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# WHO-PEN intervention in Iran's health system based on 5As healthy lifestyle counseling model: A randomized-clinical trial

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## Abstract:

**BACKGROUND:** Skill Training Intervention Based on the Healthy Lifestyle Counselling Module (5As model) in the Ira PEN Program.

**MATERIALS AND METHODS:** This study was a randomized controlled trial in Iran. Participants were 184 health workers and 184 clients (92 in each study group). The training program entailed an online training course, educational video, and clip. The behavior related to a healthy lifestyle in clients was also followed-up 2 months later. Data were analyzed using SPSS 22 software.

**RESULTS:** Based on the observations, significant improvement in lifestyle counseling skills among health workers in the intervention group compared to the control group in terms of healthy nutrition ( $P < 0.001$ ), physical activity ( $P < 0.001$ ), smoking cessation ( $P = 0.03$ ), and withdrawal of alcohol consumption ( $P < 0.001$ ) was observed. Also, lifestyle-related behaviors among clients in terms of healthy nutrition ( $P < 0.001$ ), physical activity ( $P < 0.001$ ), and withdrawal smoking ( $P < 0.001$ ) increased significantly. Furthermore, waist circumference ( $P < 0.024$ ) and BMI ( $P < 0.001$ ) among clients were significantly reduced.

**CONCLUSION:** The training program for health personnel in healthy lifestyle has a more effective role in changing people's behavior and prevention of noncommunicable risk factors. Healthy life style counselling in primary health cares may lead to control risk factors for Noncommunicable disease.

## Keywords:

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

## Introduction

The Sustainable Development Goals stated that one third of all noncommunicable disease (NCDs) deaths should be reduced globally by 2030.<sup>[1]</sup> NCDs are the underlying causes behind 41 million of annual deaths, which is equivalent to 71% of the total deaths worldwide.<sup>[2]</sup> Of these records, 17.9 million people died from cardiovascular diseases (CVDs) in 2019;<sup>[3]</sup> if this trend

continues, the annual number of CVD-related deaths will elevate up to 22.2 million by 2030.<sup>[4]</sup> CVD is can also lead to disability and premature death worldwide.<sup>[5]</sup> In Iran, mortality rate associated with CVDs is higher than the global average.<sup>[6]</sup> In total, NCDs in Iran account for 76.4% of the total mortality.<sup>[7]</sup> According to STEPS study conducted in 2016, the prevalence of overweight and obesity is 59.3%, sedentary lifestyle 90.3%, smoking 10.1%,

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and consumption of fruits and vegetables more than 5 shares per day 48.6%.<sup>[8]</sup> The growing emergence of such diseases can be due to changes in diet content, physical inactivity and sedentary lifestyle, smoking, poor diet.<sup>[9]</sup> Successful prevention and control of NCDs depends in part on the willingness of individuals and their families to decide on their habits.<sup>[10]</sup> WHO constantly evaluates the role of health care providers and their competencies in supporting self-care interventions.<sup>[11]</sup> Two-thirds of premature deaths from NCDs, including CVDs, can be avoided through empowering the role of providers at primary health care.<sup>[12]</sup> Primary care providers play an important role in tobacco control, which is one of the risk factors for CVDs.<sup>[13]</sup> The WHO package for essential NCDs (WHO-PEN) includes the minimum standards for combating NCDs to strengthen national capacity to integrate and increase NCD care in the primary health care.<sup>[14]</sup> The effectiveness of national guidelines for managing blood pressure, cholesterol, and blood sugar rests on how well health care providers implement clinical recommendations and how well patients adhere accordingly.<sup>[15]</sup> Lifestyle counseling, encompassing quitting tobacco, modifying diet, avoiding alcohol abuse, and increasing physical activity, involves regular and targeted utilization of information and technologies to support this positive change.<sup>[16]</sup> Encouraging people with CVDs to avert unhealthy activities and adopt healthy practices is an evidence-based intervention to improve cardiovascular health and reduce associated risk.<sup>[17]</sup> In the Irapen program, health workers used to calculate the "10-year risk of fatal or non-fatal heart attacks and strokes" using a risk assessment chart and then teach people how to improve their healthy lifestyle.<sup>[18]</sup> There are six modules within the HEARTS package. The first module, the Healthy Lifestyle Module, provides information on four risk-related behaviors for CVDs and short interventions based on the 5As model [Figure 1].<sup>[19]</sup> The 5As model was originally employed by the U.S. Department of Health and Welfare to quit smoking.<sup>[20]</sup> The 5As framework is based on trans theoretical model.<sup>[21]</sup> This study tried to design, implement, and evaluate a healthy lifestyle counseling training program based on the HLS module of the WHO and to empower health professionals to provide effective lifestyle counseling.

## Materials and Methods

### Study design and setting

This study is a randomized clinical trial in two stages. In the first stage, tools were designed and psychometrically tested based on the WHO module. The second stage also involved planning, implementing, and evaluating a counseling training program [Figure 2]. This study was conducted at health centers from TUMS<sup>1</sup>. from January 20 to May 21, 2021.

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### Study participations and sampling

Considering a power level of 0.90, an alpha level of 0.05, the sample size according to the formula below, is at least 84 participants. Considering 10% as a drop-out percentage, 92 were included in each group:  $n = 2 (Z_1 - \alpha/2 + Z_1 - \beta)^2 / (\Delta/S)^2$ .

The sampling method was the same for both groups of health workers and clients. For sampling among the health networks covered by TUMS, two networks were randomly selected and then randomly assigned to the intervention and control groups. The intervention health network had 101 health bases and the control health network had 42 health bases. Since each health center has 3 health workers in each health network, based on the sample size (92 people), 31 health centers were randomly selected from the existing list. Samples were available in each study in each database and all three health care providers and three clients aged 30–70 years in the health database, if desired, participated in the study.

Participants in this study were two groups: health workers and clients. Inclusion criteria in the group of health workers were working in health centers and willingness to participate in the study. Inclusion criteria in the group of clients were 30–70 years old, receiving active health services and willingness to participate in the study. Exclusion criteria in both groups were unwillingness to continue cooperation during the study. A total of 190 health workers and 284 people who referred to health centers as clients were included in the study. In the group of 248 clients, 53 people did not meet the entry requirements and 5 people did not want to participate, and finally 190 people were included in the study. Then, by random assignment of both groups, 95 people in the intervention group and 95 people in the control group were included. One week later, one person in the intervention group and two people in the control group were excluded from the study. At follow-up, 1 month later, three clients were excluded from the study in the case group and two in the control group [Figure 3].

### Intervention

The intervention included designing, implementing, and evaluating the 5As Healthy Lifestyle Counseling Skills training program for health workers. The content was designed based on Ols and Cement planning model [Figure 4].<sup>[22]</sup> First, the WHO module on healthy lifestyle counseling was translated and localized and used as educational content. At this stage, the researchers found it appropriate to hold a training workshop and develop a virtual training course. The Workshop was also uploaded to the virtual education system as an in-service training course. Also, an educational video for 50 min and a motion graphic for 10 min were prepared. At the end of the workshop, participants entered a virtual

group on WhatsApp and received the link to download educational materials.

### Data collection tools and techniques

In this study, a checklist and a questionnaire were designed based on the 5As model.

Each tool had four sections: advice on proper nutrition, increasing physical activity, quitting smoking, and quitting alcohol. In this study, the number of specialists was 15; the CVR was higher than 0.49 for all questions and was deemed necessary according to the Laoche table. Also, the CVI was higher than 0.97 for all questions and was deemed appropriate. The reliability measurement for the checklist, by Cohen's Kappa coefficient, was performed, and its value was 0.71,<sup>[23]</sup> for the questionnaire, ICC was 0/85 and Cronbach's

### Analysis

First, the normality of the data was checked using Kolmogorov-Smirnov test. As the distribution of data was normal, ANCOVA test was applied to evaluate the effect of the intervention on skills in each group. Chi-square ( $\chi^2$ ) test was used to evaluate the similarity of contextual variables in the intervention and control groups. It is worthy to mention that the vast majority of participants ( $n = 183$ ) were not alcohol abusers, thereby the sample in this regard was not representative.

