho – correlation coefficient, p – significance

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Table 3. A correlation between work experience and different aspects of health

		Work experience in nursing	Work experience in a given workplace
Somatic symptoms	Spearman's rho	-0.05	0.21
	p	0.650	0.071
Anxiety and insomnia	Spearman's rho	0.09	0.21
	p	0.445	0.066
Mental health problems	Spearman's rho	0.08	0.24
	p	0.473	0.041
Symptoms of depression	Spearman's rho	0.03	0.03
	p	0.786	0.774
General health – overall results	Spearman's rho	0.05	0.23
	p	0.702	0.050

Spearman's rho – correlation coefficient, p – significance

Discussion

The subject of occupational burnout among nursing staff has been widely examined in a Polish and international context. The aim of the following study was to research the correlation between different socio-demographic variables and the development of occupational symptoms among nurses working in psychiatric wards.

The following variables have been analysed: age, gender, marital status, work experience in a nursing setting, work experience in a given workplace, educational background as well as courses and training completed. The level of education and work experience in a given workplace are important factors in determining the quality of life of mental health nurses as confirmed by the results of the author's own research. According to these, educational background and work experience in psychiatric wards differentiate statistically the overall value of occupational burnout, emotional exhaustion and the assessment of personal accompli-

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shment. Occupational burnout affects an increasing number of psychiatric nurses [18] causing a decrease in their productivity and the quality of patients' care. Work-related burnout syndrome has an impact on nurses' health and their work absence and it is the cause of a growing frustration among this particular group of health professionals [19].

In an MBI test carried out by Klejda and Szewczyk, in which fifty psychiatric nurses took part, 30% of nurses achieved the highest score in the aspect of emotional exhaustion and 20% – in work satisfaction [9]. A Swedish study conducted by A. Berg and I. R. Hallberg involving a qualitative transcription of semi-structured interviews with twenty two psychiatric nurses reveals that the most challenging task appears to be coping with the unpredictable behaviour of patients. Nurses in psychiatric settings need to be prepared for unpredictable situations, in which they are left on their own. Their struggle with professional autonomy leads to a loss of work-related reliance. Nurses have also less influence on decisions about general care plans even though they have a number of duties to perform. The study highlighted the contextual aspects such as organisational obstacles, difficulties in the work environment and a poor cooperation with patients [20]. According to a Dutch study conducted by Peter de Looff and his co-authors on a group of 114 psychiatric nurses, the experience of physical aggression is closely linked to the symptoms of occupational burnout. The highest correlation between aggression and work-related burnout has been established among nurses claiming to possess a greater ability to cope with stress [21]. In another study carried out by Grzywna and Cieślik using an MBI questionnaire, in which seventy psychiatric nurses working in locked wards took part, 87.1% of them perceive their work environment as stressful [10]. A study by Rużyczka and her co-authors with an MBI and an Effort Reward Imbalance (ERI) questionnaires, the latter assessing work environment, in which 104 nurses from various wards took part, reveals that emotional exhaustion correlates with all levels of occupational stress. Moreover, there is a link between the educational level of nurses and work-related burnout. The higher the level of education in non-surgical nurses, the lower their emotional exhaustion

while a higher educational level of surgical nurses causes an increase in dissatisfaction with rewards. An analysis of a correlation between work experience and the age of non-surgical nurses demonstrates that the level of emotional exhaustion rises with the nurses' age. In addition, the older the age of the nurses and the longer their work experience, the lower the sense of lack of personal accomplishment. No correlation has been established between occupational burnout and the age and work experience among non-surgical nurses [22]. Emotional exhaustion and depersonalisation were the main aspects of occupational burnout found among randomly selected 250 nurses from the South of Poland in a study conducted by Wilczek-Rużyczka and Iska-Golec using an MBI inventory [23]. In a study on 110 nurses of various specialisms in which an MBI questionnaire has been used, Kupcewicz and Szczypiński show that work experience has a statistical impact on the level of emotional exhaustion – the latter increases with the years worked in nursing [24].

A study by Zaczyk and co-authors on a group of 74 mental health nurses from the South of Poland using an MBI inventory and a questionnaire of the author's own survey reveals a link between aggression experienced by psychiatric nurses and two aspects of occupational burnout in particular: emotional exhaustion and depersonalisation [25].

In conclusion, it can be stated that occupational burnout of nurses proves to be a work-related problem which requires preventive measures. There is a need for an in-depth research of the factors influencing the development of occupational burnout in psychiatric nurses. This particular group of professionals has not been examined sufficiently and the following study confirms that there are discrepancies between the factors leading to the development of work-related burnout in nurses in psychiatric wards and those of different specialisms.

Conclusions

The analysed group of psychiatric nurses proves to be affected by two dimensions of occupational burnout: emotional exhaustion and asses-

sment of personal accomplishment. A higher educational background of the nurses has an impact on the overall value of work-related burnout. It has been established that both emotional exhaustion and the level of mental health problems increase with the number of years worked in a given workplace. Furthermore, there is a correlation between the length of the employment period in a given workplace and somatic symptoms such as anxiety, insomnia as well as general health and well-being.

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Evaluating Functional Abilities of People with Spinal Cord Injuries at Later Stages of Rehabilitation

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Abstract

Purpose: *The Motor impairments patients with spinal cord injury affect their functional abilities and restrict independence in performing everyday activities. This paper collates data about the times patients required assistance with daily activities, the people who would normally provide such help, and about those aspects of daily living where caregiver assistance was the most needed.*

Aim: *Aim of this study was to present different functional abilities in people with spinal cord injuries and indication of the determinants of this condition*

Materials and methods: *The study included 75 people, who had experienced incomplete traumatic spinal cord injury at least 12 months before this study. The patients were categorized into groups according to injury location. Functional ability was assessed with the Barthel Index and an interview questionnaire. Injury locations were determined with patients' medical records.*

Results: *There were significant differences ($p<0.05$) between the groups in how they self-assessed their functional independence. On average, subjects with SCI required 4.7±8.8 hours of assistance daily. The three groups differed in the degree of demonstrated functional independence ($p<0.001$).*

Conclusions: *People with SCI are not fully independent to perform activities of daily living by themselves. Supporting a patient's self-management usually becomes the responsibility of their immediate family.*

Key words: *function, spinal cord injury, self-assessment, people with disabilities, activities of daily living*

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Introduction

The precondition for performing even the least complex of activities is a healthy nervous system (information pathways) and the musculoskeletal system (the performative system). It is these neural pathways that get partially or completely damaged in spinal cord injuries. A spinal cord injury entails physical, psychological and social consequences [1,2]. Even incomplete SCI, the prevailing type in clinical practice, leads to serious disabilities. Such disability restrains the ability to perform ADL and renders patients dependent on other people's help and care [3].

Nursing and rehabilitation of a patient after spinal cord injury is a very difficult and complex process. It requires extensive knowledge and experience from the entire therapeutic team. Naturally, the patient's self-service ability depends on the level of spinal damage. Patients with damage in the upper sections require more help from other people and are most at risk of developing complications. The degree of independence also depends on early treatment, proper care combined with education, and properly targeted rehabilitation aimed at mastering new movement patterns based on compensatory mechanisms. Nursing care plays an important role in facilitating and accelerating the rehabilitation process and in adapting to life in a changed situation. He accomplishes these goals through a properly planned and conducted care process and proper education of the patient and family [4].

Beingable to satisfy one's life needs independently (e.g. performing self- care activities) not only has a positiveeffect on the hysical and mental state of a person with SCI it also motivates them to further actively engage in day-to-day life [5]. Undoubtedly, SCI reduces functional abilities and transforms everyday routines. These patients' disabilities mostly manifest as impaired motor functions. These dysfunctions include paresis or quadriplegia as well as loss of sensation [6,7].

The extent to which parts of the body are affected by reduced sensory and motor functions depends on the anatomical location of the injury. The disabilities suffered by patients with cervical cord injury (tetraplegia,

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tetraparesis) are greater than those with lower spine sections injured (i.e. thoracic or lumbar cords – paraplegia, paraparesis) [8,9].

Functional ability is understood here as the capacity to maintain autonomy in performing activities of daily living [10]. In this sense, functional ability includes e.g. independence in preparing and consuming food, being mobile, changing body position, having control over the excretory system, maintaining body hygiene, using the toilet, or self-dressing [10,11]. It needs to be emphasized again that functional ability relies on retained motor functions.

Overall, paraplegics are more independent due to the fact they actively use their upper limbs, and so they typically enjoy greater autonomy. They can actively participate in daily living activities, and if they use a wheelchair with some skill, they are able to meet their needs by themselves to a large degree [5,12-14]. For instance: patients who demonstrate higher autonomy with regards to e.g. locomotion or wheelchair-to-bed transfers are people with injuries in lower spinal cord sections and those who after intense rehabilitation learnt to independently perform transfers. Not having to rely on other people's care is a source of considerable freedom in planning and executing activities of daily living [5,15-17]. Therefore, tetraplegia is the most severe of motor impairments, as it renders SCI patients dependant on the help and care provided by other people.

Undoubtedly, what results from the previous studies of a person with a higher level of spinal cord injury will show a greater reduction in motor and sensory abilities, thus it will undoubtedly condition their level of functional independence. However, it is worth paying attention to how functional fitness affects other areas of the person's life. Is there a relationship between the level of injury and the actual functional efficiency of these patients affects their ability to work. Does the number of family members in some way determine the degree of independence of a person after SCI. It is interesting that people with a large family do not receive excessive help, which can adversely affects the development of their functional ability.

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Material and methods

Aim

The project's main aim was to present different functional abilities in people with spinal cord injuries and indication of the determinants of this condition. 3 groups of different SCI levels were examined and compared (C – cervical, TH-thoracial and L – lumbar groups).

The study presents:

1. Self-assessment of functional independence.
2. The daily activities that required assistance from other people.
3. The usual caregivers.
4. Daily amounts of essential care time for different SCI patients.

Data source and sample population

The study subjects were people who sustained incomplete spinal cord injury and were treated patients in the neurological rehabilitation ward for paresis or limb paralysis. The study encompassed people aged 18-60 who were at the time adapting to post-traumatic changes one year or more after the injury [18,19]. After reviewing a given patient's motor and sensory impairments using ASIA's assessment criteria (American Spinal Injury Association) a doctor would determine incomplete spinal cord injury [17]. Age and date of sustaining injury were obtained from patients' medical records.

Clinical measures

Functional ability was established with the Barthel Index (BI). The scale measures the extent to which a patient is able to independently perform activities of daily living such as dressing, bathing, controlling urination and defecation, maintaining personal hygiene, moving up and down stairs or consuming food. A given patient's functional ability is assessed depending on the degree to which they can independently carry out a given activity. The highest possible score is 100 points, which suggests complete independence, whereas the lowest is 0 points and represents a person completely dependent on others [18].

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Interviews with SCI patients provided information about their current professional life, number of family members, and self-reported level of dependence on other people's help with everyday activities. Additionally, subjects indicated the number of hours daily they required assistance and who would normally provide it. The subject's answers were recorded on an interview questionnaire form.

From among 122 hospitalized persons, only 75 were finally included in the study (met admission criteria and agreed participate). The studied group was divided into three subgroups depending on the level of spinal cord injury where 25 had cervical (C=25), 25 thoracic (Th=25), and 25 lumbar (L=25) cord injury.

The research project was submitted to and approved by the Bioethics Committee

Statistical analysis

Statistical data were compiled using PQStat ver. 1.6.8 statistical packages together with the Microsoft Excel 2000 spreadsheet.

To measure the differences between values in the ordinal scale, non-parametric testing was applied. The Mann-Whitney test was used to compare two groups of independent variables and the Kruskal-Wallis test to compare a few of such groups. For multiple comparisons, the post-hoc test and the Dunn-Sidak correction were applied. Non-parametric tests were used to assess the relations between variables in the nominal scale. Depending on the number of variables and number of group members, the Chi^2 (RxC) test was applied and, for smaller groups, the accurate Fisher (RxC) test.

The following assessment criteria were employed when comparing the three groups of different injury locations (C, Th, L): $p<0.05$ for statistically significant correlations, $p<0.01$ for highly significant statistical correlations, and $p<0.001$ for the most statistically significant correlations.

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Results

The average age of the subjects was 34. In line with with the study inclusion criteria, they were adapting to post-traumatic changes, i.e. one year or more had elapsed after the injury [19,20]. The average time between sustaining the injury and the day of the study was comparable between the three groups and amounted to 7 years. A detailed breakdown of individual groups is presented in Table 1.

Analysis of marital status (single, married, divorced) prior and post injury did not reveal any differences between the groups. Three persons got married after injury, and two divorced. Details are shown in Table 2.

The groups differed significantly in how subjects self-assessed their independence or dependence ($p<0.05$; Man-Withney test). The cervical cord injury group was the one with with the lowest self-reported independence (Table 3).

The number of hours daily of essential help varies considerably between the compared groups ($p<0.05$, Kruskal-Wallis test). The most significant differences were found in average care times required by people in the cervical cord injury group and the lumbar group ($p<0.05$, Kruskal--Wallis with a post-hoc Dunn-Sidak test). Detailed results are presented in Table 4.

People who are typically committed to providing assistance and care for patients with cervical and thoracic cord injuries are family members and friends. More than half of the patients with the lowest injury position (lumbar cord) declared sufficient levels of independence and no need for caregivers (Table 5).

The majority of spinal cord injury patients in the current study are wheelchair-bound. With regards tomobility aids most often used in given groups, there were significant differences found between patients using wheelchairs and other orthotics aids such as walking frames or crutches ($p<0.05$; Man-Withney test). Active wheelchair is the prevailing type of wheelchairs used by post-SCI patients. Results are presented in Table 6.

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In the examined groups, independence in daily living activities was inversely proportional to the height of the spinal cord injury position. Poorest functional abilities and highest caregiver dependence were exhibited by people with spinal cord injury located in the cervical spine. Analysis of obtained BI measures showed highly significant differences compared to individual groups ($p<0.001$; Kruskal-Wallis test). Those differences were found between the cervical and the lumbar group ($p<0.001$; Kruskal-Wallis test with post-hoc Dunn Sidak test) as well as the thoracic and the lumbar group ($p<0.05$; Kruskal-Wallis test with post-hoc Dunn Sidak test). Measured levels of functional ability per group are shown in Table 7.

In percentage terms, the subjects reported activities related to urinary control as the most challenging ones when performed unassisted (86.7%). Using the stairs (40%) and maintaining personal hygiene (38.7%) were the two next aspects preventing independence from other people's assistance. The highest level of functional independence, on the other hand, was observed in two areas: food consumption (78.7%) and dressing/undressing (66.7%). No relevant differences between the groups were found in terms of being mobile (on even surfaces) as well as defecation control. However, self-reported independence varied significantly ($p<0.01$; Chi2 test) between the groups with regard to movement across surfaces, maintaining hygiene and using the toilet and highly significantly ($p<0.001$; Chi2 test) in the remaining BI areas. Details of independence characteristics of studied patients per injury group is presented in Table 8.

We investigated whether a patient's functional ability affects their employment. BI-measured functional ability among professionally active people and the unemployed were similar. It was found that only cervical spine injury affected patients' functional ability affected employment. Table 9 outlines results on the connection between functional ability and employment.

There was no correlation between numbers of family members and patients' functional ability (according to BI measures) (Table 10).

