

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 Scale, 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 envelopes 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakouti

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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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Mahboubeh Dadfar

Position

Clinical psychologist

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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 researches

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