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Using theory of reasoned action to reduce high-risk sexual behaviors among patients with HPV: A randomized controlled trial

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Abstract:

BACKGROUND: Sexually transmitted diseases are a major health problem in all countries. Human papillomavirus (HPV) infection is the most common viral sexually transmitted disease in both genders. High-risk sexual behaviors (HRSBs) are among the major risk factors for HPV infection. Lack of knowledge can contribute to HRSBs and hence, education can potentially reduce HRSB risk. This is a study using theory of reasoned action to reduce the high-risk sexual behaviors among patients with HPV.

MATERIALS AND METHODS: This study was a two-grouped, randomized, controlled trial. The educational program was developed based on the results of a survey into the most important components of the theory of reasoned action contributing to HRSBs among 100 patients recruited from Razi hospital, Tehran, Iran. Then, 110 patients from the same hospital were consecutively recruited and randomly allocated to a control ($n = 55$) and an intervention ($n = 55$) group. Then, each participant in the intervention group was provided with the developed educational program. Their counterparts in the control group solely received routine care services. Three months after the first educational session, HRSBs were reassessed in both groups. Data were analyzed via the SPSS software (v. 21.0).

RESULTS: After the intervention, the mean score of HRSBs significantly decreased in the intervention group ($P < 0.001$) but did not significantly change in the control group ($P = 0.70$). The post-test mean score of HRSBs in the intervention group was significantly less than the control group ($P = 0.015$).

CONCLUSION: Education based on the theory of reasoned action is effective in significantly reducing HRSBs. Nurses can develop and use educational interventions based on this theory to reduce HRSBs and HPV infection.

Keywords:

Education, health promotion, HPV, sexual behavior

Introduction

Sexually transmitted diseases (STDs) are a wide range of clinical syndromes and infections caused by pathogens transmitted through sexual activity.^[1] With an annual incidence rate of twenty million cases and an annual healthcare cost of more than sixteen billion dollars, STDs are a major

health problem in both developing and developed countries.^[2] There are no reliable data about the prevalence and the incidence of STDs in Iran.

Human papillomavirus (HPV) infection is an STD. It is classified as low- and high-risk infection depending on its neoplastic alterations.^[3] HPV infection is highly

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prevalent such that 20% of sexually-active adolescent girls are at risk of contracting it.^[4] HPV infection is a significant risk factor for cancer in both genders. It is the cause of 4.5% or 640,000 of all new cases of cancer worldwide (8.6% in women and 0.9% in men). It is apparently associated with more than 95% of cervical cancers and 88% of anal cancers.^[5] Moreover, it is associated with colon, cervix, rectum, anus, vulva and oropharynx cancers.^[6,7]

High-risk sexual behaviors (HRSBs) include a wide range of sexual behaviors—from multiplicity of sexual partners to unprotected sexual activity—which impair mental health and emotional and behavioral balance and are usually associated with other high-risk behaviors such as cigarette smoking, drug abuse, and alcohol consumption.^[8] HRSBs have various adverse outcomes such as unwanted pregnancy, STDs, increased risk of cervical cancer, and mental disorders, and hence, are considered more important than other high-risk behaviors.^[9]

One of the factors contributing to the increasing prevalence of HRSBs is the individual's lack of knowledge about them and also about the transmission routes of STDs.^[10] It is shown that the level of health-related knowledge has an indirect relationship with the prevalence of HRSBs.^[11] Therefore, education is considered as one of the interventions with potential positive effects on the prevalence and prevention of HRSBs.^[12,13] Education can help modify attitudes and behaviors and thereby, reduce the prevalence of HRSBs and STDs.^[14]

Engagement in high-risk behaviors is a complex phenomenon affected by a wide range of personal and sociocultural factors. Therefore, their management necessitates multi-component educational interventions developed based on firm scientific evidence and behavior modification theories. One of these theories is the theory of reasoned action (TRA) which focuses on the intention to engage in a given behavior.^[15] TRA introduces behavioral

intention as the most important factor for a given behavior. Factors which determine behavioral intention are attitude toward the behavior and subjective norms.^[16] Attitude toward the behavior is in turn determined by behavioral beliefs and evaluation of behavior outcome, while subjective norms are formed by normative beliefs and motivation to comply with them [Figure 1].

