

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Impact of laughter therapy on fatigue and depression in patients undergoing hemodialysis in Sowmesara and Fuman city (Year 2018)

Protocol summary

Study aim

1. The effect of laughter therapy on fatigue in patients undergoing hemodialysis 2. Effect of laughter therapy on depression in patients undergoing hemodialysis 3. Use laughter therapy as a complementary or alternative treatment in diseases

Design

A clinical trial with a control group, a community based and pragmatic, sample size of 70, selected by census, without blinding

Settings and conduct

This study was performed on 70 patients with chronic renal failure who were undergoing chronic hemodialysis and referred to two hospitals in Fuman County or Sowmeh Sara. In this study, for the intervention group, During hemodialysis Comedy shows and films were used for 30 - 45 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: * The samples are over 18 years of age. * Have the ability to see, hear, and consent to participate in the study. Exit criteria: * The questionnaires are not completely completed. * Samples decide to leave the study.

Intervention groups

In the laughter therapy intervention, for the intervention group, comedy shows and comedies are used during hemodialysis, while the control group only receives hemodialysis routine therapies.

Main outcome variables

The effect of laughter therapy on the amount of depression - the effect of laughter therapy on the severity of fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180329039157N1**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **retrospective**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Leila Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

leila.sharifi2014@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-22, 1396/05/31

Expected recruitment end date

2017-09-30, 1396/07/08

Actual recruitment start date

2017-08-21, 1396/05/30

Actual recruitment end date

2017-09-30, 1396/07/08

Trial completion date

empty

Scientific title

Impact of laughter therapy on fatigue and depression in patients undergoing hemodialysis in Sowmesara and Fuman city (Year 2018)

Public title

"Impact of laughter therapy on depression and fatigue"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with renal failure undergoing hemodialysis. Having a visual and auditory ability and satisfaction to participate in the study. Have at least 18 years of age to enter the study.

Exclusion criteria:

The questionnaire should not be filled completely by the subject. The subject leaves the study during the research.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

The Ethics Committee of the University of Social Welfare and Rehabilitation Sciences of Tehran

Street address

University of Social Welfare and Rehabilitation Sciences Tehran, Evin, Student Blvd, Childhood Death

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

ir.uswr.rec.1396.373

Health conditions studied

1

Description of health condition studied

Patients with End Stage Renal Disease (ESRD) under hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Depression score in Beck's questionnaire

Timepoint

Measure the patient's depression score before intervention and then at the end of the last intervention session

Method of measurement

Beck Depression Inventory 2

2

Description

Fatigue score in multi-dimensional fatigue inventory (MFI)

Timepoint

Measure the fatigue score before the intervention and then at the end of the last intervention session

Method of measurement

multidimensional fatigue inventory (MFI)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention was used to watch comedy and show videos for 40 samples referred to the dialysis department of Imam Khomeini Hospital in the city of Sowmehsara, which was used for 45-30 minutes, twice a week for 4 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Leila Sharifi

Street address

Imam Khomeini Hospital, Shohada Street,
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Full name of responsible person

Leila Sharifi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khankeh

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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

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Leila Sharifi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

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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

No more information.

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