### Ethical considerations

The project has been approved by SBMU<sup>2</sup> (ID: IR.SBMU.PHNS.REC.1398.172, 2020/2/4), and Iranian Randomized Clinical Trial (ID: IRCT20201222049800N1, 2021-05-03).

## Results

The participants in the health worker group were no statistically significant differences in case of age, education level, major, and employment status between the intervention and control groups [Table 1]. The results also showed that in the intervention group of health workers, the average score of how to provide counseling using a checklist and expert observation method in four sections was significant. This includes healthy nutrition ( $P < 0.001$ ), physical activity ( $P < 0.001$ ), smoking ( $P = 0.003$ ), and alcohol ( $P < 0.001$ ).

In the nutrition counseling domain, according to the 5As model, the score for skill Ask was not significant ( $P = 0.167$ ), while that for the skills Advise, Assess, Assist, and Arrange were significant in the intervention group, ( $P = 0.046$ ), ( $P < 0.001$ ), ( $P < 0.001$ ), and ( $P < 0.001$ ), respectively. In the same vein, the skill (Ask) in the physical activity counseling domain

did not show a significant difference ( $P = 0.263$ ), but the skill (Advise) ( $P = 0.027$ ), the skill (Assess) ( $P < 0.001$ ), Assist ( $P < 0.001$ ), and Arrange ( $P < 0.001$ ) showed a significant increase in the intervention group. In the smoking cessation counseling section, the following skills showed significant differences: Ask ( $P = 0.016$ ), Advise ( $P < 0.001$ ), and Arrange ( $P = 0.03$ ). However, the skills like Assessing ( $P = 0.328$ ) and Assisting ( $P = 1$ ) did not show any remarkable differences. In the section of alcohol quitting, the skills such as Asking ( $P = 0.663$ ) did not lead to any significant difference; nevertheless, the skill Advise ( $P < 0.001$ ) increased in the intervention group. Other skills like Assess, Assist, and Arrange could not be assessed due to the nonrepresentative samples [Table 2].

The participants in the clients group were no significant differences regarding age, gender, education level, and marital status between the intervention and control groups when employing Chi-square test [Table 3]. The mean score of how to provide counseling based on the questionnaire and the use of self-assessment in the group of counseling recipients in the four sections, healthy nutrition ( $P < 0.001$ ), physical activity ( $P < 0.001$ ), smoking ( $P < 0.001$ ), and Alcohol ( $P < 0.001$ ), also significantly increased when compared with the control group. In the physical activity counseling domain, the skill (Ask) showed no notable difference. On the other hand, skills Advise ( $P < 0.001$ ), Assess ( $P < 0.001$ ), Assist ( $P < 0.001$ ), and Arrange ( $P = 0.001$ ) showed a positively significant difference in the intervention group. In the smoking cessation counseling domain, Ask ( $P < 0.001$ ), Advise ( $P < 0.001$ ), Assess ( $P = 0.008$ ), Assist ( $P = 0.001$ ), and Arrange skills ( $P = 0.41$ ) in the intervention group showed a significant increase. In the domain of alcohol withdrawal counseling, the skill Ask ( $P = 0.057$ ) did not show a difference, but the skill Advise ( $P < 0.001$ ) increased in the intervention. Furthermore, because most clients in both intervention and control groups reported not consuming alcohol ( $n = 183$ ), the comparison between both groups was not possible regarding other skills like Assess, Assist, and Arrange [Table 4].

On the other hand, the average score of lifestyle behavior among clients based on the information of their electronic health system in the four domains, healthy nutrition ( $P < 0.001$ ), physical activity ( $P < 0.001$ ), significantly outweighs those of the control group. For the smoking domain ( $P = 0.287$ ), it was not statistically significant, and in the alcohol quitting domain ( $P < 0.001$ ), the samples were not representative. In addition, changes in BMI ( $P < 0.001$ ) and waist circumference ( $P = 0.023$ ), before and 2 months after the intervention, in the counseling of the intervention group showed a significant decrease compared to the control group [Table 5].

