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The effect of decision-aid-based counseling on cervical cancer screening behavior among women: An interventional study

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Abstract:

BACKGROUND: Performing appropriate and regular screening can effectively reduce cervical cancer and mortality rate, however, the available evidence suggests that women's participation in cervical cancer screening remains low in middle- and low-income countries, and that it is necessary to identify appropriate intervention methods to change behavior. The present study was designed to determine the effect of decision-aid-based counseling on cervical cancer screening behavior among women.

MATERIALS AND METHODS: This trial study was conducted on 154 women with no history of Pap smear during the past 3 years and refers to Tabriz health care centers. The participants were assigned to the intervention (decision aid based counseling) and control (routine health education) groups through randomized block design with block sizes of 4 and 6 and a 1:1 allocation ratio. The data were collected using the sociodemographic and fertility characteristics, stages of change checklist, and shared decision-making (SDM) and decisional conflict (DC) questionnaire before and 6 months after the intervention by interview and then, analyzed by SPSS24 software. The independent *t*-test, ANCOVA tests were used.

RESULTS: A significant difference was observed between the two groups in terms of changing the stages of cervical cancer screening behavior 6 months after the intervention. As after the intervention, the frequency of individuals entered the preparation or action stage was more than the control group ($P = 0.001$). The mean score of SDM in the intervention group was significantly higher than the control group after intervention ($[45.49 \pm 1.18]$ vs. $[27.56 \pm 1.18]$ [Mean Difference (MD): 17.92; 95% confidence interval [CI]: 14.59–21.25; $P < 0.001$]). The mean score of DC in the intervention group was significantly lower than the control group after intervention ($[29.16 \pm 1.09]$ vs. $[34.14 \pm 1.09]$ [MD: -4.97; 95% CI: 1.09–8.04; $P < 0.002$]).

CONCLUSIONS: This study revealed that evidence-based information communicated between clients and clinicians has very important role in clients' health-related behavior. It is recommended, health care providers apply decision-aid-based counseling for promoting the cervical cancer screening behavior among women.

Keywords:

Cervical cancer, decision-aid, Pap smear, stages of behavior change

Introduction

Cervical cancer is identified as the fourth most common cancer among women in the world, especially in developing

countries.^[1,2] More than 80% of deaths due to cervical cancer occur in the low- and middle-income countries,^[3] which made the World Health Organization call for the global control of cervical cancer in May 2018 to eradicate the disease in the world^[4] since

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this cancer is potentially one of the most preventable cancers.^[5]

The standard approaches for early detection of cervical cancer are screening women through cytology (Pap smear) and performing an Human Papilloma Virus (HPV) test (cotesting).^[6] In fact, early detection of cervical cancer through Pap smear is very important in reducing its complications and mortality.^[7] However, the available evidence indicates the low level of women's knowledge about screening for cervical cancer, which increase the need to design programs to promotion women's knowledge in this field.^[8,9]

On the other hand, performing screening for cervical cancer is a decision which people make after receiving sufficient information about the method of testing and performing screening and its advantages and disadvantages. It is worth noting that choosing the best option is difficult for patients in many health-related decisions. The intervention programs to encourage women for performing screening influence the women's willingness to make a decision and subsequently change their behavior to participate in screening programs.^[10] As stages of the change model address how informed decisions have been made, and the specified stages toward making a change in behavior.

Selecting the best option in many health-related decisions is difficult for patients. This type of decisions is regarded as "sensitive preferences," requiring to consider the advantages and disadvantages of the options ahead.^[11] Decision-aid helps individuals make informed decisions and perform or not perform behavior by providing evidence-based information and expressing the benefits and harms of health care and consequently, influences the decisional conflict (DC) or the satisfaction with the decision. It is worth noting that decision-aid is designed as a tool to support and complement counseling, and it is not considered as a substitute for counseling.^[12] But the point to consider is that so far a study in the Iranian cultural context has not examined the effect of this method on changing health-related behaviors. Shared decision making (SDM) is defined as a process in which health options are selected by the participation of patient and healthcare provider.^[13] Further, SDM is actually considered as the most important part of patient-centered care.^[14] Obviously, patients, as the consumers of health services, have rights such as individual care, respecting for their beliefs and values, and knowing and participating in care decisions. In the same way, the first condition for participating in decision making is to have sufficient information about medical methods and procedures.^[15]

The results of a study that examined the use of SDM in Iran indicated that despite the legislation of the Ministry

of Health regarding patient's informed consent, SDM is still rarely used in the health care delivery system. Further, it is suggested further studies investigate the impact of SDM in Iran, due to the lack of research in this field.^[16] Furthermore, it should be noted that previous interventional studies with different approaches such as motivational counseling conducted in Iran, have often focused on the effect of such interventions on changing breast cancer screening behavior in women^[17-20] and it is the first study with the approach of decision aid based counseling in Iran.

Given the low frequency of cervical cancer screening behavior (lower than 50% reported in the Ezzati study), the interventions should be performed, and the effect of the interventions on changing women's screening behavior should be investigated based on the theory of behavior change, indicating a person's behavior change in stages. The innovation of this intervention method, compared to other methods, is providing advice to decision-making based on up-to-date scientific information about the advantages and disadvantages of screening so that the person has the ability to weigh the advantages and disadvantages of screening. Therefore, considering the importance of cervical cancer screening in reducing mortality and in order to identify the appropriate intervention method to increase women's participation in the cervical cancer screening programs, the present study aimed to determine the effect of decision-aid-based counseling on women's screening behavior.

Materials and Methods

Study design and setting

This trial study was conducted from July 2019 to December 2019. The study population were married women aged 21–65, who referred to health centers in Tabriz, Iran. The inclusion criteria consisted of: Married women aged 21–65 years with no history of doing Pap smear in the past 3 years and no intention to do it in the next 6 months, no history of cervical cancer or a history of cervical cancer among first degree relatives, literacy, and having a telephone number for follow-up. The exclusion criteria included: Pregnant women, history of participating in training and interventions programs related to cervical cancer screening, a history of spotting or bleeding after intercourse, or irregular uterine bleeding.

The change of stages of behavior 6 months after the intervention in the decision-aid and control groups as a primary outcome and the change of SDM and DC 6 months after the intervention in the decision-aid and control groups, as the secondary outcomes were considered.

Based on the study of Ezzati *et al.*^[17] and the variable of cervical cancer screening behavior and considering (P1 = 0.55) with a 35% increase in the frequency caused by intervention (P2 = 0.75) and with respect to the power = 80%, one-sided $\alpha = 0.05$ in G power software (version 3.1.9.4, Heinrich Heine University, Dusseldorf, Germany, 2017), the sample size was calculated 70 subjects for each group, which increased to 77, due to a 10% probability of sample loss.

Study participants and sampling

The city of Tabriz, with 85 healthcare centers, includes the health records of all married women aged 21–59, such as telephone number and addresses. Participants were selected with simple sampling from the healthcare centers in various areas with different socioeconomic classes. The author visited the 15 selected centers and obtained data on married women aged 21–59 years using the integrated health system, known as “SIB System.” Then, she called eligible women, provided them with a brief description of the research objective and method, and obtained written informed consent from them to participate in the study.

The participants were assigned to the intervention (decision-aid based counseling) and control groups using a randomized block design with block sizes of 4 and 6 and a 1:1 allocation ratio. A co-researcher, noninvolved in the intervention and data analysis, generated the random allocation sequence using Random Allocation software. The intervention type was written on a piece of paper and placed in opaque envelopes, numbered consecutively to conceal the allocation sequence. Envelopes from 1 to 154 were given to the study participants based on the entry order.

Data collection tool and technique

Data collection tools included the sociodemographic and fertility characteristics questionnaire, checklist of change stages, SDM, and DC questionnaire, which were completed through an interview by the first author. The sociodemographic questionnaire included items, such as age, number of children, level of education, occupation, adequacy of household income, and midwifery history including the number of pregnancies, age of first menstruation, age of menopause, and age of first pregnancy.

The checklist of change stages is designed based on the transtheoretical model of behavior change.^[18] The responses were scored based on 5-point Likert scale as follows: Precontemplation stage: I do not intend to do in the next 6 months (score 1), contemplation stage: I intend to do in the next 6 months (score 2), preparation stage: I intend to do in the next 30 days (score 3), action stage: I have done recently (score 4), and maintenance

stage (score 5). The maintenance stage was not measured in the present study due to the time limit of the researcher. The reliability of the tool was 0.71 using Kappa index by measuring twice with an interval of 2 weeks.^[19]

Shared decision making

The SDM is used to assess SDM among participants.^[20] The final version included nine items, and the English version was used for validation in Iran. Participants answer each item using a 6-point Likert scale ranging from 0 (strongly disagree) to 5 (strongly agree). In a study conducted by Ebrahimi *et al.*, the Persian version of the questionnaire was validated, The Pearson coefficient in questions 1, 2, 4, and 5 was between 0.5 and 0.7, representing a high correlation between questions.^[21]

Decisional conflict

O’Conner’s DC tool is a 16-item questionnaire.^[13]

The questions are answered using a 5-point Likert scale ranging from 0 (completely agree) to 4 (completely disagree). All items’ scores are summed, divided by 16, and multiplied by 25 to calculate the total score, which is between 0 and 100. The scores below 25 are associated with decision making, while the scores above 37.5 are related to the delayed decision making or uncertainty about decision making.^[22]

In a study in Iran, Ghiyasvandian *et al.* confirmed the psychometric properties of the questionnaire. Moreover, the Cronbach’s alpha coefficient was obtained 0.94 for the DC questionnaire.^[23]

Intervention

The pretest questionnaires, including sociodemographic and midwifery questionnaire, checklist of the stage of behavior change, and SDM questionnaire, and DC questionnaire, were completed through interview by control and intervention groups (154 women). In the intervention group (77 people), a 60–90 min individual counseling session based on the content of decision-aid and along with routine trainings was held and in the training room of the relevant health center. Based on COVID-19 pandemic in Iran in that time, the intervention was performed individually in the training room of the health center by observing health protocols to prevent COVID19 infection (observing social distance and using a mask).

In the session, the author sought to establish good relationships with participants and gave them a feeling of assurance. The information on the prevalence of the disease and the risks of infection, the introduction of cervical cancer screening methods, and the advantages and disadvantages of performing and avoiding screening was provided during the in-person session. The possible

advantages and disadvantages of cervix cancer screening methods (including; cervix cytology, HPV test, colposcopy) were presented, participants' questions were answered, and a decision-aid book was provided for reading at the end of the session. The content of decision-aid booklet was prepared according to booklet on the Ottawa site^[24] and national guideline^[25] based entirely on up-to-date evidence of cervical cancer screening by the research team, and even how to perform screening was described by images. The contact number of the first author and corresponding author was written in the booklet for more information. The control group just received routine trainings about cervix cancer screening.

The first telephone counseling session was provided by the author 4 weeks later for about 10 min, to follow-up and encourage them to carry out their questions about cervical cancer screening tests. The second follow-up session was held for all participants in the intervention group and all the questions about cervical cancer were answered.

Six months after the intervention, the questionnaires were completed again by control and intervention groups by in-person interview. Adherence to the Pap smear (action stage) was checked according to the health profile documented by health care providers. The decision-aid-based counseling was presented at the end of the study to the control group to comply with the ethical principles.

Ethical consideration

The sampling process was started after obtaining the permission of the Ethics Committee of Tabriz University of Medical Sciences (Code: IR.TBZMED.REC.1398.319).

Statistic analysis

First, the normality of quantitative data was investigated using Kolmogorov–Smirnov, indicated normal distribution for all data. The independent *t*-test and Chi-square test were used to compare the sociodemographic characteristics between groups. The Chi-square test was used to compare the stages of change before the intervention, and ordinal regression was used after the intervention. In order to compare the mean score obtained from SDM and DC between groups, independent *t*-test was used before the intervention and ANCOVA test with adjustment of baseline values was used after the intervention. The SPSS (version 24, SPSS, IBM, Armonk, NY, 2016). statistical software was used for data analysis. Moreover, the significance level was considered 0.05.

Results

The present study was conducted on 154 women from April

2020 to June 2020, and follow-up continued until September 2020 (6-month follow-up) [Figure 1]. The mean (standard deviation) age of the intervention and control groups was 39.53 (10.1) and 38.44 (6.8), respectively. Most participants were homemaker. There was no significant difference between the intervention and control groups in terms of the demographic and midwifery characteristics [Table 1].

A total of 380 women were assessed, of whom 216 eligible individuals aged 21–59 without a history of doing cervix cytology in the last 3 years were enrolled. Forty-one individuals were excluded, due to not having eligibility criteria (poor educational attainments or illiteracy (*n* = 41), having postcoital bleeding or abnormal uterine bleeding (*n* = 21). Finally, 154 women allocated in to tow group randomized. Among 154 included

Table 1: The sociodemographic and midwifery characteristics

Variable	Intervention group (<i>n</i> =77), <i>n</i> (%)	Control group (<i>n</i> =77), <i>n</i> (%)	<i>P</i>
Age (years)*	39.53±10.1	38.44±6.8	0.436**
Spouse age*	46.10±9.5	44.25±9.1	0.219**
Marriage age*	21.64±3.4	20.84±4.7	0.239**
Education			
Under diploma	26 (33.8)	25 (32.5)	0.616 ^c
Diploma	36 (46.8)	32 (41.6)	
University	15 (19.5)	20 (26.0)	
Spouse education			
Illiterate	5 (6.5)	4 (5.2)	0.817 ^c
Under diploma	19 (24.7)	24 (31.2)	
Diploma	18 (23.4)	18 (23.4)	
University	35 (45.5)	31 (40.3)	
Employment status			
Homemaker	46 (59.7)	49 (63.6)	0.469 ^c
Employed	20 (26.0)	14 (18.2)	
Other	11 (14.3)	14 (18.2)	
Spouse employment status			
Unemployed	6 (7.8)	10 (13.0)	0.687 ^c
Manual worker	19 (24.7)	20 (26.0)	
Employee and retiree	30 (39.0)	25 (32.5)	
Other	22 (28.6)	22 (28.6)	
Family income level			
Not enough	11 (14.3)	8 (10.4)	0.712 ^c
Somewhat enough	41 (53.2)	45 (58.4)	
Enough	25 (32.5)	24 (31.2)	
Insurance status			
Yes	68 (88.3)	59 (76.6)	0.089 ^c
No	9 (11.7)	18 (23.4)	
Suffering from genital warts			
Yes	3 (3.9)	4 (5.2)	1.000 ^c
No	74 (96.1)	73 (94.8)	
Number of deliveries			
0	1 (1.3)	4 (5.2)	0.196 ^c
1 and 2	60 (77.9)	63 (81.8)	
>2	16 (20.8)	10 (13.0)	

