Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 disesase 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 reveive 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 disesase 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 Daneshva
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 reveived 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 preperation.
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