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Design, implementation and evaluation of an intervention based on a social cognitive theory of physical activity and nutritional behaviors in middle-aged people at the risk of coronary artery disease in Bandar Abbas: A study protocol

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Abstract:

BACKGROUND: Coronary artery disease (CAD) is the most common cardiovascular disease (CVD) and the main cause of mortality in developed and developing countries. Physical activity and nutritional behaviors are modifiable factors in people at the risk of CAD and its risk factors; thus, the present study aimed to design, implement, and evaluate an intervention based on the social cognitive theory for physical activity and nutritional behaviors in the middle-aged population at the risk of CAD residing in Bandar Abbas city.

MATERIALS AND METHODS: The present study will be conducted in three phases: qualitative, cross-sectional, and community-based intervention. The middle-aged population with less than 150 minutes of physical activity a week with at least one other risk factor of CAD (hyperlipidemia, hypertension, diabetes, overweight and obesity, smoking) will be included in the study. In the qualitative phase of study, the participants will be selected with maximum diversity and with the aim of obtaining comprehensive information to clarify the nature and dimensions of the phenomenon in question. The cross-sectional phase aimed to determine the intensity of physical activity and nutritional behaviors. By analyzing the data obtained from the cross-sectional phase, the most important constructs of the social-cognitive theory in physical activity and nutritional behaviors will be determined, and accordingly, an effective intervention will be designed. The third phase of the pre-test-post-test intervention study will include a randomized control group. The interventions will be a combination of face-to-face meetings and the use of educational technologies. Individuals in the control group will not undergo the educational intervention. Those in the intervention group will be evaluated in two phases (before the implementation of the intervention, and 3 months after the intervention).

CONCLUSION: The findings of the present study can be used as a strategic plan to help policy makers to strengthen CVD prevention and management alternatives to include physical activity and nutritional behavior as part of their preventive measures.

Keywords:

Coronary artery disease, middle-aged, physical activity, social cognitive theory

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Introduction

The high prevalence of chronic diseases has attracted attention on a global scale in recent years. Chronic diseases such as type II diabetes, heart disease, obesity, and certain types of cancer account for more than 60% of mortalities worldwide.^[1]

CVDs are a main cause of mortality worldwide. The CAD is the most common CVD with a prevalence of more than 110 million cases worldwide.^[2,3] CAD is a serious cardiovascular disorder that affects approximately half of the middle-aged population and one-third of middle-aged women in developed countries.^[4-7]

There are many risk factors for CAD some of which can be controlled while others not. Controllable risk factors include a high blood pressure, high blood cholesterol level, smoking, diabetes, overweight or obesity, and lack of physical activity. Those that cannot be controlled are age, gender, family history, and genetics.^[8,9] Although only one risk factor suffices to increase the risk of a disease, these factors are so strongly correlated that susceptibility to a particular disease increases with the addition of another risk factor. Studies have shown that a combination of different risk factors can increase the risk of CVDs and mortality.^[10]

Diet and physical activity can be considered as the most effective lifestyle behaviors to reduce the risk of non-infectious disease.^[11]

Inactivity is the fourth leading cause of mortality in the world, accounting for approximately 30% of CVDs, 27% of all types of diabetes, and 21–25% of breast and colon cancers. Inadequate physical activity, defined as failure to meet physical activity guidelines, has been found as an independent risk factor for CAD in large population-based studies.^[12,13]

Nutritional factors have been identified as preventable risk factors for CVDs.^[14] Many of the main risk factors for CVDs, including hyperlipidemia, hypertension, obesity, and diabetes, are related to inappropriate eating habits.^[15,16] There is research evidence that unhealthy eating habits develop dramatically in middle age and old age.^[17]

Community-based interventions have been accepted as a promising approach to address health issues. Community-based interventions will not be successful without the support of the community in general and that of participants in particular.^[18] The effectiveness of health education depends on the skill of using appropriate theories.^[19,20] Interventions based on a theory are more likely to succeed. The social cognitive theory (SCT) helps to understand health behaviors such as physical activity and nutritional behaviors due to the interaction between the person, environment, and behavior.^[21] SCT focuses on the fact that individuals learn by observing others' behaviors, and this learning occurs at both cognitive and social levels.^[22]

SCT helps researchers to determine the drivers of health behaviors and then design health interventions that cause behavioral change after understanding these factors.^[23] In SCT, human behavior is explained in terms of a threefold dynamic model of causality, in which behavior, personal cognitive factors, and social-environmental influences interact, known as the reciprocal determinism.^[24]

Decreasing inactivity and increasing healthy eating are among the important goals of the World Health Organization^[25] and the National Document of preventing non-infectious diseases.^[26] Physical activity and nutritional behaviors are modifiable factors among people at the risk of vascular disease.

