Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of reminiscence therapy on cognitive disorders and depression in hemodialysis' patients

Protocol summary

Summary

Objective: To determine the effect of reminiscence therapy on cognitive disorders and depression in hemodialysis' patients. Inclusion criteria: age 25 to 75 years; ability to read; write; visual and verbal communication; lack of cognitive or chronic mental disorders; no deaths of a close family and friends in the last three months; lack of addiction to drugs abuse or alcohol; get Mini Mental State Examination (MMSE) questionnaire score 25-10. Exclusion criteria: having a history of suicidal thoughts; psychosis; mental retardation; vision and hearing problems; absence more than one session. Population under Study: hemodialysis' patients of Imam Hussein (AS) hospital and dialysis center of Red Crescent Organization in Shahrod. Sample size: A pilot study including 10 patients from each group, would determine the size of samples. Intervention group 1: participates in 12 sessions Stinson reminiscence, attended nurse and psychotherapist, for 30 to 35 minutes, twice a week. Intervention group 2: in 12 sessions for 35 to 30 minutes and twice a week talking about everyday issues with the nurse and psychotherapist. Control group: hemodialysis was done with previous process. Participants complete questionnaires of MMSE cognitive status and the Beck depression before, immediately after and one month after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607186318N8**
Registration date: **2016-08-06, 1395/05/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-06, 1395/05/16

Registrant information

Name
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Semnan University of Medical Seiences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of reminiscence therapy on cognitive disorders and depression in hemodialysis' patients

Public title

The effect of reminiscence therapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 25 to 75 years; ability to read;

write; visual and verbal communication; lack of cognitive or chronic mental disorders; no deaths of a close family and friends in the last three months; lack of addiction to drugs abuse or alcohol; get MMSE questionnaire score 25-10. Exclusion criteria: having a history of suicidal thoughts; psychosis; mental retardation; vision and hearing problems; absence more than one session.

Age
From **25 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Random blocks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Boulvar Basij, Semnan

City
Semnan

Postal code

Approval date
2016-07-13, 1395/04/23

Ethics committee reference number
IR.SEMUMS.REC.1395.57

Health conditions studied

1

Description of health condition studied
Cognitive disorders and depression in hemodialysis' patients

ICD-10 code
F02.8

ICD-10 code description
Dementia in other specified diseases classified elsewhere

Primary outcomes

1

Description
Cognitive status

Timepoint
Before, immediately after and one month after the intervention.

Method of measurement
Variable measurement method: In this study, Cognitive status is measured by using MMSE questionnaire. Score of cognitive health (25-30), mild cognitive disorders (21-24), moderate (10-20) severe (<9). Information for each person will be recorded in a specific questionnaire for each patient.

Secondary outcomes

1

Description
Depression

Timepoint
Before, immediately after and one month after the intervention.

Method of measurement
Depression is measured by using the Beck Depression Inventory. Beck Depression Inventory tests their polls. There are a total of 21 tests of four-point scale from zero to three to respond. Scores range from zero to 63. Score and severity of depression is divided to mild (11-16), moderate (17-29) and major (30-63). Information for each person will be recorded in a specific questionnaire for each patient.

Intervention groups

1

Description
Intervention group 1, participates in 12 sessions Stinson reminiscence, attended nurse and psychotherapist, for 30 to 35 minutes, twice a week.

Category
Behavior

2

Description
Intervention group 2, in 12 sessions for 35 to 30 minutes and twice a week talking about everyday issues with the nurse and psychotherapist.

Category
Behavior

3

Description
Control group, hemodialysis was done with previous process.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hussein (AS) hospital and dialysis center of Red Crescent Organization in Shahrod.
Full name of responsible person
Monir Nobahar
Street address
Faculty of Nursing and Paramedical, Semnan University of Medical Sciences, Semnan
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Semnan University of Medical Sciences
Full name of responsible person
Dr. Ali Rashidypour
Street address
Semnan University of Medical Sciences, Boulvar Basij, Semnan
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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
Vice Chancellor for research of Semnan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty