

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Mental health and hopefulness following laughter therapy and cognitive behavior therapy among dialysis patients

Protocol summary

Study aim

This study was aimed to examine the effects of laughter therapy (LT) and cognitive behavior therapy (CBT) on mental health and hopefulness of dialysis patients.

Design

Clinical trial with two intervention groups (n=48, each of them) and control group (n=49), computer base randomization, workshop in the hospital setting

Settings and conduct

The subjects were selected among patients undergoing dialysis in teaching hospitals affiliated to the Isfahan University of Medical Sciences: Noor and Hazrat Ali Ashgar, Al-Zahra, Amin, and Farabi.

Participants/Inclusion and exclusion criteria

The existence of patient's permanent medical records in selected hospitals, willingness to be included in the study, the ability to read and write in Persian, absence of any signs of mental retardation, no concomitant use of medications for mental disorders, no use of other non-medication treatment, absence of any report on severe stress during the previous 6-month period, no history of participation in similar interventions and being treated with dialysis at last 6 months, were considered as inclusion criteria. Exclusion criteria consisted of unwillingness to complete intervention process, absence for more than 2 sessions, facing with major physical or mental conditions during intervention period which can affect the study results, and emigration from the region where the study will take place.

Intervention groups

Patients were assigned to 3 groups: LT (n=48), CBT (n=48) and the control group (n=49) through the computer-generated randomization procedure.

Main outcome variables

Mental health and hopefulness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101013004922N2**

Registration date: **2018-02-09, 1396/11/20**

Registration timing: **retrospective**

Last update: **2018-02-09, 1396/11/20**

Update count: **0**

Registration date

2018-02-09, 1396/11/20

Registrant information

Name

Mohammad Sahebzamani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-27, 1396/01/07

Expected recruitment end date

2017-04-16, 1396/01/27

Actual recruitment start date

2017-03-27, 1396/01/07

Actual recruitment end date

2017-04-16, 1396/01/27

Trial completion date

empty

Scientific title

Mental health and hopefulness following laughter therapy and cognitive behavior therapy among dialysis patients

Public title

Laughter therapy and cognitive behavior therapy among dialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The existence of patient's permanent medical records in selected hospitals Willingness to be included in the study The ability to read and write in Persian Absence of any signs of mental retardation No concomitant use of medications for mental disorders Absence of any report on severe stress during the previous 6-month period No history of participation in similar interventions Being treated with dialysis at last 6 months

Exclusion criteria:

Unwillingness to complete intervention process Absence for more than 2 sessions Facing with major physical or mental conditions during intervention period which can affect the study results Emigration from the region where the study was being carried out

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **145**

Actual sample size reached: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Then patients were assigned to 3 groups: LT (n=48), CBT (n=48) and the control group (n=49) through the computer-generated randomization procedure.

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 Islamic Azad University Tehran
Medical Sciences Branch

Street address

Tehran Province, Tehran, Danesh Rd

City

Tehran

Province

Tehran

Postal code

1477893855

Approval date

2017-03-14, 1395/12/24

Ethics committee reference number

IR.IAU.REC.1395.374

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

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

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

Mental health

Timepoint

Before and 2 days after intervention

Method of measurement

Symptom Checklist (SCL-90-R) was used before intervention and 2 days after it.

2**Description**

Hopefulness

Timepoint

Before and 2 days after intervention

Method of measurement

Snyder Hope Scale (SHS)

Secondary outcomes

empty

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

Intervention group A: laughter therapy: In this study, 8 one-hour Laughter Therapy (LT) sessions were held from April 22, 2017 to May 31, 2017. The researcher (Sima Vadaei) is a laughter therapist and has a certificate from the Iran Laughter Club. During the first session, exercises such as deep respiration, physical movements (clapping), induction of a feeling of gratitude toward God and laughing in a shy manner (by placing the hands over the eyes) were practiced. During the subsequent sessions, drills such as laughing with a loud sound (gaff), long laughs and other kinds of laughing were

presented in association with physical exercises, deep respiration and focus on positive aspects of life.

Category

Behavior

2

Description

Intervention group B: Cognitive behavior therapy: In this study, 8 one-hour Cognitive Behaviour Therapy (CBT) sessions were held from April 22, 2017 to May 31, 2017. The researcher (Sima Vadaei) has an official certificate on cognitive-behavioral interventions under the supervision of Dr. Mahdi Nasre Esfahani, who is a psychiatrist. The contents of the sessions were confirmed by psychologists, and they were implemented through counseling with them. The contents of each session consisted of reviewing the drills of the previous session, instructing new subjects, practicing and assigning the next session's exercises. During the first session, some explanations were provided about the A-B-C system, behaviors and physiology. During the subsequent sessions, the cognitive therapy of mental health, positive thinking approach, classification of beliefs, data organizing, altering beliefs, rational analysis, desensitization, etc., were presented and exercised.

Category

Behavior

3

Description

Control group: Routine therapy with dialysis

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Teaching hospitals: Noor and Hazrat Ali Asgar, Al-Zahra, Amin, and Farabi

Full name of responsible person

Sima Vadaei

Street address

Ostandari st, Noor and Hazrat Ali Asgar hospital, Esfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

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Islamic Azad University- Tehran Medical Branch- khaghani st- shariati Ave- Tehran- Iran

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Web page address

<http://www.iautmu.ac.ir/research/index.asp>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mohammad Sahenalmazamani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available