It is shown that TRA significantly contributes to behavior modification.^[17] For instance, several studies showed its effectiveness in predicting and explaining a wide range of health-related behaviors such as cigarette smoking, drug abuse, alcohol consumption, use of healthcare services, physical activity, sun protection, breastfeeding, STD-related behaviors, use of contraceptive pills, mammography, and use of safety belt and helmet.^[18,19] Another study reported that the use of TRA helped improve Hispanic families' knowledge about the human immunodeficiency virus (HIV) and thereby, empowered them for more effective prevention of high-risk behaviors among their adolescents.^[20]

Also, the results of a study by Jeihooni *et al.*,^[21] who used TRA in their curriculum on the self-care behaviors of women with type 2 diabetes, showed that educational intervention had a significant effect on promoting the patient's self-care behaviors in the experiment. Furthermore, this study showed that the extended theory of reasoned action can be a good framework for designing educational interventions to promote self-care behaviors in diabetic patients. It should be noted that most previous studies used TRA to explain behaviors instead of correcting them. In addition, studies that used TRA to correct behavior were more relevant to substance abuse. Therefore, if available, there is limited reliable data on the effects of TRA on HRSB modification. The present study was designed and implemented to close this gap. The aim of the study was to reduce the high-risk sexual behaviors among patients with HPV.

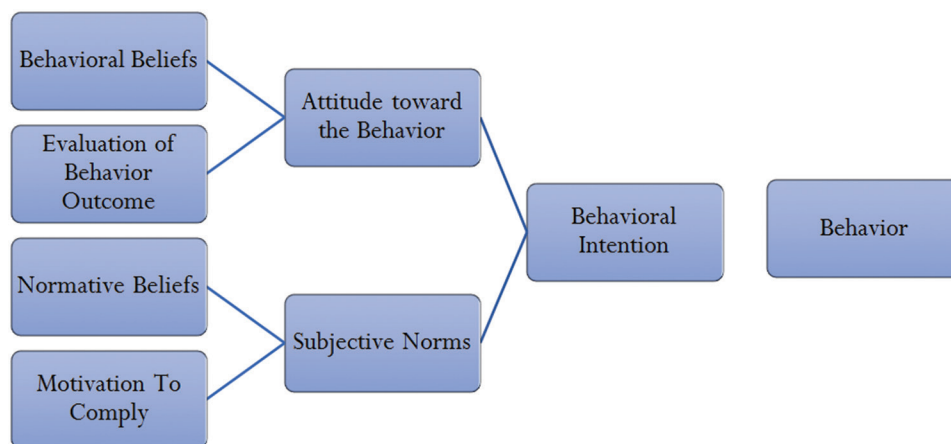


Figure 1: The components of TRA

Materials and Methods

Study design and setting

This study was a two-grouped, randomized, controlled trial which was completed in 2020.

Study setting was the STD Clinic of Tehran University of Medical Sciences which is located in Razi Dermatology Hospital, Tehran, Iran. Established in 1934, Razi Hospital is one of the oldest teaching healthcare centers in Iran.

Study participants and sampling

Participants were 110 patients with HPV infection diagnosed by an infectious disease specialist. This study adheres to CONSORT guidelines [Figure 2].

Inclusion and exclusion criteria

Inclusion criteria were an age of more than 18, basic literacy skills, and no affliction by physical or mental disabilities. Participants were excluded if they received HRSB-related education from other sources, developed acute physical or mental problems, had one absence from the educational sessions of the study intervention, did not answer our follow-up telephone contacts, did not refer to the study setting for follow-up HRSB assessment, or voluntarily withdraw from the study.

