Association of Research Ethics knowledge with Previous Research Exposure and Academic Qualification among Food and Nutrition Graduates in Pakistan

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ABSTRACT

Introduction: Research ethics is an integral part of graduate education in developed countries. The study aimed to assess the knowledge and attitude regarding research ethics and its association with previous research exposure and academic qualification among food and nutrition graduate students of Pakistan.

Methods: In a cross sectional survey, a structured questionnaire was e-mailed to food and nutrition students in Pakistan. The questionnaire had four parts; demography, prior exposure to research, knowledge and attitude regarding research ethics. Chi Square Test and Fisher's Exact Test was applied to assess association and data was analyzed using SPPS version 20.

Results: A total of 280 respondents completed the questionnaire. More than 80% of the respondents stated that they had knowledge about key concepts of research ethics but only 40% knew about Nuremberg Code and Helsinki Declaration. Previous exposure to research and being a post graduate was associated with knowledge of ethical principles ($p<0.05$).

Conclusion: Teaching research ethics to undergraduates will increase their knowledge and attitude towards research and improve quality of research.

Key words: knowledge, attitude, ethical principles, academic qualification, food and nutrition, Pakistan.

INTRODUCTION

There is an increased need to conduct research in developing countries. Researches involving human participants need to be guided by fundamental ethical principles to ensure the

protection of their rights, dignity and welfare [1]. To maintain ethical standards in health research and publication certain norms are laid down by various National and International Agencies. The Nuremberg Code [2] and Declaration of Helsinki [1] is the benchmark in ethical standards followed worldwide for biomedical research and uniform requirements for manuscripts submitted to biomedical journals (formulated by International Committee of Medical Journal Editors) for publication in scientific journals [3]. Regardless of the existing guidelines for research ethics, in the developing nations regulations do not exist and there is an alarming concern about the existence of functional ethical review systems of individual and institutional research ethics [4]. Previously knowledge of research ethics education has been assessed among new graduate students [5], graduate students of basic medical sciences, clinical sciences, dentistry and public health [6], and medical and dental post graduate students in South India [7].

Food and nutrition graduates are involved with human subjects for counseling, diet modification and research. They should have knowledge of research ethics as a responsibility toward achieving the highest standards of services. Since, there is no research which has investigated the knowledge and attitude of food and nutrition graduate students toward research ethics in Pakistan. So, the present study was conducted with an objective to assess the knowledge and attitude regarding research ethics and its association with previous research exposure and academic qualification among food and nutrition graduate students of Pakistan.

METHODS

Study Design & Settings: The current research was an online cross-sectional survey. The questionnaire was e-mailed to food and nutrition graduate students in Pakistan. Data collection took place between April-May 2016.

Population & Sample: The entire population whose emails were available constituted the sample. The email addresses of the students were retrieved from a registered society of nutritionists and dietitians. The questionnaire was emailed to head of departments of all universities in Pakistan offering food and nutrition to circulate the questionnaire in their alumni. A total of 280 respondents completed the questionnaire.

Instrument: A self administered structured questionnaire was made for the current research after review of literature [1, 2, 8, 9]. It was piloted to rephrase ambiguous questions and eliminate unnecessary questions. Content and face validity was ensured by consulting experts in the field. The 35 item questionnaire had four parts; demography, previous exposure to research, knowledge and attitude regarding research ethics. The demographic part had multiple options with an open ended blank stating others. The previous exposure to research and knowledge part had dichotomous options; yes and no. The attitude part had statement like "Research Ethics Committee (REC) is helpful and every institute should have REC" and participants had to select from likert scale options, strongly agree, agree, neutral, disagree and strongly disagree.

Data Analysis: Frequencies and percentages were calculated for responses. Chi Square Test was applied to assess association and Fisher's Exact Test was applied where cell frequency was less than 5. A p-value less than 0.05 was taken as significant and data was analyzed using SPPS version 20.

RESULTS

The mean age of the participants was 29.153 years (range 21-59). Majority of the participants were aged less than 30 years. Majority of the participants belonged to Lahore (57.4%), followed by Karachi. Majority of the participants were females and 60% had completed

post graduate education. 57.1% specialized in food and nutrition and 17.3% specialized in food science and human nutrition. 33.9% had a household income more than Rs. 100,000 while 39.2% belonged to income group Rs. 50,000-100,000 and 23.2% less than Rs. 50,000 (Table 1).

