



Knowledge, Attitudes and Nursing Self-Evaluation Related to Clinical Research

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Abstract

Background/Aim: Clinical research nursing is a well-known concept in Europe and other countries. The purpose of this study was to investigate the nurses' knowledge and attitudes towards clinical research and their opinions and self-evaluation about clinical research nursing and factors affecting them.

Methods: A cross sectional study was conducted at the University Clinical Centre of the Republic of Srpska (UCCRS). A questionnaire included 50 questions/statements was created in order to address the aims of the research and afterwards distributed to 120 nurses from 6 departments.

Results: Response rate was 91.6 %. Most of the respondents showed a low level of knowledge, but positive attitude related to clinical research. Nurses who participated in clinical research were confident in their competencies according to their self-evaluation.

Conclusion: Systematic approach to the additional nurses education could have a significant impact on a success of clinical research.

Key words: Clinical research nurse; Self-evaluation; Practice; Clinical centre.

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Introduction

Clinical research plays an important role in the development of health services and it can significantly influence the quality of patient care.¹⁻⁴ Clinical research is strictly regulated and should be conducted in accordance with the principles of Good Clinical Practice (GCP).⁵ The availability of new treatment options or the improvement of existing treatments can only be achieved and justified through clinical research.⁶ It is well known that clinical research could provide additional benefits for patients, health personals, health institutions, society and to the state economy.

Despite all values and benefits, no more than 20 clinical research studies have been conducted in Bosnia and Herzegovina (B&H) annually⁷ and approximately 17 of those at the University Clinical Centre of the Republic of Srpska (UCCRS).⁸

The success of clinical research depends on involvement and contribution of different profiles of health professionals, such as: physicians, nurses, pharmacists, statisticians and professional bodies like Ethics committee, Contract Research Organisations (CRO) and other participants.^{6, 9}

According to Organisation for Economic Cooperation and Development (OECD) recommendation, the education, training and infrastructure have been emphasised as key elements for success of clinical research.¹⁰ German Scientific Council also states that qualified and experienced staff are essential at several levels for conducting the clinical research.¹¹

According to European survey on national training activities in clinical research an important role in clinical research team belongs to the Clinical Research Nurse (CRN).¹² On the other hand, the clinical research nursing in Turkey is recognised as a new concept, but framework and legislation in this subject have not yet been put into practice.⁶ In B&H there is no specific study for CRN and that kind of concept has not been recognised at practice level yet. By the *Ordinance on clinical trials on medicinal products and medical devices*, published by the Agency for Medicinal Products and Medical Devices of B&H, the principal investigator creates clinical research team, without obligation to include nursing staff.¹³ However, the standard operational procedures of the UCCRS Ethics Committee have clear demand for principal investigators to involve nurses into clinical research team.

There are only few studies globally which analysed nurses' knowledge, attitudes and opinions towards clinical research. To the best of authors' knowledge there are no such studies in West Balkan region including B&H.^{6,9} The purpose of this study was to investigate the nurses' knowledge and attitudes towards clinical research and their opinions and self-evaluation related to the clinical research nursing and factors affecting them.

Methods

The questionnaire-based study was designed as a cross-sectional study performed at the UCCRS from 14-18 March 2022. The study was approved by the UCCRS Ethics committee (No 01-19-94-2/22) and was conducted in accordance with the Declaration of Helsinki. The questionnaire containing 50 questions/statements was created, according to previously used tools, to address the aims of the research.^{6,14} The main researcher contacted principal nurses at the departments of: oncology, neurology, pulmonology, haematology,

gastroenterology and rheumatology in order to distribute questionnaires to 120 nurses at their belonging departments. In these 6 departments most of the clinical research was conducted in the past years.

The first part of the questionnaire consisted of 8 questions related to the main characteristics of the respondents: gender, years of work experience, level of education, whether they have received education in the field of clinical research and GCP and which one, whether they were satisfied with their education in the field of clinical research, as well as whether they have participated in clinical research so far.

