



Design and evaluation of a theory-based intervention of knowledge and perceptions to improve self-care amongst relatives of esophageal cancer patients: A randomised controlled trial study protocol

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ABSTRACT

Background: Esophageal cancer, as one of the most unknown cancers, is largely preventable through life-style modifications. In this study, a theory-based intervention will be designed and evaluated on the knowledge and perceptions of relatives of patients with cancer to improve their self-care.

Methods: This research will be carried out in two phases in Golestan province, located in north of Iran. A researcher-made questionnaire will be designed based on the extended parallel process model using a detailed literature review and the panel of experts' opinions. This questionnaire will aim to investigate the levels of knowledge, perception, and practice of respondents regarding esophageal cancer. Later, a comprehensive program will be designed over esophageal cancer self-care based on the information collected from the questionnaire, the information obtained from detailed literature review, and the experts' opinions. The second phase of the study will include implementation of an educational intervention with pretest–posttest design using the intervention and control groups to measure the effectiveness of this educational program on the knowledge, perception, and practice of the patients' relatives.

Discussion: The findings will provide valuable evidences regarding the efficacy of the educational intervention and will help the participants to improve their self-care behaviours. Consequently, policy-makers and planners can use the results to set appropriate policies.

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1. Background

Cancer, a major public health problem [1], is the second leading cause of death worldwide [2,3]. The World Health Organization predicted about 16 million new cancer cases per year by 2020. It also predicted that 70% of the cases would occur in the developing countries [4]. Esophageal cancer is the eighth most common cancers worldwide with more than 450,000 new cases every year [6]. The highest incidence of this cancer was reported in Asia and Africa [5]. Among the patients with esophageal cancer, the 5-year relative survival rate is about 19% depending on the stage at diagnosis [1]. About 80% of the cases occur in the developing countries

[6]. A unique epidemiological feature of esophageal cancer is its very uneven geographic distribution with high incidence found within sharply demarcated geographic confines. These hot-spots include areas in northern Iran, Kazakhstan, South Africa, and northern China [7]. Esophageal cancer is the second and third most common malignancy in Iranian males and females, respectively [8]. According to the literature, risk factors of this cancer include: low intake of fruits and vegetables, intake of hot tea, consumption of opium and tobacco, *H. pylori* stomach infection, consumption of unhealthy water from cisterns, and genetic susceptibility. However, cancer risk can be reduced by avoiding tobacco, adhering to a balanced diet, exercising, and seeking routine cancer screenings [9]. Furthermore, lack of a relationship between people's attitudes and behaviours was a focus for social psychology regarding this cancer. The researchers argue that a focus on people's attitudes does not account for the range of influences that may guide beha-

Abbreviations: EPPM, extended parallel process model.

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viour [10]. Hence, health officials and medical community are required to take preventive measures in this area [11]. To meet these challenges, education can affect the individuals' attitudinal and behavioural patterns [12]. Moreover, increasing the effectiveness of health education depends on appropriate use of behavioural patterns [13].

Despite the advances in early diagnosis and treatment of many cancers, a census showed that one-third to half of the population in the United States and the United Kingdom had high anxiety regarding cancers compared with other diseases [14]. Such fear appeal messages are effective in behaviour change as they highlight the risk(s) an individual faces in performing or not performing a recommended behaviour [15]. The extended parallel process model (EPPM) is a theoretical framework for improving the effectiveness of health risk communication efforts [16]. The EPPM is rooted in theories of health protective behaviours, such as the protection motivation theory. It integrates components of the transactional stress model and self-efficacy theory with the parallel process model of fear and danger control [17]. This model suggests that people will act if the perceived threat (severity and susceptibility) is high enough and if the efficacy levels (self-efficacy and response efficacy) are likewise high [18]. According to Shi and Smith, EPPM predictions are likely to be operative after three exposures to a persuasive message [19].

Since disease-induced fear has devastating effects on the relatives of patients, this study will attempt to uncover the effective factors on performing self-care behaviours to prevent esophageal cancer. Therefore, the purpose of this study is designing and evaluating a theory-based intervention on the knowledge and perceptions of relatives of patients with cancer to improve their self-care behaviours.

2. Methods/design

This research will be carried out in Golestan province, north of Iran in two phases. In the first phase, a researcher-made questionnaire will be designed based on the EPPM using a detailed literature review and experts' opinions about the level of knowledge, perceptions, and practice of the target group regarding esophageal cancer. Next, a comprehensive program will be designed over esophageal cancer self-care based on the information collected from the first phase of the study using questionnaires, detailed literature review, and experts' opinions. The second phase will include implementation of the educational intervention with a pretest–posttest design using intervention and control groups to measure the effectiveness of this program on the knowledge, perceptions, and practice of the patients' relatives.

2.1. Aim

The study goal is to design a theory-based educational program on EPPM for the relatives of patients with esophageal cancer. Furthermore, the aim is to raise the participants' knowledge, change their perceptions, and improve their self-care practice towards esophageal cancer. As a result, the burden imposed by esophageal cancer disease will be reduced in Golestan province of Iran.