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**Table 1: Characteristics of health providers in the study groups**

Characteristics	Total (n=224)	Intervention Group (n=112)	Control Group (n=112)	P, $\chi^2$ test
Age n (%)				
20-29 years	66 (34.7)	27 (28.4)	39 (41.1)	0.07
30-39 years	78 (41.1)	39 (41.1)	39 (41.1)	
40-49 years	46 (24.2)	29 (30.5)	17 (17.9)	
Education level n (%)				
Associate's degree	72 (37.9)	37 (38.9)	35 (36.8)	0.704
Bachelor's degree and above	118 (62.1)	58 (61.1)	60 (63.2)	
Field of Study n (%)				
Midwifery	107 (56.3)	59 (62.1)	48 (50.5)	0.072
Public Health	83 (43.7)	36 (37.9)	47 (49.5)	
Type of Employment n (%)				
Contractual employment	68 (35.8)	32 (33.7)	36 (37.9)	0.325
Recruitment outsourcing	122 (64.2)	63 (66.3)	59 (62.1)	

Significant at  $P < 0.05$

**Table 2: Comparison of score of healthy lifestyle counseling checklist between groups**

Characteristics	Intervention Group Mean (SD)	Control Group Mean (SD)	P, ANCOVA test
Diet	13.92 (2.06)	7.13 (2.48)	<0.001
Ask	0.99 (0.1)	0.96 (0.2)	0.167
Advise	0.96 (0.2)	0.85 (0.35)	0.046
Assess	1.87 (0.39)	0.84 (0.7)	<0.001
Assist	4.63 (0.85)	2.29 (1.3)	<0.001
Arrange	5.46 (1.31)	1.89 (1.1)	<0.001
Physical activity	16.27 (1.85)	6.78 (3.02)	<0.001
Ask	0.99 (0.1)	0.97 (0.17)	0.263
Advise	0.97 (0.17)	0.88 (0.32)	0.027
Assess	2.06 (0.5)	1.21 (0.87)	<0.001
Assist	7.61 (0.9)	2.26 (1.85)	<0.001
Arrange	4.64 (1.18)	1.46 (0.88)	<0.001
Tobacco use	6.24 (6.05)	4.27 (1.97)	0.003
Ask	2.98 (0.14)	2.88 (0.35)	0.016
Advise	0.95 (0.26)	0.55 (0.54)	<0.001
Assess	0.27 (0.69)	0.17 (0.53)	0.328
Assist	0.23 (0.59)	0.16 (0.68)	1
Arrange	1.15 (2.97)	0.55 (0.83)	0.03
Alcohol use	2 (0)	1.35 (0.58)	<0.001
Ask	1 (0)	1.01 (0.23)	0.663
Advise	1 (0)	0.35 (0.47)	<0.001
Assess	*-	-	-
Assist	-	-	-
Arrange	-	-	-

Significant at  $P < 0.05$ . \*Insufficient sample for analysis

## Discussion

The present study revealed that the intervention employed was able to significantly increase the skills of health workers in the areas of healthy nutrition counseling, physical activity, smoking, and alcohol cessation. This increase was seen both by the checklist and self-reporting methods. These results were in line with some other studies in the literature.

Training program for life style counseling showed a significant improvement among patients in LDL, systolic BP and HbA1c,<sup>[17]</sup> and in general for healthy people.<sup>[24]</sup> Educational program based on 5As was effective at the primary health care in Africa.<sup>[25,26]</sup> Knowledge due to counseling in health workers was 41% in Sweden.<sup>[27]</sup> Too patients may be aware of the importance of lifestyle behaviors; however, it has not led to a change in actual behavior.<sup>[26]</sup> According to these studies, the role of counseling in the field of healthy lifestyle is effective and highly demanded in PHC centers.