Studies for the prevention of diseases in people at risk are very important and valuable. No study has been conducted in Iran based on social cognitive theory to improve physical activity and nutritional behavior in middle-aged at risk of coronary artery disease, and past studies have been based on other groups and theories.^[27-30] Also health promotion strategies such as empowerment, strengthening social action with community-based approach will be used in this study. This study will use quantitative and qualitative data in combination that helps to understand the subject and proper analysis. Using social cognitive theory (SCT) as a theory-based approach strengthens all phases of the study. So far, no study has been conducted on middle-aged people at risk of vascular disease with the aim of increasing physical activity and improving nutritional behavior in Bandar Abbas city.

Thus, the present study aims to design, implement, and evaluate an intervention based on the SCT in physical activity and nutritional behaviors of middle-aged population at the risk of CAD residing in the city of Bandar Abbas, located in the south of Iran.

Materials and Methods

Study design and setting

The present research will be conducted in three phases: qualitative, cross-sectional, and interventional. After reviewing the related literature, to investigate the physical activity and the causes of inactivity and nutritional behaviors as closely as possible and to identify the SCT influential constructs, there is a need for qualitative research. In the qualitative phase of the study, first, the household health records in the Seeb system (integrated health system) will be reviewed to find individuals who meet the inclusion criteria. The Seeb system is an electronic system developed by the Ministry of Health, Treatment and Medical Education's Vice-Chancellor to form part of the electronic health file for all citizens of Iran. This system has been used since the beginning of 2015.^[31]

Selecting the participants with a maximum diversity and with the aim of obtaining comprehensive information will clarify the nature and different dimensions of the phenomenon in question. Data collection will continue without any limitations set on the number of participants so that the researcher can ensure data saturation.

The cross-sectional phase of study will be conducted with the aim of determining the intensity of physical activity and nutritional behaviors as well as the role of the SCT constructs in predicting physical activity and nutritional behaviors in individuals at the risk of CAD. Also, by analyzing the data obtained from the cross-sectional study, the most important constructs affecting physical activity and nutritional behaviors will be identified.

The educational content will be developed according to the predictive value of each construct as well as the physical activity and nutritional behaviors of the research subjects. The aim will be to implement an effective intervention to change physical activity and nutritional behaviors. The third phase of the intervention is a pre-test-post-test study with a randomized control group, which will be conducted in order to compare the effect of the intervention based on the SCT on increasing physical activity and improving nutritional behaviors in those at the risk of CAD. At first, four centers are randomly selected from among the healthcare centers in Bandar Abbas city, out of which two centers are randomly selected as the intervention group and two centers as the control. Participants are randomly selected for the study after checking the inclusion criteria. The participants will be homogenized in terms of social class. For the participants in the intervention group, there will be an intervention based on the SCT and community-based approach through a general education and a program to "strengthen social action" to increase physical activity and improve nutritional behaviors. The interventions will be a combination of face-to-face meetings and the use of educational technologies. Participants in the control group will not receive the educational intervention. The participants will be evaluated in two phases, before implementing the intervention and 3 months after the intervention through the questionnaires [Table 1].

This study will last from May 2022 to February 2024. The qualitative phase will be conducted from June to December 2022. The cross-sectional phase will begin in February 2022 and continue until July 2023, and the intervention phase will be from July to March 2023.

Study participant and sampling

The research population consists of middle-aged individuals visiting Bandar Abbas health centers who have electronic medical records in these centers, with less than 150-minute physical activity a week and at least one other risk factor of CAD (hyperlipidemia, hypertension, overweight and obesity, diabetes, and smoking).

Inclusion criteria

The inclusion criteria for the participants are:

- Having at least one risk factor of CAD (hyperlipidemia, hypertension, diabetes, overweight and obesity, and smoking).
- 35-55 years of age
- Physical activity less than 150 minutes in week.

