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Knowledge of midwives about clinical trials

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Abstract

Introduction: Proper level of knowledge of midwives on the subject of clinical trials is influenced by the participant's safety and the quality of conducted clinical trials.

Aim: The aim of the study was to assess midwives knowledge of clinical trials.

Material and method: The study involved 105 midwives, at the age of 20–54years. The method of a diagnostic survey was used. The study was conducted in period April - December 2018 year.

Results: The majority of respondents - 81% (n=85) knew the correct definition of the clinical trial. The most important benefit of clinical trials for the study group was "creating new treatment standards" (69,5%, n=74), and the greatest risk resulting from clinical trials "was" the possibility of adverse events and events "(92,4%, n=97).

Conclusions: Midwives knowledge about clinical trials is on a sufficient level.

Keywords: midwives, clinical trials, opinions

Introduction

According to various literatures, the global market for clinical trials is estimated at USD 50-80 billion, and in 2018 around 29,000 people were registered in the world. new clinical trials [1]. In Poland, the value of the clinical trials market in 2014 was estimated at PLN 950 million. Currently, 6036 clinical trials are conducted in Poland [2]. In our country, the number of clinical trials is growing every year, and health care professionals will more and more often meet clinical trial participants on their professional path. Considering the above issues, it is important that representatives of medical professions represent a high level of knowledge in clinical trials.

Objective

The aim of the study was to assess the level of knowledge of midwives on clinical trials. The detailed objectives included determining the level of midwife's awareness of the basics of clinical trials, identifying the benefits of clinical trials, but also the risks, problems, and doubts associated with them, identifying midwives' motives for possible work in the field of clinical trials.

Material and method

The respondents with medical education and the right to practice the profession of midwives constituted the group of respondents.

For the purposes of this work, an original questionnaire was created, the questions of which were created on the basis of the knowledge on clinical trials obtained during the studies and in connection with the professional work of one of the authors of this work. The questionnaire included questions about basic knowledge related to clinical research. The survey consisted of 20 questions and preliminary information explaining to the respondents the principles and purpose of the study.

The survey was conducted by placing an electronic survey form on groups on the social networking site, which brings together people from the professional group of midwives.

The questionnaire form was available in April-December 2018. Participation in the study was anonymous and voluntary.

The results of statistical analyzes are presented to present indicators of the level of knowledge about clinical trials among midwives. The calculations were made in the Gretl program.

Characteristics of the studied population

105 people participated in the study, including 100% of respondents. The dominant group of respondents - 52.4% (n = 55) were residents of cities with a population exceeding 250,000. residents. The respondents were aged 20-54, the largest group were women in the 20-29 age group, which constituted 69.5% (n = 73) of the respondents. In terms of education, in the study group, there were 60.9% (n = 64) of people who completed higher-level studies, that is, they obtained a master's degree. Most of the midwives worked in one place - a state hospital - 41.9% (n = 44). The majority of respondents - 63.7% (n = 67) were people whose work experience was shorter than 5 years. The characteristics of the population was presented in Table 1.

Table 1. Characteristics of the study group

Feature	N (%)
Gender	
women	105 (100)
Place of residence	
city ≥ 250 000 residents	55 (52,4)
city to 250 000 residents	9 (8,6)
city to 100 000 residents	13 (12,4)
city to 50 000 residents	14 (13,3)
rural	14 (13,3)
Age	
Range: 20-54 lata/ years. Mean ± SD: 23 ± 1,1 lat/ year	
Professional education	
higher master-level	64 (60,9)
higher professional	36 (34,3)
medical vocational high school	3 (2,9)
medical highschool	2 (1,9)
Workplace	
public hospital	44 (41,9)
does not work	22 (20,9)
public hospital + non-public Primary Health Care	15 (14,3)
non-public Primary Health Care	11 (10,5)
public Primary Health Care	8 7,6)
own business	3 (2,9)
pharmaceutical company	2 (1,9)
Seniority	
< 5 years	67 (63,8)
5-15 years	21 (20)
> 15 years	17 (16,2)

Source: author's own analysis

Results

The vast majority of respondents - 81% (n = 85) indicated that clinical trials are "A series of medical tests involving patients and / or healthy volunteers, whose aim is to determine whether a particular drug or therapy brings the expected medical benefit, while it is effective and safe for the patient ", ie the correct definition of the clinical trial.