The second part consisted of 18 statements related to basic knowledge about clinical research, ethical concepts, etc. For each question, 3 answers were offered: *true*, *false* or *I don't know*. Each correct answer was scored with 1 point, while an incorrect answer (or *I don't know*) was scored with 0 points. A higher total score represented the higher level of knowledge about clinical research.

In the third part, respondents were offered with 8 statements related to clinical research, based on nurses' attitudes towards clinical research. Three choices were offered for each statement: *true*, *false* or *I don't know*. All statements marked with *true* were scored with 1 point and the rest with 0 points. A higher score indicated a more positive attitude towards clinical research.

In the fourth part, 3 questions were offered to assess the respondents' opinion regarding necessity of education and the position of nurses in clinical research.

Fifth part was created in order to assess the role and self-evaluation of nurses who participated in clinical research in the UCCRS.

Data were processed using IBM SPSS v 18.0 for Windows. After the normality of data distribution was determined using the Kolmogorov-Smirnov test, adequate parametric/non-parametric statistical tests were applied. Categorical data were compared by Chi-squared test and continual data with Student t-test and One-way ANOVA or Man-Whitney U-test and Kolmogorov-Smirnov test for non-parametric data. Unanswered questions were excluded from the statistics. The questions in Table 3, 4, 5 were related to knowledge regarding clinical research and the questions in

Table 6 related with attitudes about clinical research. Therefore, correlations of respondents' characteristics with their knowledge and attitudes were analysed. $P < 0.05$ was taken as the level of statistical significance.

Results

A 110 nurses contributed to this study. The response rate was 91.6 %. Majority of them were female with working experience of less than 20 years. Nearly 71 % of them finished secondary nursing school and less than 12 % finished high nursing school. The basic characteristics of the respondents are shown in Table 1.

Table 1: Basic data on respondents

Parameter	N	%
Gender		
Female	95	86.36
Male	15	13.64
Experience (years)		
1-10	50	45.45
11-20	34	30.91
21-40	25	22.73
Missing	1	0.91
Education		
Secondary nursing school	78	70.91
High nursing school	13	11.82
Nursing college	18	16.36
Missing	1	0.91

N: number of participants (total number of respondents was 110);

The largest number of respondents did not have any education related to clinical research and those who had some kind of education got it either online or by CRO. Majority of respondents were not satisfied with their knowledge in this area and just a small number of them participated in 1 or more clinical research (Table 2).

In the part of the questionnaire that refers to knowledge about clinical research related to ethical concepts and regulations, it was noticed that a significant number of the respondents showed a lower level of knowledge (Table 3).

In the part of the questionnaire that refers to the knowledge of the term volunteering in clinical research, the lowest level of knowledge was shown in connection with following statements S2, S7, S8 and S9 (Table 4).

In the part related to the design of clinical re-

Table 2: Participation and education of respondents in clinical research

Question	Answer	N	%
Have you received training in clinical research and good clinical practice (GCP)?	Yes	23	21.90
	No	82	78.10
If so, the education was conducted by:	CRO	8	32.00
	State institutions	2	8.00
	On-line	12	48.00
	Other	3	12.00
How satisfied are you with your current education in the field of clinical research?	I am not	42	51.22
	A little	17	20.73
	Average	18	21.95
	Very much	5	4.10
How many clinical research have you participated in?	None	69	71.88
	1-3	20	20.83
	4-5	3	3.12
	6 or more	4	4.17

CRO: Contract Research Organisation; N: number of participants (total number of respondents was 110);

Table 3: Knowledge of clinical research, ethical concepts and regulations

Statement	%	Statement	%	Statement	%
S1		S3		S5	
True	89.72	True	76.85	True	60.19
False	0.00	False	6.48	False	0.00
No idea	10.28	No idea	16.67	No idea	39.81
S2		S4		S6	
True	92.52	True	75.00	True	62.96
False	3.74	False	0.00	False	0.00
No idea	3.74	No idea	25.00	No idea	37.04

S1: Clinical research is study of a drug, biological drug or medical device in humans with the intention of discovering potential beneficial effects and/or determining its safety and effectiveness.

