

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Designing the message and the effect of educational intervention based on health promotion theories on promotion of drug dependents therapeutic behavior in sabzevar substance abuse treatment centers.

#### Protocol summary

##### Summary

The objective of this quasi experimental study is designing the message and determination the effect of educational intervention based on health promotion theories on promotion of drug dependents therapeutic behavior in Sabzevar substance abuse treatment centers. Design: A randomized intervention and control groups. Setting: Addicts who are referred to addiction center. Inclusion criteria: (a) Being male; (b) Having medical records in addiction centers; (c) Having consent. Exclusion criteria: (a) Addiction for a specific health disorders (such as cancer) or certain psychiatric (such as schizophrenia); (b) Not regular attendance in educational sessions. Sample size: 160 persons (each group 80). Interventions: After the pretest in both groups of addicts, participating addicts in the intervention group were invited to participate in five educational sessions (during five weeks). Educational program held based on trans-theoretical model, designing the message, group discussions and educational video. Nine months after end of the program, from each group will be taken post-test and the results will be compared. Measured variables include: (a) Trans-theoretical model structures; (b) Demographic variables. Main outcome: improving lifestyle of addicts.

#### General information

##### Acronym

Transtheoretical model

##### IRCT registration information

IRCT registration number: **IRCT2016051313893N3**

Registration date: **2016-06-08, 1395/03/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-06-08, 1395/03/19

##### Registrant information

###### Name

Reza Shahrabadi

###### Name of organization / entity

Tehran university of medical science, school of public health

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5633 7696

###### Email address

r.shahrabadi@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for Research the Technology, Tehran University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Designing the message and the effect of educational intervention based on health promotion theories on promotion of drug dependents therapeutic behavior in sabzevar substance abuse treatment centers.

##### Public title

Substance abuse treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: (a) Being male; (b) Having medical records in addiction centers; (c) Having consent.  
Exclusion criteria: (a) Addiction for a specific health disorders (such as cancer) or certain psychiatric (such as schizophrenia); (b) Not regular attendance in educational sessions.

**Age**

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Vice-chancellor of Research the Technology, Tehran University of Medical Sciences

**City**

Tehran

**Postal code**

**Approval date**

2015-12-15, 1394/09/24

**Ethics committee reference number**

IR.TUMS.REC.1394.1406

**Health conditions studied**

1

**Description of health condition studied**

Drug addiction

**ICD-10 code**

f11

**ICD-10 code description**

Mental and behavioural disorders due to use of opioid

**Primary outcomes**

1

**Description**

The number of relapses

**Timepoint**

Before intervention and nine months after intervention

**Method of measurement**

Questionnaire

2

**Description**

Promote stages of change

**Timepoint**

Before intervention and nine months after intervention

**Method of measurement**

Questionnaire

**Secondary outcomes**

1

**Description**

Stages of Change

**Timepoint**

Before intervention and nine months after intervention

**Method of measurement**

Questionnaire

2

**Description**

Self-Efficacy

**Timepoint**

Before intervention and nine months after intervention

**Method of measurement**

Questionnaire

3

**Description**

Decisional Balance

**Timepoint**

Before intervention and nine months after intervention

**Method of measurement**

Questionnaire

4

**Description**

Processes of change

**Timepoint**

Before intervention and nine months after intervention

**Method of measurement**

Questionnaire

## Intervention groups

### 1

#### Description

After the pre-test in both groups of addicts, participating addicts in the intervention group were invited to participate in five educational sessions (during five weeks). Educational program held based on transtheoretical model, group discussions and educational video. Nine months after end of the program, from each group will be taken post-test and the results will be compared.

#### Category

Lifestyle

### 2

#### Description

Control group: no intervention.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Therapeutic community center sabzevar

##### Full name of responsible person

Reza Shahrabadi

##### Street address

##### City

sabzevar

### 2

#### Recruitment center

##### Name of recruitment center

Azimi nejad substance abuse treatment center

##### Full name of responsible person

Reza Shahrabadi

##### Street address

Sinalox Crossroads, Sabzevar

##### City

Sabzevar

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for Research the Technology, Tehran  
University of Medical Sciences

##### Full name of responsible person

Dr Masud Yunesian

##### Street address

Tehran. Vice chancellor for Research the Technology,  
Tehran University of Medical Sciences

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for Research the Technology, Tehran  
University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tehran university of medical science, school of public  
health

##### Full name of responsible person

Reza shahrabadi

##### Position

Ph.D student in Health education & promotion

##### Other areas of specialty/work

##### Street address

Tehran university of medical science, school of public  
health

##### City

Tehran

##### Postal code

##### Phone

+98 21 4293 3333

##### Fax

##### Email

shahrabadi.reza@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran. university of medical science, school of public  
health

##### Full name of responsible person

Gholamreza Garmaroudi

##### Position

Maternal and Child Health Specialist

##### Other areas of specialty/work

##### Street address

Tehran. university of medical science, school of public  
health

##### City

Tehran

**Postal code**  
**Phone**  
+98 21 4293 3333

**Fax**  
**Email**  
garmaroudi@tums.ac.ir  
**Web page address**

**Postal code**  
**Phone**  
+98 21 4293 3333

**Fax**  
**Email**  
shahrabadi.reza@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran university of medical science, school of public health

**Full name of responsible person**  
Reza shahrabadi

**Position**  
Ph.D student in health education & promotion

**Other areas of specialty/work**

**Street address**  
Tehran university of medical science, school of public health

**City**  
Tehran

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*

**Study Protocol**  
*empty*

**Statistical Analysis Plan**  
*empty*

**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*