Exclusion criteria

The exclusion criteria in this study are:

- Failure to complete the research questionnaire
- Failure to participate in training sessions for more than one session.

Sampling method

The sampling will be done in two phases. There are 20 comprehensive health service centers in Bandar Abbas. Four centers with similar features will be selected first, and from these four selected centers, two centers will be selected next as the intervention group and two as the control group. In each center, the eligible samples will enter the study randomly.

Ethical consideration

The explanations of the project will be given to all the participants. Furthermore, separate informed consent will be taken from the participants for any intervention. Individuals' personal information is protected an analyzed anonymously.

The Ethics Committee of Hormozgan University of Medical Sciences, Bandar Abbas, Iran, approved this study on June 18, 2022. The ethical code is IR.HUMS. REC.1401.065.

Study phases

First phase: Qualitative study

In this phase, in-depth individual and semi-structured interviews will be conducted, as well as group discussions with the middle-aged residents of Bandar Abbas. A conventional content analysis will be done to analyze the data. To this aim, the content analysis method suggested by Graneheim and Lundman will be

Phases and participants	Aim	Methods		
Phase 1 Qualitative Study				
Qualitative study on middle-aged people at the risk of coronary artery disease	Step 1: Explaining the perception of middle-aged people at risk of coronary artery disease from physical activity and nutritional behaviors and identifying effective factors	 in-depth individual and semi-structured interviews directed content analysis 		
esearcher Step 2: Design a valid and reliable instrument		 Based on step 1 		
Phase 2 Phase two: Cross-sectional Study				
Psychometrics evaluation	 To validate the questionnaire Preparation of the final questionnaire 	 qualitative and quantitative content validity face validity construct validity through CFA internal and external reliability 		
Phase 3: Interventional Study		,		
Design interventions	Step 1: Intervention group training	intervention based on the SCT and community-based approach		
Implementation	Step 2: Transfer educational content to intervention group	 2 months 16 sessions 45 minutes each session face-to-face meetings and the use of educational technologies 		
ntervention evaluation Step 3: Evaluate the program Identify the impact of the program in the intervention group		Questionnaire		

used.[32,33] The recorded interviews will be transcribed and analyzed in MAXQDA. First, the transcripts of the interview will be read several times. The meaning units and primary codes will be identified. Similar codes will be classified and placed in more layers, and the latent content in the data will be explained. To increase the validity of the results, four criteria proposed by Guba and Lincoln will be used.[34]

Instrumentation: Development and psychometrics

After extracting the concepts, primary codes, and classes, themes and primary items (indicators) will be determined based on the SCT about physical activity and nutritional behavior and the questionnaire will be developed. Then the psychometrics of this instrument will be measured, including the reliability and validity. The validation will be done in three steps. The first step is to substantiate face validity, during which all items in the questionnaire are checked by the target community. Quantitative and qualitative criteria will be used in this research. The qualitative measure includes face-to-face interviews with 15 subjects to comment on the level of difficulty, appropriateness, and ambiguity of the items. The corrections needed will be made accordingly. Quantitative criteria include testing the effect of items to shorten the statements, remove inappropriate statements, and decide on the relative importance of statements. The second step will be to establish content validity. CVR and CVI indicators can be used for this purpose. The third step will be construct validation. To this aim, a confirmatory factor analysis can be done. For the reliability test, two criteria, namely the internal consistency test and a test-retest method, will be used.

Phase two: Cross-sectional study

The cross-sectional study documents the most important determinants identified in the qualitative phase and literature review to facilitate a more effective intervention to increase physical activity and improve nutritional behaviors.

The designed questionnaire will consist of four parts. The first part will enquire about demographic variables including sex, age, marital status, smoking status, hookah consumption, alcohol consumption, body mass index, socio-economic status (SES), and comorbidities based on the related literature.[35-38] The second part of the questionnaire will contain questions related to the SCT. The third part will include the Persian version of the GPAQ standard physical activity questionnaire.^[39] This questionnaire contains 16 questions arranged in three parts. The first part evaluates physical activity at the workplace. The second part evaluates the movement and travel, and the third part evaluates physical activity in free time. One question asks the subject to state how many hours a day he/she is not engaged in physical activity. The fourth part of the questionnaire is related to nutritional behaviors. This questionnaire is an edited version of the Mediterranean diet with 13 questions about consuming olive oil, fruits and vegetables, red meat, butter and cream, carbonated drinks, legumes, seafood, sweets, nuts, chicken and turkey, and rice.^[40] Studies have shown that the Mediterranean diet has a protective effect against CVDs. These studies especially showed its protective role in the primary and secondary prevention of CVDs.[41-43]