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Table 1. Characteristics of spinal cord injury patient

	C x (SD)	Th x (SD)	L x (SD)	Total x (SD)
Age at examination	35.4 (±9.3)	5 (±9.5)	33.4 (±9.7)	34.3 (±9.6)
Age at injury	28.5 (±9.5)	26.5 (±10.4)	26.4 (±9.1)	27.2 (±9.7)
Time after injury (years)	6.9 (±3.9)	7.6 (±4.9)	7.0 (±4.2)	7.2 (±4.3)

n: number of persons' x: arithmetic mean SD – standard deviation; C – cervical, Th – thoracial; L – lumbar

Table 2. Marital status before and after spinal cord injury

Marital status	C n (%)		Th n (%)		L n (%)		Total n (%)	
	Prior to injury	After injury	Prior to injury	After injury	Prior to injury	After injury	Prior to injury	After injury
Single	17 (68%)	15 (60%)	19 76%)	17 (68%)	20 (80%)	19 (76%)	56 (74.7%)	51 (68%)
Marital relationship	8 (32%)	9 (36%)	6 (24%)	7 (28%)	5 (20%)	6 (24%)	19 (25.3%)	22 (29,3%)
Divorced	-	1 (4%)	-	1 (4%)	-	-	-	2 (2.7%)

n: number of persons; C – cervical, Th – thoracial; L – lumbar

Table 3. Number of patients self reporting functional independence

Independent person	C n (%)	Th n (%)	L n (%)	Total n (%)
No	20 (80%)	15 (60%)	11 (44%)	46 (61.3%)
Yes	5 (20%)	10 (40%)	14 (56%)	29 (38.7%)

n: number of persons; C – cervical, Th – thoracial; L – lumbar

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Table 4. Number of care hours

	n (%)	x	SD
C			
0 h	5 (20%)	7.4	8.8
1-8 h	13 (52%)		
9-15 h	1 (4%)		
≥16 h	6 (24%)		
Th			
0 h	10 (40%)	3.9	6.8
1-8 h	11 (44%)		
9-15 h	2 (8%)		
≥16 h	2 (8%)		
L			
0 h	14 (52%)	2.8	6.0
1-8 h	9 (36%)		
9-15 h			
≥16 h	2 (8%)		
Mean average			
0 h	29 (38.7%)	4.7	7.5
1-8 h	33 (44%)		
9-15 h	3 (4%)		
>16 h	10 (13.3%)		

n: number of persons; x: arithmetic mean, SD: standard deviation; C – cervical, Th – thoracial; L – lumbar

Table 5. Caregiver

	C n (%)	Th n (%)	L n (%)	Total n (%)
Family	14 (56%)	12 (48%)	10 (40%)	36 (48%)
Family and friends	6 (24%)	3 (12%)	1 (4%)	10 (13.3%)
Not applicable (independent person)	5 (20%)	10 (40%)	14 (56%)	29 (38.7%)

n: number of persons; C – cervical, Th – thoracial; L – lumbar

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Table 6. Mobility Aid

	C n (%)	Th n (%)	L n (%)	Total n (%)
Other (crutches, walking frame)	2 (8%)	2 (8%)	9 (36%)	13 (17.3%)
Wheelchair	23 (92%)	23 (92%)	16 (64%)	62 (82.7%)
Orthopaedic wheelchair	2 (8%)	3 (12%)		5 (6.7%)
Active wheelchair	16 (64%)	19 (76%)	16 (64%)	51 (68%)
Active wheelchair and electrical wheelchair	5 (20%)	1 (4%)		6 (8%)

n: number of persons; C – cervical, Th – thoracial; L – lumbar

Table 7. Barthel Index measures of functional abilities per group

	x	SD	min	max
C	47.4	22.1	15	80
Th	59.2	20.7	15	85
L	78.4	15.2	50	100
Mean average	61.7	23.2	15	100

n: number of persons; x: arithmetic mean; SD: standard deviation; min: lowest value; max: highest value; C – cervical, Th – thoracial; L – lumbar

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Table 8. BI-measured independence in performing activities of daily living per group

	C n (%)	Th n (%)	L n (%)	Total n (%)
Food consumption				
Unable to eat by themselves	2 (8%)			2 (2.7%)
Help is needed with slicing, spreading butter, etc.	11 (44%)	2 (85)	1 (4%)	14 (18.7%)
Independent, self-reliant	12 (48%)	23 (92%)	24 (96%)	59 (78.7%)
Being mobile (getting from bed to chair and back/sitting down)				
Unable, no sitting balance	1 (4%)	3 (12%)		4 (5.3%)
More help is needed (physical, from one-two people), can sit	2 (8%)	12 (48%)	1 (4%)	15 (20%)
Little help (verbal or physical)	7 (28%)	5 (20%)	6 (24%)	18 (24%)
Independent	8 (32%)	13 (52%)	18 (72%)	39 (52%)
Maintaining personal hygiene				
Needs help with personal activities	16 (64%)	7 (28%)	6 (24%)	29 (38.7%)
Independent with washing face, combing, brushing teeth, shaving (with implements provided)	9 (36%)	18 (72%)	19 (76%)	46 (61.3%)
Using the toilet				
Dependent	8 (32%)	2 (8%)	1 (4%)	11 (14.7%)
Partly needs help	8 (32%)	7 (28%)	1 (4%)	16 (21.3%)
Independent	9 (36%)	16 (64%)	23 (92%)	48 (64%)
Bathing, washing whole body				
Dependent	17 (68%)	8 (32%)	3 (12%)	28 (37.3%)
Independent	8 (32%)	17 (68%)	22 (88%)	47 (62.7%)
Mobility (even surfaces)				
Immobile or can cover <50 m	5 (20%)	2 (8%)	1 (4%)	8 (10.7%)
Up to 50 m with mobility aid or independent on wheelchair	14 (56%)	15 (60%)	11 (44%)	40 (53.3%)
Walks with help of one person >50 m	4 (16%)	2 (8%)	3 (12%)	9 (12%)

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Independent, also using mobility aid, at distances larger than 50 m	2 (8%)	3 (12%)	10 (40%)	15 (20%)
Walking up and down stairs				
Not independent	15 (60%)	11 (44%)	4 (16%)	30 (40%)
Needs physical help and assistance	9 (36%)	12 (48%)	8 (32%)	29 (38.7%)
Independent	1 (4%)	2 (8%)	13 (52%)	16 (21.3%)
Dressing and undressing				
Dependent	3 (12%)	–	1 (4%)	4 (5.3%)
Needs some help	13 (52%)	7 (28%)	1 (4%)	21 (28%)
Independent, also with buttoning, zipping, lacing, etc.	9 (36%)	18 (72%)	23 (92%)	50 (66.7%)
Controlling defecation / anal sphincter				
Has no control over defecation or excretion needs to be provoked	2 (8%)	9 (36%)	4 (16%)	15 (20%)
Sporadic uncontrolled defecation	14 (56%)	8 (32%)	10 (40%)	32 (42.7%)
Has control over defecation	9 (36%)	8 (32%)	11 (44%)	28 (37.3%)
Controlling urination/ urethral sphincter				
Can't control urination or is catheterized	18 (72%)	18 (72%)	5 (20%)	41 (54.7%)
Sporadic uncontrolled urination	5 (20%)	6 (24%)	13 (52%)	24 (32%)
Has control over urination	2 (8%)	1 (4%)	7 (28%)	10 (13.3%)

n: number of persons; C – cervical, Th – thoracial; L – lumbar

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Table 9. Functional ability (BI-measured) and patient's employment

	Employed					Unemployed				
		BI					BI			
	n	x	SD	min	max	n	x	SD	min	max
C	12	58.3	19.6	20	80	13	37.3	19.9	15	80
Th	7	68.6	14.4	40	85	18	55.6	21.9	15	85
L	9	78.9	16.7	60	100	16	78.1	14.8	50	100
Total	28	67.5	19.1	20	100	47	58.2	23.8	15	100

n: number of persons; x: arithmetic mean; SD: standard deviation; min: lowest value; max: highest value; C – cervical, Th – thoracial; L – lumbar

Table 10. Functional ability (BI-measured) and number of family members

		BI			
Number of family members	n (%)	x	SD	min	max
C					
≤2	7 (28%)	45.0	21.0	20	75
3-4	11 (44%)	51.0	23.9	15	80
≥5	7 (28%)	44.3	28.0	20	80
Th					
≤2	9 (36%)	66.7	20.6	15	85
3-4	16 (64%)	55.0	20.0	15	85
≥5			23.0	20	80
L					
≤2	10 (40%)	86	12.9	60	100
3-4	9 (36%)	74.4	15.9	50	100
≥5	6 (24%)	72.7	14.4	60	95
Total					
≤2	26 (34.7%)	68.3	24.1	15	100
3-4	36 (48%)	58.6	22.0	15	100
≥5	13 (17.3%)	56.9	23.5	20	95

n: number of persons; x: arithmetic mean; SD: standard deviation; min: lowest value; max: highest value; C – cervical, Th – thoracial; L – lumbar

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Discussion

Due to functional disability of patients with spinal cord injuries, one of the top treatment challenges is to achieve maximal level of motor ability (as possible from the perspective of patoanatomy), as it positively impacts other aspects of life. Anticipating achieving daily independence by SCI patients is an important component of the rehabilitation process and is therefore considered a priority in treatment [21]. Literature reveals that people after spinal cord injuries demonstrate different functional abilities depending on age, extent and location of injury, as well as other factors [17,22,23].

Functional independence

As emphasized in the introduction, functional disability in post-SCI patients means incomplete or complete loss of self-reliance and independence in everyday life. Our tests showed that more than 60% of people after SCI reported the need for assistance by another person with daily activities which they were able to do by themselves prior to injury (see Table 3). Similar proportions of independence and dependent people with spinal cord injury were found in studies by Silva et al. (59.5% of independent patients) and Coura et al. (46% of independent patients) [24,25]. Different results were presented by Garrett [26]. Among his SCI patients a mere 10% reported no need for help from caregivers with activities of daily living. The study included 35 people. It is possible, therefore, that should Garrett's subject group was larger, the results would be different.

Hours of help required

Due to considerable impairment of motor functions in patients with higher spine segments injured, those with cervical spine injury need more assistance time from caregivers for self-care (hygiene, dressing, undressing, locomotion) than paraplegics [11,25,26]. Our study led to similar results, where people in the C group required almost twice as much time of daily support than people with only lower limbs and/or torso paralysed.

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Caregiver

The presented results (Table 5) include interesting characteristics of people helping post-SCI patients. In nearly 50% of cases, close family members are the ones who provide SCI patients with necessary help. It is worth noting, however, that over half of the subjects live outside marital relationships. Therefore, the responsibility to offer care is borne by parents, siblings, and/or children of SCI patients. Also Khazaeipour et al. showed that most often caregivers come from the patient's family [27]. In 35% of cases they are spouses, 37% are parents, and in merely 5.9% the nurse was the caregiver.

Functional ability based on the Barthel Index

The average number of points determining functional ability in the BI was 62 for all subjects. This corresponds to the lower threshold of mild functional dependence [18]. Similar results were reported by Menon et al. who examined SCI and its implications for Indian citizens [28].

The examined group showed a correlation between the level of independence and injury location. People with cervical spine injury showed moderate dependency (mean BI value of 47 points) [18]. Other studies also reported higher functional dependency in the case of cervical spine injuries compared to thoracic and lumbar injuries [29,30].

Patients' independence in ADL based on the Barthel Index

It is worth considering which everyday activities are the most difficult ones to perform individually by SCI patients. Our study found that regardless of injury location, SCI patients most often required help with miction control (86.7% of subjects) followed by mobility on stairs (78.7% of subjects). For instance Coura et al. used a similar SCI group size (75 people) and showed greatest dependence with waling on stairs (92%) and moving on flat surfaces (82.7%) [25]. Whereas when we compare our results with the Brazilian study, we see that for dressing/undressing patients showed comparable, high degree of independence [29]. Our subject group, likewise in the study by Coura et al. the highest independence

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was found in people self-assessing their food consumption (78.7% and 93.3%, accordingly) [24,25].

The only difference in results between our study and that of Coura's team regards assessments of independence in maintaining personal hygiene [25]. Our study found 88% of SCI subjects declared independence in activities such as washing face, cleaning teeth, shaving, whereas the study by Coura et al. reported only 36% [25].

Analysing independence with regard to injury location using the BI, we found significant differences between the three groups we examined (C, Th, L). Namely, people with cervical spine injury are more dependant than paraplegics mainly with regards to activities such as miction (72% of C subjects did not control urination or were catheterized), washing, bathing (68%), maintaining personal hygiene 64%). People with better functional abilities were members of the lumbar (L) group. Subjects in the L group are fully independent with food consumption (96%), dressing and undressing (92%), washing and bathing (88%). This is certainly the result of their current motor abilities, which are on the other hand determined by pathomechanism and the height at which the spinal cord injury occurred [31].

Functional ability in relation to other factors

We decided to investigate SCI patient's size of family. The number of family members was of little significance for the degree of functional ability. As in the case of some cited studies over half of people with SCI were part of a 3 or 4-person family [27,32].

The BI-measured functional ability of professionally active and inactive people was comparable. The only clear difference in BI results as compared with the employed and unemployed was observed in the cervical injury group. Here, people who did work scored 60 on the BI, whereas the unemployed's mean score was 37. Many authors have demonstrated similar impact of the injury and its severity on functional ability [27,33,34].

Analyzed employment and people after SCI gave an interesting picture. Referring to the anatomical motor and sensory fitness associated with

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core damage, it seems that with lower spinal cord injury, so that with greater sraveness preserved they will probably have greater functional abilities compared to high level injuries (tetraplegic). As we can see from our research, in the studied group of patients after SCI is the opposite – a definitely greater percentage of people with lumbar damage is unemployed. This fact undoubtedly requires further research. What can be the cause of this condition – whether intensive rehabilitation and stays on medical stays, or maybe the availability of permanent care (also financial) of other people or institutions, or incomplete acceptance of acquired disability to undertake professionalism and work often in a different industry than the original one. This is an interesting area for further multifaceted research to find the explanation of this observation.

Conclusions

The greatest therapeutic challenge is disability resulting from injuries to the cervical section of the spinal cord. This type of disability results in the need for assistance with activities of daily living. Activities that usually demand support from others include: miction control, mobility on stairs, and personal hygiene. Supporting a patient's self-management usually becomes the responsibility of their immediate family. Since using the stairs is the most challenging one out of all the functional limitations, it is crucial to consider architectural adaptation of a SCI patient's dwelling.

Limitations

The study carried out does have some limitations, and one of them includes self-reported data. The subjects were asked, inter alia, to describe their functional independence. The accuracy and reliability of the self-reported data was not verified. The provided statements may be exaggerated and not entirely reflect actual behaviour

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Hierarchy of Conditions of Happy Life as Described by Elderly People Using Social Help in a City Environment

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Abstract

Introduction: *The demographic situation in Poland shows that the ageing process is advanced. One of the most essential strategies and solutions in the area of social and health policy created for the elderly includes creating conditions which would enable this generation of people to remain fit and healthy, and stay self-reliant for as long as possible*

Aim: *The aim of the study was to establish a hierarchy of conditions for happy life in recipients of social services.*

Material and methods: *A group of 466 social services recipients aged 65 or over living in Łódź, central Poland, were surveyed with a questionnaire containing questions on their socio-demographic situation, the quality of their life, the conditions needed for a happy life and whether life was better before or after the year 1989: a year marked by great economic and political transformations in Poland. Statistical analysis was performed to identify the arithmetic mean, median and modal ages, as well as structure indicators (percentages and fractions). The* χ^2 *independence test* ($p<0.05$) *was used to evaluate the relationship between the characteristics.*

Results: *In most cases the subjects claimed that health (86.5%) and children (35.8%) are the most important conditions of a satisfying and happy life. Further positions were occupied by God (27.5%) and money (25.5%). In total, 72.5% of the studied respondents claimed that their life had been better before 1989. Only 7.5% of the subjects believed that the economic and political transformations of 1989 had contributed to a better life.*

Conclusions: *An understanding of the conditions needed for a happy life as understood by elderly people applying for social help should enable the creation of tailored programmes of help aimed at improving the quality of life of the elderly.*

Key words: *values, happiness, social help, Poland*

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Introduction

The demographic situation in Poland shows that the ageing process is advanced. In 2013, 13.6% of the population was aged 65 and older, and is projected to grow to 22.2% in 2030 [1-3]. Life expectancy is the most synthetic measure of mortality [4], and in this regard, the Łódź Province is atypical of the rest of Poland: in 2011, the inhabitants of the Łódź Province had the shortest lifespan in Poland (males 70.4 years; females 79.5 years) [5]. Therefore, many epidemiological measures of health have their most negative values in Łódź [6,7].

Since prehistoric times, man has striven to feel happiness, joy and satisfaction with life. However, the vast number of measures of the quality of life and human needs makes it difficult to conclusively state whether a person is experiencing a happy life [8,9].

The feeling of happiness perceived in life is a highly complex notion and factors correlating with it are extremely varied. The theory that is most often quoted in literature is the Czapiński 'onion' theory of happiness [10]. According to this theory, there are three layers of psychological well-being: an inner one (genetically determined) being the will to live, a middle layer comprising hedonic and eudaimonic measures of well-being, i.e. the subjective values of an individual's life, and an outer layer comprising current affective experiences and partial satisfactions, i.e. those referring to such particular aspects of life as family, work and economic situation.

The values of an individual play an important role. They are one of the problems of human existence which have evolved together with history and culture. The word "value" is often used in many scientific fields, and as is understood and interpreted in many ways, it cannot be defined unambiguously [11], in fact it has been explicitly claimed that "it is highly difficult, or even impossible to define a value" [12]. All academic fields incorporate various theories of values, observed from different perspectives and analyzed with various research methods. According to sociological thought, a system of values, being part of the structure of the

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world, is the very element which makes a clear difference between the social world and the natural world. Man not only evaluates values but also creates them, implying that values are social products. For a man, everything can be potentially valuable and it is he who decides what is or is not valuable.

