Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Effectiveness of religious spiritual integrated therapy on the reduction of death distress in outpatients with generalized anxiety disorder

Protocol summary

Study aim
Effectiveness of RSIT on the reduction of death distress in GAD outpatients

Design
A randomised, blinded, controlled clinical trial, outcome assessment, and followed for two months

Settings and conduct
Case finding by psychiatrist or an announcement in the clinic; selection of 60 outpatient patients with generalized anxiety disorder using available sampling and semi-structured interview; obtaining written consent, implementation of Death Anxiety Ṡcale, Death Obsession Scale, and Death Depression Scale; selection of 30 patients randomly among the patients who obtained the highest scores in the scales; training of two clinical psychologists with Msc degrees by the researcher alternately for implementing and scoring the scales; placement of selected patients randomly in two experimental and control groups, each group 15 patients;. re-evaluating participated patients in the treatment as well as the control group after the completion of the treatment, with the mentioned scales; and follow up patients after two months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Outpatients; Generalized Anxiety Disorder's patients; and no receiving of treatment/training Exclusion criteria: Chronic physical illness; primary diagnosis of other anxiety disorders; primary diagnosis of Major Depression Disorder; psychotic disorder; drug dependence disorders

Intervention groups
Religious spiritual integrated therapy include relaxation, cognitive reconstruction, thought stopping, forgiveness, anxious behaviors stopping, behavioral activation, sleep health, problem solving along with religious spiritual methods in 8 sessions weekly. For control group no receiving treatment and being in waiting list.

Main outcome variables
Death anxiety; death obsession; death depression

General information

Reason for update

Acronym
RSIT

IRCT registration information
IRCT registration number: **IRCT20180310039024N1**
Registration date: **2018-05-11, 1397/02/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-11, 1397/02/21**
Update count: **0**

Registration date
2018-05-11, 1397/02/21

Registrant information

Name
Mehrdad Kazemzadeh Atoofi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6655 1666

Email address
atoofi.m@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-19, 1397/01/30

Expected recruitment end date
2018-09-22, 1397/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of religious spiritual integrated therapy on the reduction of death distress in outpatients with generalized anxiety disorder

Public title
Effectiveness of religious spiritual integrated therapy on the reduction of death distress in outpatients with generalized anxiety disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Outpatients Generalized Anxiety Disorder's patients
Exclusion criteria:
Chronic physical illness Primary diagnosis of other anxiety disorders Primary diagnosis of Major depression Disorder Psychotic disorder Drug dependence disorders No individually/group psychological treatment or training

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In the first step, the simple randomization method is based on a random number table, and first to read of numbers their direction will be determined that in this study it will be on the right direction. In the second step, the random allocation concealment will be done, which it will be used by envelops shuffling with random sequence through using of SNOSE method. In the third stage, the random allocation process will be implemented and to prevent the bias, it will be included selection an individual who is separated from other researchers to develop a random program in order to reduce probable bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher will be blind of the scores of patients on the scales in each of the two stages.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
No. 1, Sattarkhan St., Mansouri Ave.,Tehran
City
Tehran
Province
Tehran
Postal code
1445613111

Approval date
2017-12-05, 1396/09/14

Ethics committee reference number
IR.IUMS.REC 1396.31073

Health conditions studied

1

Description of health condition studied
Generalized anxiety disorder

ICD-10 code
F41.1

ICD-10 code description
F41.1

Primary outcomes

1

Description
Death distress

Timepoint
Before of therapy, 2 weeks after of therapy, and 2 months after of therapy

Method of measurement
Death Anxiety Scale; Death Obsession Scale;, Death Depression Scale Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic at the School of Behavioral Sciences and Mental Health

Full name of responsible person
Dr.Jaafar Bolhari

Street address
No. 1,Mansouri Ave., Sattarkhan St., Tehrann

City
Tehran

Province
Tehran

Postal code
1445613111

Phone
+98 21 6655 1666

Email
bolharij@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Kazem Malakouti

Street address
No. sattarkhan St., Mansouri Ave., Tehran

City
Tehran

Province
Tehran

Postal code
1445613111

Phone
+98 21 8670 2503

Email
malakouti@iums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Merdad Kazemzadeh Atoofi

Position
Deputy of School, Clinical Psychologist

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
No. 1, Sattarkhan St., Mansouri Ave., Tehran

City
Tehran

Province
Tehran

Postal code
1445613111

Phone
+98 21 6655 1666

Email
atoofi.m@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mahboubeh Dadfar

Position
Clinical psychologist

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
No. 1, Sattarkhan St., Mansouri Ave., Tehran

City
Tehran

Province
Tehran

Postal code
1445613111

Phone
+98 21 6655 1666

Email
mahboubehdadfar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mahboubeh Dadfar

Position
Clinical psychologist

Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No. 1, Sattarkhan St., Mansouri Ave., Tehran
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1666
Email
mahboubehdadfar@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
Using of future studies by researchers
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
Yes - There is 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
Title and more details about the data/document
Only part of data related to main consequence will be available.
When the data will become available and for how long
6 months after publishing of the results
To whom data/document is available
Academic and scientific researchres
Under which criteria data/document could be used
Study citation
From where data/document is obtainable
Mehrdad Kazemzadeh Atoofi
What processes are involved for a request to access data/document
By email
Comments