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The Effect of Multiple Interventions for Women at Risk for Cervical Cancer on Their Health Responsibility, Beliefs Regarding Cervical Cancer, and Having Screening: A Randomized Controlled Study Protocol•

Serviks Kanseri Yönünden Riskli Kadınlara Yönelik Çoklu Girişimlerin Sağlık Sorumluluğu, Serviks Kanserine İlişkin İnanç ve Tarama Yaptırmaya Etkisi: Randomize Kontrollü Çalışma Protokolü

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• Bu çalışma, doktora tezinin çalışma protokolüdür. "2nd INTERNATIONAL CONGRESS OF NURSING (ICON-2018) 13-15 Nisan 2018, İstanbul"da sözel bildiri olarak sunulmuştur.

ABSTRACT

Objective: This randomized study aimed to examine the effect of multiple initiations, including education, home visits, or phone call reminders, on the beliefs about cervical cancer, health responsibility, and screening participation of women aged between 40 and 55 who were at risk for cervical cancer.

Methodology: This pretest-posttest, randomized, and controlled experimental study was conducted with women aged between 40 and 55 who had not had a Pap smear test. The study had an experimental and control group comprising 134 women (67 women in the experimental group and 67 in the control group). Participants had at least one of the most frequent risk factors in Turkey directly associated with cervical cancer. The experimental and control groups were randomly assigned. Interventions for the experimental group included group education, home visits, phone call reminders and were completed within 14 weeks. Women having Pap smear testing was the primary output. The data were collected and then coded into a computer by an assistant researcher who did not know which group the participants were in. A statistician conducted the statistical analysis of the coded data. All analysis were performed in SPSS 20.

Conclusion: This study provides an example and evidence for future studies to increase participation in cervical cancer screening for women at risk of cervical cancer.

Keywords: *Cervical cancer, nursing, randomized controlled study protocol, risk group.*

ÖZ

Amaç: Bu çalışmanın amacı, serviks kanseri yönünden riskli grupta bulunan 40-55 yaş arası kadınlara yönelik yapılan grup eğitimi, ev ziyaretleri ve telefonla anımsatıcı aramalardan oluşan çoklu girişimlerin kadınların sağlık sorumluluğu, serviks kanserine ilişkin inanç ve tarama yaptırmasına etkisinin incelendiği randomize çalışma protokolüdür.

Yöntem: Bu çalışma 40-55 yaş arası hiç pap smear yaptırmamış kadınlar ile ön test-son test randomize kontrollü deneysel çalışma şeklinde yürütülmüştür. Çalışma grubunu, Türkiye'de en sık görülen ve serviks kanseri ile ilişkili risk faktörlerinden en az birine sahip 40-55 yaş arası hiç pap smear testi yaptırmamış 67 deney, 67 kontrol grubunda olmak üzere random atanan 134 kadın oluşturmuştur. Deney grubuna yönelik yapılan grup eğitimi, ev ziyaretleri, telefonla hatırlatmayı içeren uygulamalar 14 haftada tamamlanmıştır. Birincil sonuç çıktısı kadınların Pap smear testi yaptırma durumlarıdır. İkincil sonuç çıktıları, Rahim Ağzı Kanseri ve Pap-Smear Testi Sağlık İnanç Modeli Ölçeği ve Sağlıklı Yaşam Biçimi Davranışları Ölçeği II puan düzeyleridir. Veriler katılımcıların hangi grupta olduğunu bilmeyen yardımcı araştırmacı tarafından toplanmış ve bilgisayara kayıt edilmiştir. Gruplara göre kodlama yapılan verilerin analizi istatistik uzmanı tarafından yapılmıştır. Veriler SPSS 20 paket programı ile hesaplanmıştır.

Sonuç: Bu çalışma, serviks kanseri yönünden riskli kadınların serviks kanseri erken tanısına katılımlarını artırmak için yapılacak olan çalışmalara örnek olması ve kanıt sağlaması yönünden önem taşımaktadır.

Anahtar kelimeler: *Serviks kanseri, hemşirelik, randomize kontrollü çalışma protokolü, riskli grup.*

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Clinical trial: *The clinical trial was registered on ClinicalTrials.gov on September 26, 2017 with the title 'Increasing Participation in Cervical Cancer Screening and Risk for Beliefs/Attitudes Among Women at Risk' (NCT03076879).*

Deneme kaydı: *'Increasing Participation in Cervical Cancer Screening and Risk for Beliefs/Attitudes Among Women at Risk' başlığı ile ClinicalTrials.gov, NCT03076879. 26 Eylül 2017'de tescil edildi.*

Cervical cancer is the fourth most frequent cancer among women from all age groups in the world.[1] Cervical cancer death rate is high: every two minutes around the world, a woman dies from cervical cancer.[1,2] Cervical cancer, which is caused by a virus called Human Papilloma Virus (HPV), is the most serious health problem (particularly HPV16 and HPV18). Nearly all cases of cervical cancer can be attributable to HPV infection (99,7%).[3]

There are many cofactors for cervical cancer outside the HPV.[2,3,4] In the screening of cervical cancer, it is important to ensure that individuals at risk take priority in screening, taking into account the risk factors for the regions.[4]

Cervical cancer is preventable, treatable, and curable if it is diagnosed early. Cervical cancer can be detected at an early stage as it has a long preclinical phase.[3,5,6] Therefore, the World Health Organization (WHO) recommends the integrating of cervical cancer screening programs (Pap Smear testing, HPV testing, cytology and visual inspection with acetic acid (VIA) are all recommended screening tests).[3,7] Regular screening for cervical cancer is effective in reducing the disease incidence and mortality.[8,9] The high incidence and mortality rates in developing countries are due to the lack of screening programs. In accordance with the national cancer screening program standards in Turkey, the Pap smear test is offered to women aged 30-65 every five years.[2]

The Pap smear test or HPV DNA test in recent years is important for the early detection of cervical cancer. However, not enough women currently receive the test in Turkey or the World.[10,11,12] The cervical cancer screening rate in developed countries is more than or equal to 60%,[13,14,15,16] whereas it is less than 20% in less-developed and developing countries.[17,18] In Turkey, 73.7% of eligible women older than 20 have not had a Pap smear test.[19]

It is stated that face-to-face training and interventions by health personnel are more effective than opportunistic screening based on the application of individuals in developing countries.[20,21,22,23] In a systematic review by Lu et al. (2012), it was found that there were not sufficient Randomized Controlled Trial (RCT) research about participation in cervical cancer screening in developing countries, general public education was insufficient to increase the participation in screening, and culture-specific education and initiatives were effective in this context.[12,24, 25]

The early detection of cervical cancer extends life and increases survival rates. The early detection of cervical cancer occurs using a simple, convenient, and economical method. Therefore, determining the factors affecting women's behavior regarding early detection of cervical cancer will allow planning and implementing nursing interventions to promote early detection of cervical cancer. Multiple interventions including education about cervical cancer and its early diagnosis will increase screening participation.

Aim of the Study

This study is a randomized study protocol that examines evaluated the effect of multiple interventions including education, home visits, and phone call reminders on the attitudes towards an early diagnosis of cervical cancer among women aged between 40 and 55 who were at risk of cervical cancer.

Method

Type of the Study

This is a randomized controlled experimental study using a pretest-posttest design.

Study Population/Sample and Inclusion/Exclusion Criteria

The research population constituted of 40-55 years old women registered at Konya a Family Health Center. The incidence rate of cervical cancer starts to increase after age 40 in Turkey (7.6 in 100.000), and it reaches the highest level between ages 50-55 (11.7 in 100.000). They had never had a Pap smear test and had at least one of the most frequent risk factors in Turkey directly associated with cervical cancer (use of oral contraceptives for more than five years, given birth to three or more children, first intercourse under age 16, first full-term pregnancy before age 17, or a family member (especially mother or sister) with cervical cancer). The number of women who between the ages of 40-55 registered in this family health center is 1016. In order to determine the research universe, it is aimed to reach all the women.

