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# World health organization-package of essential noncommunicable disease intervention in iran's health system based on 5As healthy lifestyle counseling model: A randomized-controlled trial protocol

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## Abstract

**BACKGROUND:** The Iran Package for Essential Noncommunicable Disease (Ira-PEN) program has been established since 2018 with the aim of controlling and caring of noncommunicable diseases (NCDs) as well as their underlying causes in Iran. In this study protocol, a healthy lifestyle module will be used for the first time in Iran, which was recommended in 2018 by the World Health Organization to train health workers. This module relies on the 5As model, a training intervention design, then, implement, evaluate, and present the results to the managers and decision makers of the Ira-PEN program.

**MATERIALS AND METHODS:** This study will be performed in 2 stages, including 2 steps per stage. The first stage involves designing the 2 steps and validation of the healthy lifestyle counseling skills tool. The tool will encompass a health counseling evaluation checklist and a counseling assessment questionnaire according to the counseling recipients. The second stage also entails 2 steps; designing a training program for health workers in the field of healthy lifestyle counseling based on the Oles-Cement model followed by implementation and evaluation.

**CONCLUSIONS:** The training program and the results obtained in this study will be presented to the managers and decision makers of both the Ira-PEN program and NCDs control in Iran, and it is suggested to enhance the training program, network, and educational curriculum of health workers in providing healthy lifestyle counseling to play a more effective role in changing the public behavior toward a healthy lifestyle and preventing the risk factors of NCDs.

## Keywords:

Counseling model, healthy lifestyle, noncommunicable diseases, primary health care, randomized-controlled trial

## Introduction

According to the Sustainable Development Goals, one-third of all deaths related to noncommunicable diseases (NCDs) should be reduced globally by 2030 through prevention, treatment,

and mental health and well-being.<sup>[1]</sup> NCDs result in 41 million deaths annually, which is equivalent to 71% of the total deaths around the world.<sup>[2]</sup> Cardiovascular diseases (CVDs) are the leading cause of death worldwide,<sup>[3]</sup> if this trend persists,

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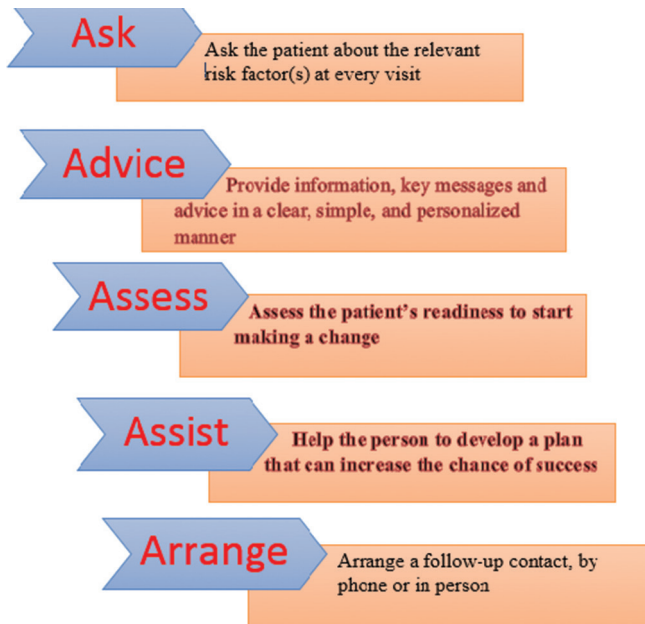