*Mean±SD, **Independent *t*-test, ^cChi-square. SD=Standard deviation

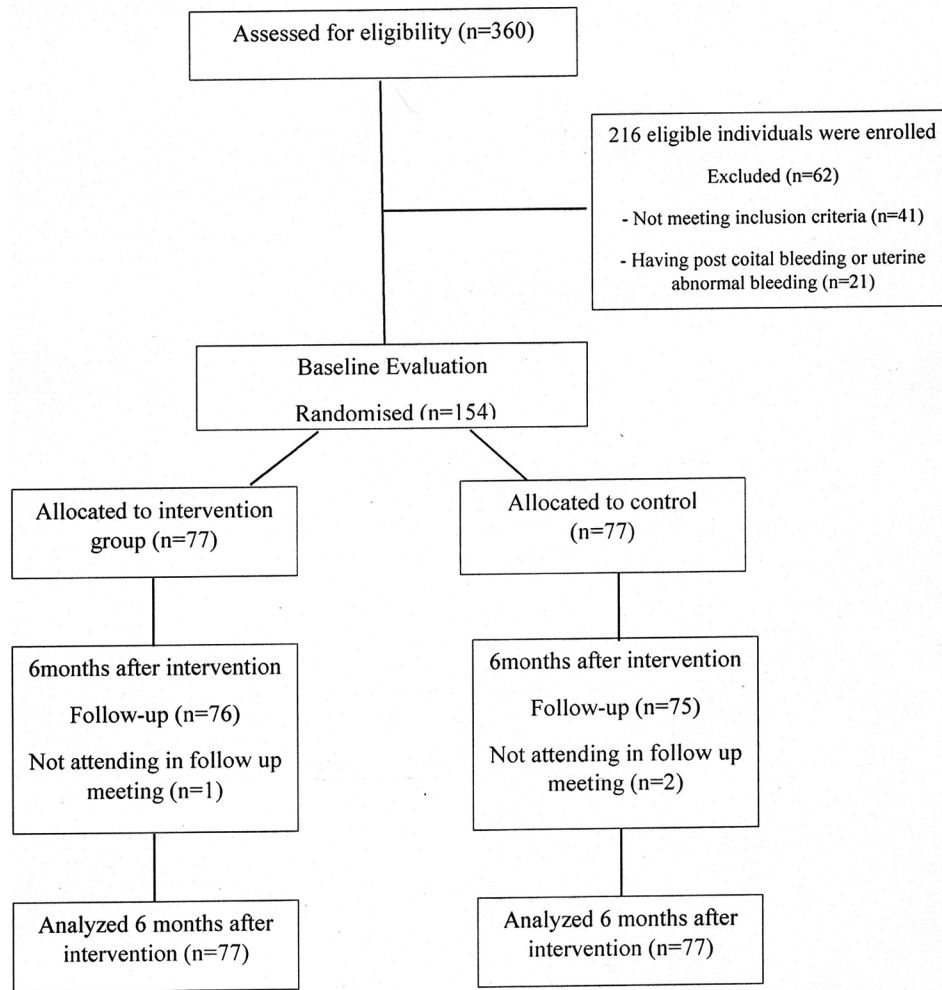


Figure 1: Diagram of study

participants (77 in each group), two individuals were withdrawn from control group (unwillingness to cooperate, $n = 2$), and one other was withdrawn from the intervention group (unwillingness to cooperate, $n = 1$) [Figure 1].

Before the intervention, the comparison of the stages of behavior change in cervical cancer screening demonstrated that 57 women (74.0%) were in the precontemplation stage, and 20 (26.0%) were in the contemplation stage in the intervention group. In the intervention group, 22 subjects (28.6%) entered the contemplation stage, 15 (19.5%) entered the preparation stage, and 19 (24.7%) entered the action stage ($P < 0.0001$) after the intervention [Table 2].

The mean score of SDM of the intervention group was significantly higher than that of the control group (mean difference [MD]: 17.92 with 95% confidence interval [CI]: 21.25–14.59 [$P < 0.001$]). Further, the mean score of DC of the intervention group was significantly lower than that of the control group (MD: -4.97 with 95% CI: 8.04–1.09 [$P < 0.002$]) [Table 3].

Discussion

The results of the present study indicated that following decision-aid-based counseling in the intervention group, 15 (19.5) subjects were in the stage of preparation for doing Pap smear, and 19 (24.7) were in the action stage. While in the control group, 5 (6.5) women were in the preparation stage, and 7 (9.1) entered the action stage. The findings of the present study are significant in line with the study results of Van Agt *et al.*, who similarly reported a higher intention to participate in the breast cancer screening programs in the group received decision-aid-based counseling.^[26] Akbari *et al.* (2020) examined the effect of decision-aid on the stages of the behavior change of women in the programs of breast cancer screening. They found that the frequency of women who participated in the breast screening increased in intervention group compared to the control group received the usual training.^[27] Further, Suzanne Miller *et al.* conducted a study on 279 women at the Atlantic Regional Cancer Care Center, entitled “facilitating informed decision-making about breast cancer risk and genetic counseling using

Table 2: The frequency distribution and the comparison of behavior change in performing Pap smear in the intervention and control groups

