

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Designing, Implementation and Evaluation of Skill Training Intervention Based on the Healthy Lifestyle Counselling Module (5As model) in the IraPEN Program among Health Workers: A Methodological and Interventional Study

Protocol summary

Study aim

Design and psychometrics of a healthy lifestyle counseling skill assessment tool by health workers in the IraPEN program Determining the Impact of Skill Intervention in Healthy Lifestyle Counseling based on 5As Model in the IraPEN Program for Health Workers

Design

This study is a field trial with a control group, single-blind, randomized and has a 2-month follow-up phase. To randomize, several numbers are randomly selected from the list of health databases.

Settings and conduct

This study is performed in the environment of health centers. After selecting the intervention and control group, a checklist for health providers and a questionnaire for clients about healthy lifestyle counseling are completed. Then, for the members of the intervention group, a training workshop will implement and a short training clip will be shown to them and they will participate in a virtual training course. After the intervention, the checklist and questionnaire are completed again. In this study, health providers do not know whether they are in the intervention group or not. Observers that will be complete checklist and questionnaire, are also blind to the intervention and control group.

Participants/Inclusion and exclusion criteria

Health workers Group: Inclusion criteria, Health workers that work in health centers Exclusion criteria, Reluctance to continue cooperation during the study Recipients Consulting Group: Inclusion criteria, People in their 30s and 70s Exclusion criteria, Reluctance to continue cooperation during the study

Intervention groups

1. Participate in a training workshop 2. Participate in a virtual training course 3. Watch educational short videos

Main outcome variables

1. Change the skills of health workers in providing healthy lifestyle counseling 2. Change counselors' behavior in relation to a healthy lifestyle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201222049800N1**

Registration date: **2021-05-03, 1400/02/13**

Registration timing: **prospective**

Last update: **2021-05-03, 1400/02/13**

Update count: **0**

Registration date

2021-05-03, 1400/02/13

Registrant information

Name

Najmoolmoolook Amini

Name of organization / entity

Tehran University of Medical sciences

Country

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Phone

+98 21 6345 3342

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, Implementation and Evaluation of Skill Training Intervention Based on the Healthy Lifestyle Counselling Module (5As model) in the Ira PEN Program among Health Workers: A Methodological and Interventional Study

Public title

The effect of Skill Training Intervention Based on the Healthy Lifestyle Counselling Module(5As model)

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Health workers working in health centers People between the ages of 30 and 70 who receive cardiovascular risk assessment services from health centers

Exclusion criteria:

Reluctance to cooperate in the study

AgeFrom **30 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **184****Randomization (investigator's opinion)**

Randomized

Randomization description

For sampling between 3 health networks under coverage of Tehran University of Medical Sciences, 2 networks were selected by simple randomization and lottery method, then 2 networks were again, assigned to the intervention and control groups by simple randomization and lottery method. Since each network covers 45 or more health centers and there are 3 health workers in each health centers, sampling at this stage will be done in a stratified. randomization manner. That is, in each network, according to the sample size (92 people), 31 health centers will be randomly selected from the list according to the table of random numbers, and in each center, all 3 health providers will be included in the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, health providers did not know whether they were in the intervention or control group. Counseling service is provided routinely and the checklist is

completed by an observer imperceptibly during routine monitoring of the health system. 2. Observers complete the counseling checklist imperceptibly at the same time as monitoring other health services. However, they do not know in which intervention or control group health care providers are.

Placebo

Not used

Assignment

Parallel

Other design features

n this study, for the first time in Iran, using a healthy lifestyle module that is recommended in 2018 by the World Health Organization for the training of health workers and is based on the 5As model, a training intervention, be designed, implemented and evaluated and its results presented to the managers and decision makers of the IraPEN program. One of the innovative aspects of this research is the design and psychometrics of the counseling skills training checklist and the innovation of educational intervention in the form of electronic content and its sharing through the virtual education system and social network. In this study, the intervention is performed only for the intervention group and includes a healthy lifestyle counseling training program. And no intervention is performed on the control group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of School of Health and Neuroscience Research Center, Shahid Beheshti University

Street address

School of Health and Safety, Daneshjoo Blvd, Velenjak St.

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Postal code

198396-9411

Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.SBMU.PHNS.REC.1398.172

Health conditions studied**1****Description of health condition studied**

Healthy Life Style Counsseling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Healthy lifestyle counseling skill

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Observation with checklist

2

Description

Healthy lifestyle behaviors based on SIB system

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Data recorded in the SIB system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1. Participate in a healthy lifestyle counseling workshop for 2 days and 16 hours with a role-playing teamwork 2. Watch a healthy lifestyle counseling training video for 45 minutes. Watch a healthy lifestyle training motion graph for 10 minutes 3. Participate in a virtual training course and online exam and receive a course certificate

Category

Behavior

2

Description

Control group: They do not participate in any training course and have received only the relevant instructions, and when providing the service, the electronic system provides general recommendations for training to the clients.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health services

Full name of responsible person

Najmolmolook Amini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Najmoldmoolook Amini
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the privacy of participants' personal information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to
make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to
make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to
make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to
make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to
make this available