Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Adapting and evaluating a transdiagnostic cognitive behavioral therapy (TCBT) on common mental health problems in Iranian adults

Protocol summary

Study aim
To evaluate the effectiveness of a transdiagnostic CBT approach in reduction of common mental health problems

Design
A single-center, two-armed, single-blind, randomized, controlled trial with 459 participants, balanced block randomization with four blocks was used

Settings and conduct
This clinical trial was performed in 14 urban health centers in Garmsar and Semnan, Iran. Based on inclusion criteria, clients were invited to participate in the study. The pretest was done. Participants who obtained a score at least above the cut-off point for the examined mental health problems were taken as the trial group. All of the subjects had to sign consent forms. Then, they randomly assigned an ID number to the treatment or control groups made by a third independent researcher out of the study. Therefore, only the participants did not know how to be arranged in the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age at least 18 years old; referring to Urban Health Center and assigned positive in Kessler Psychological Distress Scale (K6). Exclusion criteria: psychosis; suicide thought; psychiatric treatment.

Intervention groups
Intervention group: received 8 weekly sessions Transdiagnositc CBT performed by general trained healthcare providers. Control group: received 3 to 4 monthly sessions usual treatment

Main outcome variables
Reduction in signs and symptoms of depression, anxiety and OCD based on study instrument

General information

Reason for update

Acronym
TCBT

IRCT registration information
IRCT registration number: **IRCT20210609051527N1**
Registration date: **2021-08-01, 1400/05/10**
Registration timing: **retrospective**

Last update: **2021-08-01, 1400/05/10**
Update count: **0**

Registration date
2021-08-01, 1400/05/10

Registrant information

Name
Ameneh Setareh Forouzan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7173 2831

Email address
am.forouzan@uswr.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-06, 1397/09/15

Expected recruitment end date
2019-06-21, 1398/03/31

Actual recruitment start date
2018-12-06, 1397/09/15

Actual recruitment end date
2019-06-21, 1398/03/31

Trial completion date
2019-08-24, 1398/06/02

Scientific title
Adapting and evaluating a transdiagnostic cognitive behavioral therapy (TCBT) on common mental health problems in Iranian adults

Public title
Evaluating TCBT on mental health problems
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age at least 18 years old Referring to Urban Health Center Tested positive in the initial mental health screening using the Kessler Psychological Distress Scale (K6)
Exclusion criteria:
The presence of active suicide ideation, active psychosis, or major developmental delay Anyone currently receiving services for mental health or taking medication for mental health problems
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **500**
Actual sample size reached: **520**
Randomization (investigator's opinion)
Randomized
Randomization description
The assessment Healthcare providers in Urban Health centers assigned an ID number to each participant in the treatment or control groups. A third independent researcher made the random ID number list using computer-generated random numbers. This list included a sequence of C (Control) and T (Treatment) using balanced block randomization with four blocks. The details of the block series were unknown to all the researchers and healthcare providers. The random allocation to the intervention or control groups was also blinded (unknown to assessment healthcare providers prior to participating).
Blinding (investigator's opinion)
Single blinded
Blinding description
As the information about randomization was inserted on the allocation form, which was kept only by the independent researcher, all the healthcare providers and their supervisors remained blinded to the randomized assignment and selection bias was thus reduced. Also all participants remained blinded to their assignment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the National Institute for Medical Research Development (NIMAD)
Street address
No. 21, Besaat Ave, West Dr Fatemi Ave, Amirabad
City
Tehran
Province
Tehran
Postal code
1419693111
Approval date
2016-09-17, 1395/06/27
Ethics committee reference number
IR.NIMAD.REC.1395.047

2

Ethics committee
Name of ethics committee
Ethics Committee of University of Social Welfare and Rehabilitation Sciences
Street address
Kodakyar Blvd., Daneshjoo Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2016-05-23, 1395/03/03
Ethics committee reference number
IR.USWR.REC.1395.113

Health conditions studied

1

Description of health condition studied
Depression Symptoms
ICD-10 code
F32.8
ICD-10 code description
Other depressive episodes

2

Description of health condition studied
Anxiety Symptoms
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

3

Description of health condition studied
Obsessive Compulsive Disorder Symptoms
ICD-10 code
F42
ICD-10 code description
Obsessive-compulsive disorder

Primary outcomes

1

Description
The Depression score based on Persian Version of Beck Depression Inventory
Timepoint
Before the beginning of the intervention and 8 weeks after that
Method of measurement
The Persian version of Beck Depression Inventory

2

Description
Anxiety score based on Persian Version of Beck Anxiety Inventory
Timepoint
Before the beginning of the intervention and 8 weeks after that
Method of measurement
The Persian version Beck Anxiety Inventory

3

Description
Obsessive Compulsive Disorder score based on Yale-Brown Obsessive Compulsive Scale
Timepoint
Before the beginning of the intervention and 8 weeks after
Method of measurement
The Persian Version of Yale-Brown Obsessive Compulsive Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: All the individuals rated positive in the Urban Health Centers initial mental health screening using K6 were referred to enter the study. After the introduction process and providing information about the study and its objectives, the screening interviews were conducted using the study instrument. All the participants who obtained a score at least above the cut-off point for the examined mental health problems were taken as the trial group. The participants entered the randomization, and their screening results were recorded as the baseline measurements. All the intervention participants received Transdiagnostic Cognitive Behavioral Therapy (TCBT) inspired by the Common Elements Treatment Approach (CETA). This approach allows the provider to select and compose common treatment techniques to construct a different structural treatment according to the patients' symptom presentation or existing problems. TCBT was developed to cover the three common mental health problems in Semnan Province, namely depression, OCD, and anxiety. All participants in intervention group received eight weekly sessions lasting 60 minutes. This approach implemented by trained community healthcare providers with no mental health training background. All the community healthcare providers were taught how to manage the therapy sessions, communicate properly and apply the techniques they had learned (using simplest and most applicable and culturally possible therapies for each mental health problem under study). The post test interviews were conducted after the completion of 8 treatment sessions.
Category
Behavior

2

Description
Control group: All the controls were referred to receive Mental health service as usual within the national PHC network. This service which is provided by UHC's mental health provider (mostly psychologist) includes three to four training and counseling sessions (approximately one session per month). These sessions consist of some simple and popular counseling techniques and general mental health advice within the scope of the nationally-approved instructions based on Cognitive and Behavioral Psychotherapy (CBT). The mental health provider is also responsible for the follow-up process. In this study, all the participants in control group followed up on the process of treatment service as usual through monthly phone calls. The post test interviews were conducted after four months.It should be noted that all follow-ups and completion of study instrument (initial assessment and post test interviews) were performed in both intervention and control group by the UHC healthcare providers who had received the necessary training for this study.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
14 Urban Health Centers in Semnan and Garmsar; Semnan University of Medical Sciences
Full name of responsible person
Shahla Haghighat
Street address

Second Flr, Deputy for health, Semnan University of Medical Sciences, Basij Blv

City
Semnan

Province
Semnan

Postal code
3519899951

Phone
+98 23 3344 1022

Fax
+98 23 3344 8999

Email
info@semums.ac.ir

Web page address
https://health.semums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Jafar Jandaghi

Street address
Semnan University of Medical Sciences, Basij Blvd.

City
Semnan

Province
Semnan

Postal code
35147-99442

Phone
+98 23 3344 1022

Fax
+98 23 3344 8999

Email
info@semums.ac.ir

Web page address
https://health.semums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
National Institute For medical Research Development

Proportion provided by this source
90

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
Other

2

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamid Reza Khoramkhorshid

Street address
Koudakyar Blvd., Daneshjoo Blvd., Velenjak

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0083

Fax
+98 21 2218 0109

Email
pr@uswr.ac.ir

Web page address
https://www.uswr.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
University of social welfare and rehabilitation sciences

Proportion provided by this source
10

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

Person responsible for general inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Masoumeh Dejman

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychiatrics

Street address
Koudakyar Blvd., Daneshjou Blvd., Velenjak

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0083
Email
dejman.masoumeh@gmail.com
Web page address
https://www.uswr.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Masoumeh Dejman
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychiatrics
Street address
Koudakyar Blvd., Daneshjou Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 2218 0083
Email
dejman.masoumeh@gmail.com
Web page address
https://www.uswr.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Masoumeh Dejman
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychiatrics
Street address
Koudakyar Blvd., Daneshjou Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 2218 0083
Email
dejman.masoumeh@gmail.com
Web page address
https://www.uswr.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Personal data
When the data will become available and for how long
from date of publication to one year
To whom data/document is available
Journal editors and researchers according to their requests
Under which criteria data/document could be used
Only analyses based on study objectives
From where data/document is obtainable
Data sharing will be done based on publication and request from corresponding author
What processes are involved for a request to access data/document
sending email to corresponding author
Comments