Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Development and evaluation an Intervention Program for Prevention of Substance Abuse Based on Multi Theory Model(MTM) (in sequential exploratory mixed-method)

Protocol summary

Study aim
Determining the effect of an educational intervention program based on Multi Theory Model on substance abuse prevention.

Design
Quantitative sampling is done in two steps. In instrument psychometric, a sample will be systematically selected randomly from the Morgan table. There is no blinding. In the intervention section, the sample size will be 60 people and available sampling random assignment will be used.

Settings and conduct
In the qualitative phase, interviews will be conducted in the neighborhood mosque. Interviews are conducted as a focus group discussion. In the quantitative phase of the study, the pre-test questionnaire will be completed by visiting the homes of the selected individuals. Then the training program will be implemented and 6 months later the post-test questionnaires will be completed with the procedure of completing the pre-test stage. There is no blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Resident of the neighborhood, age group 15-50 years. Exclusion criteria: Addicted, mentally disabled and unable to cooperate

Intervention groups
The intervention group is trained based on the results of the qualitative stage and with the cooperation of experts who will determine the exact type and duration of the training. The intervention is done through an intervention group based on multi-theory model constructs at least 10 sessions in 6 months. The control group does not take any intervention, but after the end of the study, an educational package is provided to the control group.

Main outcome variables
Initiation of addictive preventive behaviors; Maintaining addiction-preventive behaviors; Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200922048805N1**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-10, 1400/10/20**
Update count: **0**

Registration date
2022-01-10, 1400/10/20

Registrant information

Name
Nahid Ardian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3822 7659

Email address
n_ardian1382@hotmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Development and evaluation an Intervention Program for Prevention of Substance Abuse Based on Multi Theory Model(MTM) (in sequential exploratory mixed-method)

Public title
Effectiveness of Interventional Program Based on Multi Theory Model on Prevention of Substance Abuse

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Having lived in the neighborhood for at least two years In the age group of 15 to 50 years old, immigrant or native, female or male
Exclusion criteria:
Addicted people (self-report) People with mental disabilities or who unable to participate in the study

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **280**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using the stratified randomization method. Samples are divided into control and intervention groups. In addition to sufficient accuracy in the conditions of inclusion criteria, homogenization is based on the variables of age and sex status. Random allocation software is used for randomization. For concealment, we use allocation concealment, which is the method used to execute a random sequence on study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed in a random sequence (Sequentially numbered, sealed, opaque envelopes) in which each of the random sequences created is recorded on a card and the cards are placed in the envelopes respectively. In order to maintain a random sequence, the numbering on the outer surface of the envelopes is done in the same way. Finally, the letter envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The present study is carried out by a sequential combination exploratory method including qualitative phase and quantitative phase, in which the intervention is performed in a quantitative phase.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic comittee of Shahid Sadoughi University of Medical Sciences
Street address
School of Public Health, Shahid Sadoughi Univesity of Medical Sciences , Alem Squ - Shohadaye Gomnam Street, Yazd.Iran
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Province
Yazd
Postal code
8915173160

Approval date
2019-11-12, 1398/08/21

Ethics committee reference number
IR.SSU.SPH.REC.1398.106

Health conditions studied

1

Description of health condition studied
Prevention of Substance Abuse Based on Multi Theory Model

ICD-10 code
F19.1

ICD-10 code description
Other psychoactive substance abuse

Primary outcomes

1

Description
Institutionalization of addiction prevention behaviors among people aged 15 to 50 years

Timepoint
Before and 6 months after the intervention in both groups, the behavior score is measured by completing a questionnaire.

Method of measurement
The score obtained from the designed questionnaire

Secondary outcomes

1

Description
Start preventive behavior from addiction
Timepoint
Before and 6 months after the intervention
Method of measurement
Research made Questionnaire

Intervention groups

1

Description
An intervention group is a group that is randomly selected from the participants and is trained based on the results of the qualitative stage and with the cooperation of experts who will determine the exact type and duration of the training. The content of the training is designed based on the structures of the multi-theory model on the prevention of substance abuse.
Intervention group: The internship is done through group training of at least ten 90-minute sessions over 6 months and with appropriate methods (lectures, questions and answers and the use of educational videos).
Category
Prevention

2

Description
Control group: After the end of the study, three group training sessions are considered for the control group and the educational content is provided to them in the form of brochures and educational videos.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Akramieh neighborhood
Full name of responsible person
Nahid Ardian
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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
Yazd 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
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Full name of responsible person
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only part of the data related to this research can be shared, such as information about the main result of the study. Of course, this information is done after the applicant's application is reviewed by the council at the University Vice Chancellor for Research. Also, the data will be provided to the applicants after the data owners are not identified.

When the data will become available and for how long
The access period starts 6 months after the results are published.

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data of this study are allowed after the permission of Shahid Sadoughi University of Medical Sciences for the analyzes that are to be performed on the data.

From where data/document is obtainable
Social determinants of Health Research Center, School of Health, Shahid Sadoughi University of Medical Sciences, Shohadae Gomnam Blvd, Alam Sq. Dr. Seyed Saeed Mazloomy Mahmoodabad 0098 35 38209100 0098 9132506563

What processes are involved for a request to access data/document
The application should be sent to the address listed above in the box. After review, which takes about two to four weeks, the applicant will be contacted after coordination with the Vice-Chancellor for Research and Technology Affairs.

Comments