Sample size

Sample size was calculated based on the mean and standard deviation of HRSBs reported in a former study and with a confidence level of 0.95 and a power of 0.80. Accordingly, the sample size calculation formula showed that 45 patients were needed for each group.

Yet, considering the probability of the participants' withdrawal from the study and to increase the power of the study, the sample size was increased to 55.

$$n = \frac{(z_1 - \alpha/2 + z_1 - \beta)^2 \times (s_1^2 + s_2^2)}{d^2}$$

$$= \frac{(1.96 + 0.84)^2 \times (12^2 + 12^2)}{7^2} = 45$$

Data collection tool and technique

Participants were recruited to the study through consecutive sampling and were allocated to a control and an intervention group through permuted block randomization with block size of 4. Allocation sequence was generated by the statistical advisor of the study.

Data collection instruments were a demographic questionnaire and the Sexual Risk Behaviors Scale. The demographic questionnaire had items on age, gender, marital and employment status, educational level, income, insurance, residence, hospitalization history, living arrangement, religion, cigarette smoking, drug abuse, alcohol consumption, and number of sexual partners. The Sexual Risk Scale consists of 38 items for HRSB assessment.^[22] Each of its items is responded as either "Agree", "I have no idea", or "Disagree". At the beginning, a total score of 80 is assigned to each respondent. Then, one point is subtracted for each item that is answered with "I have no idea". Moreover, if the respondent provides the "Agree" response to odd items and item 38, two points per item are subtracted;

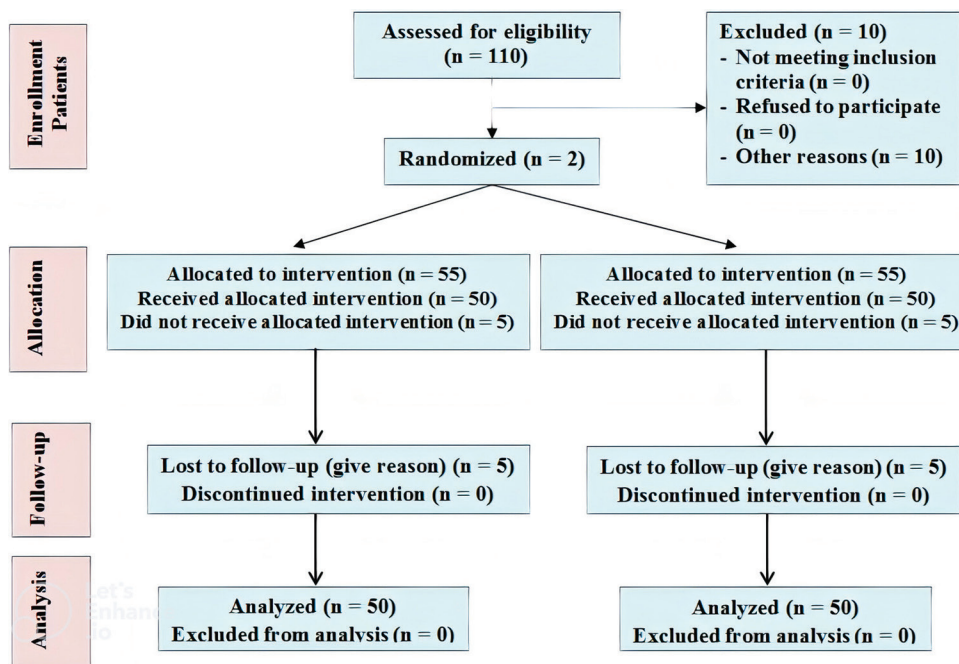


Figure 2: The CONSORT flow diagram of the study

otherwise, no point is subtracted. For even items except for item 38, two points per item are subtracted if the respondent responds with the “Disagree” answer, while no point is subtracted if he/she responds these items using the “Agree” answer. Consequently, the lowest and the highest possible scores for the scale are 4 and 80, respectively. The total score of the scale is interpreted as the following: Scores less than 15 indicate low risk of HRSBs; scores 15–37 indicate moderate risk of HRSBs; and scores more than 38 indicate high risk of HRSBs.^[22] In the present study, content validity assessment was performed for the cross-cultural adaptation of the scale. Accordingly, ten instructors of the Faculty of Nursing and Midwifery of Tehran University of Medical Sciences, Tehran, Iran, assessed and confirmed the content validity of the scale. The reliability of the scale was also confirmed with a Cronbach’s alpha of 0.763 and a test-retest correlation coefficient of 0.849. Data for reliability assessment were collected from 15 patients who twice completed the scale with a one-week interval.

Intervention

The study intervention was a TRA-based, HRSB-related educational program. Primarily, a survey was conducted in the study population in order to identify the most important concepts of TRA among the study population and to design the TRA-based educational program of the study. Accordingly, 100 patients with HPV infection were consecutively recruited to complete a researcher-made TRA-based HRSB-related questionnaire. The collected data were analyzed and the most important factors affecting HRSBs were identified. Survey findings revealed subjective norms as the most important factor contributing to HRSBs. Therefore, the educational program was designed mostly based on this concept as well as participants’ conditions.

After primary HRSB assessment, the TRA-based HRSB-related educational program was implemented for participants in the intervention group. Education was provided to participants in two 60-minute face-to-face sessions with a one-month interval. The instructor for the male patients was the first author, while the instructor for the female patients was a female nurse trained and supervised by the first author. Besides face-to-face education, an educational booklet containing HRSB-related materials was prepared and provided to patients to review educational materials during the study. After the first educational session, follow-up contact via the telephone were made with participants every two weeks for three months to review education, remind them of reviewing education using the booklet, answer their probable questions, and assess their conditions. Participants in the control group received routine care services which included no TRA-based HRSB-related

education. Three months after the first educational session, participants’ HRSBs were reassessed.

Ethical consideration

The Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran, approved the study (code: IR.TUMS.FNM.REC.1396.2095) and the study was registered in the Iranian Registry of Clinical Trials (code: IRCT2016121831453N1). Verbal and written informed consents were obtained from all participants and they were ensured that the data would be reported anonymously.

Data analysis

Data were analyzed via the Statistical Package for the Social Sciences (SPSS) v. 21.0 and were described via the measures of descriptive statistics (including frequency, percentage, mean, and standard deviation). Within- and between-group comparisons were made at a significance level of less than 0.05 using the paired sample *t*, independent sample *t*, Chi-squared, and Fisher’s exact tests.

Results

In total, 110 patients were recruited and divided into two 55-person groups. Five participants were excluded from the intervention group due to absence from the educational sessions ($n = 3$) and not answering follow-up telephonic communication ($n = 2$). Moreover, five participants were excluded from the control group because they did not refer to the study setting three months after the study onset for follow-up treatments and HRSB assessment. Consequently, final analysis was performed on the data retrieved from 100 participants [Figure 2].

As Table 1 shows, groups did not significantly differ from each other with respect to the participants’ age, gender, marital and employment statuses, educational level, income, place of residence, number of children, hospitalization history, and sexual partnership ($P > 0.05$). However, there were significant between-group differences with respect to their insurance status ($P = 0.009$), religion ($P = 0.031$), type of residence ($P = 0.008$), and living arrangement ($P = 0.016$). The results of the independent sample *t* test revealed that participants’ mean score of HRSBs had no significant relationship with their insurance status ($P = 0.87$), religion ($P = 0.27$), home status ($P = 0.10$), and living arrangement ($P = 0.12$), denoting that these variables were not confounders.

The results of the primary survey illustrated that all components of TRA contributed to behavioral intention and engagement in HRSBs, and the highest

Table 1: Between-group comparisons respecting participants' characteristics

Group\ Characteristics	Control n (%)	Intervention n (%)	P	Group\Characteristics	Control n (%)	Intervention (n=50)	P
Age (years)				Marital status			
15-25	19 (38)	20 (40)	0.57 [†]	Single	21 (42)	16 (32)	0.09 [*]
26-35	26 (52)	26 (52)		Married	26 (52)	33 (66)	
36-45	5 (10)	4 (8)		Divorced/Widowed	3 (6)	1 (2)	
Gender				Insurance			
Male	36 (72)	39 (78)	0.48 [^]	Yes	44 (88)	33 (66)	0.009 [^]
Female	14 (28)	11 (22)		No	12 (12)	17 (34)	
Educational level				Number of children			
Below diploma	3 (6)	4 (8)	0.73 [*]	0	34 (68)	38 (76)	0.50 [^]
Diploma	24 (48)	20 (40)		1	7 (14)	7 (14)	
University	23 (46)	26 (52)		2	9 (18)	5 (10)	
Income				Housing type			
Insufficient	26 (52)	16 (32)	0.09 [^]	Private	13 (26)	26 (52)	0.008 [*]
Almost sufficient	16 (32)	19 (38)		Rented	34 (74)	23 (46)	
Sufficient	8 (16)	15 (30)		Organizational	0 (0)	1 (2)	
Employment status				Religion			
Employee	10 (20)	9 (18.4)	0.58 [*]	Shiite	42 (84)	49 (98)	0.031 [*]
Laborer	2 (4)	4 (8.2)		Sunni	8 (16)	1 (2)	
Self-employed	10 (20)	10 (20.4)					
Housewife	15 (30)	19 (38.8)		Previous history of hospitalization			
Student	13 (26)	7 (14.3)		Yes	14 (28)	13 (26)	0.82 [^]
Place of residence				No	36 (72)	37 (74)	
Urban areas	44 (88)	45 (90)	0.74 [^]				
Rural areas	6 (12)	5 (10)		Sexual partnership			
Living arrangement				Yes	2 (4)	0 (0)	0.49 [*]
Alone	16 (41)	1 (29.5)	0.016 [*]	No	48 (96)	50 (100)	
With family	24 (59)	37 (70.5)					

[†]The results of the independent sample *t* test. ^{*}The results of the Fisher's exact test. [^]The results of the Chi-squared test

Table 2: The mean scores and ranges of TRA components in the primary survey

Components	Mean±SD	Minimum	Maximum
Behavioral beliefs (-18-18)	-13.75±4.13	-18	3
Evaluation of behavior outcomes (-18-18)	-14.24±3.86	-18	0
Subjective norms (-18-18)	-9.56±6.05	-18	12
Motivation to comply (-18-18)	-13.29±4.35	-18	0

and the lowest mean scores were related to the subjective norms (-9.56 ± 6.05) and the evaluation of behavior outcomes (-14.24 ± 3.686) components, respectively [Table 2]. Consequently, the most significant and the least significant factors for HRSBs were determined to be subjective norms and evaluation of behavior outcomes, respectively.

The paired sample *t* test showed that the mean score of HRSBs in the intervention group significantly reduced from 30.90 ± 11.83 at pre-test to 22.94 ± 11.43 at post-test (*P* < 0.001). The mean score of HRSBs in the control group was 27.54 ± 7.89 at pre-test, which insignificantly changed to 27.80 ± 7.72 at post-test (*P* = 0.70; Table 3). Consequently, although the between-group difference respecting pre-test mean score

of HRSBs was not statistically significant (*P* = 0.099), the post-test mean score of HRSBs in the intervention group was significantly less than the control group (*P* = 0.015; Table 3). The mean difference between the pre-test and post-test of HRSBs in the intervention group was also significantly greater than that in the control group (-7.96 ± 7.84 vs 0.26 ± 4.78; *P* < 0.001; Table 3).