The purpose of the cross-sectional study is to analyze the psychometrics of the instrument. The sample size will be decided on based on the standards of psychological literature that require at least five subjects per item.^[44] Considering that the theory has 11 constructs and probably 6 questions will be designed for each construct from the model and there are a total number of 66 questions, the minimum sample size required for the cross-sectional phase is 330 subjects.

For the data analysis, SPSS 21 will be used. Linear regression analysis will be run to determine the most important predictors of physical activity. Pearson's correlation test will be used to test the correlation between the model constructs. All findings will be interpreted at a significance level of 0.05. Also, confirmatory factor analysis will be done in Amos to measure the reliability of the instrument.

Phase three: Interventional study

This quasi-experimental interventional study will follow a pre-test and post-test design.

As one purpose of the present study is to compare the mean duration of physical activity between the two research groups, the intervention and control, the following formula will be used to calculate the sample size, to compare the two mean scores of the two independent research groups.

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 (s_1^2 + s_2^2)}{(\mu_1 - \mu_2)^2}$$

 $\mu_1 - \mu_2$ = Minimal significant difference between two groups.

 S_1 = Standard deviation of the intervention group.

$$\alpha = 0.05 \rightarrow z_{1-\frac{\alpha}{2}} = 1.96$$

 S_2 = Standard deviation of the control group.

$$\beta = 0.2 \rightarrow z_{1-\beta} = 0.84$$

In a similar study (Shamizadeh *et al.*),^[45] the mean \pm standard deviation of the duration of physical activity in the intervention group and the control was, respectively, 620 ± 138.6 and 616.7 ± 122.9 . The minimum significant mean difference between the two groups was considered to be 50 minutes, and using the above formula, the sample size in each group was estimated at 108. Since it is expected to have an attrition rate of 15% in each group, the final sample size for each group is estimated to be 127 [Figure 1].

$$n = \frac{n'}{1 - \% \text{lost}} = \frac{108}{1 - 0.15} = 127$$



Figure 1: Consort flow diagram

Conceptual framework

The SCT can facilitate the understanding of healthy behaviors such as physical activity and nutritional behaviors due to the interaction between the individual, environment, and behavior.^[21] The SCT focuses on the fact that individuals learn by observing others' behaviors and this learning occurs at both cognitive and social levels.^[22] The SCT emphasizes reciprocal determinism in the interaction of the individual and the environment. An individual's behavior is uniquely determined by a combination of these factors.^[24] The constructs within this theory include self-efficacy, collective efficacy, expected outcomes, knowledge, observational learning, normative beliefs, social support, barriers and opportunities, behavioral skills, intentions, reinforcement, and punishment^[46] [Figure 2].

The SCT has helped researchers to determine the drivers of health behaviors. If they adequately understand these factors, they can better design health interventions that cause behavior change.^[23]

Education and promotion

A community-based intervention can include awareness-raising, general education, and providing a program to enhance social action to increase physical activity and improve nutritional behaviors in a target community. Community-based intervention activities



Figure 2: Constructs of social cognitive theory

include the distribution of printed educational materials such as brochures and posters, holding educational classes, posting up advertisements in streets of the affected neighborhood, sending educational text messages, holding a conference on public walking and healthy cookery, and putting up posters to encourage walking on public sidewalks. The key message of the intervention reads: "a healthy heart with healthy activity and healthy nutrition." Before developing and publishing the educational content, they will be evaluated by a group of the target community members in terms of legibility of content, the associated feelings, and perceptions.

In order to increase physical activity and improve nutritional behavior in the intervention group, actions will be taken in line with the application of this strategy. Examples are to arrange for meetings to construct a special sport space for the middle-aged in parks, to offer discounts at the available clubs, to give discounts for organic and healthy foods, to provide access to coaches in parks for morning exercises, to form self-assisting groups and send short text messages to the participants' spouses and families to gain their support and cooperation for visits to cardiologists and nutritionists. Another strategy in implementing the intervention will be to select and train the representatives of the target community and to use facilitators with a specific logo and slogan.