Figure 1: 5As model for healthy lifestyle counseling<sup>[20]</sup>

the annual number of deaths from CVDs is projected to elevate from 17.5 million in 2012 to 22.2 million by 2030.<sup>[4]</sup> Causes of heart attacks and strokes are usually associated with risk factors, such as smoking, unhealthy diet and obesity, physical inactivity and alcohol abuse, high blood pressure, diabetes, and hyperlipidemia.<sup>[3]</sup> In Iran, the mortality rate of CVDs is higher than the global average.<sup>[5]</sup> In total, NCDs in Iran stand for 76.4% of the total mortality, of which 45.7% is due to CVDs, 13.5% is related to cancers, 8.3% is because of respiratory diseases, and diabetes accounts for 2.2%.<sup>[6]</sup> Furthermore, in the STEPS study in 2016, among people over 18 years of age, the prevalence of overweight and obesity (body mass index 25 and more) was 59.3% in Iran, sedentary 90.3%, smoking 10.1%, and consumption of fruits and vegetables was more than 5 servings per day 48.6%.<sup>[7]</sup> Successful prevention and control of NCDs partially depend on individuals' and their families' willingness to make decisions about healthy behaviors and to consider the change of risk factors.<sup>[8]</sup> The World Health Organization (WHO) evaluates the role of health-care providers and their competencies in supporting self-care interventions.<sup>[9]</sup> Two-thirds of early deaths due to NCDs, including CVDs, can be prevented through the activation of PHC role.<sup>[10]</sup> The WHO Package for Essential NCDs (WHO-PEN) entails a minimum set of standards for combating NCDs to strengthen the national capacity to integrate and enhance the care against NCDs in the PHC system, especially in the environments experiencing scarcity in resources.<sup>[11]</sup> The effectiveness of national guidelines for managing blood pressure, cholesterol, and blood sugar relies on how well health-care providers implement recommendations on treatment and to what extent patients adhere to these guidelines.<sup>[12]</sup>

Lifestyle counseling, encompassing tobacco cessation, diet modification, avoidance of excessive alcohol consumption, and increasing physical activity, involves the regular and purposeful utilization of information and techniques to support individual behavior change.<sup>[13]</sup> Encouraging people with CVDs to prevent unhealthy activities, meanwhile, to adopt the healthy and useful ones is an evidence-based intervention to improve cardiovascular health and reduce risk.<sup>[14]</sup> In the Iran PEN (Ira-PEN) program run by Behvarz/Health Care, the "10-year risk of fatal or nonfatal heart attacks and strokes" using the risk assessment chart and using information about sex, age, having diabetes or not, smoking status, the systolic blood pressure and the amount of total cholesterol in the blood are calculated.<sup>[15]</sup> The six modules of the HEARTS package are for use by policymakers and program managers at various levels of the Ministry of Health that can be effective in providing PHC services for CVDs. The first module, the Healthy Lifestyle Module, provides information on four risk-related behaviors for CVDs, and short interventions based on the 5As model as an approach to advising on risk factors and encouraging people to adopt a healthy lifestyle Figure 1.<sup>[16]</sup> Many health-care providers are not sufficiently trained to provide professional advises, and their role is usually limited to general instructions such as "stop smoking," "eat better," and "be more active."<sup>[17]</sup> In this study, for the first time in Iran, a healthy lifestyle module is employed, a skillful intervention is designed, implemented and evaluated, and its results are presented to the managers and decision makers involved in the Ira-PEN program. It is hoped that by executing this study and applying its results, a small step will be moved forward to improve the health system and ensure the health of the Iranian society.

## Materials and Methods

### Study design

This study will be carried out throughout 2 stages. The first stage is a methodological study consisting of 3 steps, and the second stage is an experimental study of 2 steps [Tables 1 and 2 and Figure 2].

#### First stage

The first stage is a methodological study. At this stage, the Healthy Lifestyle Counseling Module (WHO 2018) will be translated and locally tailored first. Next, according to the module, a checklist and a healthy lifestyle counseling questionnaire based on the 5As framework will be developed and validated.

Step 1: Identify the terms of the checklist (review list) and questionnaire based on the Healthy Lifestyle Counseling Module (WHO 2018). Each tool has 5 sections: A general section related to providing behavior change counseling in general and 4 specific sections related to the healthy

lifestyle counseling for each of the proper eating behaviors, increasing physical activity, quitting smoking, and stop alcohol consumption.

Step 2: Check face and content validity by an expert panel and health-care staff.

Step 3: Assess the reliability of the review list by Cohen's Kappa coefficient<sup>[18]</sup> and assure the reliability of the checklist by test-retest technique.

*Second stage*

The second stage of the study is an experimental intervention. The intervention involves designing, implementing, and evaluating a 5As-based healthy lifestyle counseling training program, as well as applying new tools among health workers. This step also comprises 2 steps:

**Table 1: Study stages including design, implementation, and evaluation of the intervention related to the Ira-package of essential noncommunicable disease program in the health system**

Stage	Step	Process
Design and psychometrics of tools	First	Designing a checklist and questionnaire for healthy lifestyle counseling
	Second	Determining the content and face validity of the tool
	Third	Determining the reliability of the tool
Intervention	First	Designing a training program according to the Ols and Cement model
	Second	Implementation and evaluation of the training program based on the designed tools

Step 1: Design the intervention. In this step, an educational program will be firstly designed with the aim of raising the skills of health workers in providing healthy lifestyle counseling for the target group of the Ira-PEN program. This design will follow the planning model of Ewlen and Simnett (1999).<sup>[19]</sup>

The seven stages of intervention design based on Oles and Cement model [Figure 3] are as follow:

- Determining the needs of the group of health workers in the field of providing healthy lifestyle counseling
- Ascertaining the general and specific goals of a healthy lifestyle counseling training program
- Defining the appropriate practices for training such as workshops
- Determining and preparing the resources required for the training program
- Planning for how to evaluate the program using well-designed tools
- Setting an action plan for implementation
- Running the program

Step 2: Implement and evaluate the intervention. The execution step will be undertaken carefully according to the designed training pattern. Evaluation of the program will be done according to the schedule and implemented in 3 parts:

- For this purpose, based on the checklist (review list), the researcher will observe the steps of providing healthy lifestyle counseling following the 5As model and complete the checklist accordingly. In this way, the likely bias which might occur by the presence of different observers will be prevented

**Table 2: Measurement of the main study variables**

Variable	Measurement tools	Measurement method	Number of tools' questions	Measurement times	Measurement timing			
					Before intervention	Two months later	One week after intervention	Two months later
Healthy lifestyle counseling skills among health workers based on the 5As model	Checklist in 4 sections (each section has 5 model structures)	Direct observation	Nutrition 17, physical activity 19, Tobacco 23, Alcohol 9	2	√		√	
Healthy lifestyle counseling skills among health workers	Questionnaire in 4 parts (each section has 5 model structures)	Interviews with participants	Nutrition 10, physical activity 9, Tobacco 13, Alcohol 6	2	√		√	
Nutrition behavior of participant	System questions	Measurement, self-assessment	14	4	√	√	√	√
Physical activity behavior of participant	System questions	Self-assessment	8	4	√	√	√	√
Smoking behavior of participant	System questions	Self-assessment	7	4	√	√	√	√
Alcohol consumption behavior of participant	System questions	Self-assessment	3	4	√	√	√	√

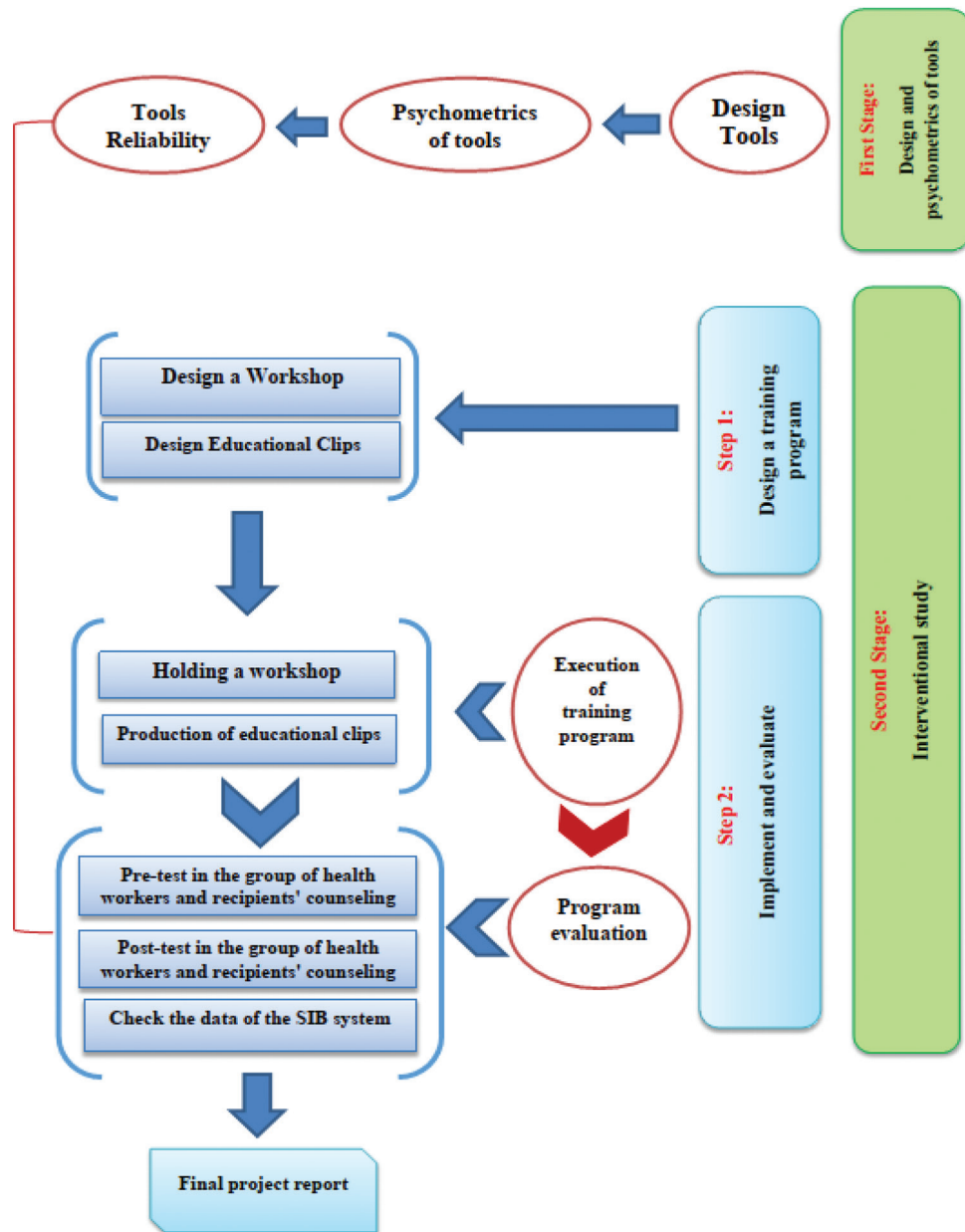


Figure 2: Flow diagram of the study

- To examine the opinion of counseling recipients on counseling provision, a questionnaire developed by those recipients before and 1 week after the intervention will be completed in both two groups, experimental and control
- Data of electronic system related to healthy lifestyle behaviors among counseling recipients will be reviewed before and 2 months after the intervention in both groups, experimental and control [Table 2].

### Participants

The participants in this study will be classified into two groups:

1. Health workers
2. Recipients of counseling from health workers.

### Inclusion/exclusion criteria

Inclusion criteria for health workers entail:

- Those who work at health centers
  - Their willingness to take part in the study
- Inclusion criteria for counseling recipients encompass:
- Those whose their age ranges between 30 and 70 years
  - Those who receive Ira-PEN program services from health centers.
  - Their willingness to participate in the study.