Discussion

This study evaluated the effects of a TRA-based educational program on HRSBs among patients with HPV. The pretest mean scores of HRSBs in the intervention and the control groups were 30.90 ± 11.83 and 27.54 ± 7.89, respectively, denoting moderate risk of HRSBs.^[22] In line with this finding, a study on 202 people in Nigeria reported moderate risk of HRSBs with an HRSB mean score of 30.38 ± 12.14.^[23]

Our findings also showed that the subjective norms component of TRA was the most significant factor for HRSB-related behavioral intention. Subjective norms refer to the effects of social beliefs and values on a given behavior or the approval or disapproval of the behavior by family members and peers.^[24] The more significant

Table 3: Within- and between-group comparisons regarding HRSBs

Time\Group	Before Mean±SD	After Mean±SD	HRSB risk	Before n (%)	After n (%)	P*
Control	27.54±7.89	27.80±7.72	Low	2 (4)	0 (0)	0.70
			Moderate	44 (88)	45 (90)	
			High	4 (8)	5 (10)	
Intervention	30.90±11.83	22.94±11.43	Low	5 (10)	17 (34)	<0.001
			Moderate	26 (52)	28 (56)	
			High	19 (38)	5 (10)	
P	0.099	0.015				

*The results of the paired sample t-test. ^The results of the independent sample t-test

effects of subjective norms in the present study may be due to the fact that the sociocultural context in Iran prevents family members from explicitly talking about sexual issues and HRSBs.^[25] In other words, if family members in the present study had more explicitly talked with each other about sexual issues, subjective norms could have exerted more significant preventive effects on HRSBs. Another study in Iran showed that some parents strongly disapproved talking about sexual issues, and hence, their children discussed these issues with their friends.^[26] Other studies in Iran and Saudi Arabia also confirmed that most adolescents preferred to talk about sexual issues mostly with their friends than their family members.^[26,27] Adolescents' communication with their parents, particularly between daughters and mothers, can have protective effects against HRSBs.^[28]

Between-group comparisons in the present study showed that while there was no significant difference between groups regarding the pre-test mean score of HRSBs, the post-test mean score of HRSBs in the intervention group was significantly less than the control group. In agreement with this finding, a study in Iran showed the effectiveness of the implementation of sex education programs in schools and the media and social networks.^[29] Sabouri *et al.* according to their research showed that educational intervention that shaped based on TPB theory can significantly improve women's view about health care empowerment.^[30]

In their study, Karimi *et al.*^[31] showed that problem-based health literacy intervention program and real-life practice in the form of scenarios can improve the lifestyle of adolescents.

Our findings also showed the positive effects of TRA-based HRSB-related education on HRSBs among patients with HPV infection. Most previous studies on TRA had been conducted mostly for behavior prediction than behavior modification.^[32,33] For instance, a meta-analysis of the roles of TRA and the theory of planned behavior in the prediction of the intention to use condoms showed that TRA components had good predictive value while the theory of planned behavior did not have good predictive value in relation to the condom use behavior.^[18] Another study showed that all

components of TRA were significant predictors of drug abuse among women of reproductive age. That study also indicated that attitude was the most significant predictor of drug abuse while behavioral intention resulted in the drug abuse behavior only after six months.^[34] Some studies in Iran also reported the effectiveness of TRA in both behavior prediction and modification.^[35,36]

Limitations and recommendation

One of the limitations of this study was that it was conducted in a single health care center and hence, findings may have limited generalizability. Moreover, as patients referred to the study setting only three months after receiving the first treatments, assessing their HRSBs for longer periods of time was not possible. But this study emphasizes the power of rational, action-based, training program theory, which significantly reduces high-risk sexual behaviors in patients with HPV infection. The findings of this study can help members of the health care team develop and use educational theories based on rational action theory to reduce high-risk sexual behaviors and HPV infection. Replication of the present study among patients with other STDs (such as acquired immunodeficiency syndrome) is recommended. Moreover, studies are recommended to assess the effects of longer educational programs with greater number of educational sessions on HRSBs.

Conclusion

This study concludes the effectiveness of TRA-based educational program in significantly reducing HRSBs among patients with HPV. Educational interventions are usually simple, inexpensive, and easily applicable. Therefore, TRA-based educational interventions are recommended for reducing and preventing HRSBs and STDs.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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