Table 1 Demographic and Academic Characteristic of the Participants

Characteristics		**%**
Gender	Female	91.1
	Male	8.9
Degree	PhD	10
	M Phil	50
	M Sc (hons)/ MS	9
	M Sc/ BS	30.3
Specialization	Food & Nutrition	57.1
	Nutrition & Dietetics	16.0
	Food Science & Human Nutrition	16.0
	Community Health & Nutrition	3.5
	Public Health & Nutrition	5.3
	Human Nutrition	1.7
Household Income (PKR)	>100,000	33.9
	50,000-100,000	39.2
	<50,000	23.2

Almost all participants reported prior involvement in research but only 21.4% had international publications. Knowledge regarding key concepts of research ethics is evident from

Table 2. Participants had knowledge about informed consent (85.7%), voluntary nature of participation (98.2%), right to withdrawal (92.9%), confidentiality (96.4%), program debriefing (80%), anonymity (91.1%), justice (89.3%), beneficence (83.9%), minimizing possible risks (83.9%), potential benefits (92.9%), Nuremberg Code (41.1%) and Helsinki Declaration (42.9%).

Table 2 Previous Exposure with Research and Knowledge Regarding Ethical Principles

Previous Exposure with Research	**Yes (%)**	**No (%)**
Prior involvement in research	96.4%	3.6%
Prior training in research ethics	53.9%	46.1%
International publications	21.4%	78.6%
Previously applied for approval from REC	37.9%	62.1%
Knowledge Regarding Ethical Principles	**Yes (%)**	**No (%)**
Informed consent	85.7	14.3
Program debriefing	80.4	19.6
Voluntary participation	98.2	1.8
Right to withdrawal	92.9	7.1
Confidentiality	96.4	3.6
Anonymity	91.1	8.9
Justice	89.3	10.7
Beneficence	83.9	16.1
Possible risks	83.9	16.1
Potential benefits	92.9	7.1
Nuremberg code	41.1	58.9

Helsinki declaration	42.9	57.1

Table 3 shows attitudes towards research ethics. Positive statements like REC is helpful, research ethics as mandatory module, informing patients about aims, purpose, benefits and risks, anonymity and confidentiality scored better. Statements regarding use of deception and dissemination of results were mixed. Results of negative statements were mixed too. Only 52% answered correctly about Ethical Review (ER) being necessary for inter collaborative research. 43% disagreed that ER would delay research and yet 60% were of opinion it is necessary even after being approved from Advanced Board of Studies. 55% disagreed that informed consent is only necessary when using biological samples and 40% disagreed that vulnerable groups can be included if guardian is not available for consent. 62% were against fabrication of data and 33% disagree with the view that once enrolled participants have to complete the study.

Table 3 Attitude Regarding Ethical Principles

	SA (%)	A (%)	N (%)	DA (%)	SDA (%)
POSITIVE STATEMENTS					
1. Research ethic committee (REC) is helpful & every institute should have REC.	60	36	4	0	0
2. Research ethics should be taught as a mandatory post graduate module.	44	52	4	0	0
3. Patients should be informed of aims and purpose of the research including risks and benefits.	59	35	4	2	0

4. Deception can be used when potential benefits outweigh the risks involved.	10	14	32	25	19
5. Ideally participant's identity should not be known to researcher and it should not be revealed to anyone outside the researcher or his staff.	31	50	13	6	0
6. There should be measures to protect patient data from being accidently exposed.	67	31	0	0	2
7. The study results should be disseminated and everyone should benefit from the contributions.	0	54	44	2	0
NEGETIVE STATEMENTS					
8. Ethical review of research by an REC is only necessary for international collaborative research.	9	28	11	31	21
9. Ethical review by an REC would delay research and make it harder for the researcher.	2	22	33	28	15
10. Ethical review of research by an REC is not necessary since it has passed Advanced board of studies.	4	15	21	44	16
11. Informed consent is necessary only	9	18	18	44	11

when using biological samples and presentation of data as pictures.					
12. If no surrogate/guardian is available to give informed consent for vulnerable group they could still be included.	4	23	33	32	8
13. It is ok to fabricate data to improve outcomes of research as long as there is no harm to the participants.	4	30	4	29	33
14. We should tell the participants that once enrolled they have to complete the study.	13	41	13	24	9

KEY: SA= Strongly Agree; A= Agree; N= Neutral; DA= Disagree; SDA= Strongly Disagree

Prior involvement in research was associated with knowledge of informed consent (p=0.001), program debriefing (p=0.016), Nuremberg Code (p=0.006) and Helsinki Declaration (p=0.002). Prior training in research ethics was associated with knowledge of voluntary nature (p=0.029), program debriefing (p=0.002), anonymity (p=0.007), beneficence (p=0.028), Nuremberg Code (p=0.001) and Helsinki Declaration (p=0.001) (Table 4).