2.2. Research hypotheses

According to the main purpose of this study, hypotheses will be considered according to the viewpoints of the health education, Gastroenterology, and Oncology professionals. The research hypothesis is that the mean scores of knowledge, perceptions, and practice will increase significantly in the intervention group members towards performing self-care behaviours after the inter-

vention. Furthermore, the intervention group will have significantly higher mean scores in constructs of the self-care behaviour model (perceived sensitivity, perceived severity, perceived fear, self-efficacy, perceived response efficacy) than the control group after the intervention.

2.3. Phase I: designing the questionnaire and the educational intervention

Initially, a detailed literature review will be conducted to investigate and select the appropriate model. Later, a panel of experts in health education, health promotion, Gastroenterology, Oncology, and epidemiology fields will be interviewed in this regard. As a result, a questionnaire will be designed based on the EPPM constructs: knowledge, perceived sensitivity, perceived severity, perceived fear, self-efficacy, perceived response efficacy, intentions, and behaviours. To assess the validity of the questionnaire, a 15-person panel of professionals will be asked to review the questionnaire. Consequently, CVR and CVI will be obtained to verify validity of the questionnaire. To confirm reliability of the questionnaire, internal consistency will be measured using alpha Cronbach. The questionnaire will be administered in the pre-test and post-test of the intervention phase.

In the second stage of this phase, the educational intervention will be designed and the target population will be determined based on a review of the literature as well as the information collected from the questionnaire. The educational package will include individual counseling sessions, educational pamphlets, two educational posters, and short message service (SMS) reminder (end of each week for a period of two months) with regard to self-care. Types of the educational messages are listed in Table 1.

Educational package (counseling sessions, educational pamphlet, two educational posters):

The educational pamphlet will contain scientific information on esophageal cancer, disease statistics, risk factors, signs and symptoms of the disease, and behavioural advice. The counseling session will be conducted to raise the individuals' knowledge and provide them with some simple steps to enhance self-care and to increase self-efficacy.

Considering the posters, the first one will include simple tips on preventing esophageal cancer and improving self-care motivation. The second poster will represent the risk factors and complications of esophageal cancer.

2.3.1. Follow up and maintaining education (SMS reminder)

After the intervention, all participants will receive an alert SMS at the end of each week for two months. These messages will provide the participants with some recommendations about self-care.

2.3.2. Panel of experts

The content and visual validity of the questionnaire and educational program will be examined by a panel of experts including professionals in the fields of health education, health promotion, epidemiology, Gastroenterology, and Oncology. The administered questionnaire will be revised according to the experts' revisions.

2.4. Phase II: implementation of the educational intervention

2.4.1. Sample size

The present study will be conducted on relatives of patients with esophageal cancer, who referred to health clinics of Golestan province in 2019. The study sample will include 100 participants selected by the convenience sampling method. The sample size was estimated as 90 persons based on a pilot study considering the significance level of $\alpha = 0.05$, test power of $\beta = 80\%$, and max-

Table 1
Types of educational package messages.

- **Educational messages:** Scientific information on esophageal cancer, disease statistics, risk factors, signs and symptoms of the disease, behavioural advices
- **Self-efficacy promotion messages:** Breaking complex behaviours into simple steps, which will be presented in a pamphlet and two posters (e.g., Simple steps to improve nutritional habits and self-care strategies, key sentences about the ability to target group and sensitize them).
- **Alert or reminder messages:** Message to remind the participants about self-care and prevention behaviours with regard to esophageal cancer.

imum standard deviation of $S = 4$. Considering a 10% attrition, a total of 100 individuals will be selected to participate in the study.

The study design will be guided by the CONSORT (Consolidated Standards of Reporting Trials) statements [20]. As a result, the participants will be randomly classified into the intervention and control groups using random number sequence. The intervention group will receive an educational intervention designed in the first phase of the study, while the control group will receive no intervention. Both study groups will be required to complete the administered questionnaires prior to and after the intervention.

2.4.2. Study environment and population

This interventional study will be conducted in hospitals, chemotherapy clinics, and centers affiliated to Golestan University of Medical Sciences, Iran.

2.4.3. Sampling method

Convenience sampling method will be applied to select the participants. The participants will be classified into the intervention and control groups using a table of random numbers. This randomization approach is simple and easy to implement in a clinical research. Moreover, all participants will be listed on a unit list consisting of all files recorded during the study period. The files will be numbered from 1 and the numbers will be selected randomly.

2.5. Inclusion criteria

Involvement of a first-degree family member (father, mother, sister, brother, children) in esophageal cancer, Iranian nationality, aged between 20 and 70 years, ability to understand the questions or ability to read and write in order to answer the questionnaire, having no physical and cognitive problems in order to answer the questionnaire, and consent to participate in the study.

2.6. Exclusion criteria

The participants will be excluded if they do not complete the intervention for any reason, are unwilling to cooperate in the research, do not participate in the educational training and post-test.

Table 2
The primary and secondary outcome measures based on EPPM.