Human value systems are a common research problem in many scientific fields all over the world. Since 1981, within the World Value Survey and in cooperation with national research institutes, studies on changes in values and their impact on social and political life have been conducted in 97 societies: almost 90% of the world population. These studies are based on two scales: the first one comprising values ranging from traditional to lay and rational ones, and the other comprising values which range from the ones needed for survival to the ones needed for self-expression. Basic values which, in the respondent's opinion, are important include those related to family, friends and colleagues, leisure time, politics, work and religion [13]. In Psychology, the relationship between values and human needs are often evaluated. Human activity is driven by needs; this feeling of need leads to an activity which aims at achieving satisfaction and realising a certain value. Maslow observed that a need is more important than a value, reflected in his theory of motivation and hierarchy of values (physiological, safety, love and belonging, respect, self-actualization, desire to possess knowledge and understanding, aesthetic). In his opinion, the hierarchy of values reflects a hierarchy of needs. The satisfaction of needs and taking decisions with respect to a particular individual's set of values allows a happy life to be enjoyed [14].

The aim of the study was to establish a hierarchy of conditions for happy life in recipients of social help aged 65 or older.

Material and methods

The study was conducted between September 2011 and February 2012 in a group of respondents at the Municipal Social Welfare Centre Łódź-Polesie, which was randomly selected from five district centres of the

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Municipal Social Welfare Centre in Łódź. The population of the district (Łódź-Polesie) was 143,400 at the end of 2010 and the percentage of people aged 65 or more was 16.8% of the total number of inhabitants. The feminization ratio in the studied subpopulation was 121.7. In 2010, 5336 people were granted social help in the studied centre. People aged 65 or above made up 23.7% of people entitled to apply for social help (704 people – 574 females and 130 males).

The inclusion criteria comprised sufficient age (65 or over) and mental ability. The authors used the Hodgkinson Test (Abbreviated Mental Test Score – AMTS) in order to evaluate the mental state of the respondents. Fifty-four people were disqualified from the study due to a poor score on the test, which confirmed their poor mental condition.

One hundred and one people died in the study period. Thirty-four subjects refused to be included in the study. Forty-nine respondents lost their right to apply for social help during the study period. In total, 466 people aged 65 or older took part the study and underwent statistical analysis. It should be stressed that 3967 respondents aged 65 or older were entitled to ask for social help. Those under the care of the municipal social help centre constituted 17.7% of the total number of elderly people in the district. This randomly selected group was found to be a representative group, of the general subpopulation of other applicants receiving social help in Łódź, with regard to such parameters as age and sex. All beneficiaries of the Municipal Social Welfare Centre in Łódź, as well as the respondents of the study, were aged 80 to 84. Females, rather than males, used help more often; female applicants comprised 80.5% of the respondents. The kind of received help was also similar: the subjects mostly applied for nursing services (Table 1).

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Table 1. Comparison of elderly recipients of the Municipal Social Welfare Centre in Łódź and the study sample by sex, age and kinds of social help

Variable		Males		Females		Total		Comparison M-F	
		n=103	N=775	n=363	N=3192	n=466	N=3967	χ^2	p
Sex		22.1	19.5	77.9	80.5	100.0	100.0	1.966	p>0.05
Age	65-69	40.2	42.8	14.0	12.9	19.8	18.7	2.625	p>0.05
	70-74	14.7	18.9	12.9	13.2	13.3	14.3		
	75-79	21.6	12.5	20.7	19.8	20.9	18.4		
	80-84	14.7	13.4	26.9	28.9	24.2	25.9		
	85+	8.8	12.4	25.5	25.2	21.8	22.6		
Kind of help	Financial	48.5	53.5	19.0	10.7	20.3	19.0	0.499	p>0.05
	Nursing	51.5	46.5	81.0	89.3	79.7	81.0		

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A survey questionnaire composed of 77 questions concerning the demographic, financial, health and social situation of the respondents, as well as their self-rated health and self-evaluated quality of life was used as a study tool. In addition, the Activities of Daily Living Scale (ADL Scale), the Instrumental Activities of Daily Living Scale (IADL Scale), the Geriatric Depression Scale (GDS), the WHOQOL-BREF Questionnaire and the EuroQoL-5D Questionnaire were also applied.

Two survey questions were taken from the *Social Diagnosis* conducted in Poland by the Council for Social Monitoring. In the first one, the respondents were asked to give the three most important conditions for a happy life from a selection of 14: children, music, God, money, optimism, work, friends, strong personality, honesty, happy marriage, freedom, level of education, health, friendly relationships with others. The other question was "In which period was your life better?", with the three possible answers being "Before 1989", "Now" and "Difficult to say". The year 1989 was chosen as this was the year of a considerable social and economic transformation which had a considerable influence on daily life and attitudes to it.

The results were entered into Microsoft Excel, and the following values were calculated: arithmetic mean, standard deviation, the structure rates (percentages and fractions, depending on the size of the studied groups and the variables). To evaluate the dependence between selected variables, the χ^2 test of independence was used. The dependence was evaluated with C-Pearson's coefficient (C). Differences were considered statistically significant at $p<0.05$. The Bioethics Committee of the Medical University of Lodz gave consent for the study to be conducted (Resolution no. RNN/109/11/KB of 15 February 2011). The respondents gave their written consent for their participation in the study.

Results

The study included 466 respondents, 363 females (77.9%) and 103 males (22.1%). The feminization ratio in the study group was 352.0. The studied

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respondents were aged 65-101 years old (mean age: 79.0±7.8 years). The median age of the study group was 80.0 years and the modal (most common) age was 82 years. For the women, the median age was 81 years, the modal age was 82 years and the mean was 80.1 years, while for the men, the median age was 73 years, the modal age was 66 years and the mean age was 74.7 years. The largest single group of respondents were aged 80 to 84 (24.2%), and respondents aged 85 or older made up 21.8% of those studied. The group of respondents aged 70 to 74 was the smallest single group (13.3%). The minimum age for the respondents receiving help from the Municipal Social Welfare Centre was 65 years (39 respondents: 12 males and 27 females), which made up 8.4% of all the studied respondents, and the maximum age was 101 years (only 1 person – a woman). The majority of recipients were widowed women (268), who made up 57.5% of the total. Married respondents constituted the smallest group of respondents (4.1%). Divorcees made up 16.3% and unmarried people, 12.4%. The majority of the respondents had an elementary education (n=242; 51.9%) and most lived in one-person households (91.5%). Respondents who had received a university education constituted the smallest number (n=34; 7.3%). The majority of respondents had done manual work in the past: 81.6% of males and 65.8% of females. None of the recipients of social help was professionally active at the time they received that help.

The majority of both the female and male recipients of social help (50%) received a *per capita* income of PLN 1001-1500 (€ 241.7-362.3 on 14 July 2014), while 85 males and 12 females (20.8% of the respondents) received a higher income. The average monthly income for males was PLN 1094.8 (€ 264.4) and PLN 1231.9 (€ 297.6) for females: a difference of PLN 137.1 (€ 33.1). It should be noted that women received a higher monthly salary than men. The χ^2 test confirmed the presence of a significant relationship between monthly salary and sex. A Pearson's coefficient of 0.438 indicated a moderate correlation between these variables. For both males and females, a pension was the main source of income (n=368; 79.2%). Of the 466 respondents, 36 (25 males and 11 females)

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did not have any income. Such respondents were not entitled to a disability or retirement pension. Males were affected by the problem significantly more often, as every fourth man was not entitled to any regular income (χ^2 =50.784, the Pearson's coefficient was 0.31). Such a situation might have been a result of the social and economic transformations of 1989. Many inhabitants of Łódź, who were mostly working class people, lost their jobs when the factories were closed down. As they would have been close to post-productive age at the time, it would have been extremely difficult for them to find other work. As a consequence, they lost their retirement privileges.

The respondents gave various reasons for applying for social help, but the most common one, affecting 342 respondents (73.4% of total: 65% of males and 75.8% of females), was chronic disease. In addition, 42.9% of the respondents gave disability as the main reason. In many cases respondents gave more than one reason, usually two. In most cases, the respondents were provided with nursing services (79.7%). Financial help was granted to 28.3% of respondents. They received more than one kind of help if they met required criteria. Table 2 presents the characteristics of the study group.

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Table 2. Characteristics of the studied group

Variable		Males		Females		Total	
		n	%	n	%	N	%
Sex		**103**	**100.0**	**363**	**100.0**	**466**	**100.00**
Age	65-69	42	40.2	51	14.0	93	19.8
	70-74	15	14.7	46	12.9	61	13.3
	75-79	22	21.6	75	20.7	98	20.9
	80-84	15	14.7	98	26.9	113	24.2
	85 and older	9	8.8	93	25.5	101	21.8
Marital status	Single male / single female	15	14.6	43	11.8	58	12.4
	Married male /married female	10	9.7	9	2.5	19	4.1
	Widower/widow	45	43.7	268	73.9	313	67.2
	Divorcee	33	32.0	43	11.8	76	16.3
Education	Elementary	42	40.8	200	55.1	242	51.9
	Vocational	18	17.5	19	5.2	37	7.9
	Secondary	34	33.0	119	32.8	153	32.9
	University	9	8.7	25	6.9	34	7.3
Number of people in a household	One	85	82.7	340	93.7	425	91.2
	More than one	18	17.3	23	6.3	41	8.8
Income *per capita*	Up to PLN 500 (€ 120.8)	20	19.4	31	8.5	51	11.0
	501-1000 PLN (121.0-241.5 €)	21	20.4	64	17.6	85	18.2
	1001-1500 PLN (241.7-362.3 €)	50	48.5	183	50.4	233	50.0
	Above PLN 1500 (€ 362.3)	12	11.7	85	23.4	97	20.8

Cause of application for social help	Chronic disease	67	65.0	275	75.8	342	73.4
	Diasability	52	50.5	148	40.8	200	42.9
	Poverty	4	3.9	15	4.1	19	4.1
	Random event	0	0.0	4	1.0	4	0.8
Kind of provided social help	Nursing servcies	50	48.5	331	91.2	381	79.7
	Permanent benefit	45	43.7	22	6.1	67	14.4
	Special-purpose benefit	8	7.8	9	2.5	17	3.6
	Temporary allowance	0	0.0	1	0.2	1	0.2
	Feeding	32	31.1	11	3.0	43	9.2
	Medical fee	2	1.9	2	0.4	4	0.9

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Table 3 presents the perceived conditions of a happy life. For the majority of the respondents (86.5%), health was the most essential condition for a happy life. The next were children (35.8%), God (27.5%) and money (25.5%). Less frequently given were optimism (19.5%), happy marriage (13.9%), friendly relationships with others (13.9%), having friends (13.5%) and honesty (11.6%). The least important conditions of happy life included work (5.4%), strong personality (4.1%), freedom (2.8%) and education (1.3%). For two respondents (0.4%) music was a condition of a happy life. Having children was given as a condition of a happy life significantly more often by females than males: a Pearson's coefficient of 0.24 indicates a moderate correlation. Moreover, the answers given by males significantly differed from those given by females: males tended to identify a happy life with optimism, work, honesty, happy marriage and friendly relationships with others. The variables were moderately correlated (the Pearson's coefficients were 0.13, 0.11, 0.19, 0.25 and 0.14 respectively).

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Table 3. Hierarchy of conditions of happy life by sex of the respondents

Condition of happy life	Males n=103		Females n=363		Total N=466		Comparison M-F	
	%	Rank	%	Rank	%	Rank	χ^2	p
Health	88.3	1	85.9	1	86.5	1	0.395	ns
Children	13.6	9	42.1	3	35.8	2	28.455	p<0.01
God	23.3	4	28.6	4	27.5	3	1.152	ns
Money	21.4	7	26.7	5	25.5	4	1.213	ns
Optimism	29.1	3	16.8	6	19.5	5	7.752	p<0.05
Happy marriage	30.1	2	9.4	8	13.9	6	28.728	p<0.01
Friendly relationships with others	23.3	4	11.3	7	13.9	6	9.636	p<0.05
Friends	15.5	8	45.6	2	13.5	8	0.459	ns
Honesty	23.3	4	8.3	9	11.6	9	17.707	p<0.01
Work	10.7	10	3.9	10	5.4	10	7.357	p<0.05
Strong personality	6.8	11	3.3	11	4.1	11	2.499	ns
Freedom	1.9	12	3.0	12	2.8	12	0.064	ns
Education	1.9	12	1.0	13	1.3	13	0.030	ns
Music	0.9	14	0.3	14	0.4	14	0.010	ns

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The year 1989 was an important date for Poland. It initiated a new period of freedom and a new social order. The constitutional transformation resulted in improved conditions for Polish citizens. They were guaranteed freedom of speech, were allowed to participate in elections. There was no censorship or state control any longer. However, these positive processes were accompanied by growing unemployment and poverty. Economic transformations have a considerable influence on the process of creating a new social order: They result in an improvement of living standards, the introduction of new technologies on the market and the appearance of new professions such as managers, organizers or urban planners. During this economic development, lifestyles changed and many everyday commodities, including foods, became available. There was greater awareness of health issues and more individual control of health, facilitated by a greater choice of private clinics providing medical services.

However, many new technologies lead to the degradation of the natural environment, which in turn, lead to the deterioration of health. In addition, the free market was not friendly to elderly people. The tendency of employers to demand more from employees, combined with the nature of a competitive market, led to greater unemployment and increased the difficulties felt by the older generation, who were sometimes not sufficiently trained to find new employment. In the new capitalist system, money gained importance and the fast pace of life and pursuit of material goods replaced family traditions, which tended to be neglected. The process of transformation brought about changes in individual perspectives, and those of entire communities, resulting in an upheaval in the whole system of values [15]. The respondents were asked in which period their life was better, before or after the social and economic transformation initiated in Poland in 1989; after the implementation of political reforms which might have been beneficial for them and contributed to a realization of plans and greater life satisfaction.

The vast majority of respondents (72.5%) claimed that their life had been easier in 1989, more so by female respondents (χ^2 =5.896, Pearso-

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n's coefficient = 0.11). Only 7.3% of the respondents claimed that their life has been better since 1989 and 20.2% of them chose the answer "Difficult to say". Male respondents chose this answer significantly more frequently than females (Table 4).

To interpret the results properly, the respondents were asked to clarify their answers. The answer "my life was better before 1989" was connected with the fact that at that time the respondents were younger, healthier, completely self-reliant, independent of other people's help and actively participated in family and social life, which confirms the opinion that being healthy and independent are believed to be the most important factors of happy life by the older generation. For 61.9% (66.9% of males and 60.4% of females) of respondents, the "better life" before 1989 was connected with good health and self-reliance. For another 30.6% of the respondents (21.4% of males and 33.3% of females) the "better life" was identified with active participation in family and social life, with the female respondents noting this significantly more frequently – $\chi^2 = 3.887$. Only 7.5% (11.7% of males and 6.3% of females) claimed that the political changes contributed to an improvement of their living standards. Hence, the above mentioned distribution of answers appears to be a result of better health and more frequent contact between the respondents and their family and friends rather than the economic and social situation at that time.

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Table 4. The studied group by sex and opinion on life before and after 1989

When was your life better?	Males		Females		Total		Comparison M-F	
	N	%	n	%	N	%	χ^2	P
Before 1989	65	63.1	273	75.2	338	72.5	5.896	p<0.05
Now	8	7.8	26	7.2	34	7.3	0.043	Ns
Difficult to say	30	29.1	64	17.6	94	20.2	6.584	p<0.05
Total	103	100.0	363	100.0	466	100.0	-	
Why was your life better?	Males		Females		Total		Comparison M-F	
	N	%	n	%	N	%	χ^2	p
Health and self-reliance	69	66.9	219	60.4	288	61.9	0.015	ns
Social activity	22	21.4	121	33.3	143	30.6	3.887	p<0.05
Political change	12	11.7	23	6.3	35	7.5	0.020	ns
Total	103	100.0	363	100.0	466	100.0	-	

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Discussion

Many factors contribute to a happy life. They include health, family relationships, social and professional activity, education and life-long learning. They improve the quality of life and create a positive image of ageing processes, old age and old people. By making senior citizens feel fulfilled and useful, their social isolation is prevented [16]. Campbell et al. observe that older people tend to be less satisfied with life. This process lasts until the age of fifty or sixty, at which point, the level of satisfaction either becomes stable or rises [17].

A review of professional literature allows for an identification of factors which substantially contribute to life satisfaction, one of which is health. It is one of the most important values, particularly for elderly people. According to many studies, health and happy children are two key values among the elderly population [18-20]. Another condition of a happy life is social support. In other words, it is identified with the relationship between the person and their social circle. Social support is particularly important for health: it prevents diseases and accelerates healing processes. A positive attitude to life and hope are other psychological factors which are important for health. According to Antonovsky's concept, living in positive relationships with other people evokes in the elderly a feeling of participation in social life, which is not limited only to the closest family members [21]. Hence, while working with elderly people, it is important to focus on the prevention of social exclusion and isolation. This can be achieved by the activation and creation of social support groups not related to family members.

