

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effect of cognitive - behavioral therapy and cognitive behavior therapy with spiritual approach on depression, anxiety symptoms and rate of relapse in self-referral addicts

Protocol summary

Summary

The objective of this research study is a randomized clinical trial with control group. Compare the effect of cognitive behavior therapy - rich with culture and religious teachings and cognitive behavior therapy to reduce depression, anxiety, and relapse rates of opioid-dependent patients. Inclusion criteria: individuals who, based on clinical interview and the Diagnostic and Statistical Mental Disorders criteria (American Psychiatric Association) affiliated with one of the opioid compounds (substance abuse) that had depression and anxiety. If you had missed three sessions of the study were excluded. The study population was patients: the addiction treatment center for addiction treatment Welfare visited the city of Yazd. And among them 30 people who were entering the main criteria were randomized into three treatment groups. The first group (Group cognitive behavioral therapy - with a religious attitude), the second group (group cognitive - behavioral) the third group (control group). Group cognitive behavioral protocols for enriched with spiritual and religious learning, cognitive-behavioral protocol commonly performed for the second group, each group of 8 had a 2-hour group therapy session. The findings showed: Cognitive behavior therapy with a spiritual approach and cognitive - behavioral therapy compared to control group in reducing depression, anxiety has been effective. But spirituality-based therapy in reducing depression, anxiety, and prevention of recurrence has been more effective.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206089973N1**
Registration date: **2012-07-25, 1391/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-25, 1391/05/04

Registrant information

Name

Mostafa Arab-Varnousfaderani

Name of organization / entity

Department of Counseling Faculty of Education and Psychology, University of Isfahan,

Country

Iran (Islamic Republic of)

Phone

+98 31 3362 6245

Email address

arabashrafi@gmail.com

Recruitment status

Recruitment complete

Funding source

Islamic Azad University roodhen

Expected recruitment start date

1997-10-07, 1376/07/15

Expected recruitment end date

1998-09-21, 1377/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of cognitive - behavioral therapy and cognitive behavior therapy with spiritual

approach on depression, anxiety symptoms and rate of relapse in self-referral addicts

Public title

Cognitive behavior therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria Subjects: All subjects are Substance abuse and The Beck Depression Inventory and Zung Anxiety scores are above the cut-off point Exclusion criteria from the study: Risk of severe psychiatric disorders and Not present in therapy sessions.

Age

From **25 years** old to **46 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Islamic Azad University

Street address

Roodehen - Islamic Azad University

City

Roodehen

Postal code

3973188981

Approval date

1999-03-13, 1377/12/22

Ethics committee reference number

1132070176108

2

Ethics committee

Name of ethics committee

Islamic Azad University Roodehen

Street address

Roodehen,Islamic Azad University

City

Roodehen

Postal code

9373188981

Approval date

1999-03-13, 1377/12/22

Ethics committee reference number

1132070176108

3

Ethics committee

Name of ethics committee

Islamic Azad University

Street address

Roodehen - Islamic Azad University

City

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Postal code

3973188981

Approval date

1999-03-13, 1377/12/22

Ethics committee reference number

1132070176108

Health conditions studied

1

Description of health condition studied

Substance abuse

ICD-10 code

F11

ICD-10 code description

behavioural disorders due to use of opioids Mental and

Primary outcomes

1

Description

Substance abuse

Timepoint

Before treatment, after treatment, three months after treatment

Method of measurement

Urinalysis

Secondary outcomes

1

Description

Depression, Anxiety

Timepoint

Before treatment - after treatment - three months after treatment.

Method of measurement

The Beck Depression Inventory standard. Zung standard questionnaire for anxiety

Intervention groups

1

Description

for group A Cognitive behavioral group therapy protocol enriched with spiritual and religious teachings

Category

Behavior

2

Description

For group B: 8 sessions of cognitive behavior group therapy

Category

Behavior

3

Description

The control group received only the drug

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient treatment center for self-referred
Mtadn, Yazd

Full name of responsible person

Mostafa Arab Varnousfaderany clinical psychologist

Street address

yazd sazman bahzisty

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Roodehen

Full name of responsible person

mostafa arab varnousfaderani

Street address

Roodehen - Islamic Azad University

City

Roodrhan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University Roodehen

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

isfahan education organization

Full name of responsible person

mostafa arab varnousfaderani

Position

MA / Clinical Psychology / Consultant

Other areas of specialty/work

Street address

isfahan education organization Secondary literature,
eight of Paradise Street,

City

isfahan

Postal code

8414884937

Phone

+98 31 1362 6245

Fax

Email

arabebrahimi@isfedu.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

amrollah ebrahimi

Position

PHD/Assistant professor

Other areas of specialty/work

Street address

Psychiatry department, NOOR medical center,
OSTANDARI St. Isfahan

City

Isfahan

Postal code

Phone

+98 31 1625 8818

Fax

Email

a_ebrahimi@med.mui.acarabebrahimi@isfedu.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

isfahan education organization

Full name of responsible person

mostafa arab varnousfaderani

Position

MA/educational consultant

Other areas of specialty/work

Street address

Hashtbahast St. ADAB high school, Isfaha

City

Isfahan

Postal code

Phone

+98 31 1222 2286

Fax

Email

arabebrahimi@isfedu.com

Web page address

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