Table 4 Association of Prior Involvement in Research & Prior Training in Research Ethics and Knowledge Regarding Ethical Principles

Principles	Prior involvement in research		P-value	Prior Training in Research Ethics		P-value
	No (%)	Yes (%)		No (%)	Yes (%)	

		n=10	n=270		n=129	n=151	
Informed consent	No	50	12.9	**10.802 (0.001)***	15.5	13.3	0.290 (0.611)
	Yes	50	87.1		84.5	86.7	
Voluntary nature	No	0	1.9	1.000	3.9	0	**0.029***
	Yes	100	98.1		96.1	100	
Right to withdrawal	No	0	5.6	1.000	7.8	3.4	2.706 (0.116)
	Yes	100	94.4		92.2	96.6	
Confidentiality	No	0	3.8	1.000	3.9	3.4	1.000
	Yes	100	96.2		96.1	96.6	
Program debriefing	No	50	18.9	**5.833 (0.016)***	27.9	13.2	**9.347 (0.002)***
	Yes	50	81.1		72.1	86.8	
Anonymity	No	0	7.4	1.000	11.6	3.3	**7.225 (0.007)***
	Yes	100	92.6		88.4	96.7	
Justice	No	0	11.5	0.609	10.9	11.3	0.012 (0.914)
	Yes	100	88.5		89.1	88.7	
Beneficence	No	40	16.3	0.072	22.5	12.6	**4.798 (0.028)***
	Yes	60	83.7		77.5	87.4	
Possible risks	No	0	11.5	0.609	15.5	7.9	3.250 (0.071)
	Yes	100	88.5		84.5	92.1	
Potential benefits	No	0	0	--	0	0	--
	Yes	100	100		100	100	
Nuremberg code	No	100	55.2	**0.006***	72.9	43	**25.212 (0.001)***
	Yes	0	44.8		27.1	57	

Helsinki declaration	No	100	52.9	**0.002***	65.9	45.1	**12.212 (0.001)***
	Yes	0	47.1		34.1	54.9	

International publications were associated with knowledge of informed consent (p=0.001), right to withdrawal (p=0.047), possible risks (p=0.005), Nuremberg code (p=0.001) and Helsinki Declaration (p=0.001). Applied to research ethics committee was associated with knowledge of informed consent (p=0.001), right to withdrawal (p=0.001), confidentiality (p=0.015), justice (p=0.014) and beneficence (p=0.026) as evident from Table 5.

Table 5 Association of International Publications & Applied to Research Ethics Committee and Knowledge Regarding Ethical Principles

Principles		**International Publications**		**P-value**	**Applied to Research Ethics Committee**		**P-value**
		No (%) n=220	**Yes (%) n=60**		**No (%) n=174**	**Yes (%) n=106**	
Informed consent	No	18.2	0	**0.001***	23	0	**0.001***
	Yes	81.8	100		77	100	
Voluntary nature	No	2.3	0	0.588	2.9	0	0.160
	Yes	97.7	100		97.1	100	
Right to withdrawal	No	6.8	0	**0.047***	8.6	0	**0.001***
	Yes	93.2	100		91.4	100	
Confidentiality	No	4.5	0	0.126	5.7	0	**0.015***
	Yes	95.5	100		94.3	100	
Program	No	20.5	18.3	0.133	23.6	14.2	3.647

debriefing	Yes	79.5	81.7	(0.436)	76.4	85.8	(0.065)
Anonymity	No	6.8	8.3	0.163	5.7	9.4	1.350
	Yes	93.2	91.7	(0.686)	94.3	90.6	(0.245)
Justice	No	14.1	0	0.001	7.5	17.0	**6.051**
	Yes	85.9	100		92.5	83.0	**(0.014)***
Beneficence	No	19.1	10	2.743	13.2	23.6	**4.984**
	Yes	80.9	90	(0.098)	86.8	76.4	**(0.026)***
Possible risks	No	13.6	1.7	**0.005***	8.6	15.1	2.804
	Yes	86.4	98.3		91.4	84.9	(0.094)
Potential benefits	No	0	0	--	0	0	--
	Yes	100	100		100	100	
Nuremberg code	No	64.5	28.3	**25.192**	60.9	50	3.201
	Yes	35.5	71.7	**(0.001)***	39.1	50	(0.074)
Helsinki declaration	No	60	35	**11.888**	58.6	48.1	2.934
	Yes	40	65	**(0.001)***	41.4	51.9	(0.087)

Academic qualification i.e. being a post graduate was associated with greatest knowledge regarding ethical principles. Being a post graduate was associated with knowledge of informed consent (p=0.001), voluntary nature (p=0.002), right to withdrawal (p=0.002), confidentiality (p=0.001), anonymity (p=0.001), justice (p=0.021), beneficence (p=0.004) and possible risks (p=0.036).