Meetings will be held as group discussions in groups of 10 depending on the needs and goals and cross-sectional data. The intervention content will concern healthy nutrition and physical activity, participants' perceived barriers to physical activity, nutritional behaviors and strategies to overcome them, goal setting and its importance in carrying out and continuing regular physical activity and healthy nutrition, how to set short-term and long-term goals to achieve the desired outcomes, and how to set up a regular physical activity program and healthy nutrition and the features of an ideal program. In this program, according to the features of the target group, brainstorming methods, group discussions, lectures with Q&As will be used. To improve learning, posters, pamphlets, and DVDs on physical activity and healthy nutrition will be shared. For the self-monitoring of behavior and motivating consistent regular physical activity and healthy eating, self-assessment cards and habit trackers will be used to check the intensity of physical activity (number of recorded steps) and healthy eating (less consumption of salt, oil, and carbonated drinks and more consumption of fruits, vegetables, milk, and nuts). The learners' blood pressure and weight will be recorded weekly [Table 2]. The activities used in previous studies have proved effective.^[47-49]

Study outcomes

The primary outcome: Determine the PA level of the participant which will be measured by GPAQ and pedometer. Also consumption of olive oil, fruits and vegetables, red meat, butter and cream, carbonated drinks, legumes, seafood, sweets, nuts, chicken and turkey, and rice with Mediterranean diet questionnaire.

The secondary outcome of the study comprises social cognitive theory constructs by the questionnaire designed in this study.

Statistical analysis and power estimation *Data analysis*

To describe the quantitative variables, if their distribution is normal, mean and standard deviation will be used. If their distribution is not normal, the median and range of variation will be used. Frequency and relative frequency will be used to describe qualitative variables. Pearson's correlation coefficient (or Spearman's correlation) will be used to test and report the correlation between the model constructs. Independent-samples t-test (or Mann-Whitney U-test) will be used to compare the mean scores of the model constructs between the two intervention and control groups. The paired-samples *t*-test (or Wilcoxon's test) will be run to compare the mean scores of the model constructs before and after the intervention. If necessary, a covariance analysis will be used to control the confounding effect of pre-intervention scores on post-intervention scores.

Discussion

CAD is a serious cardiovascular disorder that affects approximately half of middle-aged men and approximately one-third of middle-aged women in developed countries.^[4-7] Despite the significant reduction in mortality rate induced by CAD, it is still one of the main causes of death in adults over 35 years of age.^[6] There is research evidence to show that

Construct	Self-efficacy	Collective efficacy	Expected outcomes	Knowledge	Observational learning	Normative beliefs
Tasks and activities	 a video clip based on a valid model programs to reduce stress group discussions to express failures and unsuccessful experiences and attributing them to various factors motivational interviews 	 forming several groups of 10 setting group goals and strategies to achieve goals selecting multiple representatives to better guide groups planning proper physical activity such as walking and doing physical exercises in parks using sport facilities local and traditional sport competitions several healthy food competitions 	 group discussions consulting a nutritionist to provide information about correct nutritional behaviors lectures and brainstorming to moderate expectations consulting a cardiologist to provide information about preventing CAD training workshops on the effect of physical activity on physical, mental, and social health 	 educational posters about CAD, appropriate physical activity, and healthy eating behaviors educational video clips about how to perform physical activity correctly, the frequency, and the time needed to do physical activity Preparing an educational booklet about healthy eating behaviors 	 observing an effective model of peer education mass media 	 brainstorming sessions to determine existing cultural norms and beliefs group discussions to correct normative beliefs
Construct	Social support	Barriers and opportunities	Behavioral skills	Intentions	Reinforcement and punishment	
Tasks and activities	 child care during training sessions compassionate conversation with people training sessions for families to support individuals educational campaign to support friends, family, and neighbors in the neighborhood 	 focus groups to explore the social or physical features of environment that make it harder or easier to show healthy behaviors giving solutions to adjust and remove perceived barriers through brainstorming 	 teaching the required skills via appropriate educational content and appropriate educational modes teaching self-regulation skills including: goal-setting, planning, organizing, and managing physical activities and healthy eating behaviors 	 setting short-term and medium-term goals to promote physical activities, maintain, and improve nutritional behaviors jotting down or stating goals, setting dates and target activities for skill mastery and monitoring progress 	 arranging for strolls, healthy cooking contests and awarding winners to encourage people to do regular physical activity and improve nutritional behaviors 	

