

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effectiveness of Rational Emotional Behavior Therapy on cognitive distortions of hospitalized tubercular patients

Protocol summary

Study aim

Determining the effectiveness of REBT on the amount of cognitive distortions.

Design

Randomized controlled trial by allocation of tubercular patients in to two experimental and control groups, with 45 members in each group.

Settings and conduct

The sample group was selected randomly in Massih Daneshvari Hospital. All members of the sample group gave informed verbal consent for participation in the project. Several psychologists interviewed the patients for obtaining the demographic information and cognitive distortions scale from two groups of patients under the supervision of an academic psychiatrist in a quiet environment. The patients were assured that their information would be completely confidential, and they would be presented generally just in article format. Then the psychological interventions executed on experimental group.

Participants/Inclusion and exclusion criteria

The inclusion criteria: The existence of relative mental health according to psychiatrist diagnosis, definite diagnosis of tuberculosis disease diagnosed by the infectionist, informed consent for participation in the research, ability to participate in 90 minutes psychotherapy sessions. The exclusion criteria: acute psychiatric disorders diagnosed by psychiatrist, existence of other diseases other than tuberculosis, withdrawal or intoxication phase of of substance use.

Intervention groups

The experimental group received REBT as a psychotherapy method, but the control group did not receive any psychotherapy.

Main outcome variables

Ten types of cognitive distortions were assessed before and after the psychological intervention as outcome variables.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131115015405N3**

Registration date: **2019-01-21, 1397/11/01**

Registration timing: **retrospective**

Last update: **2019-01-21, 1397/11/01**

Update count: **0**

Registration date

2019-01-21, 1397/11/01

Registrant information

Name

Mitra Safa

Name of organization / entity

Massih Daneshvari Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2607

Email address

m.safa@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

2015-09-23, 1394/07/01

Actual recruitment end date

2017-09-22, 1396/06/31

Trial completion date

2017-09-22, 1396/06/31

Scientific title

Effectiveness of Rational Emotional Behavior Therapy on cognitive distortions of hospitalized tubercular patients

Public title

REBT on cognitive distortions of tubercular patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Relative mental health diagnosed by psychiatrist
Definite diagnosis of tuberculosis disease diagnosed by the infectionist
Informed consent for participation in the research
Ability to understand and reply to questions and participate in 90 minutes psychotherapy sessions

Exclusion criteria:

Acute psychiatric disorder which is the barrier for performing the research process
Having other diseases in addition to tuberculosis
Reluctancy to participate in the research project
Having intoxication or withdrawal syndroms of substance use

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The techeniqe of randomization was simple randomization by using computer-generated random numbers.

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 National research institute of tuberculosis and lung diseases of Massih Daneshvha

Street address

Massih Daneshvari Hospital, Darabad Street, Niavaran, Tehran

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2016-02-03, 1394/11/14

Ethics committee reference number

IR.SBMU.NRITLD.REC.1397.056

Health conditions studied**1****Description of health condition studied**

tuberculosis disease

ICD-10 code

A15.0

ICD-10 code description

Tuberculosis of lung

Primary outcomes**1****Description**

cognitive distortion

Timepoint

a day before the intervention, and a day after completeion of the intervention

Method of measurement

cognitive distortions scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: tubercular patients received REBT psychotherapy.

Category

Behavior

2**Description**

Control group: tubercular patients just received routin care.

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center

Dr Massih Daneshvari Hospital
Full name of responsible person
Mitra Safa
Street address
Massih Daneshvari Hospital- Darabad Street-Niavaran
Street
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2607
Email
mitra.safa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parisa Farnia
Street address
Massih Daneshvari Hospital, Darabad St., Niavaran St.
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2008
Email
pfarnia@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Safa

Position

Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Massih Daneshvari Hospital, Darabad, Niavaran,
Tehran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 2607

Fax

Email

mitra.safa@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Safa

Position

professor-psychiatrist

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Massih Daneshvari Hospital, Darabad, Niavaran,
Tehran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 2607

Fax

+98 21 2712 2607

Email

m.safa@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Safa

Position

professor-psychiatrist

Latest degree

Specialist

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

Massih Daneshvari Hospital, Darabad, Niavaran,
Tehran

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 2607

Fax

+98 21 2712 2607

Email

mitra.safa@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It will be decided in the phase of the article preparation.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available