S2: Before a new drug can become available to the public, it must be tested on humans.

S3: Clinical research cannot be initiated without the approval of the ethics committee of the institution where they are conducted, as well as without the decision of the state regulatory body.

S4: Clinical research must be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and must be in accordance with good clinical practice (GCP) and legal regulations.

S5: The GCP is an international ethical and scientific quality standard for the design, conduct, recording and reporting of research involving the participation of human subjects.

S6: Compliance with this GCP provides public assurance that the rights, safety and well-being of subjects are protected in research.

search, it is noticeable that more than half of respondents were not familiar with basic terms in clinical research such as blinding and randomisation and a high number of respondents were not sure whether a placebo can be used in clinical research (Table 5).

Correlation of knowledge and characteristics of respondents showed that there was no significant difference in relation to gender. The knowledge of

Table 4: Knowledge of voluntary concept in clinical research

Statement	%	Statement	%	Statement	%
S1		S4		S7	
True	80.55	True	89.81	True	64.81
False	0.93	False	0.93	False	0.93
No idea	18.52	No idea	9.26	No idea	34.26
S2		S5		S8	
True	69.44	True	80.56	True	55.56
False	0.00	False	0.00	False	5.56
No idea	30.56	No idea	19.44	No idea	38.89
S3		S6		S9	
True	63.89	True	87.74	True	62.96
False	0.00	False	3.77	False	2.78
No idea	36.11	No idea	8.49	No idea	34.26

S1: A volunteer is defined as a patient or healthy person participating in clinical research who must give written informed consent to participate in the research either in person or through a legally authorised representative of the participant.

S2: An informed consent form (ICF) is a document that provides a potential volunteer with detailed and comprehensible information about clinical research and must be signed by the participant or his legally authorised representative.

S3: The volunteer must sign the ICF before participating in the clinical research.

S4: The safety of clinical research participants is a high priority.

S5: Clinical research on children, pregnant and lactating women are strictly prohibited by national legislation.

S6: In clinical research, participants' personal and medical information is kept confidential.

S7: Volunteers must not be offered high fees to induce them to participate in clinical research.

S8: A participant can leave clinical research at any time without giving a reason.

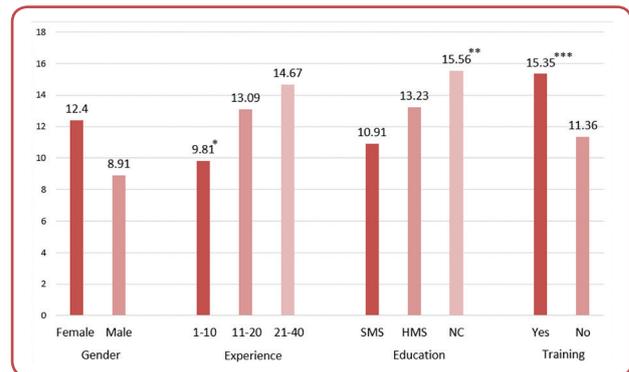
S9: The costs of treatment of adverse events occurring during the clinical research are covered by the sponsor.

Table 5: Knowledge of clinical research

Statement	N	%
It is possible to use a placebo in clinical research	True	79 73.15
	False	3 2.78
	No idea	26 24.07
Blinding (single-blind, double-blind) is used in clinical research to avoid errors arising from bias	True	44 41.51
	False	2 1.89
	No idea	60 56.60
Randomisation is used in clinical research to avoid errors due to bias	True	49 46.67
	False	3 2.86
	No idea	53 50.48

nurses who have worked for less than 10 years was significantly lower compared to the other groups ($p < 0.001$) and nurses with a university degree have significantly better knowledge compared to those who completed secondary nursing school ($p < 0.001$). Nurses who had training related to clinical research showed significantly better knowledge ($p < 0.001$) (Figure 1).

In the assessment of attitudes regarding clinical research, it is worrying that half of the respondents did not have a positive attitude towards the reliability of clinical research and that only a quarter of the respondents believed that standard treatment is not always more reliable com-

**Figure 1: Average knowledge of nurses about clinical research**

SMS: Secondary nursing school; HMS: high nursing school; NC: nursing college; Training: previous training in clinical research; A higher total score is represented as a higher level of knowledge about clinical research.

*The knowledge of nurses who have worked for less than 10 years was significantly lower compared to the other groups ($p < 0.001$).

**Nurses with a university degree have significantly better knowledge compared to those who completed secondary nursing school ($p < 0.001$).

***Nurses who had training related to clinical research showed significantly better knowledge ($p < 0.001$).

pared to the drugs being tested. A large number of respondents did not have a certain attitude related to ethics in conducting clinical research (Table 6).

Correlation of attitudes and characteristics of respondents shows that females had a more positive attitude compared to males ($p = 0.011$). The

Table 6: Attitudes about clinical research

Statement	N	%	Statement	N	%
S1			S5		
Agree	88	83.02	Agree	2	1.87
Disagree	3	2.83	Disagree	65	60.75
Neither	15	14.15	Neither	40	37.38
S2			S6		
Agree	101	94.39	Agree	15	14.02
Disagree	1	0.93	Disagree	29	27.10
Neither	5	4.67	Neither	63	58.88
S3			S7		
Agree	106	99.07	Agree	106	73.33
Disagree	0	0.00	Disagree	0	4.76
Neither	1	0.93	Neither	1	21.90
S4			S8		
Agree	50	46.73	Agree	98	93.33
Disagree	12	11.21	Disagree	2	1.90
Neither	45	42.06	Neither	5	4.76

S1: Clinical research improve the quality of care for patients.

S2: Clinical research are beneficial to society.

S3: Clinical research are important for the advancement of medicine.

S4: Clinical research are reliable.

S5: It is not ethical to conduct clinical research.

S6: Standard treatments are always more trustworthy than new investigational drugs.

S7: Patients can refuse to participate in clinical research without affecting their further treatment.

S8: Nurses should have more knowledge about clinical research.

Neither: neither agree nor disagree.

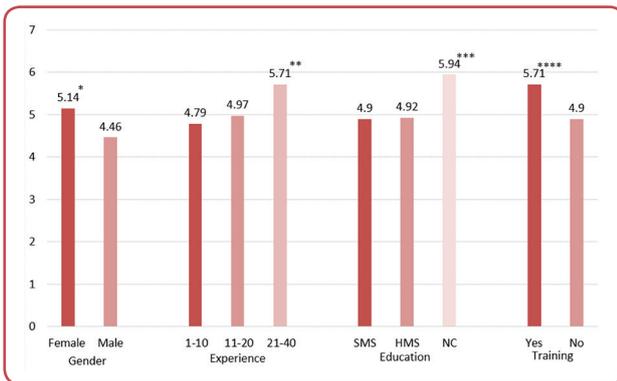


Figure 2: Average attitudes of nurses about clinical research

SMS: Secondary medical school; HMS: high medical school; NC: nursing college; Training: previous training in clinical research; A higher score indicated a more positive attitude towards clinical research.

*Females had a more positive attitude compared to males ($p = 0.011$).

**The attitudes of technicians who have been working for more than 20 years were more positive than the other two groups ($p = 0.005$).

***Technicians with a university degree have significantly more positive attitudes compared to both groups ($p = 0.003$).

****Technicians who had training related to clinical research show a significantly more positive attitude about clinical research ($p = 0.002$).

attitudes of technicians who have been working for more than 20 years were more positive than the other two groups ($p = 0.005$). Technicians with a university degree had significantly more positive attitudes compared to both groups ($p = 0.003$). Technicians who had training related to clinical research showed a significantly more positive attitude about clinical research ($p = 0.002$) (Figure 2).

In the part that refers to the opinion about the place of nurses in clinical research, it was evident that more than half of the respondents believed that a new specialisation for nurses, as nurses in clinical research, should be proposed and must be a mandatory part of the nurses' education. Also, more than half of the respondents expressed their desire to participate in clinical research (Table 7).

Opinions about clinical research in relation to knowledge and attitudes are shown in Figure 3. A higher score indicated a more positive attitude

Table 7: Opinions about clinical research

Statement	N	%
Nurses who work in clinical research should be considered as a separate profession	Yes	57 53.77
	No	20 18.87
	Not sure	29 27.36
Clinical research must be part of the education of nurses	Yes	77 72.64
	No	12 11.32
	Not sure	17 16.04
Would you like to participate in a clinical research?	Yes	63 59.43
	No	29 27.36
	Not sure	14 13.21

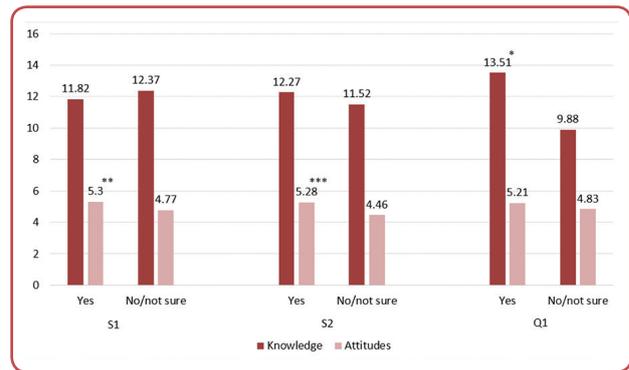


Figure 3: Opinions about clinical research related to knowledge and attitudes about clinical research

S1: Nurses who work in clinical research should be considered a separate profession.

S2: Clinical research must be part of the education of nurses.

Q1: Would you like to participate in a clinical research?

A higher total score is represented as a higher level of knowledge about clinical research. A higher score indicated a more positive attitude towards clinical research.

*Nurses with better knowledge about clinical research were more willing to participate in clinical research ($p = 0.027$).

Nurses with more positive attitudes more often thought that nurses who work in clinical research should be a separate profession *and that clinical research should be part of nurses' education ($p = 0.009$ and $p = 0.009$, respectively).

***Nurses with experience in clinical research.

towards clinical research. Nurses with more positive attitudes more often thought that nurses who work in clinical research should be a separate profession and that clinical research should be part of nurses' education ($p = 0.009$ and $p = 0.009$, respectively). Nurses with better knowledge about clinical research were more willing to participate in clinical research ($p = 0.027$).

The fifth part of questionnaire, related to those nurses (27/110) who had some experience in clinical research, was additionally evaluated. Almost 96 % of nurses were engaged in collecting and preparing specimens from patients according to study protocol, while 52 % documented study participants' data. Only 5 of them were involved in screening of study participants and 6 participated in the informed consent process. Forty percent of them reported issues related to adverse events and 44 % collaborated with research team. Only 5 of them were engaged as educators for their research team.

Self-evaluation showed that most of the nurses were confident and very confident in their competencies to adequately explain all procedures to patients involved in clinical research (84.62 %), including the terms related to randomisation or placebo (61.5 %) and possible adverse events (73.08 %). On other hand, 65.4 % nurses felt unpleasant when placebo as comparator and 42.3 % when the new treatment was offered.