Other results in the present study showed that in the section of nutrition counseling and physical mobility, no significant change was observed in Ask skill, but other skills such as Advise, Assess, Assist, and Arrange showed statistically significant differences. These results indicate that health workers have the skills to ask questions carefully about nutrition and physical activity behaviors. Nevertheless, other counseling skills require practical training. In the smoking cessation counseling section, the skills Ask, Advise, and Arrange had improved significantly by checklist, but Assess and Assist skills have not differed. It seems that health workers only asked questions and gave advice for counseling, but they did not have enough skills to evaluate and help identify and remove barriers, and at the same time, they can set the time for the next visit, so, the skill Arrange was appropriate. However, there are no nearby support centers in the health network system to refer and receive specialized services if needed. On the other hand, because the number of smokers was small, it was not possible to examine the skills of assessing and assisting. In regards to alcohol consumption, the skill "Ask" with the observation method based on the checklist showed no significant difference. In the same vein, it seems that asking questions about alcohol consumption behavior was not done transparently and accurately because it has a social stigma, but the skill "Advise" demonstrated a remarkable



**Table 3: Characteristics of clients in the study groups**

Characteristics	Total (n=224)	Intervention Group (n=112)	Control Group (n=112)	P ( $\chi^2$ Test)
Age, n (%)				
31-40	109 (57.4)	61 (64.2)	48 (50.5)	0.214
41-50	45 (23.7)	18 (18.9)	27 (28.4)	
51-60	32 (16.8)	15 (15.8)	17 (17.9)	
61-70	4 (2.1)	1 (1.1)	3 (3.2)	
Gender, n (%)				
Male	39 (20.5)	19 (20)	20 (21.1)	0.5
Female	151 (79.5)	76 (80)	75 (78.9)	
Education, n (%)				
Primary	43 (21.9)	18 (18.9)	25 (26.3)	0.062
Secondary	25 (12.8)	10 (10.5)	15 (15.8)	
Diploma	84 (42.9)	41 (43.2)	43 (45.3)	
University	38 (19.4)	26 (27.4)	12 (12.6)	
Marriage status, n (%)				
Single	7 (3.7)	4 (4.2)	3 (3.2)	0.665
Married	177 (90.3)	89 (93.7)	88 (92.6)	
Divorced	0	0	0	
Widow	6 (3.1)	2 (2.1)	4 (4.2)	

Significant at  $P < 0.05$

**Table 4: Comparison of score of a healthy lifestyle counseling questionnaire between groups**

Characteristics	Intervention Group Mean (SD)	Control Group Mean (SD)	P (ANCOVA test)
Diet	9.38 (0.87)	4.76 (1.41)	<0.001
Ask	1 (0)	0.98 (0.14)	0.29
Advise	1 (0)	0.93 (0.26)	<0.001
Assess	0.91 (0.29)	0.62 (0.48)	<0.001
Assist	4.83 (0.37)	1.15 (1.1)	<0.001
Arrange	1.64 (0.48)	1.08 (0.37)	<0.001
Physical activity	7.92 (0.51)	4.06 (1.11)	<0.001
Ask	1 (0)	1 (0)	-*
Advise	1 (0)	0.92 (0.27)	<0.001
Assess	1 (0)	0.49 (0.5)	<0.001
Assist	3.82 (0.38)	0.69 (0.75)	<0.001
Arrange	1.09 (0.29)	0.96 (0.28)	0.001
Tobacco use	3.93 (2.63)	2.68 (1.1)	<0.001
Ask	2 (0)	1.91 (0.29)	<0.001
Advise	0.91 (0.29)	0.52 (0.5)	<0.001
Assess	0.13 (.33)	0.03 (0.17)	0.008
Assist	0.63 (1.6)	0.13 (0.33)	0.001
Arrange	0.26 (0.67)	0.11 (0.3)	0.41
Alcohol use	1.91 (0.29)	1.18 (0.41)	<0.001
Ask	1 (0)	0.99 (0.1)	0.057
Advise	0.91 (0.29)	0.19 (0.39)	<0.001
Assess	*-	-	-
Assist	-	-	-
Arrange	-	-	-

Significant:  $P < 0.05$ . \*Insufficient sample for analysis

rise in the intervention group, because in each, there was a substantial recommendation to never drink or quitting and to reduce alcohol consumption. Other skills "Assess" and "Arrange" could not be evaluated due to the small number of alcohol abusers in the study.

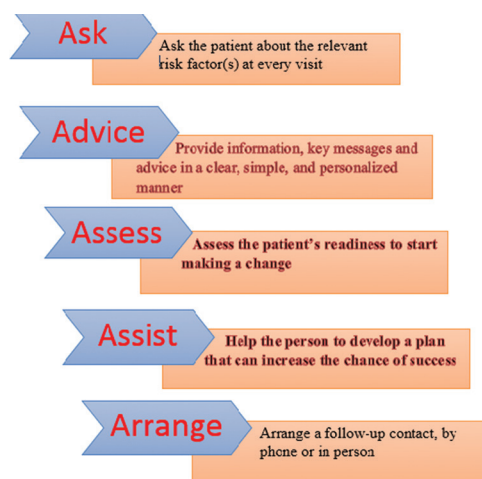


Figure 1: 5As model for healthy lifestyle counseling<sup>[19]</sup>

The 5As model, which was used to stop smoking, could also be used in case of obesity counseling.<sup>[28]</sup> The results showed in an online smoking cessation training course, the means for the first 3As were moderate and for the last 2As were low. Having a positive experience and a sense of competence was positively associated with implementing 5As model; moreover, having organizational support with "Assist" and "Arrange" was proportionally associated. Smoking was negatively associated with "Advice" and "Arrange." The results showed that clinical health workers had not completed 5As.<sup>[29]</sup> In all these studies including the present study, the interventions were designed to train and empower health workers to gain the sufficient skills to provide counseling on healthy lifestyle and to measure the effectiveness of interventions by examining the performance of that program.