Inclusion Criteria

- Have no previous pap smear test
- Being literate
- Have no previously received training in cervical cancer
- Not be pregnant or postpartum quarterly
- Not having already been diagnosed with any cancer
- Having sexual experience
- Not having undergone hysterectomy operation

Study Group and Power Analysis

The sample size of the randomized, blinded study was determined using power analysis in accordance with a two-sided p value. The regional Pap smear test participation rate was 51%, as ascertained during the determination of the study population. In a Turkish study on education and counseling to increase the rates of the women's participation in the Pap smear test, the rate of Pap smear participation increased by 23.1%,[26] which had an effect size of 0.231 calculated by the G*Power software. The sample size of the randomized controlled study was determined by the Power analysis, and it was determined that each group should have 57 women with a 95% confidence interval. We have added 10 women to each group as additional support to alleviate any absence.

Randomization and Blinding

Randomization

As a result of the sample size determined by the power analysis, 134 women were selected from the 223 women in the at-risk group using the simple randomization method. Random number tables were used to select 134 women and randomly assign them to the experimental or control group (67 women were assigned to each group). In addition to the researcher, a statistician randomly assigned the subjects to the experimental and control group to decrease selection bias and control variables that may affect the outcomes. The stratified sampling method (number of births) was used to ensure randomization. After stratification, a statistician randomly assigned participants to either the control or experimental group using the computer-based simple randomization method. Prior to the research, the women in the experimental and control group were informed and their written consent was received. Experimental and control groups randomization show on Figure 1.

Before initiating the study, the researchers informed women in both the experimental and control groups about the study and obtained their verbal and written general consent regarding study participation.

After the separation according to randomization, the groups were determined to be similar.

Blinding

Blinding of data collectors and the statistician was implemented in this randomized blinded study. Another researcher (assistant researcher) who did not know the group assignments conducted the post-tests and coded the data in the computer. After statistical analysis was conducted and the research report was written, the assistant researcher explained the codes for the experimental and control group. Therefore, blinding of data collectors, statistical analysis, and report writing was provided.

Instruments and Data Collection:

In the clinical research, Information Form, Healthy Lifestyle Behaviors Scale II (Health Responsibility), Cervical Cancer and

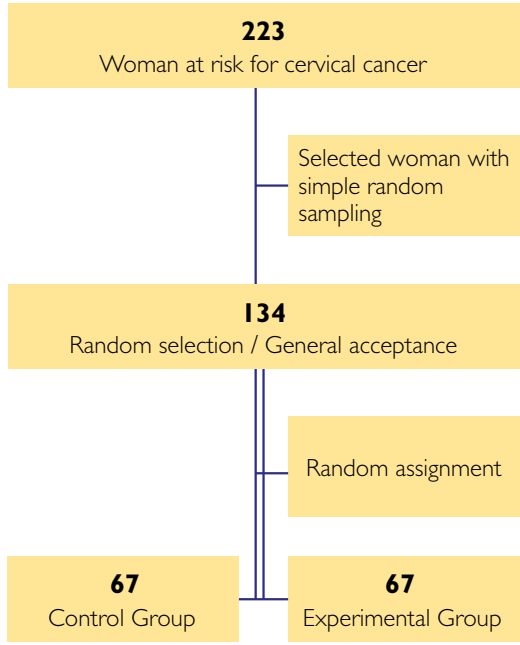

Figure 1. Distribution of experimental and control groups

Pap-Smear Test Health Belief Model Scale and Evaluation Form for the Participation of Cervical Cancer Screening were used to collect data.

Information Form: The form prepared according to the literature [2,3] by the researcher to be used in the experimental study, consists of 10 questions aimed at determining the basic characteristics of the individuals.

Healthy Lifestyle Behaviors Scale II (Health Responsibility): In this study, the 'Health Responsibility' sub-dimension of the Turkish version of the 'Healthy Lifestyle Behavior Scale II' was used.[27] The Cronbach Alpha coefficient of the Healthy Lifestyle Behavior Scale is 0.92 and the Cronbach Alpha coefficient of the Health Responsibility sub-dimension is 0.77. The lowest score in the health responsibility sub-dimension is 9 and the highest score is 36. Increase of score shows that health responsibility also increases.