Discussion

A lot of nurses globally have been involved in clinical research, but small attention is dedicated to their real professional role. Presented study showed that more than half of the respondents stated low levels of satisfaction with their education in clinical research. There is a lack of studies which analyse nurses' experience and contribution in this field. Furthermore, many nurses from various fields do not understand defined role of CRN and have a perception of CRN as nurses who have a more administrative role and that they are excluded from daily care for patients.^{9,15}

In this study, it was found that most of respondents were women who had up to 10 years of experience as nurse and most of them had only secondary education in nursing school. In the Turkish study most of the respondents were also women, but with higher education (Bachelor's degree).⁶ On the other hand, compared to the Turkish study there were significantly higher percentage of nurses in presented study who passed the training in clinical research and had experience in clinical research, 44 % and 85 %, respectively. Most of the nurses from study passed the training online, while other were educated by CRO and for only 8 % of them the education was organised by the different state institutions.

This study analysed knowledge of nurses about regulations in clinical research. It revealed the lack of knowledge related to ethic principles and legislations in clinical research which is congruent with literature findings.^{6,16-18} The lowest knowledge related to items linked to patients' voluntariness, were for knowledge due to: informed consent form, payments for participation in the research and "reasons" for leaving the clinical research. These results were congruent with the results that only 5 respondents from presented study were involved in screening of study participants and 6 actually participated in the inform consent process. Considering that nurses spend more time with patients than other health professionals, they were in a position to make the best assessment of patients' benefits with participation in certain clinical research.^{3,9} In contrary to this results, findings from other studies showed that nurses were quite knowledgeable on volunteering issues.^{6,17} Regulatory bodies in certain countries also provide formal trainings

on appropriate procedures involved in informed consent in each specific clinical site.¹⁹

Around half of the respondents in study were not familiar with basic knowledge related to placebo, blindness and randomisation in clinical research. This lack of knowledge was seen in other studies as well and may lead to staff nurses difficulties in communication with the clinical research team and patients as well.^{6,16} On the other hand, in presented study the self-evaluation of the nurses, who participated in clinical research, showed that most of them were confident in their competencies to adequately explain all procedures to patients during clinical research, including the terms like randomisation, placebo or possible adverse events.

Nurses' positive attitudes towards clinical research affect the collaboration with the clinical research team, the number of volunteers and finally hence the success of clinical research, as it was suggested by many studies.^{3,20-25} Nurses play a vital role in increasing the quality of patient care and the progress of the medical science. However, if there is no obligatory training in clinical research on national and institutional level there is a high possibility that nurses could not have positive attitudes related to clinical research, as it was found in this analyses. This result is a message to institutions to make an effort for performing more education and training in this field. On the other hand, it is encouraging that most of the nurses from presented study were willing to participate in clinical research and had awareness of needed qualification for CRN. Those nurses who had higher education and knowledge levels showed better willingness to participate in clinical research. Furthermore, women and those who had more than 20 years of work experience were more positively oriented toward clinical research in presented study.

Strengths and limitations

The strength of this study is that its subject is of practical significance, which evidently deserves further investigations. On the other hand, limitations are relatively small sample size from single centre and the questionnaire which have not been tested for reliability and validity.

Conclusion

Many nurses participate in clinical research but small attention is paid to defining their actual roles and evaluating their work in the process of conducting clinical research. Results from study showed that the largest number of nurses did not have education related to clinical research and most of them were not satisfied with their knowledge in this area. Nurses showed low level of knowledge in field of ethical principles and legislations, as well as in volunteering concept and design in clinical research. It is encouraging that most of nurses from study were willing to participate in clinical research and had awareness of needed additional education about clinical research. Those nurses who had higher education and knowledge levels showed better willingness to participate in clinical research. Additionally, self-evaluation of nurses who participated in clinical research showed that they were confident in many competencies related to their involvement in clinical research. It is needed to design and impose a systematic approach to the education of nurses having in mind its significant impact on a success of clinical research.

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None.

Conflict of interest

None.

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