Exclusion criteria in both groups are unwillingness or the withdrawal from the study.



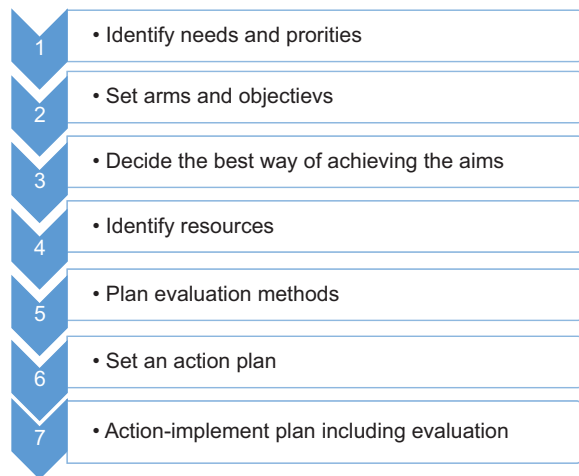


Figure 3: Ewlen and Simnett Planning Model (1999)

## Sampling

### Sampling Part 1: Design and psychometrics

- Face validity of the checklist and questionnaire will be checked by 15 health workers and consultants, respectively
- Content validity of the tools will be investigated by 10 experts
- To examine the reliability, the agreement method (kappa) and internal consistency will be employed. For that, 20 health workers and consultants will contribute in doing so, respectively.

### Sampling Part II: Intervention study

Sampling method in this part of the study is multistage sampling, and this technique will be utilized again for both groups of health workers (providers) and counseling recipients.

Concerning sampling among the health networks under the health department at the University of Medical Sciences, 2 networks will be randomly selected and then also randomly assigned to the intervention and control groups. As such, on average, each affiliated health center embraces 3 health care providers.

Therefore, in each health network, sampling will be carried out from among 31 health centers based on the sample size (92 participants). These 31 health centers will be randomly selected from the current list. Samples are readily available in each database as all the 3 health-care providers will be included in addition to those people who refer to those health centers and their age between 30 and 70 years if they are willing to participate in the study [Figure 4].

### Estimating sample size

Since no study on healthy lifestyle counseling for health workers has been conducted following the module prepared by the WHO in Iran nor globally, and the

standard deviation of staff variables and lifestyle behavior of counseling recipients is also unknown to the researchers, the sample size required to achieve the three objectives of the intervention part of the study, will be at least 84 participants, and by considering 10% drop-out, the estimated sample size will be 92 participants in each group according to the formula below:

$$n = \frac{2 \left( Z_{1-\frac{\alpha}{2}} + Z_{1-\beta} \right)^2}{\left( \frac{\Delta}{S} \right)^2}$$

- Z1: A 95% confidence interval of 1.96.
- Z2: The test power factor is 90%, i.e., 1.28.
- S is an estimate of the standard deviation of the skill score between the two groups.
- d is the minimum difference in the mean skill score between the two groups, which indicates a significant difference when S is  $\leq 0.5$ .

### Main measures and outcomes

- Healthy lifestyle counseling skills among health workers in accordance with both checklists and observation
- Skills of healthy lifestyle counseling among health workers based on the used questionnaire and clients' opinions
- Nutrition behavior of patients according to the integrated health system (SIB<sup>1</sup>) questions
- Behavior of clients in the field of physical activity respective to the questions of the SIB
- Patients' behavior in the field of tobacco and alcohol consumption based on the questions of the SIB.

### Data analysis

#### Step 1: Design and psychometrics of tools

In the psychometric stage, content validity ratio and content validity index will be calculated to determine the validity of the questionnaire. In testing the reliability of the instrument, the calculation of kappa agreement coefficient is used to check the reliability of the checklist and Cronbach's alpha for the questionnaire to examine its reproducibility.