A highly important source of life satisfaction in elderly people is the family [22]. However, it should be emphasized that the economic processes initiated in the 1990s appear to have reversed formerly observed tendencies, with the needs and problems of family life now tending to be subordinated to those of work and professional achievements, which often leads to the neglect of family problems. The hierarchy of values is reversing. The term "yuppies" is used to describe young people who identify success in work with success in life [23].

As well as the value of knowing of the conditions required for a happy life, identification of these conditions will facilitate gerontological prophylaxis, which will improve the quality of life of the elderly and prevent them from being socially excluded. In the majority of cases, health was regarded as the most essential element of a happy life (86.5%), followed by children (35.8%), and then God (27.5%) and money (25.5%). Women identified a happy life with having children significantly more frequently than men, whereas for men, optimism, work, honesty, happy marriage and friendly relationships with others appeared to be more important.

A similar observation was made in an Indian study conducted on a group of 216 people, aged 60 or older. Of this group, 41.3% considered the reason for their unhappiness to be bad health [24]. The difference in the conditions required for life satisfaction observed between studies partly confirms the hypothesis of deficit: the subjects tend to respect what they lack most [25]. According to the World Value Survey the most important value observed in Poland is family. Work is in second position, being a source of income rather than a source of personal fulfilment, and religion takes third place. However, unlike the present study, health did not take any of the first three positions. In other post-communist countries, material goods are often considered most important [26].

Religion is often considered to be one of the most important personal values and a factor contributing to life satisfaction. Religion may protect against depression and negative fears and stresses [27]. It can help elderly people to cope with social exclusion. Religion is regarded as adding meaning to life; it can be viewed as a drive used to overcome everyday problems and make life more satisfying [28]. However, the individual, the surrounding world and God can be perceived in different ways [29]. A study conducted in 2000-2001 in a group of people aged 70 or older in India confirmed that the most essential value for the elderly is religious practice: It was found to reduce the incidence of depression in this subpopulation, help elderly people to adapt to old age and make the process of ageing less stressful and frustrating [30]. Similarly, Hooyman observes that active participation in religious life improves general health and con-

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tributes to higher quality of life [31]. Thorson reports that religion significantly affected the quality of life of respondents, they identified happiness with God, and that religion was the third most important condition of a happy life. For elderly people included in this study, children were the second most important condition of happy life [32].

The determinants of a happy life were also the focus of a study conducted by Molesztak [33]. Polish and German respondents considered health to be most important, while the American respondents valued friends most highly. All groups rated honesty second. While different values were noted in third position, it is worth mentioning that the Americans put health. For money, the Germans rated it third, the Poles eighth and Americans tenth. These findings imply that the Polish respondents need to be healthy, honest and remain in friendly relationships with others to feel happy, while the German respondents need money and the Americans, friends.

All the studies given above found health and family life to be the most appreciated values in the hierarchy of values. Although this may appear obvious, the results of the present study in Poland reveal that in the period preceding the economic and political transformation of 1989, work was highly valued, and was awarded a greater value than it is now. It must be norne in mind that the system of values of people aged 60, 70 or 80 years old were shaped in the first half of the 20th century, when the social, economic, political and technological context was completely different from now.

Two other factors affect the system of values and have a strong influence on the way current life is perceived and experienced: passed years of life and the course of life. Kukołowicz notes that over the course of time, people limit their contacts with the external world and start focusing on their own, internal world [34]. Seniors tend to focus on being with themselves and reminisce over their past life; they develop their own personality, evaluate facts from their life and arrange them in a proper hierarchy [35,36]. All around the world, the structure of societies is changing, and with this change, there is a need to modify projections of the

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future of those societies. Ageing generations must be provided with security and the means to bridge the gap between generations [37,38].

Conclusions

Elderly people using social services consider a range of values to be important for a happy life, the most important being health, family life and religion. Gerontological prophylaxis aimed at improving the health and the quality of life of the elderly should be prioritised, together with the implementation of initiatives preventing disability. Elderly people and the problem of ageing needs to be viewed in a more complex way. The image of old age and the lifestyle of old people should be modified, but this will require changes to the perspectives of both individuals and society as a whole. Multidirectional steps need to be taken in order to prepare people for inevitable old age, such as ensuring support for families. Apart from confirming that a family is an unquestionable value, pro-family policies should be implemented and foster all functions of a family. By identifying the conditions required by elderly people using social help to enjoy a happy life, individually tailored and implemented care programmes may be created to improve quality of life.

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Organization of Multi-specialist Medical Care and Physiotherapy for Patients with Tinnitus

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Abstract

Tinnitus is a medical problem for MD and Health Specialists like: otorhinolaryngologists, neurologists, dentists, internists, cardiologists, nephrologists, psychiatrists, psychologists and physiotherapists. Symptoms of tinnitus significantly worsen patients' quality of life. Organization of treatment and treatment raise many challenges. No universally accepted therapeutic method has been developed for patients suffering from tinnitus. The variety of methods could be taken into account. It is also important to look for effective organizational solutions that allow for efficient care of these patients. The effectiveness of the mentioned diagnostic and therapeutic methods is diverse and is a challenge for health care organizations. Patients who have tinnitus are most often older people struggling with concomitant diseases. The interdisciplinary approach is the key to successful treatment of this ailment, and its multifactorial etiology indicates the need for combined treatment, which should take place in centers offering the possibility of consultation, diagnosis and therapy in the field of various medical specialties.

Key words: *organization of tinnitus treatment, tinnitus, therapy*

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And if I hear what I hear
It's just tinnitus
Blank noise
Kazimierz Wierzyński, "I hear time" [1]

Introduction

Tinnitus (tinnitus auris) is a great diagnostic and therapeutic problem for doctors of many medical specialties. Their prevalence, symptoms that significantly worsen patients' quality of life, cause anxiety, cause insomnia, as well as difficulties in achieving therapeutic success, require an interdisciplinary approach involving the cooperation of doctors of many specialties: otorhinolaryngologists, neurologists, dentists, internists, cardiologists, nephrologists, psychiatrists, psychologists and physiotherapists. Leading patients in coordinated care, involving the cooperation of many specialists, results from a holistic approach to patients and is the only right way to achieve success, which is to improve the quality of life and functioning of patients [2]. This is a huge challenge for the healthcare system with extremely important interaction between medical science and practice. An example of such action is the foundation supporting the development of research on the treatment of tinnitus – Tinnitus Research Initiative, whose mission is to support scientists in interdisciplinary research and to educate and develop clinicians in the field of diagnosis and treatment. To date, no universally accepted algorithm for diagnostic and therapeutic management has been developed for patients suffering from tinnitus. It is also important to look for effective organizational solutions that allow for efficient care of these patients.

Literature Review

Tinnitus as a condition that worsens the quality of life has been known for centuries. The first notes about the treatment of tinnitus appeared in

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Ancient Egypt. In the Ebers papyrus from 1550 B.C.E. there is a mention of „tinnitus singing, whispered and spoken". More than 20 ways to treat tinnitus come from Babylon. Numerous reports on its occurrence and treatment can be found in manuscripts from Persia, India, ancient Greece and Rome. A broad chapter on this ailment is contained in Du Verney's first otology textbook published in 1683, "Traite de L'organ de L'ouie". Famous people suffering from tinnitus included: German religious reformer Martin Luther, writer Jean-Jacques Rousseau, composer of the European anthem Ludvig van Beethoven, actress and singer Barbara Streisand, Rossalyn Carter, wife of former US president who was treated by P.J. Jastreboff using the TRT method, Zbigniew Hołdys, Jan Borysewicz, and English rock guitarist Pete Townshend, Chris Martin, leader of the British rock band Coldplay [3].

Tinnitus is defined as sound sensations appearing in one or both ears at the same time, in the absence of an acoustic stimulus in the environment that would generate sound. This ailment can be divided into two main groups: subjective and objective. Objective tinnitus: vascular and mechanical, are diagnosed less often. They are caused by vascular pathologies, arteriovenous fistulas, haemangiomas, intracranial glomeruli, intraocular muscle spasms, soft palate, trumpetopharynx, sphincter muscle [4]. Subjective tinnitus is only heard by the patient. It is estimated that in Poland the occurrence of this ailment affects 5-10% of patients, and among people over 75 this percentage increases to 30% of patients [5]. The incidence of tinnitus in children with good hearing reported in the literature ranges from 13% to 37.7% [6]. Due to the incidence of complaints, the International Week of Tinnitus Knowledge Week was established, which falls on February 5-11 [7]. Its cause may be in different parts of the hearing organ. It can be conductive, caused by diseases of the outer or middle ear. Sensory and nervous ones have a different etiology. There are 4 types of noise depending on the location of damage in the inner ear (I – in external hair cells, II – in internal hair cells, III – irregularities in the signal from internal hair cells to the auditory nerve fibers, IV – arising in extra-neural structures of the cochlear duct) [8]. A large percentage of

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causes are of central origin, and chronic exposure to noise generates this disease in 50% of patients. They can also be the result of ototoxic drugs, the aging process or chronic systemic diseases (diabetes, hypertension, lipid disorders, kidney diseases). Tinnitus can also be a consequence of head injury, as well as degenerative changes of the spine, mainly its cervical segment [9]. Paweł J. Jastreboff, neuroscientist, professor at the Department of Otolaryngology, Emory University School of Medicine, creator of the first Center for Tinnitus Rehabilitation and Auditory Hypersensitivity and TRT (Tinnitus Retraining Therapy) established in the USA, defined multifactorial etiology of tinnitus as arising in all sections of the auditory pathway, centers of the central nervous system, including subcortical centers, cerebral cortex, limbic and autonomic system [10]. Symptoms that accompany tinnitus are: hearing impairment, feeling of fullness in the ear, balance disorder, dizziness, headache, anxiety, depressed mood, difficulty falling asleep, insomnia.

Tinnitus is described by patients as reminiscent of the sound of the waves of the sea or wind, playing crickets, but also penetrating clicks or squeaks [11]. The diverse etiology of tinnitus obliges doctors of various specialties to thorough diagnostic procedures of a multidisciplinary nature. Research in the field of ENT is particularly important, including a comprehensive medical history, full otolaryngological examination with otoscopy complemented by comprehensive audiological diagnostics: threshold and threshold threshold audiometry (SISI recruitment test), impedance audiometry, verbal audiometry, auditory brainstem evoked potentials (ABR), measurements of sound emission (TEOAE, DPOAE and SOAE), subjective assessment of tinnitus loudness. It is also advisable to perform nystagmographic tests (ENG and VNG) [12]. After diagnostics of the scope of otorhinolaryngology, patients undergo imaging tests: computed tomography of the head, magnetic resonance imaging of the head and bridge-cerebellar angles, review and functional x-ray of the cervical spine, Doppler ultrasound of the cervical vessels and numerous laboratory tests, including: morphology with smear, full lipidogram, glucose level, hormonal tests [13].

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To date, no universally accepted therapeutic path has been developed for patients suffering from tinnitus. Pharmacological, surgical, acupuncture, diet and spa treatments, psychotherapy, music therapy, electrostimulation, hyperbaric oxygen chambers, laser therapy, noise masking with the use of Tinnitus Masker devices, hypnosis and physical therapy are used [14].

In pharmacological therapy of acute (lasting up to 3 months) and chronic (lasting over 1 year) tinnitus, drugs from various therapeutic groups are used: betahistine [15], vasodilators, improving brain metabolism, vitamins, sedatives, topical anesthetics, hypnotics, steroids, melatonin, homeopathic remedies [16]. Acamprosate, a homotaurin derivative with GABAergic properties, has also been found to be effective in reducing abstinence symptoms in patients with alcohol dependence [17]. In surgical therapy, vascular decompression of the vestibulocochlear nerve, or removal of neuroma VIII, otosclerosis, tympanosclerosis, and treatments for chronic otitis media are used [18]. Dietitians recommend a low-fat diet with a reduced supply of sodium chloride with the recommendation of limiting strong tea, coffee, cigarettes and alcohol. The electrostimulation group of the hearing organ is another therapeutic method [19]. The best results are obtained by therapeutic management based on neurophysiological theory of tinnitus treatment by Jastreboff's TRT habituation method. The patient learns to live with tinnitus by minimizing its negative impact on the quality of life. Another method is psychological therapy involving learning to deal with your own problems and understanding your body [20]. Numerous studies have confirmed that chronic tinnitus can lead to disturbances in the emotional and functional sphere of patients [21]. Neuromonics, or acoustic desensitization, is a similar method. This concept of therapy was developed by Dr. Paul Davis from Australia. Neuromonics uses therapy specially prepared in terms of amplitude and tempo with music filtered to higher frequencies (above 10,000 Hz). The recordings are intended for listening in headphones for 2 to 4 hours a day, for a period of not shorter than 6 months [22]. Music therapy including a block of sound therapy exercises focuses on ple-

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asant sounds. This puts the patient in a state of relaxation, reducing his irritability and anxiety. Responsible for this phenomenon is the effect of nitric oxide, which produced in the auditory system under the influence of appropriately selected music improves the blood supply to the cochlea [23]. Physiotherapeutic treatment complements other therapeutic techniques. Treatments in this field that improve the quality of life of patients include: laser biostimulation, acupuncture, hyperbaric oxygen therapy, kinesitherapy, and electrostimulation. The effectiveness of acupuncture in tinnitus has been confirmed by tests carried out by Cai W, Chen AW, Ding L, Shen WD. Patients with tinnitus were treated with this method in TE3 and TE5. The infrared thermography (IRT) test of the bilateral auditory areas of each participant and the results of a visual analogue scale performed before and after the first session of acupuncture treatment showed that the temperature differences on both sides were significantly reduced, but the maximum, minimum and average temperature of the bilateral auditory areas did not have any significant difference before and after the acupuncture session. Thus, an improvement in cochlear blood flow was obtained [24].

Laser therapy as a therapeutic method is used in the treatment of tinnitus, in which the etiological factor is temporomandibular joint dysfunction (TMJ, TMD) and Costen's syndrome. Both Nd: YAG (low-level yttrium-aluminum – 1064 nm (LLLT) diode lasers with neodymium-doped aluminum yttrium are used) as well as LLLT with an 810 nm diode laser [25]. In manual therapy, the indications relate to procedures involving the mobilization of the cervical spine and chest, as well as muscle strengthening, stretching and instructing on correct posture [26]. The usefulness of hyperbaric oxygen therapy (HBOT) has been proven in the acute phase of acoustic trauma. In the studies of Japan Maritime Self-Defense Force Undersea Medical Center researchers conducted in 1997-2017 among persons treated with HBOT, 70.2% showed improved hearing and 83.9% reduced subjective symptoms [27].

Yoga is also a supportive method in the treatment of tinnitus. In one study patients complaining of chronic tinnitus underwent a 12-week

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yoga training. All participants were assessed using the Tinnitus Functional Index and described a sense of better tinnitus control, improved sleep quality and quality of life [28]. Clinical studies have shown that the use of manual cervical-mandibular therapies in combination with exercise and education have yielded better results than the use of exercise/education alone in people with TMD-associated tinnitus [29].

Researchers-inventors from the Modern Audiology Center of the Warsaw Kinetic clinic are also looking for a remedy for the described ailment. They developed headphones connected to a device resembling an mp3 player. It is a neuroprocessor that instead of music gives to the ear a signal individually selected for a given patient, reducing his perception of noise. The invention received Focus Lens award in a plebiscite of important scientific discoveries of the editors of the Focus monthly for 2018 [30].

Organizational Innovations in Tinnitus Treatment

The European Union is currently funding an international research project on „UNITI" tinnitus treatment methods. The project is chaired by Dr. Winfried Schlee, of the Tinnitus Center and Center for Neuromodulation of the University of Regensburg at Bezirksklinikum. The program combines genetic, medical, audiological research, etc. The end of the three-year project is to be a computer model recommending the best possible therapy dedicated to a patient with tinnitus. UNITI (EU Action no. 848261) will start at the beginning of 2021, currently recruiting patients for the program. Several leading European centers will take part in them: Regensburg (Germany), Berlin (Germany), Leuven (Belgium), Granada (Spain) and Athens (Greece) [31].

Summary

The effectiveness of the mentioned diagnostic and therapeutic methods is diverse and is a challenge for health care organizations. Patients who

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have tinnitus are most often older people struggling with concomitant diseases. The interdisciplinary approach is key to successful treatment of this ailment, and its multifactorial etiology indicates the need for combined treatment, which should take place in centers offering the possibility of consultation, diagnosis and therapy in the field of various medical specialties.