The question "What are the most important benefits of clinical trials?", the most frequently chosen response was "creating new treatment standards" (69.5%, n = 74).

On the question "What are the biggest threats resulting from clinical trials?", the majority of respondents (92.4%, n = 97) chose the answer "the possibility of occurrence of adverse events and events".

The question "What therapeutic areas are currently the most intense clinical trials in progress?", up to 85.7% (n = 90) of the respondents chose the answer "oncology".

On the question "Would you decide to take part in a clinical trial as a participant?", the majority of respondents - 50.5% (n = 53) chose the answer "I do not know".

The next question was about the safety of clinical trials, "Are clinical trials safe?". Half (49.5%) of respondents (n = 52) answered the above question in the affirmative.

Another question "What are the main problems associated with conducting clinical trials?", showed that for 75.2% of respondents (n = 79) this is "low level of public awareness".

To the question "Have you ever considered a career path in the field of clinical trials?", the majority of midwives surveyed admitted that they are not considering a career in this area (61.9%, n = 65).

The question "What are the main motivations for undertaking work in the field of clinical trials?" showed that after 75.2% (n = 79) midwives believes that the reason for a career in this area is "the opportunity to raise education, obtain a higher academic degree" and "opportunity professional development".

Another question related to the duration of clinical trials and was "What period of time does the clinical trial take on average?". Most respondents (47.6%, n = 50) answered that "it depends on the survey".

The question "Usually, how many phases does a clinical trial consist of?" indicated that the majority of respondents believe that this is dependent on the study (45.7%, n = 48).

In response to the question "How do you rate your knowledge about clinical trials?", the majority of respondents (61%, n = 64) indicated that they assessed their knowledge as insufficient.

The question "What sources of knowledge do you have about clinical trials?" showed that 44.8% (n = 47) answered "Internet" and "books, journals".

Detailed answers to individual questions are presented in table 2.

Table 2. Knowledge of study group about clinical trials

Question	Respondents' answers	N	%
1. Clinical trials is:	a) a retrospective study involving the selection of an appropriate group of disease cases to investigate how some of them were exposed to the alleged aetiological agent	5	4,8
	b) research to verify the hypothesis about the aetiology of the disease and the effectiveness of prophylaxis or therapy	11	10,5
	c) a test based on the use of relatively simple and inexpensive diagnostic tests in the study of large population groups to detect early stages of the disease	2	1,9
	d) a study involving the induction of a natural phenomenon under strictly defined conditions that allow us to accurately trace the course of this phenomenon	2	1,9
	e) or healthy volunteers, whose aim is to determine whether a particular drug or therapy brings the expected medical benefit and at the same time is effective and safe for the patient	85	81,0
2. What are the most important benefits of clinical trials? *	a) registration of modern medicines	71	67,6
	b) the best possible therapy	73	69,5
	c) a higher standard of care	58	55,2
	d) a chance to prolong life	53	50,5
	e) benefits for patients not included in the study	27	25,7
	f) increasing the knowledge and experience of researchers/	66	62,9
	g) access to research tools	16	15,2
	h) an additional source of financing for hospitals	13	12,4
	i) creating new treatment standards	74	70,5
	j) development of medical technologies	66	62,9
	k) development of a knowledge-based economy	18	17,1
3. What are the most important risks of clinical trials? *	l) tax revenues	4	3,8
	a) inclusion in a clinical trial without expressing informed consent	16	15,2
	b) failure to comply with the right of withdrawal of the participant	15	14,3
	c) the possibility of adverse events and events	97	92,4
	d) the participant's relaxed attitude	29	27,6
4. In which therapeutic areas the most clinical trials are conducted? *	e) lack of proper care over the participant from the research team	36	34,3
	a) orthopedics	10	9,5
	b) gastrology	10	9,5
	c) gynecology	13	12,4
	d) pulmonology	5	4,8
	e) paediatrics	13	12,4