#### Step 2: Quantitative section, interventional study

At this stage, based on the study goals and variables, data will be analyzed using IBM SPSS Statistics for Windows, version XX (IBM Corp., Armonk, N.Y., USA)<sup>[6]</sup>. First, the Kolmogorov-Smirnov test will be used to check the data normality. In case of normal distribution, evaluation of the intervention effect on skills in the pre- and post-intervention stages in each group will be performed using paired *t*-tests, and Wilcoxon test will be applied in case of abnormal distribution of the data.

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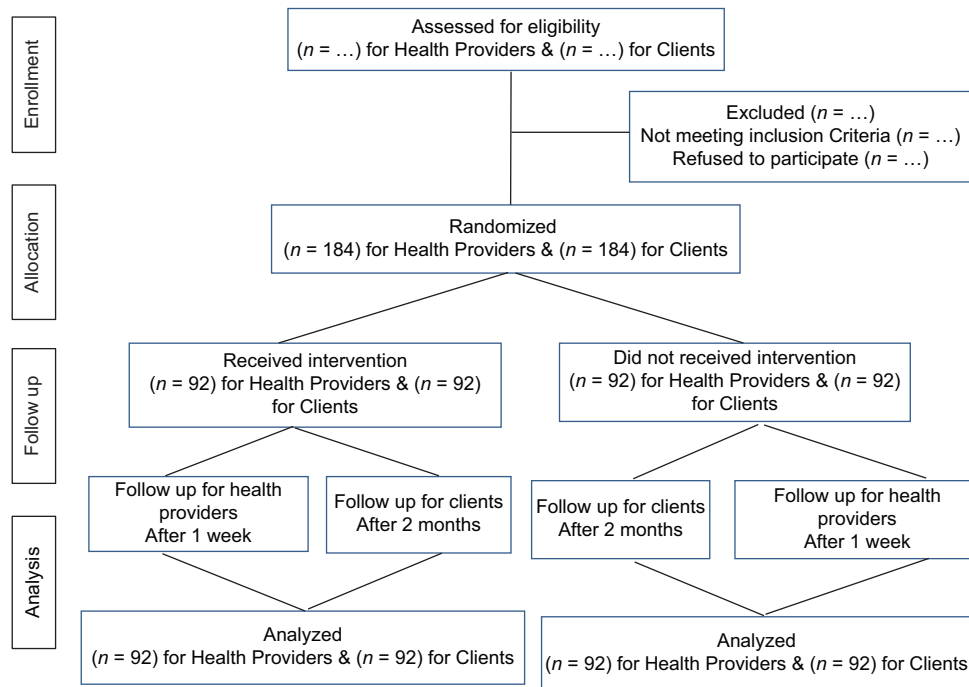


Figure 4: Design of step 2: Interventional study of sampling and stages

ANCOVA is also used to modify the effect of the pretest. Furthermore, to examine the variables of this section in the intervention and control groups when the distribution is normal, independent *t*-test will be utilized, while Mann–Whitney test will be used in case of abnormal distribution.

### Ethical considerations

Approval will be obtained to conduct the research from the relevant authorities and the ethics committee in the faculty research, and the goals and nature of the study will be clearly and accurately explained to the participants. Participants should feel free to take part or not in the research, and an informed consent will be obtained ahead. Privacy and confidentiality will be assured for all participants.

### Applications

By doing this research, at the macro level, the quality of providing healthy lifestyle counseling is going to ameliorate. As a result, the prevention and control of risk factors for NCDs will be more effective, and eventually, the prevalence of NCDs will be reduced or become more controllable.

Therefore, while improving the level of public health, Iran also will be closer to reach out the goals of the National Document on NCDs and Sustainable Development.

Further, at the micro level, the rate of attention and application of standard technical instructions, including

the healthy lifestyle module, will escalate, and the results can be presented to scientific conferences and policymakers as follow:

- Management of NCDs at the level of the national medical universities and the Ministry of Health and Medical Education
- National Committee for control and care of NCDs
- WHO-PEN program officers at the WHO and the Eastern Mediterranean Region
- Students and professors of health education and promotion and also from other professions will show more interest in designing training programs for healthy lifestyle counseling and 5As model.