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Use of E-cigarettes and Other Unconventional Nicotine-containing Products among Pregnant Women

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Abstract

Indtroduction: *Electronic cigarettes (e-cigarettes) are products that deliver an aerosol (commonly called steam) containing nicotine. The impact of e-cigarettes on human health has so far been studied mainly in healthy people after short-term exposure. Only minor side effects were revealed. Polish statistics on the prevalence of smoking among pregnant women indicate that around 15-30% of women smoke cigarettes during pregnancy. The data come from a few researches conducted in Poland. However, there is no assessment of the prevalence of e-cigarette use among pregnant women. It can be suspected that this could be a growing problem in this group. Foreign studies among pregnant women are still scarce. There are voices that the conviction about the safety of e-cigarettes can lead to their more frequent use during pregnancy.*

Aim: *The aim of the study was to assess the frequency of using e-cigarettes and other nicotine-containing tobacco products among pregnant women. Knowledge about their harmfulness was also examined.*

Material and metods: *A cross-sectional study was conducted among pregnant women receiving antenatal care at the Poviat Health Care Complex in Piotrków Trybunalski in 2018. The research tool was a questionnaire. The study design received a positive opinion of the Bioethics Committee at the Medical University of Lodz RNN/ 386/17/EC of December 19, 2017 and the consent of the head of this unit.*

Results: *600 pregnant women participated in the study, the response rate was 45.2%. About 15% of respondents thought that compared to traditional cigarettes, e-cigarettes are more harmful, 59.2% are just as harmful, and 25.8% are less harmful. Every fifth pregnant woman in the last 12 months was asked by the doctor about the use of e-cigarettes, 12.5% obtained advice to quit, 3.1% obtained to reduce the level of use of e-cigarettes, the doctor advised not to quit e-cigarettes 3,1% of respondents, and did not give any guidance to 31.3% women. Less than 2% of respondents thought that e-cigarettes are safe*

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and can be used during pregnancy, 20.0% – e-cigarettes are less harmful than traditional cigarettes, and 79.3% – e-cigarettes can affect pregnancy as well as traditional cigarettes. Less than 12% of respondents said they had heard about smokeless electronic devices for heating tobacco (e.g. IQOS). However, 2.5% declared that they used the product at least once in their life.

Conclusions: *The use of e-cigarettes and other unconventional nicotine-containing products by pregnant women is a significant problem. Pregnant women should be educated about the possible negative health effects of using e-cigarettes.*

Key words: *e-cigarettes, unconventional nicotine containing products, pregnancy, nicotine*

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Introduction

Electronic cigarettes (e-cigarettes) provide an aerosol (commonly referred to as steam) containing nicotine, formed by heating a solution, which usually consists of propylene glycol or glycerol (glycerin), nicotine and flavoring [1]. So far, the effects of e-cigarettes on human health have been studied, mainly in healthy people after short-term exposure. Only minor side effects were revealed. People with asthma and chronic obstructive pulmonary disease may be afraid of respiratory irritation and bronchospasm caused by the propylene glycol contained in the aerosol. There are no reports on the safety of using e-cigarettes in patients with known cardiovascular disease. Only a few studies directly check the health effects of exposure to e-cigarette aerosol. The effects of acute, short-term use of e-cigarettes were studied among people who were also smokers of traditional cigarettes [2,3]. Polish statistics on the prevalence of smoking among pregnant women indicate that around 15-30% of women smoke during pregnancy [4-7]. The data come from the few surveys conducted in Poland. However, there is no assessment of the prevalence of e-cigarettes in pregnant women. It can be suspected that this could be a growing problem in this group. Foreign studies among pregnant women are still scarce. Data from the US indicate that the number of e-cigarette users (6.5%) exceeded the number of those who smoke traditional cigarettes (5.6%) with a still significant percentage of so-called dual users, i.e. people using both products interchangeably (8.54%) [8]. There are voices that the conviction about the safety of e-cigarettes may lead to their more frequent use during pregnancy [9].

Material and methods

A cross-sectional study was conducted among pregnant women receiving antenatal care at the Poviat Health Care Complex in Piotrków Trybunalski in 2018. The respondents were recruited at the outpatient clinic of the Poviat Health Care Team in Piotrków Trybunalski. The study de-

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sign received a positive opinion of the Bioethics Committee at the Medical University of Lodz RNN/386/17/EC of December 19, 2017 and the consent of the head of this unit. All women who agreed to participate in the study or for women under 18 years of age after obtaining the written consent of a parent or legal guardian were included in the study. The study was conducted from January 2018 to December 2018. The research tool was a questionnaire. The questions in the questionnaire relate to the following issues: sociodemographic data, smoking and use of e-cigarettes by both a pregnant woman and partner, smoking intentions, exposure to secondhand smoke. Smokers were also asked about a subjective assessment of quitting methods, motivators and barriers to smoking cessation. The research tool was previously used in Poland by Balwicki et al. [4,10].

Results

The study involved 600 pregnant women out of 1,326 patients from the Poviat Health Care Center in Piotrków Trybunalski in 2018. The response rate was 45.2%. The age of pregnant women included in the study is 19 to 41 years old. The average age was 26 years. The most numerous group were women aged 25-29. Most women were married (79%); 19.5% were single and 1.5% were widows or divorced. 21% of pregnant women had primary education, 25.5% vocational education, 38.5% secondary education and 14.5% higher education. Almost half of the respondents (45%) were pregnant for the first time. Most of the examined women (81%) were in the third trimester of pregnancy; 15.9% were in the second trimester and 2.0% were in the first trimester. Multifarines constituted over half of the pregnant women (55%). Professionally active women constituted 77% of the study group. The most common type of work declared by working respondents is mental work. The average monthly income per family member in most pregnant families (35.5%) ranged from 700 to 1000 per person in the family. Among 45.5% of respondents, the income per person in a household was so low that it is difficult (including with

great difficulty, difficulty, and some difficulty) to make ends meet. Over 85% of respondents rated their health as good or very good, 11.7% as neither good nor bad and 1.6% as bad or very bad (Table 1). Data obtained from questionnaire interviews indicate that 26.7% of respondents have ever used e-cigarettes, and 73.3% have never tried e-cigarettes (Table 2). 16 surveyed women used e-cigarettes during pregnancy (2.6% of all respondents). Users of e-cigarettes most often chose aerosols with lower nicotine concentrations containing 6 to 12 mg/ ml of nicotine or none at all (6.2%). It was found that 23 women included in the study used them as a method of quitting smoking from traditional cigarettes, 15 used them alternately with traditional cigarettes (Table 2). Every fifth pregnant woman has been asked by the doctor in the last 12 months if she has used e-cigarettes, and 12.5% have been advised to quit smoking. In contrast, 3.1% were advised to reduce the level of e-cigarette use. The doctor advised not to quit e-cigarettes 3.1% of respondents, and did not give any instructions to 31.3% of women. Around 15% of respondents thought that compared to traditional cigarettes, e-cigarettes were more harmful, 59.2% thought they were just as harmful and 25.8% were less harmful (Table 3). Regarding the impact of e-cigarettes on pregnancies, nearly 2% expressed the opinion that e-cigarettes are safe and can be used during pregnancy, 20.0% thought that e-cigarettes are less harmful to the course and outcome of pregnancy than traditional cigarettes, and 79.3% thought that e-cigarettes could affect pregnancy as well as traditional cigarettes. Less than 12% of respondents said they had heard about smokeless electronic devices for heating tobacco (e.g. IQOS). On the other hand, 2.5% declared that they had already taken such a tobacco product at least once in their life. The vast majority do not use such products at all (Table 4).

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Table 1. Characteristics of the study population (n=600)

Characteristic		N	%
Age in years			
	min-max average median	19-41 26 5,6	
	<19	10	1,7
	20-24	120	20,0
	25-29	243	40,5
	30-34	159	26,5
	35-39	65	10,8
	40-44	3	0,5
	45+	0	0,0
Week of pregnancy at the time of the study		$\bar{x}$ 31,5; median 35,0 SD 9,5	
Trimester of pregnancy			
	I trimester	32	2,0
	II trimester	128	15,9
	III trimester	440	82,1
Education			
	basic	129	21,5
	professional	153	25,5
	average	231	38,5
	higher	87	14,5
Currently pregnancy			
	1	270	45,0
	2	210	35,0
	3	85	14,2
	4	20	3,3
	5	10	1,7
	6	5	0,8
Delivery			
	one delivery	270	45,0
	many deliveries	330	55,0
Number of deliveries			
	0	270	45,0
	1	245	40,8
	2	60	10,0
	3	15	2,5
	4	5	0,8
	5	5	0,8

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Employment			
	employed	465	77,5
	unemployed	35	5,8
	other	90	15,0
	no answer	10	1,7
Type of work			
	physical work (predominance of physical effort)	180	38,7
	intellectual work (predominance of mental effort)	285	61,3
Marital status			
	married	474	79,0
	single	117	19,5
	widow / divorced	9	1,5
Living with a partner			
	Yes	562	93,7
	No	38	6,3
Subjective income assessment „makes ends meet”			
	with great difficulty	0	0,0
	with difficulty	25	4,2
	with some difficulty	248	41,3
	fairly easy	206	34,3
	easily	88	14,7
	very easy	33	5,5
Monthly income			
	up to PLN 500	20	3,3
	over 500 to 700 PLN	49	8,2
	over 700 to 1000 PLN	213	35,5
	over 1000 to 1500 PLN	188	31,3
	over 1500 to 2000 PLN	86	14,3
	over 2000 to 2500 PLN	17	2,8
	over 2500 PLN	27	4,5
Subjective assessment of healthy state			
	very good	245	40,8
	good	275	45,8
	neither good nor bad	70	11,7
	bad	5	0,8
	very bad	5	0,8

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Family help and support			
	at all	30	5,0
	sometimes	110	18,3
	often	85	14,2
	always	375	62,5

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Table 2. Use of e-cigarettes among pregnant (N=600)

Answer	N	%
Have you ever taken an e-cigarette for once in your life?		
Yes	160	26,7
No	440	73,3
During the 3 months before you got pregnant, how often did you use your e-cigarette on average? 34 women 21.2% of those who used e-cigarettes used them every day	$\bar{x}$=7,6	sd=3,2
During the week (if less often than daily) 14 women 8.7% of those who used e-cigarettes used them less often every day	$\bar{x}$=71,6	sd=1,1
How often do you use an e-cigarette?		
Every day	16	10,0
Less often than every day	7	4,4
I do not use at all	137	85,6
How much nicotine do you have in your e-cigarettes? Applies to n=160		
Do not contain nicotine	10	6,2
6 mg/ml or less	15	9,4
12 mg/ml	15	9,4
18 mg/ml	0	0,0
24 mg/ml or more	0	0,0
No data	120	75,0
Which of the following best describes your situation?		
I use e-cigarettes as a way to stop smoking traditional cigarettes	23	15,6
I use alternating e-cigarettes with traditional cigarettes	15	9,4
I have always used only e-cigarettes	0	0,0
No data	120	75,0
If you have used or used an e-cigarette and smoked or smoked regular cigarettes, which one did you try first?		
Traditional cigarette	160	100,0
E-cigarette	0	0,0
Over the past 12 months, has your doctor asked you whether you smoke e-cigarettes?		
Yes	30	18,7
No	90	56,3
No data	40	25,0
What did the doctor advise?		

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He advised to quit	20	12,5
Advised reducing the use of e-cigarettes	5	3,1
Advised not to quit	5	3,1
He gave no instructions	50	31,3
No data	80	50,0
In the last 12 months, have you received from the doctor or other medical staff professional advice on quitting smoking or educational materials on quitting smoking?		
Yes	5	3,1
No	105	65,6
No data	50	31,2
Does your husband / partner use e-cigarettes?		
Yes	122	20,3
No	478	79,7
Do your friends use e-cigarettes?		
None of them	130	21,7
Some of them	400	66,7
Most or all	70	11,7

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Table 3. Pregnant women opinions about the harmfulness of using e-cigarettes (N=600)

Answer	N	%
Compared to traditional cigarettes, how harmful they are electronic cigarettes (e-cigarettes) in your opinion?		
E-cigarettes are more harmful than traditional cigarettes	90	15,0
E-cigarettes are just as harmful as traditional cigarettes	355	59,2
E-cigarettes are less harmful than traditional cigarettes	155	25,8
What is your opinion about the impact of e-cigarettes on pregnancy?		
E-cigarettes are safe and can be used during pregnancy	10	1,7
E-cigarettes are less harmful to the course and outcome of pregnancy than traditional cigarettes	120	20,0
E-cigarettes can affect pregnancy as well as traditional cigarettes	470	79,3

Table 4. Use by a pregnant smokeless electronic device for heating tobacco (N=600)

Answer	N	%
Have you heard of a smokeless electronic device for heating tobacco (eg IQOS)		
Yes	70	11,7
No	530	88,3
Have you used an IQOS product at least once in your life?		
Yes	15	2,5
No	585	97,5
How often do you use smokeless electronic device for heating tobacco today? / only for 15 women who have ever signed up for IQO		
Every day	5	33,3
Less often than every day	0	0,0
I do not use at all	10	66,7

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Discussion

It should be emphasized that there are few studies describing the frequency of using e-cigarettes, especially by pregnant women. In a study by Nicholas et al. It was found that 5.62% (n=25) women smoked traditional cigarettes, 6.52% (n=29) used e-cigarettes, 8.54% (n=38) used both tobacco cigarettes and e-cigarettes, and 79.33% (n=353) did not use tobacco cigarettes or e-cigarettes. Of the users of e-cigarettes, 74.6% (n=50) reported the transition to e-cigarettes from tobacco cigarettes during pregnancy [11]. The Kantar Public report for the Chief Sanitary Inspectorate has been published on the use of e-cigarettes in the general population in Poland. According to data from this report, among smokers of traditional cigarettes, 5% of women used e-cigarettes. The desire to quit smoking was the most frequently cited reason for using e-cigarettes (54%) [12]. In a study by Mark et al. (2015), results showed that 45% of pregnant participants believed that e-cigarettes were less harmful than traditional cigarettes, and 43% thought that e-cigarettes were less harmful to their child's health [13]. Interestingly, in the analysis taking into account the status of „smoking" of e-cigarettes („smoking", „never smoking"), differences appeared. Most e-cigarette users believe that e--cigarettes are less harmful than traditional cigarettes for themselves and for the child (78% and 68%, respectively). Conversely, less than half of women who have never used e-cigarettes said that e-cigarettes are less harmful than traditional cigarettes for themselves and for the child (31% and 31%, respectively). While the majority (61%) of respondents considered e-cigarettes to be addictive, 43% said that they do not know that e-cigarettes contain nicotine [13]. A qualitative study conducted in Houston, Texas by Kahr et al. (2015) assessed the perceived risk associated with e-cigarettes and smoking during pregnancy at three clinics in the Houston area. Study participants were actively involved in prenatal care Centering Pregnancy (CP). Kahr et al. found that pregnant women believed that e-cigarettes are generally a safer and healthier alternative to smoking traditional cigarettes [14]. However, study participants also

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expressed the opinion that during pregnancy, e-cigarettes are not safe and potentially harmful to the fetus and probably as harmful as traditional cigarettes. Interestingly, a conflicting subtopic emerged in this study that suggested that using e-cigarettes in pregnancy is not as harmful as smoking traditional cigarettes when used as an aid to stop smoking. Although the participants had knowledge about how and where buy e-cigarettes, they had less knowledge about the composition of the e-cigarette and the health consequences of its use. Baeza-Loya et al. conducted a cross-sectional study to assess the opinion on the safety of e-cigarettes compared to traditional cigarettes. Participants in the study were both women and men using and not using e-cigarettes and traditional cigarettes. The age ranges included 'young adults' and 'older adults'. The survey included questions about traditional tobacco cigarettes and e-cigarettes, in particular participants were asked about opinions about the harmfulness of traditional cigarettes and e-cigarettes for pregnant women. While almost 100% of respondents (in all age categories) indicated that traditional tobacco cigarettes are harmful to pregnant women, only 50-75% of participants indicated that e-cigarettes are harmful to pregnant women. These results suggest that although study participants saw potential harm in using e-cigarettes during pregnancy, they still considered e-cigarettes to be safer than traditional tobacco cigarettes [15]. England et al. conducted a study to assess the perception of newly formed tobacco products among pregnant women and women planning pregnancy. Questions were asked about the status of smoking, as well as opinions on the health effects of new tobacco products (such as e-cigarettes, snus, soluble products) and the use of nicotine replacement therapy (NRT) during pregnancy and in general. 31% of respondents were pregnant smokers, 26% were pregnant and quit smoking, and 42% were smokers planning pregnancy. Participants of the study expressed the opinion that nicotine-containing products are harmful during pregnancy, but they could not answer which product they think is the most harmful. While several women considered NRT or soluble drugs to be least harmful during pregnancy, most participants most often mentioned ENDS (electro-

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nic nicotine delivery systems) or e-cigarettes as the least harmful [16]. In addition, Farquhar, Mark, Terplan, Chisolm have shown that there is a widespread belief that e-cigarettes are potentially safer than traditional cigarettes [17]. They conducted a case study of a 22-year-old single woman who participated in the perinatal treatment program. The patient said that she knew that e-cigarettes contain nicotine, but in her opinion the use of e-cigarettes during pregnancy was less harmful to her and her child's health. The patient also expressed her belief that e-cigarettes provided her child with less nicotine than traditional cigarettes. Ashford et al. conducted a study of women, including pregnant women. This study evaluated opinions about the health risks associated with the use of e-cigarettes. While 69% of participants perceived e-cigarettes as a moderate or minor health risk, 20% perceived products as not posing any health risk. In the assessment of the reasons why participants decided to use e-cigarettes, „less harmful (for others and for themselves)" was one of the four most frequently mentioned reasons [18]. Fallin et al. conducted a study to assess knowledge, attitudes and insights about the use of e-cigarettes among pregnant women (n=8) and after delivery (n=4). Knowledge on e-cigarettes, patterns of use and perception of e-cigarettes as beneficial/ harmful to health were examined. It was found that participants were convinced that e-cigarettes are less harmful than traditional cigarettes; one participant described e-cigarettes as „not as dangerous as regular cigarettes" and „cleaner option". However, participants also revealed their ignorance of the health effects of using e-cigarettes regarding potential side effects and unknown product composition [19]. Mark et al. observed that three-quarters of pregnant respondents perceive e-cigarettes as a tool to help stop smoking. Interestingly, there were no differences between those using and not using e-cigarettes, and those who had previously quit smoking and those who had never tried to quit before [20]. Kahr et al. observed that pregnant women believe that e-cigarettes can be used as a tool to stop smoking traditional cigarettes. This point of view was particularly often expressed by current smokers [14]. Fallin et al. also observed that respondents believe that an e-cigarette can serve

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as a smoking cessation device [19]. England et al. noted similar results in their study [16]. In a case study conducted by Farquhar, Mark, Terplan and Chisolm, it was found that the participant switched to the use of e-cigarettes during pregnancy to reduce the number of traditional cigarettes smoked per day [17].