Stages of behavior change in performing a Pap smear	Before intervention			After the intervention		
	Intervention, n (%)	Control, n (%)	P*	Intervention, n (%)	Control, n (%)	P**
Precontemplation stage	57 (74.0)	60 (77.9)	0.736	21 (27.3)	52 (67.5)	<0.001
Contemplation stage	20 (26.6)	17 (22.1)		22 (28.6)	13 (16.9)	
Preparation stage	0	0		15 (19.5)	5 (6.5)	
Action stage	0	0		19 (24.7)	7 (9.1)	

*Chi-square test, **Ordinal logistic regression test

Table 3: The comparison of mean (standard deviation) of shared decision making, conflict, remorse, and decision self-efficacy in the intervention and control groups

Variable	Mean±SD		Mean difference (95% CI)	P
	Intervention	Control		
SDM score range (0-45)				
Before intervention	20.67 (13.62)	23.38 (9.69)	-2.71 (-6.47-1.05)	0.156*
After completion of the intervention	45.49 (1.18)	27.56 (1.18)	17.92 (14.59-21.25)	>0.0001**
Decisional conflict score range (0-64)				
Before intervention	42.07 (10.92)	40.01 (10.71)	2.06 (-1.38-5.51)	0.238*
After completion of the intervention	29.16 (1.09)	34.14 (1.09)	-4.97 (-8.04--1.09)	>0.002**

*t-test, **ANCOVA test with base effect control. SD=Standard deviation, CI=Confidence interval, SDM=Shared decision making

decision-aid-based counseling.” They concluded that the women received decision-aid-based counseling were more likely to enter the stage of the contemplation to do genetic testing.^[28]

In the present study, the mean score of SDM in the intervention group was significantly higher than that of the control group, and women in the intervention group had a sense of participation in decision-making, which is consistent with the study results of Han *et al.* indicated that the use of the SDM approach and the relationship between health care providers and clients increase the willingness to perform screening.^[29]

In addition, some studies^[30-32] examined the impact of SDM on the cancer-related preventive care. The results indicated the participants’ satisfaction with the participation of health care providers and physicians in the decision-making process for preventative measures and even their cancer treatment decisions. Further, these studies investigated the effect of decision-aid on SDM, improving knowledge, and reducing DC among patients. In the present study, the mean score of DC in the intervention group was lower than that of the control group. Schapira *et al.* investigated the effect of web-based decision-aid on the menopausal hormone therapy decision among 177 patients in the United States. They reported a significant difference between the group received decision-aid and the control group in relation to the DC,^[33] which is consistent with the result of the present study. Similarly, Metcalfe *et al.* evaluated the effect of decision-aid among women aged 25–60 years who were genetically predisposed to breast cancer. The results indicated that providing decision-aid to guide

patients for genetic testing to prevent breast cancer reduced the DC among women receiving decision-aid.^[34]

Applying random allocation, the allocation concealment of the participants, and a relatively high sample size with different sociodemographic features were the strengths of the present study. The impossibility of financing the screening costs and the lack of insurance support were among the factors influencing women decision-making for screening, which was one of the limitations of the present study.

Limitation and recommendation

In this study, the prolonged follow-up was difficult and researcher has to continuously contact with participants to prevention of high rate of loss. Some strengths of this study included using random selection and allocation method and allocation concealment technique, selecting the participants among all health centers across the study area, using the participants’ native language during counseling sessions, providing the participants with a telephone number, and answering their questions. Therefore, due to the high burden of disease of cervical cancer, especially for developing countries, it is recommended that healthcare providers use decision-aid-based counseling for increasing tendency to cervical cancer screening as a complementary method along with routine trainings, and it is recommended to study and compare another consultation approaches such as motivational interview with SDM on women screening behavior.

Conclusions

The findings of the present study, which is the first study in Iran, indicated the effect of decision-aid-based

counseling on promoting SDM and reducing DC about cervical cancer screening, resulted in the informed decision-making and behavior change for performing screening. Despite the different cultural background of Iranian women, the findings of the present study showed that providing counseling based on the content of the decision aid, promoted screening behavior because it empowers women to weigh the benefits and harms of doing and not doing screening.

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Conflicts of interest

There are no conflicts of interest.

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