	f) neurology	49	46,7
	g) cardiology	46	43,8
	h) rheumatology	14	13,3
	i) immunology	53	50,5
	j) oncology	90	85,7
5. Would you participate in a clinical trial as a participant?	a) yes	37	35,2
	b) no	15	14,3
	c) I do not know	53	50,5
6. Are clinical trials safe?	a) yes	52	49,5
	b) no	17	16,2
	c) I do not know	36	34,3
7. What are the main problems associated with conducting clinical trials? *	a) lack of willing participants	53	50,5
	b) administrative obstacles	52	49,5
	c) insufficient transparency of legal regulations	42	40,0
	d) low level of public awareness	79	75,2
	e) lack of interest in research among scientists	25	23,8
8. Have you ever considered a career path in the field of clinical trials?	a) yes	26	24,8
	b) no	65	61,9
	c) I do not know	14	13,3
9. What are the main motivations for undertaking work in the field of clinical trials? *	a) financial advantage	52	49,5
	b) the possibility of raising education, gaining a higher academic degree	79	75,2
	c) the possibility of professional development	79	75,2
	d) social prestige	26	24,8
	e) work with qualified specialists	55	52,4
	f) the need to help others	32	30,5
10. What period of time does the average clinical trial take?	a) several months	12	11,4
	b) a few years	37	35,2
	c) over a dozen years	6	5,7
	d) it depends on the test	50	47,6
11. Usually, how many phases does a clinical trial consist of?	a) two	5	4,8
	b) three	26	24,8
	c) four	25	23,8
	d) more	1	1,0
	e) it depends on the test	48	45,7
12. How would you rate your knowledge about clinical trials?	a) very good	7	6,7
	b) good	4	3,8
	c) enough	30	28,6

	d) insufficiently	64	61,0
13. From what sources do you get knowledge about clinical trials? *	a) doctor	8	7,6
	b) family, friends	6	5,7
	c) Internet	47	44,8
	d) books, journals	47	44,8
	e) I'm not interested in this area	32	30,5
	f) studies	9	8,6

* multiple choice question

Source: author's own analysis

Results of statistical analysis

The relationship between the correct indication was examined:

1) the definition of a clinical trial by the respondents and the correct indication of the average duration of clinical trials, the average number of phases of clinical trials, the self-assessment of the surveyed clinical trials, occupational situation, education, seniority, age of respondents and place of residence.

2) the average duration of clinical trials and the correct indication of the average number of phases of clinical trials, self-assessment of subjects on clinical trials, occupational status, level of education, seniority, age of the midwives and place of residence.

3) the average number of phases of clinical trials and the self-assessment of the respondents on the subject of clinical trials, occupational situation, level of education, seniority, age of respondents and place of residence.

In each case, Spearman's rho correlations were used. The obtained results are presented in Table 3,4,5 respectively.

Table 3. Spearman's rho correlation values between the correct indication of the clinical trial definition and the individual variables

		Correct indication of the clinical trial definition
Correct indication of the average duration of clinical trials	<i>rho</i>	0,09
	<i>p</i>	0,37
Correct indication of the average number of phases of clinical trials	<i>rho</i>	0,03
	<i>p</i>	0,76
Self-assessment of respondents on the subject of clinical trials	<i>rho</i>	-0,16
	<i>p</i>	0,61
Workplace	<i>rho</i>	0,05
	<i>p</i>	0,61
Professional education	<i>rho</i>	0,01
	<i>p</i>	0,95
Seniority	<i>rho</i>	-0,06
	<i>p</i>	0,53
Age	<i>rho</i>	0,02
	<i>p</i>	0,81
Place of residence	<i>rho</i>	0,23*
	<i>p</i>	0,02

* $p < 0,05$

Source: author's own analysis

The results presented in Table III showed one statistically significant correlation. A correct indication of the definition of a clinical trial correlates positively with respondents' place of residence. Midwives living in cities with more than 250,000 inhabitants more often indicated the correct definition of a clinical trial.