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Risk-reducing Mastectomy along with Breast Reconstruction – the Current State of Knowledge

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Abstract

Risk-reducing mastectomy (RRM) with breast reconstruction is performed in women at high risk and highest risk of breast cancer incidence. The objective of this work is to discuss current recommendations with regard to performance of such a type of surgeries based on recommendations accepted both in Western Europe, as well as in the United States and recently, also in Poland. The work presents principles of qualification for RRM, the types of performed surgeries of breast removal and reconstruction as well as complications related to them. Risk-reducing mastectomy consists in bilateral breast removal in women at high and highest risk of the disease and is a form of primary prevention. After RRM performance there is a possibility of surgical restorative treatment - breast reconstruction.

Reconstruction may be carried out using implants, tissues of a patient (most often musculocutaneus flap) or a combination of these methods, either in a in deferred mode or immediately after breast amputation. An informed decision is taken by a patient after a very detailed and in-depth analysis of pros and risks related to the surgery presented to her by a team consisting of: an oncologist surgeon, a medical geneticist, a psychologist and a rehabilitator. The scope of psychological and rehabilitation care of women after the RRM has not been clearly defined yet. Discussion with regard to other methods of primary prevention of breast cancer goes beyond the scope of this work.

Key words: *risk-reducing mastectomy, breast reconstruction, breast cancer*

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Introduction

Women in the case of who the lifetime risk of breast cancer incidence is estimated at the level of >20% according to the National Comprehensive Cancer Network or >30% according to the National Institute for Health and Care Excellence, should be informed about a procedure that reduces the risk of breast cancer incidence, such as: removal of ovaries and fallopian tubes, taking hormonal drugs (e.g. tamoxifen, exemestan) or bilateral breast amputation (RRM) with the possibility of a surgical restorative treatment (breast reconstruction).

Surgeries reducing the risk of breast cancer incidence may be carried out only in women older than 18 years of age, who are at high or very high lifetime risk of this cancer incidence and their life expectancy is ≥10 years. A decision to choose this method of conduct should always be conscious [1,2,3,4,5].

Determination of the groups of a high and very high risc of breast cancer incidence

Selecting women with risk factors for breast and/or ovarian cancer incidence from the general population requires performance of genetic analyses. Women from families with a history of breast and/or ovarian cancer (including male breast cancer) and other malignancies, especially those diagnosed when <50 years of age, are eligible for the examinations.

Carriers of pathogenic gene mutations should have preventive examinations aimed at early detection of breast and/or ovarian cancer or other malignant neoplasms performed more frequently and they should be informed about surgical and conservative procedures reducing the risk of developing these neoplasms.

Based on statistical methods and the theory of probability, a division into three groups of a risk of breast cancer incidence was developed and it is presented in Tables 1 and 2.

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The lifetime and accumulated risk (within the age range from 0-79 years) of breast cancer incidence in Poland, in 2010, amounted to 6,3% [6]. Women from the groups of a very high and high risk of breast cancer incidence are qualified for RRM. The analysis of genetic and family predispositions is presented in Tables 3 and 4 [7,8,9,10,11,12].

Table 1. A moderate, high and very high risk of breast cancer incidence expressed as a chance of the disease occurrence (%) (National Institute for Health and Care Excellence, 2013, updated 2017) [13,14]

A woman's age	A moderate risk (indirect)	A high risk	A very high risk (the highest risk)
Accumulated risk of incidence 40-50 years of age	3%-8%	≥8%	8%-30%
Lifetime risk of incidence*	17-30%	>30%	≥50%

*The lifetime risk of breast cancer incidence, assuming the age of 20 as the lower limit, and the upper limit for the age close to the average life expectancy of women in the Polish population (mainly includes women who are at risk of developing cancer being a new case in the population).

Table 2. A moderate, high and very high risk of breast cancer incidence expressed as a number (a relative risk) defining the risk of the disease development in the group of women exposed to a potentially pathogenic agent compared to the group of women who are not exposed (understood as the general population) [13,14]

A woman's age	A moderate relative risk** (indirect)	A high relative risk	A very high relative risk (the highest risk)
0-79 years	2-3	~5	≥10

**The risk of breast cancer incidence in the group of women exposed to a potentially pathogenic agent in comparison with the non-exposed group (understood as the general population).

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Table 3. The group of a very high lifetime risk of breast cancer incidence (≥50%) [13,14]

The group of the highest risk of breast cancer incidence includes individuals with a defined:	
Genetic factor and/or	A pathogenic mutation of the BRCA1 or BRCA2 or TP53 or PTEN*** gene confirmed in a molecular study
Family factor and/or	≥3 breast cancer cases in the 1st or 2nd degree relatives (including a female probant) in one family line regardless of the age at which the disease occurred
	Female probants whose first degree relatives had breast and ovarian cancer (synchronous or metachronic disease)
	Female probants whose first-degree relatives had a few (≥2) primary cancer of the pancreas, prostate, endometrium, thyroid, leukemia or malignant brain tumor
Other	Chest radiation below 30 years of age (relative risk: 7.0-17.0)

***A lifetime risk of breast cancer incidence among carriers of PTEN gene mutation amounts to 25%-85% and depends on the kind of mutation and the frequency of breast cancer incidence among relatives of the mutation carrier.

Table 4. The group of a high lifetime risk of breast cancer incidence (>30%) [15,16]

The group of a high risk of breast cancer incidence includes individuals with a defined:	
Genetic factor and/or	Pathogenic mutation of the CDH1 or STK11 gene confirmed in molecular studies (the risk is also referred to as elevated or equivocal) or PALB2 or NF1
Family factor and/or	Female probants who had two breast cancer cases among the first or second degree relatives in the same family line (i.e. on the paternal or maternal side), with at least one incidence <50 years old
	Female probants whose first and/or second degree relatives suffered from bilateral breast cancer
	Probants whose mothers or sisters had breast cancer before the age of 40
Other	A history of atypical ductal hyperplasia or lobular, or lobular carcinoma (LCIS) in situ (relative risk: 4.0-5.0)

Rules for quantifying woman for genetic testing

Before qualification for genetic testing it is recommended to assess an individual risk of carrying pathogenic mutations of specific genes in a gi-

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ven probant. The minimum probability of detecting irregularities of genetic material, authorizing the person to have genetic tests performed, is considered to be equal to or above 10%. Determination of the probability of detecting a pathogenic mutation is based on the pedigree analysis and clinical-pathomorphological data if a probant suffers from breast cancer. Risk assessment programmes the sensitivity of which amounts to 80%-90% may also be used. They are a kind of mathematical models in which selected individual-clinical-pathomorphological parameters are assigned a specific score. The simplest and clinically useful programmes for predicting detection of BRCA1/2 gene mutation are the Manchester Scoring system and Referral Screening Tool allowing for determination of the likelihood of detecting BRCA1/2 gene mutation both in breast and/or ovarian cancer patients and healthy women with aggravating family factor. One of the most important parameters for qualification for genetic testing is the age of the onset of a malignant neoplasm (the age of the probant and/or her relatives) – the younger the age, the higher the risk of carrying a mutation. Correct estimation of the risk of carrying BRCA1/2 genes in a patient with breast and/or ovarian cancer should also include at least one parameter of pathomorphological assessment. A person with a high probability of carrying BRCA1/2 gene mutation (> 25%) is a woman/man with primary invasive breast cancer without a special type (NOS), neither expressing estrogen and progesterone (ER-/PgR-) steroid receptors nor overexpression receptor for human epidermal growth factor type 2 (HER-2), with a high degree of histological malignancy (grade 3 or 2), diagnosed before the age of 40 in the case of women or – regardless of age – in the case of men. Positive results of molecular tests constitute the final confirmation of carrying BRCA1/2 genes mutation (http://annals.org/on07/29/2018). Therefore, they should be performed in women who have been diagnosed with metachronic or synchronous breast and ovarian cancer or breast and endometrial (or cervical or pancreatic cancer or melanoma), in those whose first-degree relatives had

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breast and ovarian cancer, women with primary ovarian cancer, men with primary breast cancer as well as in people at highest and high risk of breast and/or ovarian cancer incidence based on the pedigree analysis, supported by appropriate medical documentation [17,18,19,20,21].

Bilateral risk-reducing mastectomy – BRRM

Bilateral risk-reducing mastectomy lowering the risk of breast cancer in healthy women with a high and highest risk of its occurrence should be considered for all carriers of the pathogenic mutation of BRCA1 and/or BRCA2 gene.

It is also recommended for all young women below 30 years of age who have received therapeutic chest irradiation and have an expected life expectancy of >10 years. Scientific reports describe breast cancer cases in patients with Hodkin's lymphoma, who were radically irradiated in the mediastinal area and the area of axillary pits. This risk increases especially when a high dose is used – above 40Gy, showing a linear relationship between the dose and the tumor development [22,23]. Modern irradiation techniques as well as multi-drug chemotherapy have improved the prognosis of patients with Hodkin's lymphoma significantly, extended the survival time at the same time increasing the risk of secondary cancers, including breast cancer by about 10% [24].

Bilateral breast amputation in a healthy woman is not only a mutilating procedure, but it also involves a risk of complications, which is why the decision to perform it should be carefully considered, with taking into account primarily a patient's well-being. In each case it is necessary to weigh the benefits against the risks, taking into account, among others a patient's age and individual risk factors for a malignant neoplasm. Every woman before being subjected to BRRM should undergo a genetic and psychological consultation.

Before taking the final decision, a patient must be informed about the possibility of breast reconstruction and about the methods (e.g. implant, musculocutaneusy flap) and the time of its performance (immediate, de-

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ferred). Pros and cons of each type of amputation should be explained to a patient and she should have a free and independent choice of it.

A decision whether mastectomy and reconstruction are to be performed simultaneously (an immediate reconstruction), or as a two-stage procedure with prior placement of an expander, or as a multi-stage procedure with a deferred reconstruction and reconstruction of the papilla-areola complex, is taken by a patient herself.

Regular preventive examinations constitute an alternative to RRM. A patient should be clearly informed about the benefits of oncological surveillance and its effectiveness compared to performing a risk-reducing mastectomy (RRM). A patient should be also informed about other methods of primary prevention of breast cancer, i.e. ovariectomy or the use of hormonal drugs [25,26].

Studies have shown that different ethnic groups of women perceive the risk of breast cancer incidence differently, which translates into the choice of different options for its reduction. In an ethnically and racially heterogeneous population of 1,700 healthy women aged 40 to 74 years who underwent mammography, Caucasian women were more open to discussion about breast cancer prevention than women of other races. Detection of primary breast lesions during mammography significantly increased their interest in the issue of reducing breast cancer risk, including the possibility of having RRM [27].

Contralateral risk-reducing mastectomy in women with primary breast cancer from the groups of a high and the highest risk of breast cancer incidence

Patients with primary breast cancer diagnosed before the age of 50, who at the same time are also carriers of pathogenic mutations of the BRCA1/2, PALB2, TP53, PTEN, CDH1, STK11, NF1, CHECK2 genes have a 40% risk of developing second breast cancer.

Such patients should be offered a contralateral risk-reducing mastectomy to reduce the risk of second breast cancer (CRRM). Candidates for

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this type of treatment may also be patients who are not carriers of pathogenic mutations, but who have a positive family history of -2 or more documented cases of breast and/or ovarian cancer [AGCA, Wright recommendations from 2017 and by ESMO and SEOM].

The Polish Society of Clinical Oncology extends indications for CRRM in patients with infiltrating breast cancer detected before the age of 40 or in situ lobular carcinoma (LCIS) if it has been diagnosed before the age of 40 and, in addition, the patient is a carrier of the BRCA1/2 gene pathogen aggravating family history: multiple cases of breast and/or ovarian cancer or breast cancer in a first degree relative below 40 years of age or male breast cancer regardless of age.

It has been indicated that the risk of second breast cancer incidence within 10 years from the first diagnosis is estimated to be at the level of 32% in carriers of BRCA1 gene mutation and 24.5% in carriers of BRCA2 gene mutation [28]. The risk increase has been associated with the age of patients at the moment of the first diagnosis of breast cancer and amounted to 31% and 23.5% for the patients below and over 50 years of age, respectively. Similar observations have been reported by Menes et al., though they have not confirmed the association for carriers of BRCA2 gene mutation. The risk of second breast cancer incidence in a 10-year follow-up amounted to 21% for patients diagnosed with breast cancer before the age of 40 and 11% for patients with breast cancer diagnosed after 40 years of age.

A meta-analysis of Molina-Montes et al. has shown that in the case of carriers of mutations in the BRCA1 and/or BRCA2 genes the risk of second breast cancer incidence during 5 years of follow-up was 15% and 9%, respectively, and it increased with time, reaching 27% and 19% after 10 years. In patients without a detected BRCA1/2 genes mutation, the risk of second breast cancer incidence in a 5-year and a 10-year follow-up was significantly lower and amounted to 3% and 5%, respectively [29]. In a study of 506 women with unilateral breast cancer without a confirmed BRCA1/BRCA2 gene mutation, 112 of them (22.1%) selected a contralateral risk-reducing mastectomy. Women who chose CLRRM were youn-

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ger; the second breast cancer had a non-invasive nature; they had less pre-operative satisfaction associated with the appearance of their breasts and a lower level of optimism [30].

Types of risk-reducing mastectomy

Research conducted by Hartmann LC, Schaid DJ, Woods JE has shown that preventive mastectomy provides a 90-94% risk reduction for patients at high risk of breast cancer incidence and 89.5% risk reduction for patients at medium risk of breast cancer incidence. The data correlate with the current recommendations of NCCN and Wright 2017. No differences have been indicated between clinical efficacy and the applied surgical method [31]. The cosmetic effect of a properly performed surgery is satisfactory, acceptable by a patient and does not disturb anatomical proportions. Also the influence on the level of self-esteem, quality of life and sexual activity of a woman is not without significance[1].

Breast reconstruction is performed at the same time as mastectomy or as a deferred/ two-stage procedure, using an artificial implant or own tissues.