Variable	SCALE	MEASUREMENT STRATEGIES
Primary outcome variables		
Intention	1 (Strongly disagree) to 5 (Strongly agree)	(Examples: "I decided to quit the habit of drinking hot tea.")
Behaviour	1 (never) to 5 (always)	(Examples: "I used to drink hot drinks and meals.")
Secondary outcome variables		
Knowledge	(1 Yes, 2 No, 3 I do not know)	(Examples: "Is esophageal cancer preventable?")
Perceived sensitivity	1 (Strongly disagree) to 5 (Strongly agree)	Because of a history of esophageal cancer in the family, I am at risk of the esophageal cancer.
Perceived severity	1 (Strongly disagree) to 5 (Strongly agree)	(Examples: "I believe that If I develop esophageal cancer, my life is disrupted.")
Fear	1 (Very much) to 6 (Not at all)	(Examples: "I feel terrified about esophagus cancer.")
Self-efficacy	1 (Strongly disagree) to 5 (Strongly agree)	(Examples: "I can quit drinking hot tea and coffee to prevent esophageal cancer.")
Response efficacy	1 (Strongly disagree) to 5 (Strongly agree)	(Examples: "Avoiding tobacco and drugs is effective in preventing esophageal cancer.")
Defensive avoidance	1 (Strongly disagree) to 5 (Strongly agree)	(Examples: "Despite the history of esophageal cancer in my family, I tend to avoid thinking about it.")

2.6.1. Data collection method

The researcher-made questionnaire will be designed based on EPPM and employed in the intervention phase.

2.7. Measurement

Data will be collected by self-reported pre- and post-intervention questionnaires. The pre-intervention questionnaire will be completed before the commencement of the intervention. The post-intervention questionnaires will be completed two months after the commencement of the intervention in order to assess the mean score changes within the intervention group as well as between the control and intervention groups.

2.8. Outcome measures

The participants' mean scores will be measured using a researcher-made questionnaire in the pre-test and post test phase. The primary outcome variables will assess effectiveness of the intervention in improving the target group self-care perceptions and practices regarding the esophageal cancer. The secondary outcome variables will assess effectiveness of the intervention as a means of improving knowledge and perceptions of the target group towards performing self-care behaviours (i.e., perceived sensitivity, perceived severity, perceived fear, self-efficacy, and perceived response efficacy) (Table 2).

2.9. Data analysis

Data analyses of this randomized controlled trial will include standard descriptive statistics, Student's t-tests, chi-square, correlation, regression, and ANOVA by running SPSS version 21.

Fig. 1 illustrates an overview of the trial design based on SPIRIT guidelines.

3. Discussion

This theory-based intervention will be conducted to promote self-care behaviours among relatives of patients with esophageal cancer. To date, few studies have focused on patients' family mem-

		STUDY PERIOD																								
No	Activities breakdown	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
1	Preliminary study and proposal design	←→																								
2	Designing a questionnaire and narrative					←→																				
3	Pre-test										←→															
4	Designing a training program and conducting educational intervention													←→												
5	Perform post-test and quantitative data analysis																		←→							
6	Presentatin of the final report of the research																						←→			

Fig. 1. Schedule of enrolment, interventions and assessments according to SPIRIT, Duration of the whole project: 24 months after approval.

bers in Golestan province and other provinces of Iran. Furthermore, we are faced with a paucity of information collected from theory-based interventions to address knowledge, perception, and practice of patients’ relatives. This theory-driven multi-component intervention will account for a range of multiple factors affecting personal self-care decisions. Moreover, it will improve prevention behaviours to reduce the incidence of esophageal cancer, which will decrease the burden of disease on the community. One of the strengths of this intervention is sending SMSs to follow up the participants and continue the education process. The SMS on the cellphone, as an insistent alert, will require instant action so that the health issues can be addressed [21]. Furthermore, an SMS is a promising e-health tool to enhance adherence rates [22]. Based on the literature, using individually tailored messages can cover broad content areas and overcome restrictions related to the place and time of delivery [23]. The strategies of this educational intervention are important and cost effective. Therefore, successful implementation this educational program will facilitate taking a step toward improvement of health status in the target group and will reduce their medical and treatment costs. Further-

more, the findings of this study can be extended to other similar populations in the world, such as China.

3.1. Limitations

Potential limitations of this study may include the following issues. Assessment of self-care changes will be limited to the information on self-reported behaviour. The calculated sample size is small. The risk of attrition bias is present in both study groups, particularly in the intervention group members who attend the educational program.

Ethics approval and consent to participate

Ethical approval for this study has been obtained by the ethics committee affiliated with Shahid Sadoughi University of Medical Sciences, Yazd, Iran (reference number IR.SSU.SPH.REC.1396.125), in compliance with the Helsinki Declaration. Registration of this randomized control trial has been completed with the Iranian Reg-

istry of Clinical Trials, IRCT20180725040588N1. Written and verbal consent will obtain from the participants for Cooperation in the study.

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Author contributions

SG, MAM, LJ, developed the study concept and all authors further developed the study protocol. SG, Z K and R S are responsible for the implementation of the intervention. SG, MAM will be responsible for delivering and intervention. SG, Z K and R S was responsible for drafting the manuscript and all authors contributed to the final manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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