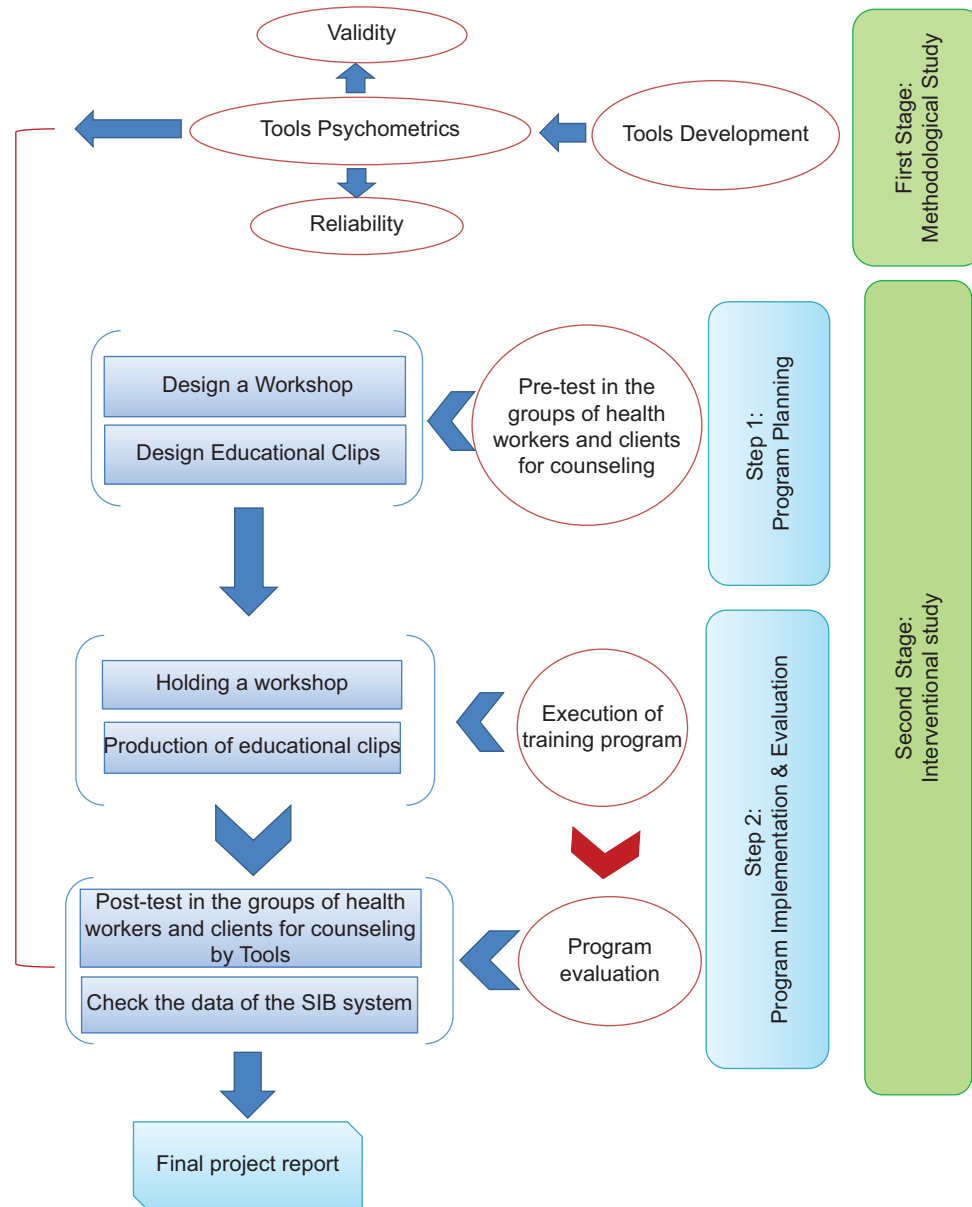


Figure 2: Flow diagram of the study

The group counseling package included an operational manual and a training program based on the WHO-5A model, which was one of the most important determinants of smoking cessation.<sup>[30]</sup> The effect of a self-management program based on Model 5As on the self-efficacy of elderly and for people with high blood pressure and diabetes sounds effective.<sup>[31,32]</sup> In addition, at the end of 3 months, it obtained a statistically significant reduction in breathless patients<sup>[33]</sup> and the behavior of physical activity in overweight pregnant women was remarkably different.<sup>[34]</sup> Many patients asked physicians to discuss weight loss, speak to themselves, especially in the aspects of "Assist" and "Arrange"; however, physicians often adhere to the aspects of "Ask" and "Evaluate" and seldom to the

aspects of "Agree," "Assist," and "Arrange." These results denoted a significant gap between patient needs and physician practices that are likely to affect patient care.<sup>[35]</sup> Therefore, based on all these studies and the present study, it can be concluded that the intervention program that depends on the 5As model is an effective program and can accurately identify the different parts of a short consultation including the apparent defect therein. In the present study, the most prominent shortcomings were in the skills of "Evaluate," "Assist," and "Arrange."

In the present study, the mean score of lifestyle behavior among clients based on the information of their electronic health system in four sections of healthy nutrition and physical activity has improved significantly when

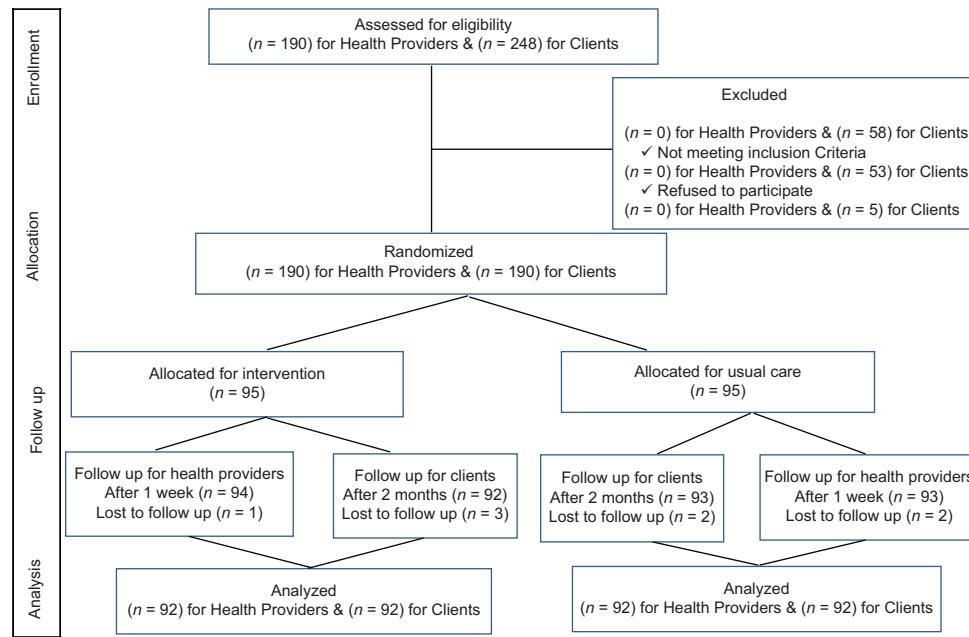


Figure 3: Flow diagram (CONSORT) of participants through each stage of a randomized trial