Table 2: Activities designed based on the SCT constructs

people who increase their physical activity in early middle age can enjoy long-term health benefits.^[50-52] Physical activity and better nutritional behaviors in middle age are known as the best effective ways to reduce health risks in later stages of life^[53]; however, evidence shows that physical activity decreases with age.^[54,55] Therefore, effective interventions to increase physical activity and improve nutritional behavior at this age are important.

Variables such as socio-economic status (SES), access to sport facilities, social support, being married, positive beliefs and attitudes, weather conditions and health condition influence the intensity of physical activity.^[56,57] Current studies have shown socio-economic and cultural factors as the main predictors of physical activity.^[58] So far, no study has been conducted to identify the predictors of physical activity and nutritional behaviors in the population at the risk of CAD in Hormozgan Province in southern Iran. Therefore, it is necessary to identify these factors in order to design more effective interventions. Nutritional factors have been identified as preventable risk factors for CVDs.^[14] Many of the major risk factors for CVDs, including hyperlipidemia, hypertension, obesity, and diabetes, are related to improper eating habits.^[15] Increasing the consumption of foods rich in saturated fat with high calories and reducing the consumption of complex carbohydrates, fiber, fruits, and vegetables can significantly affect the controllable risk factors of CVDs.^[59] It seems that identifying nutritional behaviors in populations at the risk of CVDs and developing effective interventions is essential to improve their nutritional behaviors and prevent the disease.

A body of research has proved the effectiveness of community-based interventions in increasing physical activity and improving nutritional behaviors. In a 7-year study of 23,747 Norwegian adults without a history of CVD, two weekly sessions of moderate-intensity physical activity managed to reduce the risk of CVD by 49%.^[60] A study conducted over 8 years on 41,675 Taiwanese adults showed those in the intervention

group (having at least 100 minutes of aerobic exercises on a weekly basis) had a 14% lower risk of CVD.^[61] A community-based study was conducted with the aim of evaluating the effectiveness of an interventional program in promoting dietary habits in Iran in 435 women aged 26–54. Moreover, their daily energy intake was significantly reduced in the intervention group compared to the control group.^[62]

Previous studies prove the effectiveness of community-based interventions in the light of the SCT in physical activity and nutritional behaviors. Yet, these studies have not been conducted in middle-aged people at the risk of CAD to primarily prevent the disease.

Conclusion

The present research can guide the authorities and policymakers to improve physical activity and nutritional behaviors according to the inherent features of Hormozgan Province and the dominant culture. If the barriers to physical activities and nutritional behaviors are identified, necessary plans can be made to solve them. The present findings can be used to develop a program to promote physical activity and improve nutritional behaviors in accordance with the local culture and specific social characteristics.

This research can provide a road map to the authorities to improve physical activity and nutritional behaviors in people at risk of coronary artery disease according to the characteristics of Hormozgan province and the culture of the people of this province, and by identifying the Barriers and opportunities to performing physical activities and nutritional behaviors to resolve They make the necessary plans. Using the results of the research, the program to promote physical activity and improve nutritional behaviors will be designed and adjusted according to the culture of the region and their social characteristics.

And in the case of satisfactory results and the use of this program in the province, it may be able to reduce the prevalence of coronary artery disease in the future in the province.

One strength of implementing the present interventional program is the possibility of adjusting for two behaviors at the same time: one the physical activity and the other the nutritional behavior. Also, this study aims to prevent CVDs.

Limitations

One limitation of the present study is that it is not possible to objectively observe nutritional behaviors and physical activity; thus, a self-report questionnaire survey will be used to assess the behavior, which can lead to an imprecise description of the variable. Also, sampling from only one city reduces the generalization of results. Thus, it is suggested to conduct research in a wider scope.

Authors' contributions

T.A and Z.H. contributed to the study design; SH.M. analyzed the data; R.ER. wrote the manuscript and conducted data collection; and M.N. and M.M. conceived the study and developed the study protocol. All authors have read and approved the manuscript.

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Conflicts of interest

There are no conflicts of interest.

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