### Discussion

A review on the previous studies related to healthy lifestyle counseling shows that interventions have been designed to support NCDs preventive behaviors, especially CVDs globally and locally in Iran.<sup>[12,14,20-23]</sup> A number of these interventions have taken place in health systems,<sup>[12,24,25-27]</sup> some others have been carried out on a group of employees or general public,<sup>[20,28,29-33]</sup> and another part have focused on staff training and empowerment.<sup>[26,34-36]</sup>

In a number of studies, the implementation of interventions was influential.<sup>[12,24,28,29,30-33,36]</sup> Some of these interventions were designed based on the 5As model, which demonstrated the effectiveness of the model.<sup>[30-35]</sup> Examining these studies revealed that there is a major gap between the needs of people and the

skills of health-care providers along the way. There have been some studies through which health-care providers have implemented appropriate interventions to promote healthy lifestyle.<sup>[12,34,35,37]</sup> On the other hand, there were no studies on educational interventions as a complete package including convenient and localized educational content with suitable tools for assessing the intervention. Furthermore, some of them did not have a suitable platform for the continuity of interventions. Therefore, in this study, we try to use the appropriate structure of the Ira-PEN program that is being implemented in the country and the healthy lifestyle counseling module provided by the WHO, a training intervention, along with a localized educational content for health workers was also carefully designed and implemented to provide healthy lifestyle counseling. A checklist and a healthy lifestyle counseling questionnaire will also be designed specifically to properly assess how counseling is delivered in the Iranian health system.

One of the strengths of this protocol is that it paves the road for implementers and researchers to easily access the modules provided by organizations such as the WHO in different countries according to specific language and culture as well as their particular health systems, current programs, and processes (for example, like Apples in Iran). It also introduces research on how to design and examine evaluation tools for interventions based on these modules. Another point to consider in this type of research is that it elucidates the way for implementing programs such as WHO-PEN in countries, preparing and making use of platforms which are usually neglected, and ultimately empowering health-care staff in different countries to work with these modules. In the present study, the protocol of which was presented, a skill-based design for health system employees has been considered, and lifestyle counseling skills based on the 5As model are taken into account as a serious requirement for program implementation.

## CONCLUSIONS

The training program and the results obtained in this study will be presented to the managers and decision makers of both the Ira-PEN program and NCDs control in Iran, and it is suggested to enhance the training program, network, and educational curriculum of health workers in providing healthy lifestyle counseling to play a more effective role in changing the public behavior toward a healthy lifestyle and preventing the risk factors of NCDs.

### Ethical considerations

The study design obeys the principles of the Declaration of Helsinki and shows to be in agreement with the ethical

principles and national norms/standards for conducting medical research in Iran. To respect participants' rights, certain measures will be taken such as informed consent to take part in the study permissions to take notes, anonymity of all questionnaires, and confidentiality of the data, financial and nonfinancial rights of the whole research team.

### Acknowledgment

The project is a part of a Ph.D. thesis in Health education and Promotion course and has been approved by the Ethics Committee of the School of Public Health and Neuroscience Research Centre in Shahid Beheshti University of Medical Sciences; Approval ID: IR.SBMU.PHNS.REC.1398.172(February 04, 2020).

Also, this project has been granted another approval (ID: IRCT20201222049800N1) by the Iranian Registry of Clinical Trials Center.

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### Ethical approval

The project has been approved by the Ethics Committee of the School of Public Health and Neuroscience Research Centre in Shahid Beheshti University of Medical Sciences; Approval ID: IR.SBMU.PHNS.REC.1398.172: Approval Date: February 04, 2020).

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This study was financially will support by Tehran University of Medical Sciences.

### Conflicts of interest

There are no conflicts of interest.

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