

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Investigating the effect of Spiritual therapy approach on hope and self-efficacy in hemodialysis patients

Protocol summary

Study aim

Determining the effect of spiritual therapy on hope and self-efficacy of hemodialysis patients

Design

A randomized clinical trial with two intervention and control groups, blinded,

Settings and conduct

Randomized, blind clinical trial, in Imam Reza Amol Hospital

Participants/Inclusion and exclusion criteria

Entrance criteria: Age at least 18 years old; at least 6 months of hemodialysis history; at least twice weekly hemodialysis; reading and writing comprehension; ability to understand Persian language; lack of obvious cognitive problems, including Alzheimer's, no stroke and transient brain attack, not known vision and hearing related diseases; lack of mental disorders, belief in one of the divine religions. Exit criteria: crisis incident after the start of the study; hospitalized because of relapse of the disease; having a chronic illness that reduces the function; death of the patient.

Intervention groups

Intervention group: The intervention group was treated individually 2 times a week and included 9 sessions of 45 minutes each patient. One month after the sessions, the participants were appreciated in the post-test. Therapeutic spirituality sessions include: Identify and contextualize the spiritual experience, introspection and description, sources of fear and anxiety, and our resources against them, endlessness and inheritance, inheritance on the orbit of the circuit and inheritance on Kine's circuit, meditation and calculation, forgiveness And solving the anger, self-control, and reflection of self-sustaining sessions. Control group: Only received routine care

Main outcome variables

Increased hope and self-efficacy in patients undergoing hemodialysis

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20181213041957N1**

Registration date: **2019-02-17, 1397/11/28**

Registration timing: **retrospective**

Last update: **2019-02-17, 1397/11/28**

Update count: **0**

Registration date

2019-02-17, 1397/11/28

Registrant information

Name

peiman fereidouni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3423 8444

Email address

peimanfereidounisa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-26, 1397/08/04

Expected recruitment end date

2019-01-01, 1397/10/11

Actual recruitment start date

2018-10-26, 1397/08/04

Actual recruitment end date

2019-01-01, 1397/10/11

Trial completion date

2019-01-30, 1397/11/10

Scientific title

Investigating the effect of Spiritual therapy approach on hope and self-efficacy in hemodialysis patients

Public title

Investigating the effect of Spiritual therapy approach on hope and self-efficacy in hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age at least 18 years old Having at least six months of hemodialysis history Having at least twice a week hemodialysis Reading and writing skills Ability to understand Persian language Lack of obvious cognitive problems, including Alzheimer's, non-stroke, and transient Brain attack Lack of known vision and hearing ailments, not afflicted with mental disorders approved by the doctor Belief in one of the divine religions raised

Exclusion criteria:

Crisis incident after the start of the study for the patient Hospitalization of the patient in the hospital due to relapse of the disease Chronic illness that reduces the patient's function Patient's death during the study stages

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization based on odd and even days

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

Faculty of Nursing and Midwifery, Faculty of Rehabilitation, Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Tehran, Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

Approval date

2018-08-31, 1397/06/09

Ethics committee reference number

IR.TUMS.FNM.REC.1397.092

Health conditions studied

1

Description of health condition studied

hemodialysis

ICD-10 code

N17-N19

ICD-10 code description

Chronic renal failure

Primary outcomes

1

Description

Hope

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Schnayder adolescent Inventory with a likert spectrum

2

Description

Self-efficacy

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Self-efficacy questionnaire with Likert spectrum

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

2

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: the intervention group was treated individually 2 times per week, with 9 sessions of 45 minutes each patient at the bedside of her privacy. One month after the sessions, the participants were appreciated. Spirituality therapy sessions include: identifying and grounding spiritual experience, internalizing and describing, sources of fear and anxiety and our resources against them, infiniteness and inheritance, inheritance on the orbit and inheritance of Kane's circuit, meditation and calculation, Forgiveness and resolution of anger, selflessness, and reciprocity of the sessions of self-determination and the announcement of completion of the course

Category

Prevention

2

Description

Control group: after selecting the intervention and control groups and doing the pretest, from both groups, the control group underwent their normal treatment, one month after the initial referral, again, hope and autoimmunity were checked in the control group using the questionnaire.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Masoumeh Zamani

Street address

Imam Reza Street

City

Amol

Province

Mazandaran

Postal code

4614937597

Phone

Fax

Email

Imamreza@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ziba Taghizadeh

Street address

Tehran University of Medical Sciences, Tehran, Keshavarz Blvd., Ghodss St. Corner, Tehran University of Medical Sciences, Faculty of Nursing

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Province

Tehran

Postal code

1417653761

Phone

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Email

tums_edu@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Noghani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Tohid Square - Nusrat Street East - Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Fatemeh Noghani
Position
Associate Professor
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Peiman Fereidouni
Position

Master student of psychiatric Nursing
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Master
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-
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
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