Table 4. Spearman's rho correlation values between the correct indication of the average duration of clinical trials and individual variables

		Correct indication of the average duration of clinical trials
Correct indication of the average number of phases of clinical trials	<i>rho</i>	0,06
	<i>p</i>	0,57
Self-assessment of respondents on the subject of clinical trials	<i>rho</i>	-0,14
	<i>p</i>	0,14
Workplace	<i>rho</i>	0,01
	<i>p</i>	0,96
Professional education	<i>rho</i>	-0,15
	<i>p</i>	0,13
Seniority	<i>rho</i>	-0,06
	<i>p</i>	0,54
Age	<i>rho</i>	-0,02
	<i>p</i>	0,81
Place of residence	<i>rho</i>	0,08
	<i>p</i>	0,43

Source: author's own analysis

The results presented in Table IV did not show statistically significant correlations between the correct indication of the average duration of clinical trials and the correct indication of the average number of phases of clinical trials, the self-assessment of subjects on clinical trials, occupational situation, education level, length of service, age of respondents and place of residence.

Table 5. Spearman rho correlation values between the correct indication of the average number of phases of clinical trials and individual variables

		Correct indication of the average number of phases of clinical trials
Self-assessment of respondents on the subject of clinical trials	<i>rho</i>	0,12
	<i>p</i>	0,22
Workplace	<i>rho</i>	-0,24**
	<i>p</i>	0,01
Professional education	<i>rho</i>	-0,17
	<i>p</i>	0,09
Seniority	<i>rho</i>	0,38***
	<i>p</i>	0,00
Age	<i>rho</i>	-0,39***
	<i>p</i>	0,00
Place of residence	<i>rho</i>	0,07
	<i>p</i>	0,50

** $p < 0,01$; *** $p < 0,001$

Source: author's own analysis

The results presented in Table V showed statistically significant correlations. The correct indication of the average number of phases of clinical trials correlated positively with the length of the seniority of the respondents. People with less seniority more often indicated the correct answer to the question regarding the average number of phases in the clinical trial. However, the correct indication of the average number of phases of clinical trials correlated negatively with the professional situation of the respondents. Those who did not work professionally more often indicated the correct answer to the question regarding the average number of phases in the clinical trial. A negative correlation also occurred between the correct indication of the average number of phases of clinical trials and the age of the respondents. Younger respondents more often indicated the correct answer to the question regarding the average number of phases in the clinical trial.

Discussion

Clinical trials can be performed by any of the representatives of the medical professions, eg as a member of a research team, in a company that sponsors clinical trials or a member of

the Bioethics Committee. One of the conditions for obtaining a job in the field of clinical trials is pharmaceutical, medical, nursing, biological or related education [3]. Taking into account the use of evidence-based medicine, medical personnel acquire knowledge in the field of clinical research during the course of teaching. At the Medical University of Warsaw, students learn about clinical research in the subject of 'Philosophy and ethics', 'Pharmacology', 'Clinical Pharmacology', and in the field of Public Health there is a possibility of education within the 'Clinical trials and medical technology' specialization. Students of this field acquire knowledge thanks to such subjects as 'Introduction to Clinical Trials', 'Clinical Trials' and 'Specifics of Clinical Trials in Selected Therapeutic Areas' [4]. Additionally, it is possible to take up studies as part of postgraduate studies.

