

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### **A randomized controlled clinical trial to study of the effectiveness of Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)-linked brief intervention according to Specific Substance Involvement Score in substance users referred to the Primary Health Care Setting**

#### **Protocol summary**

##### **Summary**

This study conducted as a controlled randomized clinical trial to evaluate the effectiveness of Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)-linked brief intervention on substance use disorders. In seven Primary Health Care Centers in Garmsar (Semnan Province) and Shahriar (Tehran Province), screening of the substance use disorders will be done using Alcohol, Smoking and Substance Involvement Screening Test (ASSIST). Seventy patients whose Specific Substance Involvement Score are 4-26 (9-26 for alcohol involvement, nicotine excluded) will enter. They are between the ages of 18 and 64 years. Sex ratio will be 2:1 (male to female). Intoxication or withdrawal syndromes are the main exclusion criteria. Individuals currently in drug treatment or they are injecting substance more than 4 times a month will be excluded, too. These individuals randomly assigned to a case group and a control one. For case group ASSIST-linked brief intervention will be done in one session. Control group are in waiting list. After three months, all participants will be interviewed and Specific Substance Involvement Score will be recorded again. Specific Substance Involvement Scores before and after intervention, within groups and between groups, will be compared.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT201209051958N2**  
Registration date: **2012-10-14, 1391/07/23**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### **Registration date**

2012-10-14, 1391/07/23

##### **Registrant information**

###### **Name**

Seyed Vahid Shariat

###### **Name of organization / entity**

Tehran Univeristy of Medical Sciences

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 21 6650 6862

###### **Email address**

shariatv@iums.ac.ir

##### **Recruitment status**

###### **Recruitment complete**

##### **Funding source**

Office for Psychosocial Health and Addiction, Ministry of Health and Medical Education

##### **Expected recruitment start date**

2012-10-06, 1391/07/15

##### **Expected recruitment end date**

2013-01-04, 1391/10/15

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

A randomized controlled clinical trial to study of the effectiveness of Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)-linked brief intervention according to Specific Substance Involvement Score in substance users referred to the Primary Health

Care Setting

## Public title

Brief Intervention in Substance Use Disorder

## Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusion criteria: Between the ages of 18 and 50 years; Being Iranian; Able to communicate in Persian fluently; Willing to participate in a 3 month follow-up where they return to the treatment agency for interview; Able to be followed up three months later and give contact details of at least 2-3 other people, and of fixed address and able to provide contact details of their home; Physically well enough to participate in a 30 minute interview and intervention session; Specific Substance Involvement Score of 4-26 (for alcohol: 9-26); No more than 4 injections a month, by average, within three last months; Exclusion criteria: Pending incarceration within the next three months; Severely cognitively impaired or have severe behavior; Tended to violent or aggressive behavior; Intoxicated or going through withdrawal from alcohol or other drugs at baseline; Currently in drug (excluding nicotine) treatment (within the last month.

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mental Health Research Center

##### Street address

Mental Health Research Center, Tehran Psychiatric Institute, Shahid Mansouri Lane, Niayesh Street, Satarkhan Avenue, Tehran, Iran

##### City

Tehran

## Postal code

1443813444

## Approval date

2009-08-31, 1388/06/09

## Ethics committee reference number

88/06/09/03

## Health conditions studied

### 1

#### Description of health condition studied

Substance use disorder (abuse and dependence)

#### ICD-10 code

F10

#### ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use (harmful use and dependence syndrome)

## Primary outcomes

### 1

#### Description

Specific Substance Involvement Score in ASSIST

#### Timepoint

month 0 & 3

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

Client Satisfaction Questionnaire-8 (CSQ-8)

#### Timepoint

month 3

#### Method of measurement

paper & pencil questionnaire

### 2

#### Description

Total Illicit Substance Involvement in ASSIST

#### Timepoint

month 0 & 3

#### Method of measurement

paper & pencil questionnaire

## Intervention groups

### 1

#### Description

One-session ASSIST-linked brief intervention (guided by World Health Organization), managed by a primary health care physician, length between 5 and 15 session

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Garmsar Health Network

**Full name of responsible person**

Iman Sadeghi

**Street address**

Garmsar Health Network. North Shaheed Rajaei Ave.  
Garmsar

**City**

Garmsar

### 2

#### Recruitment center

**Name of recruitment center**

Shariar Health Network

**Full name of responsible person**

Bahareh Fasihipour

**Street address**

Shariar

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Office of Psychosocial Health and Addiction, Ministry  
of Health

**Full name of responsible person**

Abbasali Nasehi

**Street address**

Ministry of Health and Medical Education, Hafez  
Street, Tehran

**City**

Tehran

**Grant name**

101034

**Grant code / Reference number**

30452

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

Yes

**Title of funding source**

Office of Psychosocial Health and Addiction, Ministry of  
Health

**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 Psychiatric Institute

**Full name of responsible person**

Kaveh Alavi

**Position**

Psychiatrist

**Other areas of specialty/work****Street address**

Mental Health Research Center, Tehran Psychiatric  
Institute, Shahid Mansouri Lane, Niayesh Street,  
Satarkhan Avenue, Tehran, Iran

**City**

Tehran

**Postal code**

1445613111

**Phone**

+98 21 6650 6862

**Fax**

+98 21 6650 6862

**Email**

kavehalavi@yahoo.com

**Web page address**

www.tehranpi.org

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mental Health Research Center

**Full name of responsible person**

Seyyed Vahid Shariat

**Position**

Psychiatrist

**Other areas of specialty/work****Street address**

Mental Health Research Center, Tehran Psychiatric  
Institute, Shahid Mansouri Lane, Niayesh Street,  
Satarkhan Avenue, Tehran, Iran

**City**

Tehran

**Postal code**

1445613111

**Phone**

+98 21 6650 6862

**Fax**

+98 21 6650 6862

**Email**

vshariat@tums.ac.ir

**Web page address**

www.tehranpi.org

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Mental Health Research Center

**Full name of responsible person**

Kaveh Alavi

**Position**

Psychiatrist

**Other areas of specialty/work****Street address**

Mental Health Research Center, Tehran Psychiatric  
Institute, Shahid Mansouri Lane, Niayesh Street,  
Satarkhan Avenue, Tehran, Iran

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**Phone**

+98 21 6650 6862

**Fax**

+98 21 6650 6862

**Email**

kavehalavi@yahoo.com

**Web page address**

[www.tehranpi.org](http://www.tehranpi.org)

**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*