

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of educational program based on Self-regulation Theory on prevention of alcohol use among Secondary high school male students in southern area of Kerman

Protocol summary

Study aim

Determining the effect of a curriculum based on self-regulation theory in the prevention of alcohol consumption in second grade high school male students in the south of Kerman province

Design

Clinical trial with control group, with parallel Two-way blinded, randomized, phase 2 and were performed on 420 students (210 in the intervention group, 210 in the control group). Cluster sampling is multi-stage and 2 high schools from each city and 1 class from each high school are randomly selected. A total of 14 classes are randomly selected

Settings and conduct

all second grade male high school students in 7 cities under the auspices of Jiroft University of Medical Sciences (south of Kerman) in the academic year 1398-1399. Jiroft, after obtaining informed consent to participate in research, the proposal to hold at least 6 sessions of intervention (experimental group) for 10 weeks will be shared with them

Participants/Inclusion and exclusion criteria

Inclusion : second grade of high school, boys and natives of the region and exclusion : lack of cooperation and unwillingness to participate in the study

Intervention groups

1: Collection of data related to alcohol prevention based on the studied structures. 2: Prepare an intervention program based on the stages of self-regulation theory (the intervention is intended to use at least 6 training sessions for 10 weeks to prevent alcohol use using self-regulation theory Will be taken.) Third stage: Performing educational intervention 4: Performing intervention program and no intervention was performed in the control group.

Main outcome variables

Behavioral inhibition; Effective memory; Internal

conversation; Motivational assessment; Behavioral reconstruction; alcohol consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200923048817N1**

Registration date: **2020-10-26, 1399/08/05**

Registration timing: **prospective**

Last update: **2020-10-26, 1399/08/05**

Update count: **0**

Registration date

2020-10-26, 1399/08/05

Registrant information

Name

Ehsan Movahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3213 3151

Email address

ehsanmovahed89@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the effect of educational program based on Self-regulation Theory on prevention of alcohol use among Secondary high school male students in southern area of Kerman

Public title
Evaluation the effect of educational program based on Self-regulation Theory on prevention of alcohol use among Secondary high school male students

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Second grade of high school boy natives of the region
Exclusion criteria:
Lack of cooperation to participate in the study

Age
From **16 years** old to **17 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **420**

Randomization (investigator's opinion)
Randomized

Randomization description
The statistical population includes second grade high school male students in 7 cities under the auspices of Jiroft University of Medical Sciences (south of Kerman) in the academic year 2010-2011. The sampling method is cluster-multi-stage sampling. Sampling is that 2 high schools from each city and 1 class from each high school are randomly selected. A total of 14 classes are randomly selected. After that, in each high school, one class is considered as the experimental group and one class as the control group, and finally 7 classes are divided as the experimental group and 7 classes as the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Study participants were unaware of the allocation in groups after consenting to participate in the study and knowledge of the purpose of the study. Data collectors and those evaluating the outcome were also unaware of the allocation of students in the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Intervention based on the structures of self-regulatory theory

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jiroft University of Medical Sciences

Street address

Pasdaran Blvd

City

Jiroft

Province

Kerman

Postal code

7618746864

Approval date

2020-02-20, 1398/12/01

Ethics committee reference number

IR.JMU.REC.1398.071

Health conditions studied

1

Description of health condition studied

alcohol use

ICD-10 code

F10.1

ICD-10 code description

Alcohol abuse

Primary outcomes

1

Description

Behavioral inhibition

Timepoint

Before and after the intervention

Method of measurement

researcher-made questionnaire (behavioral inhibition)

2

Description

Effective memory

Timepoint

Before and after the intervention

Method of measurement

Researcher-made questionnaire (effective memory)

3

Description

Internal dialogue
Timepoint
Before and after the intervention
Method of measurement
Researcher-made questionnaire (internal conversation)

4

Description
Motivational assessment;
Timepoint
Before and after the intervention
Method of measurement
Researcher-made questionnaire (motivational assessment)

5

Description
Behavioral reconstruction
Timepoint
Before and after the intervention
Method of measurement
Researcher-made questionnaire (behavioral reconstruction)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention is such that at least 6 training sessions (45 to 60 minutes each session according to the participants) are used during 10 weeks to prevent alcohol consumption using self-regulatory theory. The first session to increase knowledge and skills with lectures and questions and answers, the second session with increasing people's self-confidence through self-efficacy and performing behavioral inhibition behavior skills from short educational videos, setting up an exhibition, the third session on effective memory, which includes the ability Store and recall useful information to solve the problem. That can be activated in people with the ability to save and remember by reporting and working on a specific project or content. The fourth session is accompanied by an internal dialogue so that by expressing the inner feelings and emotions of the participants, as much as possible, people can be led to their situation, where they are and where they want to go. The fifth session is about motivational assessment: the person tries to create a hypothetical future by emotionally and motivationally evaluating past events in effective memory. By evaluating the desirable situation of people in the past and by remembering them, a bright future in people's lives can be imagined. Sixth session, including behavioral reconstruction (behavioral synthesis), should be done by analyzing or separating the past behavioral structure and their hierarchy and rearranging the past behavior and creating new

behaviors with a new structure and new sequence.
Encouraged in people.

Category
Prevention

2

Description
Control group: No intervention is made
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
High schools in the south of Kerman
Full name of responsible person
Ehsan Movahed
Street address
Pasdaran
City
Jiroft
Province
Kerman
Postal code
7618746864
Phone
+98 34 4331 7802
Email
Ehsanmovahed89@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jeeroft University of Medical Sciences
Full name of responsible person
Fatemeh seyedi
Street address
Pasdaran
City
Jiroft
Province
Kerman
Postal code
7618746864
Phone
+98 34 4331 7802
Email
ehsanmovahed89@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jeeroft 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

Jiroft

Province

Kerman

Postal code

7618746864

Phone

+98 34 4331 7802

Email

ehsanmovahed89@yahoo.com

Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Jeeroft University of Medical Sciences

Full name of responsible person

Ehsan Movahed

Position

expert in Department of research

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Pasdaran

City

Jiroft

Province

Kerman

Postal code

7618746864

Phone

+98 34 4331 7802

Email

ehsanmovahed89@yahoo.com

Contact**Name of organization / entity**

Jeeroft University of Medical Sciences

Full name of responsible person

Ehsan Movahed

Position

expert in health

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Pasdaran

City

Jiroft

Province

Kerman

Postal code

7618746864

Phone

+98 34 1331 7802

Email

ehsanmovahed89@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Jeeroft University of Medical Sciences

Full name of responsible person

Ehsan Movahed

Position

Expert in Department of research

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

pasdaran

City**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable