

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

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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

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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**

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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