Literature contains publications on student knowledge about clinical trials in developing countries. One of the previously conducted surveys among 501 medical students was aimed at defining the gaps in training in the subject of clinical trials. The survey contained six modules that form the basis of clinical trials. The questions concerned the knowledge of each module and the significance of a given statement in clinical trials. The highest level of knowledge (level 2.20 / 4) was obtained by evidence-based medicine (EBM). The lowest level of knowledge - the result of 1.64 / 4 was recorded in the module 'implementation of clinical trials'. According to the surveyed students, EBM is the most important aspect of clinical trials (level of 3.39 / 4), and the lowest result of 3.18 / 4 was obtained by clinical trial ethics. It was stated that more attention should be paid to the area of clinical trials to medical students in developing countries. It is important that the trainings are adapted to the needs of the market, they focus on performing clinical trials, biostatistics and research methodology. One should also make the medical community aware of the role of ethics as an indispensable aspect of clinical trials [5]. Our own study showed that 61% of midwives surveyed believe that their knowledge about clinical trials is insufficient, and only 30.5% of respondents admit that the area of clinical research is not in the sphere of their interest. These results may also suggest the appropriateness of appropriate training.

Another study verifying that graduates of the Jagiellonian University have appropriate qualifications for work, inter alia in pharmaceutical companies was carried out as part of the project "Balance of competences" for the life science industry in Krakow. The competences required by employers have been identified, namely: handling of office packages, care for quality, integrity, analytical skills and knowledge in the field of clinical research. The study shows that the competencies that graduates should have are support for MS Office, Open Office or Google Docs, mathematical skills, knowledge of clinical trials, international safety standards,

pharmacopoeia, and HPLC analysis. In addition, the university's tasks in the preparation of students for work in the pharmaceutical industry have been identified, which include: focus on development, scientific information, GLP principles, health and safety rules, equipment service and analysis. Competences appreciated by employers do not necessarily coincide with the university's expectations. According to the information contained in the report, universities are not willing to introduce changes to the curricula to match the currently prevailing requirements on the labor market. The entrepreneurs participating in the survey pointed to insufficient practical skills and specialist knowledge of graduates. It would be beneficial to follow the current situation of the given sector by universities and, as part of the possibilities, to adapt the curricula to the dynamic situation on the labor market [6]. In the own study, only 9% of midwives surveyed indicated studies as a source of knowledge about clinical trials. Despite the actions taken by the universities - for example, the Warsaw Medical University, which was described in the previous part of the work - it would be beneficial to extend the content of issues important to employers, such as pharmaceutical companies, because, as our own study showed, up to 25% of midwives surveyed considered taking up employment in the area of clinical trials.

In 2012, a study was conducted on clinical trials in the assessment of medical personnel. The study was conducted in a group of 100 participants who had medical education and dealt with clinical research or other related occupation in this area. As many as 61% of the respondents are nurses. The survey was conducted showed that almost $\frac{3}{4}$ of the respondents never participated in a clinical trial. In addition, 100% of the respondents indicated an affirmative answer to the question whether respondents follow standard procedures, which indicates that the respondents adhere to the principles of good clinical practice. Many people, because 85% of respondents consider clinical trials to be safe. When asked about the benefits of clinical trials, 55% of respondents indicated progress in medicine, 25% access to the latest treatment methods, 10% free comprehensive diagnostics and medical care, and 9% introduction of new medicines. In our own study, the benefit of clinical trials most frequently indicated by respondents is the creation of new treatment standards (answer chosen by 70% of respondents). Among the biggest problems related to clinical trials, 56% of respondents indicated administrative obstacles, such as bureaucracy or long registration time. The next items included insufficient transparency of legal regulations and low public awareness of clinical trials. In the own study, according to the respondents, the biggest problem associated with clinical trials is the possibility of adverse events and events [7].