DISCUSSION

There has been numerous unethical practices in the past therefore international community has made several ethical guidelines or codes to protect rights of human subjects. In the current research the participants reported a good knowledge of ethical principles. Almost 80-100% answered in yes. But the present study indicated that graduate students had unsatisfactory knowledge about various ethical guidelines such as Nuremberg Code and Helsinki Declaration. The reason behind this is that general research ethics is taught as a chapter in compulsory subject research methodology but health research ethics, history of unethical researches and development of Documents of Set of Ethical Principles i.e. Nuremberg Code, Belmont Report and Helsinki Declaration governing health and medical research is not taught.

Majority of the participants answered attitude based positive statements correctly. They agreed and understood the role and importance of Research Ethics Committee, program debriefing, anonymity and confidentiality. But mixed results were obtained regarding use of deception. The APA Ethics Code allows for its use when the benefits of using it outweigh the risks, participants cannot reasonably be expected to be harmed, there is no way to conduct the study without deception, and participants are informed of the deception as soon as possible. But according to Helsinki Declaration under no conditions deception can be used. Another attitude which received 44% neutral responses was importance of dissemination of results. Reason behind this could be that majority of students do not have good writing skills and scholarly writing is not mandatory and focused in a developing country like Pakistan. Reponses on scenario based negative statements were also mixed. Only 33-60% could choose correctly from the given options. This means that as earlier stated good knowledge of ethical principles was just for namesake and they did not understand the concepts clearly, so the attitude based scenario statements confused them.

Those participants who had previous research involvement, training in research ethics and international publications had better knowledge of ethical principles, Nuremberg Code and Helsinki Declaration. It was evident from the current research that academic qualification was associated with maximum knowledge of ethical principles. It was found so because post graduate students are more rigorously exposed to research methodology curriculum than graduate students. As Documents of Set of Ethical Principles are not taught in colleges, therefore, academic qualification was not found to be associated with knowledge of Nuremberg Code and Helsinki Declaration.

But it has to be understood that mostly graduate students work as nutritionists and dietitians in hospitals and have access to human subjects and are involved in nutrition interventions. Hence they should be well versed in research ethics. On campus or work cite training increases knowledge of principles of research ethics. A study by Brown and Kalichman [10] among graduate students in experimental sciences showed that training resulted in improved reports of knowing what to do if faced with an ethical dilemma. A study evaluating outcome of a research ethics training workshop among clinicians and scientists in a Nigerian university concluded that the training improved participants' knowledge of principles of research ethics, international guidelines and regulations and operations of IRBs. Participants retained much of the knowledge acquired from the workshop one month after its completion [11].

As previously suggested, curriculum in research ethics should be developed for university faculty [9]; in the same way there is a need to standardize the nutrition curriculum all over Pakistan and develop contextually relevant, in line with International standards research ethics curriculum. Till the curriculum is developed and implemented a short course could be developed in light of Shroder-Back et al's ethics course in public health program. They have used case

study and problem based learning approach for a 6-8 week short course [12]. Majority of the respondents were of the view that research ethics should be taught as a mandatory course. Therefore, training, short courses and revision of curriculum are mandatory to achieve the goal of improved knowledge and practice of research ethics among food and nutrition students.

Strengths and limitations

A major strength of this study is that it was the first survey to explore knowledge and attitude regarding research ethics among food and nutrition graduate students in Pakistan. The questionnaire was anonymous and participation was completely voluntary. It is hoped that anonymity assures honest responses. However, this feature could also impose a limitation that only those choose to answer who had good knowledge regarding research ethics.

CONCLUSION

Knowledge regarding key concepts of research ethics was commendable among food and nutrition graduate students in Pakistan. But knowledge regarding Documents of Set of Ethical Principles i.e. Nuremberg Code and Helsinki Declaration was inadequate. As previous exposure with research and academic qualification was significantly associated with increased research ethics knowledge, it should be added in the food and nutrition graduate curriculum in Pakistan.

DECLARATIONS

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Availability of data and materials

The questionnaire has been provided as a supplementary file. The datasets generated during the current study are not publicly available due to institutional policy.

Authors' contributions

AS was responsible for conception and design, acquisition of data, analysis and interpretation of data; drafted and revised the manuscript for intellectual content. AS has read and gave final approval of the version to be published and takes public responsibility for appropriate portions of the content.

Competing interests

The authors declare no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

The study was exempted by Ethical Review Committee University of South Asia, Lahore, as it was an online survey and did not involve human trial. The questionnaire had an introduction stating the purpose of research and whoever consented completed the questionnaire. Names of the participants were not inquired and they were ensured of confidentiality of data.

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