Cervical Cancer and Pap-Smear Test Health Belief Model Scale: It is a 5-point Likert-type scale consisting of 35 items. Each dimension of the scale is evaluated separately and not combined into a single total score. The Cronbach Alpha reliability coefficient for the whole scale ranged from 0.62-0.86 and the Cronbach Alpha reliability coefficient for the sub-dimensions ranged from 0.79 to 0.87. There are 5 sub-dimensions of the scale. Pap smear benefits and motivation sub-dimension 8, Pap smear prevents sub-dimension 14, Cervical cancer care / severity sub-dimension 7, Cervical cancer susceptibility sub-dimension 3, Cervical cancer health motivation consists of 3 items.[28]

Table 1. Distribution of Similarities in Basic and Fertility Characteristics of Women in the Experimental and Control Groups (Pre-Intervention)

	Experimental (n=67)		Control (n=67)			
	n	%	n	%	χ^{2}**	p
Education status						
Primary school	62	92.5	62	92.5	1.111	0.574
Middle school	3	4.5	3	4.5		
High school	1	1.5	2	3.0		
University	1	1.5	0	0.0		
Working status						
Working	7	10.4	6	9.0	0.085	0.770
Not working	60	89.6	61	91.0		
Economic situation perception						
Good	12	17.9	9	13.5	0.654	0.721
Middle	46	68.7	50	74.6		
Bad	9	13.4	8	11.9		
History of cervical cancer in mother or sister						
Yes	9	13.4	9	13.4	0.000	1.000
No	58	86.6	58	86.6		
Oral contraceptive use for longer than five years						
Yes	20	29.9	23	34.3	0.308	0.579
No	47	70.1	44	65.7		
Number of births						
2	8	11.9	7.0	10.4	0.964	0.915
3	29	43.3	29	43.3		
4	16	23.9	19	28.4		
5	10	14.9	7.0	10.4		
6 ve daha fazla	3	6.0	5.0	7.5		
	n	**Average**	**Std. Deviation**	**Medyan**	**Min-Maks**	**t**	**p**
Age of first sexual intercourse							
Experimental	67	19.02	3.288	19.00	14.00-28.00	0.433	0.666
Control	67	18.82	2.194	19.00	14.00-24.00		
First birth age							
Experimental	67	20.53	3.358	20.00	15.00-31.00	-0.272	0.786
Control	67	20.68	2.985	20.00	15.00-35.00		

Evaluation Form for the Participation of Cervical Cancer Screening: This form prepared by the researcher consists of four questions that question the status of participation in scans and which practice is more effective. Research flowchart show on Figure 2.

Multiple Interventians and Implementation Steps of Research

The 14-week intervention for the experimental group was divided into three sections: training on early diagnosis of cervical cancer, home visits and reminder phone calls. These practices were conducted were conducted between in March 13 and June 14, 2017

Training on early diagnosis of cervical cancer:

The women in the experimental group attended a one-time group education in the Family Health Center on cervical cancer and cervical cancer screening between in March 20-24, 2017. One-on-one education aimed to reinforce the group education. Women were invited to the Family Health Center in groups of

eight people and received a 40-minute presentation on cervical cancer and its early diagnosis. After the education was completed, an in-group interaction was provided using the question-answer method. Then, participants received a magnet reading "Hold on to life with a five-year Pap smear test" and a mug with "Stop cervical cancer with an early diagnosis! Give yourself a chance!" written on it. They also received a brochure summarizing the education. The brochure content was on cervical cancer and its screenings and addressed the following questions: What is cervical cancer? What are the risk factors? What are the signs of cervical cancer? What is a Pap smear test? How is a Pap smear test conducted? Who should have a Pap smear test? Where does the Pap smear test occur? The validity of the brochure content was approved by two professors (Public Health Nursing and Women's Health and Maternity Nursing) and a assistant professor (Women's Health and Maternity Nursing).

Home visits

After the group education, home visits were planned two times within a four-week interval. The first home visit was held on April 17-23, 2017 and the second home visit was between May 13-18, 2017. During these visits, the main subjects addressed in the group education were reviewed to clarify any missing points through an interactive question and answer session. The educational content included cervical cancer, its risks, protection from risks, the importance of cancer screening, and pursuing a healthy life style. A counseling service was also provided which included answering women's questions on gynecological diseases, making necessary referrals, and following the outcomes. During the home visit process, Pap smear test results were followed and participants were informed accordingly. Visits were 40 minutes an average. Educational objectives were evaluated for each visit.

Reminder calls

Women were asked to provide their telephone numbers after the first interview and their written approvals were received. They were called two times in total during working hours two weeks after each home visit. These calls reminded the women to participate in cervical cancer screenings.

Control Group

The women in this group were tested twice between March 13-18, 2017 pre-test and the last-test between June 12-18, 2017. This group continued routine practice. The routine practice for women in the family health center (FHC) includes the guidance of 40-55-year-old women coming to FHC for participation in screening of cervical cancer by health personnel and calling them to participate in screening. After the study was completed, women in the control group were called and were invited to the family health center for early diagnosis of cervical cancer and group training was given considering the right to be informed ethically. After group training, brochures, magnets and trophies were given to the control group.

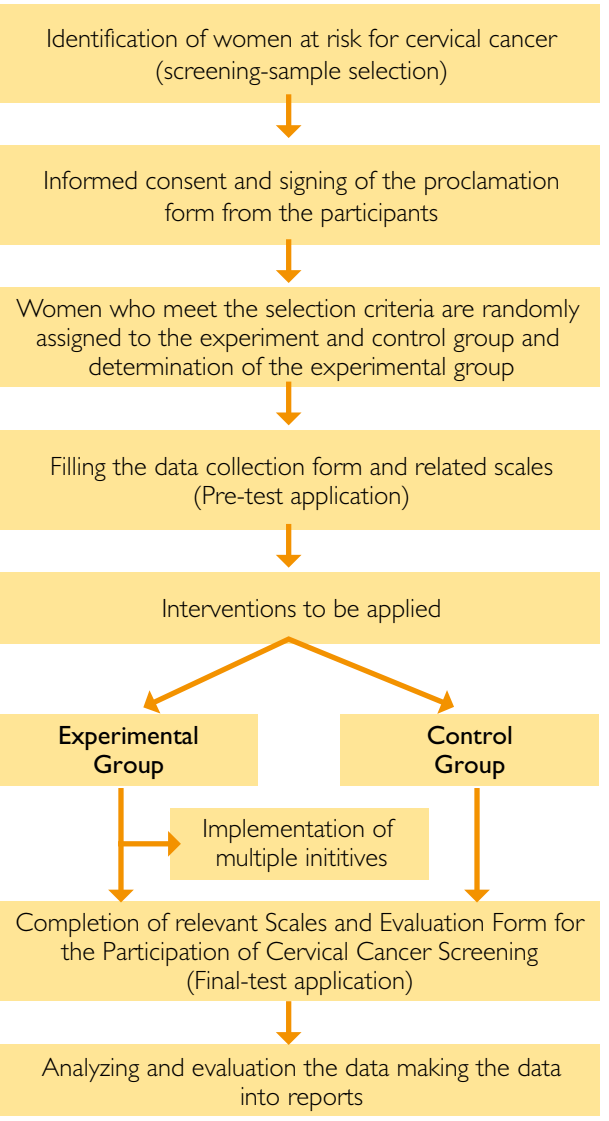

Figure 2. Research flowchart

Data Analysis

The collected study data were analyzed in by computer using SPSS 20.0 statistical analysis software. Kolmogrov–Smirnov, Shapiro–Wilk, and Anderson–Darling tests were used to assess the normality of the data. Cronbach Alpha analysis was applied to determine the reliability of the scales in order to asses internal consistency, and percentages, mean and standard deviation calculations were used for analyzing findings regarding the individual characteristics of the students. Appropriate statistical analyses were used to examine the relationship between the independent variables of the control and experimental groups and anthropometric measurement results and scale scores. A dependent samples t-test was performed to assess the pre and post-test results of the groups, and an independent samples t-

test was used to assess the relationship between the control and experimental groups. The data obtained were tested at the $p<0.05$ significance level. To prevent bias when assessing the data encoded by the assistant investigator in the experimental and control groups, data recorded in the database were analyzed by a statistician who was independent of the researcher and the study.