Patients qualifying for RRM can be offered a choice of one of the described below surgery methods:

1. Simple mastectomy – consists in the removal of the mammary gland along with the areola-papilla complex and excess skin. The end result of it is a transverse scar at the site of the removed gland. This method does not allow simultaneous reconstruction, but it is possible to postpone breast reconstruction by the use of skin-muscular flaps or an expander and an implant. This technique is rarely chosen by a surgeon in the case of women qualified for preventive mastectomy, it is more often chosen by the patients themselves.
2. Nipple sparing mastectomy, NSM – consists in the removal of the mammary gland with saving the skin above the gland and the areola-papilla complex and formation of the so-called "skin envelope" for the applied implant. This method is proposed to patients in the

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case of who simultaneous breast reconstruction using an expander, implant or autologous fat transplant is planned. In the case of preventive mastectomy, the risk of Paget's cancer or cancer that occurs locally is minimalized. Safety of this procedure has been assessed in a multicenter study conducted in 55 healthy women at high risk of breast cancer incidence and 27 patients with primary breast cancer who were qualified for preventive mastectomy of the other breast. It has been shown that breast cancer occurred in two cases – 61.8 and 24.4 months after the surgery, but none of them was located in the spared papilla-areola complex. Studies by other authors have shown that NSM, despite saving the terminal ductal lobular unit (TDLUs), does not increase the risk of cancer development in the saved nipple, even in the case of carriers of pathogenic BRCA1/2 gene mutations [31,32]. The most serious complication of this method is the risk of necrosis of the saved areola-papilla complex, which affects about 10% of the operated women, while minimal necrosis (<1/3 of the wart) concerns about 60% of the cases. Other possible complications include: separation of sutures, various degrees of necrosis of the skin over the implant and abnormal wound healing. The risk of necrosis and deterioration of cosmetic effect increases with a decrease in the thickness of the left skin and glandular flap, while the risk of breast cancer after sparing mastectomy increases along with the volume of the spared glandular tissue. Possibility of performing endoscopic mastectomies that save the areola-papilla complex, the effect of which is a smaller scar, a better cosmetic effect and a lower incidence of complications should also be mentioned [33,34].

3. Skin sparing mastectomy, SSM – consists in the removal of glandular tissue along with a partial or complete removal of the papilla-areola complex. This procedure allows simultaneous reconstruction with low skin tension, leaving a small scar and restoring the natural shape of breast. At a later stage, patients are proposed a reconstruction of the nipple and micropigmentation of the

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nipple areola. In the study conducted over the years 2001-2005 by Garwood et al. in a group of 170 patients subjected to skin sparing mastectomy, the following complications occurred: papillary-areola necrosis 5-15%, surrounding tissues necrosis 13-30%, implant loss 10-31%, skin flap necrosis 11-16%, wound infection 9-17%. The risk of failure in a form of necrosis decreases with the use of an expander, but increases with reconstruction using a patient's own tissues and removal of >30% of the papilla-areola complex [33].

Methods of breast reconstruction after risk-reducing mastectomy

The methods of breast reconstruction after risk-reducing mastectomy divided depending on type of material presented in Table 5.

Patients who do not decide to undergo breast reconstruction may use external prostheses classified as medical devices and issued upon the request of an oncologist.

Implementation of the procedure of risk-reducing mastectomy: the types of risk-reducing mastectomy and breast reconstruction carried out in accordance with the regulation of the Ministry of Health.

According to the ordinance of the Minister of Health of January 9, 2019 preventive mastectomy is a benefit reimbursed by the National Health Fund, including the procedure of unilateral or bilateral breast amputation and the procedure of unilateral or bilateral reconstruction, simultaneous or deferred. The Regulation unifies the conditions for benefit performance. The document standardizes qualification of patients for the surgery. It is recommended that the process of including patients into the treatment including risk-reducing mastectomy is carried out by a multidisciplinary team consisting of a psychologist, a physician specializing in clinical genetics and a physician specializing in the field of oncological surgery or plastic surgery. In the Regulation, it is recommended that the procedure should be performed in breast unit centers by physicians certified in the field of breast reconstruction.

Table 5. Methods of breast reconstruction after risk-reducing mastectomy

Reconstruction using an implant	Reconstruction using autologous adipose tissue	Reconstruction using musculocutneus flap
One step Two stages using an expander	Lipofiling/lipotransfer Directly to the major pectoral muscle, lateral fascia of the chest and under the skin left after removal of the mammary gland [33].	DIEP flap (deep interior epigastric perforators) LD flap (latissimus dorsi flap) TRAM flap (transverse recus abdominis musle flap) I-GAP flap (inferior gluteal artery perforator) S-GAP flap (superior gluteal artery perforator) TUG flap (transverse upper gracilis) TDAP flap (toracodorsal artery perforator flap) LICAP flap (lateral intercostal artery perforator flap)
Possible with SSM and NSM or with a simple mastectomy expander. An implant can be inserted prepectorally or subpuectorally.	As an independent reconstruction method, complementary to the reconstruction using an implant to improve the cosmetic effect. The regenerative properties of adipose tissue enable formation of the desired shape of breast. They prevent skin over the implant necrosis and increase the success of the procedure [34].	After a simple mastectomy or inability to use an implant or after unsuccessful reconstruction by the use of an implant. As an independent reconstruction method or complementary to reconstruction using an implant.

Source: own elaboration based on data from:

Stark RY, Mirzabeigi MN, Vonderhaar RJ, Bucky LP. Utilizing large volume fat grafting in breast reconstruction after nipple sparing mastectomies. Gland Surg 2018; 7(3): 337-346.

Buro JS, Toyoda Y, Celie KB, Lin AJ, Morgan JP, Spector JA. Efficacy and Outcomes of Fat Grafting Beyond the Breast: A Meta Analysis. Plast Reconstr Surg Glob Open 2018; 6(9 Suppl): 22-22.

The paper contains a review of the current guidelines of the National Comprehensive Cancer Network (NCCN), the Polish Society of Clinical Oncology (PTOK), Europen Society of Medical Oncology (ESMO), Wright 2017.

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Analysis of Clinical Trials Conducted in Oncology in the Greater Poland Voivodship against the Background of Poland

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Abstract

Introduction: *Clinical trials are an opportunity for healthcare systems to raise treatment standards, and for patients to be able to access innovative therapy. Conducting clinical research is a complex process that requires special involvement of research teams. Cancer comes second among the causes of death among Poles. The huge potential of clinical trials in oncology results in leading in the number of clinical trials by fields of medicine in Poland.*

Aim: *The aim of the study is to analyse the number and phases of clinical trials in oncology in the Greater Poland voivodship against the background of Poland.*

Material and methods: *Statistical data for work were collected from the National Cancer Registry in Poland, the European Statistical Office, the Central Statistical Office in Poland, the PwC report about clinical trials and the clinicaltrials.gov database. The clinicaltrials.gov database of clinical trials was used to analyse the individual number of studies and their phases, by type of cancer. It was also analysed in terms of the number of experiments carried out in individual cities in Greater Poland and against the background of Poland.*

Results: *In Poland there are 1523 clinical trials, of which as many as 575 are studies in oncology. The 503 clinical experiments are conducted in the Greater Poland voivodship. In Poznań 453 trials are conducted, in oncology – 225. In Poland, the majority of clinical trials (21%) are conducted in lung cancer. In the Greater Poland voivodship (31%) lung cancer trials are also dominant. The phase III clinical trial leads in both groups.*

Conclusions: *In Poland, the most clinical trials are conducted in oncology. The Greater Poland voivodship reflects the trend of clinical trials in Poland. Inhabitants of the Greater Poland voivodship have access to 39% of clinical trials in Poland in the field of oncology and 33% access to clinical trials without di-*

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vision into the therapeutic area as compared to the whole country. The implementation of phase I centres will allow for the increase of interest of potential clinical trial sponsors in Poland, which will be a positive impulse for the country's economy.

Key words: *clinical trials, research phases, cancer, phase III, clinical research*

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Introduction

Clinical trials are an indispensable element in the development of medicine, they are a chance for healthcare systems to raise treatment standards, and for patients the opportunity to access innovative therapy. Cancer in Poland is the second cause of Poles' mortality, only the cardiovascular diseases are ahead of it [1]. In the world in 2018 alone, 18.1 million new cancer cases were reported [2]. Clinical trials allow modern medicine to fight cancer better and better by introducing new drugs and treatment regimens. Unfortunately, the decreasing number of clinical trials in 2009-2014 limits the possibilities of Polish doctors to meet treatment standards in comparison with countries leading in the area of clinical trials [3]. Conducting medical experiments is a complex process, thus the analysis of ongoing clinical trials in oncology in Greater Poland voivodship against the nationwide trend allows to learn the trend in the number and phases of clinical trials for the given voivodship and Poland. The current situation of newly registered clinical trials in Poland shows a downward trend. In 2011, we recorded 495 new clinical experiments conducted in Poland, in 2014 there were only 396 of these studies [3].

Aim

The purpose of this work is to analyse clinical trials in the Greater Poland voivodship against the nationwide trend in the field of oncology. The Greater Poland voivodship is the third largest voivodship in Poland in terms of population, which is why the analysis of the number of clinical trials conducted in the voivodship will allow to identify the types of malignant neoplasms in which the most research is conducted [4]. The analysis will also provide information on the phases and status of clinical trials in the Greater Poland voivodship and Poland.

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Method

To analyse the number of ongoing clinical trials in Greater Poland against the nationwide trend, the www.clinicaltrials.gov website was used, which is the database of private and publicly funded clinical trials conducted worldwide. Information is provided by the US National Library of Medicine. Each diagram analysis used in the paper is based on the results from www.clinicaltrials.gov. 10 largest cities in terms of population of the Greater Poland voivodship were included in the analysis, i.e. Poznań, Kalisz, Konin, Piła, Ostrów Wielkopolski, Gniezno, Leszno, Luboń, Swarzędz, and Września. To assess the number of clinical trials in the field of oncology, the focus was on the most common incidence of malignancies in Poland. The phases of clinical trials have been divided into four main ones, i.e. I, II, III, IV. The analysis of individual types of malignant tumours included cancers with the most frequent incidence in Poland in 2013, without sex division i.e. lung cancer, lymphoma, breast cancer, leukaemia, prostate cancer, ovarian cancer, stomach cancer, colorectal cancer, bladder cancer, renal cell carcinoma, hepatocellular carcinoma, brain tumour, pancreatic cancer, cervical cancer [5]. All results from the www.clinicaltrials.gov website are from analysis period between 01.07.2019 to 30.07.2019. Data access day is mentioned with each analysis.

Results

There are 1523 clinical trials in Poland, of which 876 (57.5%) are in the patient recruitment phase and 647 (42.5%) are in the active phase after the recruitment process.

The largest number of clinical trials by therapeutic field is conducted in oncology – 575, which is 37% of all clinical trials in the country. The second field in which the most clinical experiments are conducted is neurology – 174, that is about 10% of market share (Figure 1). The difference in the market share of clinical trials between the first and second fields is 27%, therefore, the position of oncology as the leading field in which

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clinical trials are conducted in Poland is not expected to change in the coming years, which is also closely related to forecasts of the increase in the incidence of malignant neoplasms in Poland [6].

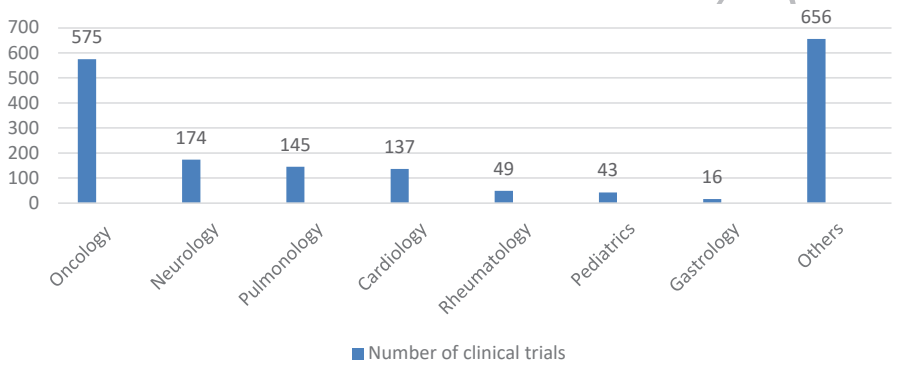

Figure 1. The number of clinical trials in Poland divided into therapeutic areas (active + recruitment)

Source: clinicaltrials.gov [cited 10.07.2019].

503 clinical trials are conducted in the Greater Poland voivodship, there are 250 (49%) in the recruitment phase, and 253 (51%) in the active phase (after the recruitment is completed). The 10 largest cities in the voivodship have been included in the analysis. 10 largest cities in terms of population of the Greater Poland voivodship were included in the analysis, i.e. Poznań, Kalisz, Konin, Piła, Ostrów Wielkopolski, Gniezno, Leszno, Luboń, Swarzędz, Września [7]. The most clinical experiments are conducted in Poznań – 453, due to the location of university clinics in the city and several times higher number of inhabitants compared to other cities. In the field of oncology 225 (44.7%) clinical trials are being conducted in Greater Poland voivodship. Most research is conducted in Poznań in the post-recruitment phase – 103 (45.7%), in the recruitment phase – 94 (41.7%). The second city in terms of the number of medicinal product trials is Konin, which carries out 21 (9.3%) trials after closing recruitment and 7 (3.1%) in recruitment to the trial. Eight out of ten cities included in the analysis in Greater Poland do not conduct clinical research in the

field of oncology, i.e. Kalisz, Piła, Ostrów Wielkopolski, Gniezno, Leszno, Luboń, Swarzędz, Września.

When comparing Greater Poland voivodship to the whole country, individual cancer diseases must be taken into account. To compare the number of clinical trials in oncology in the Greater Poland voivodship with the whole country, malignant neoplasms with the most frequent incidence in Poland were included in the analysis, i.e. lung cancer, lymphoma, breast cancer, leukaemia, prostate cancer, ovarian cancer, stomach cancer, colorectal cancer, head and neck cancer, bladder cancer, kidney cancer, liver cancer, brain cancer, pancreatic cancer, cervical cancer [8].

In Figure 2 and Figure 3 we can see that in nationwide trend in cancer diseases a lung cancer dominates. In this diagnosis 96 clinical trials are carried out, which is 21% of the total. The second cancer with 81 clinical trials (18%) is a group of cancers of the lymphatic system. Third place is breast cancer with 67 medical experiments (15%). The next one is leukaemia with 59 trials and is the last group of cancers that exceeds 10% of therapeutic experiments in Poland. Next are prostate cancer – 27 trials (6%), ovarian cancer – 24 trials (5%), stomach cancer – 17 (4%), colorectal cancer – 16 (4%), bladder cancer – 14 (3 %), renal cell carcinoma – 14 (3%), hepatocellular carcinoma – 9 (2%), brain tumour – 7 (2%), pancreatic cancer – 7 (2%), cervical cancer – 7 (2%). Analysing Figure 4 in terms of the number of clinical trials in oncology in the Greater Poland voivodship, lung cancer with 50 trials (31%) is leading, breast cancer with 30 trials (16%) is in the second place and third is ovarian cancer – 16 trials (9%). Further groups of cancers in which clinical trials are conducted in the Greater Poland voivodship are: lymphoma – 14 (8%), renal cell carcinoma – 12 (6%), stomach cancer – 8 (4%), head and neck cancer – 11 (6%) prostate cancer – 6 (3%), bladder cancer – 6 (3%), pancreatic cancer – 5 (3%), leukaemia – 4 (2%), brain tumours – 3 (2%), hepatocellular carcinoma – 2 (1%), cervical cancer – 2 (1%).

Comparing the Greater Poland voivodship to the situation of clinical trials in cancer in Poland, we can see that the largest group in which the most clinical trials are conducted is lung cancer in both study groups – 21% (Poland) to 31% (Greater Poland). In Greater Poland voivodship,

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breast cancer is in the second place with 16% of trials, in the nationwide group breast cancer ranks third (15%). The group of lymphatic neoplasms in Poland covers as much as 18% of trials, this percentage in Greater Poland is a 9% share of the total number of trials.