Another study looked at the awareness of nurses working at the Japanese University Hospital Tokushima on clinical trials. Out of 597 nurses, 453 (75.9%) completed

questionnaires. About 90% of respondents knew what registration research and clinical trials are, but less than 40% of nurses were aware of the differences between the two concepts. The own study also confirmed the knowledge of the concept of a clinical trial among respondents. The correct answer to the question regarding the definition of a clinical trial was obtained from 81% of respondents. In the questions section on clinical trial terminology, the majority of respondents knew what lies under the terms of informed consent and related issues, but $\leq 50\%$ knew concepts such as the Helsinki Declaration, ethical guidelines, Good Clinical Practice, supervisory boards of institutions and bioethical committees. No specific trend was found in the relationship between consciousness and past experience. According to the authors, these results suggest that clinical nurses have only limited knowledge about clinical trials. Due to the high importance of the possibility of raising awareness of the issues related to clinical trials to nurses, it is suggested to create an extended research team [8]. Similar conclusions can be drawn when analyzing the results of the own study. Midwives know what a clinical trial is, but the percentage distribution of answers to questions that raise more specific issues is different. When asked about the average duration of a clinical trial, 35% of respondents answered correctly, while 24% of respondents answered the question about the most frequent phases of clinical trials correctly.

Another work presented the thoughts of paramedics on the feasibility and practical aspects of pre-hospital clinical trials. A questionnaire was prepared to be completed by the participants of the study. The aim was to examine the perception of rescuers and barriers in undertaking pre-hospital tests based on a review of existing studies and semi-structural qualitative interviews with five medical rescuers. The questionnaire was sent to 300 medical rescuers at randomly selected ambulance stations in Yorkshire. 300 questionnaires were sent out of which 96 rescuers responded (32%). There has been interest in clinical trials, but barriers have been identified such as the perception of knowledge as insufficient and limited use of evidence that research is not a responsibility of paramedics, limited support for participation in research, concerns about practical aspects of randomization and consent, and time pressure. Similar results were obtained in the own study. Only 61% of midwives assessed their knowledge of clinical trials as insufficient. Among problems related to clinical trials, 75% of respondents indicated low level of public awareness, 50% lack of willing participants, and 49% of respondents indicated administrative obstacles. In the survey conducted among paramedics, no relation was found between seniority and perception of research ($p = 0.263$) or the feeling that involvement in research was a professional responsibility ($p = 0.838$). Earlier involvement in pre-hospital studies did not involve opinions about the importance of the evidence base ($p =$

0.934) or obtaining consent ($p = 0.329$). The number of years in which respondents were professionally active was not related to opinions about personal experience as compared to scientific evidence ($p = 0.582$) or the willingness to undergo training in clinical research ($p = 0.111$), while the respondents were our own showed a correlation between the correct indication of the average number of phases of clinical trials and the seniority of the midwives surveyed ($p = 0.00$). However, the authors point to a low response rate, which limited the power of the study to detect potential connections. The study concluded that paramedics reported interest and understanding of the study, but also indicated a number of practical and ethical barriers that should be resolved to increase the number of pre-hospital clinical trials [9].

At present, there are 57 clinical trials in the clinical trials of ClinicalTrials.gov under the slogan "Obstetrics" in the preparation phase for the recruitment of participants for the study, during recruitment or active testing during the course of the examination. The term "Gynecology" contains 121 studies, while "Neonatology" is 12 clinical trials [10,11,12]. This indicates the interest of pharmaceutical companies and other institutions conducting clinical trials in the area of medicine being the competence of midwives. Therefore, it is important that the knowledge of midwives about clinical research is at a high level.

Conclusions

1. Knowledge of the definition of a clinical trial among midwives is sufficient.
2. The place of residence of midwives affects the knowledge of the definition of a clinical trial.
3. The professional situation, seniority and age of the respondents influence the knowledge of the average number of phases in the clinical trial.
4. The scope of information provided in didactic classes in this field could be larger, as this is an issue that a midwife may encounter in his job.

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