Primary and Secondary Outputs

Ethical Considerations and Dissemination: The study reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 checklist. The study has been approved by Selcuk University, Faculty of Health Sciences Ethics Committee (date: 24.06.2016 and no: 2016/06). This study kept the information obtained from women confidential. Study data are used only for the present study; however, if it is desired to carry out an advanced international study, the data may be shared with other researchers. The researcher plans to issue the study findings and results as a report at international conferences and in journals to make a contribution to other researchers and society. The researchers and the fundraising institution do not have any competing or conflicting financial interests. Interventions carried out within this study had no negative effects and no participantswere harmed during the study.

Discussion and Conclusion

There have been various interventions to increase cervical cancer screening. A systematic review and meta-analysis study analyzed 440 studies conducted between 1996 and 2000 to examine the effectiveness of interventions on increasing women's awareness of cervical cancer and their participation in screening. In addition, 38 studies were added to this review by taking into consideration the research inclusion and exclusion criteria. The review indicated the cervical cancer screening participation rates in the experimental group invited to screening by calling (RR: 2.16, 95% CI: 1.70, 2.74), receiving brochures (RR: 1.11, 95% CI: 0.88, 1.41), and receiving education through home visits (RR: 2.33, 95% CI: 1.04, 5.23) were significantly higher than the screening participation rate in the control group. In studies conducted in developed countries, brochures, phone call reminders, and invitation letters were effective interventions to increase screening participation. In developing countries, the review emphasized that a phone call reminder, cooperation with healthcare professionals, and education were effective, and that multiple interventions performed together and socially accepted interventions were significantly more effective.[12,24,25] Socioeconomic disparities in cervical cancer screening were emphasized and women with a higher education status had a higher likelihood of cervical cancer screening than those with a lower status. Therefore, it was suggested that a new strategy be developed for these women specific to their culture and education level. In developing countries, the opportunistic cervical cancer screening based on individuals' applications was not an effective method, and it was emphasized that face-to-face education and interventions were more effective.[20,21,22,23]

Table 2. Primary and Secondary Outputs of the Research

Primary Outputs	Secondary Outputs
Pap Smear Making Status	- Health Belief Model Scale for Cervical Cancer and Pap-Smear Test Score - Healthy Lifestyle Behaviors Scale II (Health Responsibility) Score

Cervical cancer is a significant public health issue, particularly in developing countries. Taking into consideration its effect size and mortality rate in developing countries, cervical cancer affects more women of lower socioeconomic status. This study has significance as a randomized, controlled nursing intervention to increase the early detection of cervical cancer. It is an example for future intervention studies to increase women's participation in the early detection of cervical cancer. Group education, home visits, and other interventions have important effects on the early diagnosis of cervical cancer.

Ethics Committee Approval: Ethics committee approval was received for this study from the Selcuk University Faculty of Health Science (date and number: 24/06/2016- 2016/06).

Etik Komite Onayı: Bu çalışma için etik komite onayı, Selçuk Üniversitesi Sağlık Bilimleri Fakültesi Etik Kurulu'ndan alınmıştır (Tarih ve No. 24/06/2016- 2016/06).

Informed Consent: Informed written consents were obtained from the experimental and control groups by giving information to the women in both groups participating in the study.

Bilgilendirilmiş Onam: Çalışmaya katılan her iki gruptaki kadınlara bilgi verilerek deney ve kontrol grubundan aydınlatılmış yazılı onamlar alınmıştır.

Peer-review: Externally peer-reviewed.

Hakem Değerlendirmesi: Dış bağımsız.

Conflict of Interest: No conflict of interest was declared by the author.

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