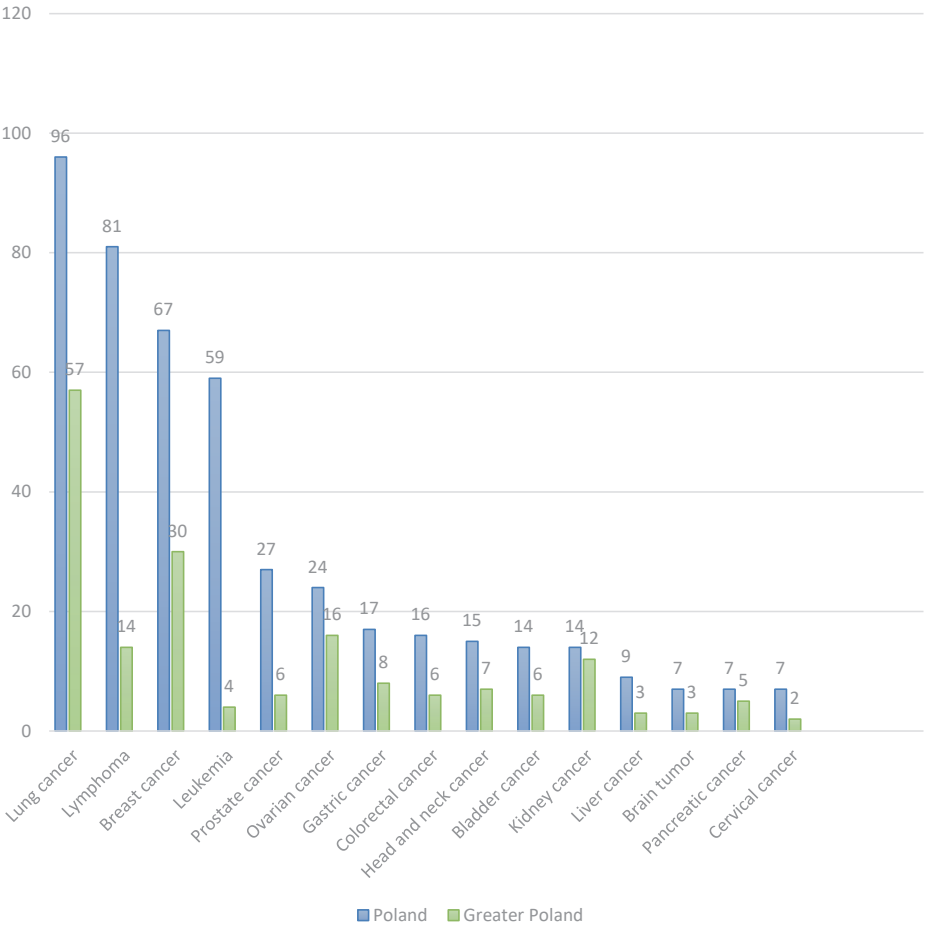

Figure 2. The number of clinical trials for specific malignancies in Greater Poland and Poland

Source: clinicaltrials.gov [cited 15.07.2019].

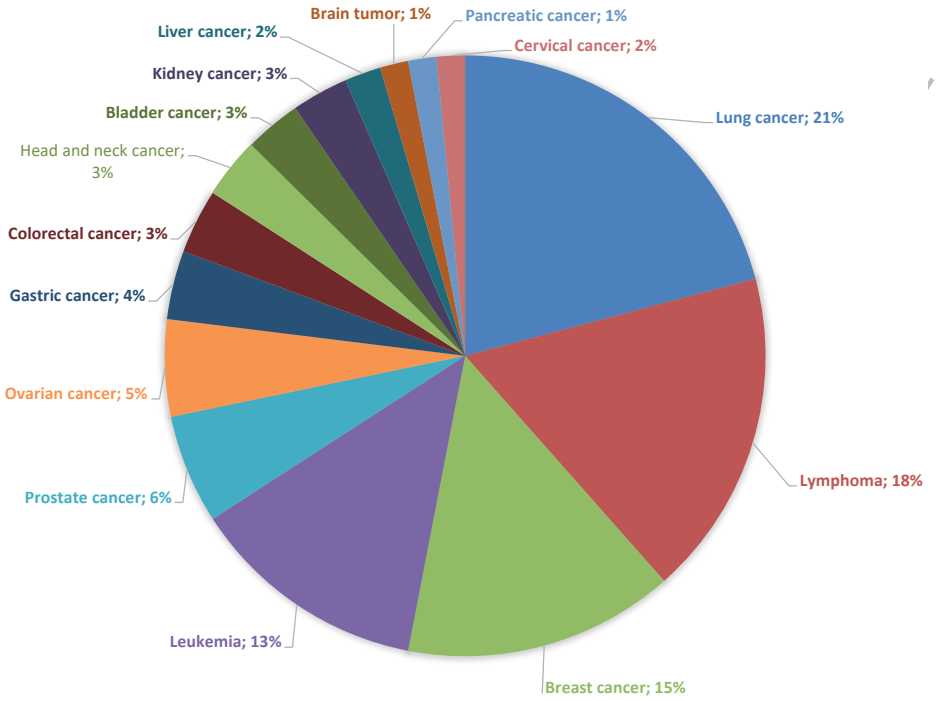

Figure 3. The number of clinical trials for specific cancer in Poland

Source: clinicaltrials.gov [cited 15.07.2019].

Analysing Figure 5, in Poland in the field of oncology, the most phase III clinical trials are conducted – 357 trials, which represents 63% of the total. The second place is phase II with 151 tests (26%), the third is phase I – 45 tests (8%), the last is phase IV – 16 tests (3%).

In the Greater Poland voivodship in the field of oncology, the most research is conducted in phase III – 130 trials, which represents 65% against all phases. Phase II is 48 studies (24%), which puts it in the second place. Phase I is 16 studies (8%), which gives it the third place. In the last place is phase IV – 6 tests (3%).

To sum up, no significant differences in Greater Poland occur in comparison to the whole country when it comes to participation in the phases of clinical research in the field of oncology. Phase III strongly dominates in Greater Poland – 65% to 63% in Poland in both groups. Phase

II trials take up 24% share in Greater Poland and 26% in Poland. Phase I, however, is at the same low level of 8% in both study groups. The marginal number of studies in phase IV is at the level of 3% in Greater Poland and Poland.

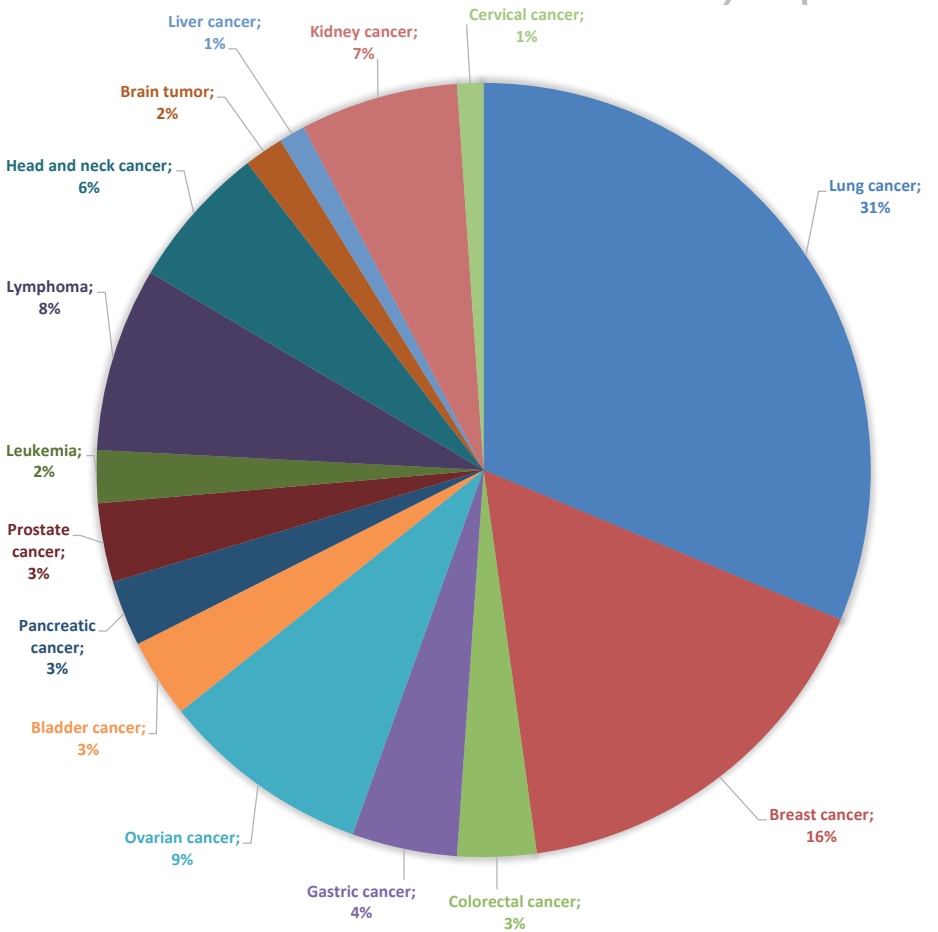

Figure 4. The number of clinical trials for specific cancer diseases in Greater Poland

Source: clinicaltrials.gov [cited 15.07.2019].

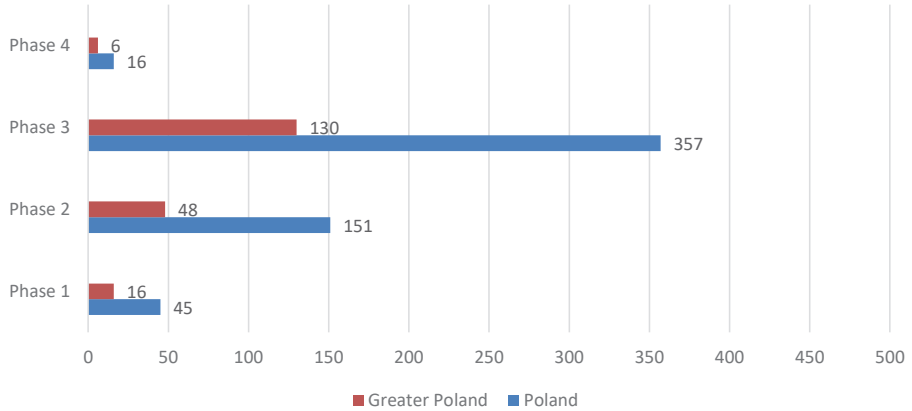

Figure 5. The number of studies divided into phases in which clinical trials in oncology is conducted Source: clinicaltrials.gov [cited 20.07.2019].

Groups of cancers with the most frequent incidence in Poland (Figure 6), i.e. lung cancer, breast cancer, and colorectal cancer were included in the analysis of the phases of clinical trials in individual cancer diseases. Analysing Figure 6, most trials are conducted in phase III. Respectively, lung cancer in Poland: phase I – 16 trials (16%), phase II – 27 (26%), phase III – 57 (56%), phase IV – 2 (2 %), in Greater Poland phase I – 7 trials (12%), phase II – 18 (30%), phase III – 34 (56%), phase IV – 1 (2%). Breast cancer in Poland: phase I – 4 trials (2%), phase II – 17 (26%), phase III – 43 (66%), phase IV – no trials, in Greater Poland – phase I – 3 trials (10%), phase II – 9 (30%), phase III – 18 (60%), phase IV no trials. Colorectal cancer in Poland: phase I – 2 trials (17%), phase II – 4 (33%), phase III – 5 (42%), phase IV – 1 (8%), in Greater Poland phase I 1 trial (20 %), phase II – 1 (20%), phase III – 3 (60%), phase IV no trials.

Summing up, in both examined groups (Poland and Greater Poland) in all neoplastic diseases (lung cancer, breast cancer, colorectal cancer) the largest number of clinical trials is conducted in phase III, followed by phase II, phase I, phase IV. There are no significant differences between the two research groups. Greater Poland reflects the trends of clinical trials

in oncology in Phase III against the background of the whole country, as the phase in which the most clinical experiments are conducted.

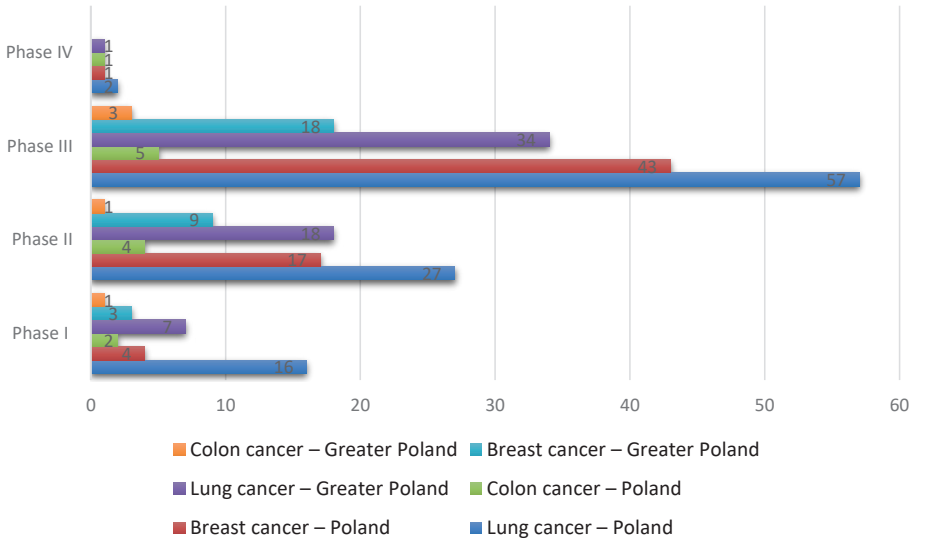

Figure 6. Individual malignancies by phases of clinical trials
Source: clinicaltrials.gov [cited 25.07.2019].

Clinical trials in the paediatric group <18 years of age are characterised by a special way of obtaining informed consent from study participants – both a written consent of a parent and a child is needed if they understand and can give such consent [9]. There are 51 such studies in Poland, and 7 in the Greater Poland voivodship (13.7%). Most trials are conducted in phase III – 24 (47%) Poland, Greater Poland – 4 (7.8%), then in phase II – 15 (29.4%) Poland, Greater Poland – 3 (5.8%), phase I and IV – 1 (1.9%) clinical trial in Poland. Also studies in the paediatric group correspond to the phase III trend, as the phase in which the most clinical trials are conducted compared to medical experiments in the group of adults >18 years of age.

Non-commercial trials (financed from own or public funds) are also carried out in Greater Poland, there are 2 such trials in colorectal cancer. Then, after 1 examination, the following tests are carried out: prostate

cancer, lung cancer, head and neck cancer, ovarian cancer, multiple myeloma, leukaemia, neuroblastoma.

Discussion

In Poland, in 2018 there were 185,630 new cases of cancer, and there were 113,388 deaths caused by cancer [10]. There are only 575 clinical trials in the field of oncology with well-defined criteria for inclusion in the trial. The increasing number of new cancer cases should increase the number of clinical trials in Poland, which would allow access to more innovative therapies for patients. There are more clinical trials being conducted in the recruitment phase in the assessed period than after its completion, which may suggest increasing interest of potential clinical trial sponsors in Poland. Raising patients' awareness of clinical trials is a key challenge for healthcare systems and pharmaceutical companies. According to a study by Bhardwaj P. et al., a strong initiative to transform clinical trials through the European Patient Academy in the field of therapeutic innovations will increase patients' awareness and responsibility [11]. The majority of phase III studies, and the small number of phase I studies indicate the need to create phase I centres that could realise the potential of Polish specialists and attract sponsors of clinical trials and challenge the leader in conducting such trials. Creating coherent recruitment strategies allows to increase the recruitment of patients [12]. One of the strategies that can increase patient knowledge is educational videos on clinical trials [13]. Clinical research is not only the development of science and innovative treatment methods for patients, but also a positive impulse for the country's economy, through the income from VAT paid by pharmaceutical companies. According to the PwC report, a rational increase in the number of clinical trials is possible in Poland, with administrative barriers being lifted, and the precise application of the requirements of Regulation of the European Parliament and of the EU Council No. 536/2014 of April 16, 2014 on clinical trials of medicinal products for human use [3,14]. The Greater Poland voivodship can beco-

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me an indicator for the rest of the voivodships in terms of the number of clinical trials conducted, if they encourage sponsors to invest in research centres not only in Poznań, but also in other cities of the voivodship.

Conclusions

503 clinical trials are conducted in the Greater Poland voivodship, 453 of which in Poznań. Most research in Greater Poland is carried out in Poznań due to the presence of university clinics and a large concentration of specialists. Other cities in Greater Poland that conduct clinical trials are Konin, Ostrów Wielkopolski, Luboń and Leszno. In the field of oncology in Greater Poland, clinical trials are conducted in Poznań and Konin. Research after recruitment in cancer predominates over research at the recruitment stage in Poznań and Konin. Comparing the types of cancers in which clinical trials are conducted in Poland, lung cancer predominates (21%), followed by lymphatic system cancers (18%) and breast cancer (15%). In Greater Poland also lung cancer trials prevail (31%), breast cancer (16%) holds the second place, and ovarian cancer (9%) is third. Comparing both groups of respondents in Greater Poland, less research is carried out on the lymphatic and circulatory system cancers. In both groups lung cancer and breast cancer as an area of clinical research strongly dominate. The division into clinical trial phases in Poland and Greater Poland suggests the overwhelming number of clinical trials in phase III: 63% (Poland), 65% (Greater Poland) in the field of oncology. Considering the types of cancers with the most frequent incidence: lung cancer, breast cancer, colorectal cancer, phase III also prevails in both groups. The number of clinical trials on the paediatric group in Poland is 51, in the Greater Poland voivodship there are 7 such trials conducted. Also here phase III dominates. Non-commercial research is also carried out in Greater Poland – 9 studies.

Inhabitants of the Greater Poland voivodship have access to 39% of clinical trials in Poland in the field of oncology and 33% of clinical trials without division into the therapeutic area as compared to the whole country.

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