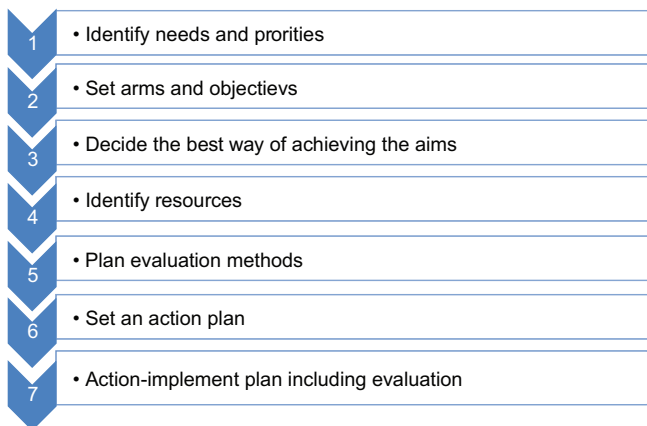


Figure 4: Ewlen and Simnett Planning Model (1999)

compared to the control group; however, it was not significant in terms of smoking cessation as health workers need more skills to do such type of counseling. Also, the number of smokers is higher among males, but they less likely go to health centers for services. As a result, health workers have fewer opportunities to gain experience. On the other hand, there are no special centers for smoking cessation. In alcohol abuse counseling section, 183 participants were not alcohol consumers, so the sample was not representative collection, which was not possible for Assess, Assist, and Arrange.

Changes in BMI and waist circumference, before and 2 months after the intervention, showed a significant difference. Therefore, it can be concluded that skills training intervention in the group of health workers will lead to improved nutrition and physical mobility in the group of clients.

Table 5: Comparison between scores of healthy lifestyle behavior among clients

Characteristics	Intervention Group Mean (SD)	Usual care Group Mean (SD)	P (ANCOVA test)
Diet	1.37 (1.48)	0.09 (0.68)	<0.001
Physical activity	0.78 (0.78)	0.01 (0.53)	<0.001
Tobacco use	0.11 (0.43)	0.05 (0.22)	0.287
Alcohol use	-*	-	-
BMI	0.5 (0.16)	0.1 (0.14)	<0.001
Waist	3.28 (10.11)	0.86 (1.7)	0.023

Significant at  $P < 0.05$ . \*Insufficient sample for analysis

The effect of counseling on anthropometric indices and healthy lifestyle among overweight and obese women and other people was examined, and the results were significant.<sup>[18,36]</sup> Other studies also found that behavioral counseling including diet and physical activity led to improved adaptation while achieving important results of moderate health status for up to 2 years.<sup>[37]</sup>

### Limitation and recommendation

The strength of this study was the preparation of tools, contents, and educational materials based on healthy lifestyle module (WHO), which was translated and localized in Iran for first time. Also, among the limitations were the low sample size and insufficient time for counseling by health workers.

### Conclusion

In total, the results of this study showed that the training program for health workers, which is based on the WHO healthy lifestyle module and the 5As model, is

effective. It can lead to a change in the clients' behavior. This study also reported that according to the 5As model, training should focus on specific skills: Assess, Assist, and Arrange. In the case of Ask and Advise, the available level of such skills was almost acceptable. However, in the smoking cessation and alcohol abuse counseling section, there were not enough support centers or the referral system was not well defined, and this issue also rests on Arrange skill, which is related to proper appointments and scheduling system. Therefore, it is necessary to provide the necessary measures for planning, implementation, and monitoring of the training program in the field of healthy lifestyle counseling, nationally.

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### Conflicts of interest

There are no conflicts of interest.

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