

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison the effect of multi-sensory stimulation intervention and aromatherapy inhalation with lavender essential oil on anxiety, depression and well-being in the elderly undergoing hemodialysis

Protocol summary

Study aim

Comparison the effect of multi-sensory stimulation intervention and aromatherapy inhalation with lavender essential oil on anxiety, depression and well-being in the elderly undergoing hemodialysis

Design

A concealed, randomized, clinical trial with a parallel group design of 44 patients, in 2019-2020, and followed for one month

Settings and conduct

The study will be performed in the hemodialysis ward of the Sari dialysis center during hemodialysis on the elderly under hemodialysis referred to the dialysis center.

Participants/Inclusion and exclusion criteria

1) Chronological age 60 and older 2) Alertness and ability to communicate 3) Normal cognitive status based on abbreviated mental test (AMT) 4) Mild to moderate anxiety 5) Mild to moderate depression 6) Having a hemodialysis history at least 6 months and at least 3 hemodialysis sessions per week 7) Having sensory health of hearing, sight and smell 8) No allergies to lavender odor 9) No alcohol use and no opioid or 10) No experience of any event that may cause increasing mental pressure on a person 6 months ago 11) No participation in the anxiety and depression classes concurrently or not being consulted with a psychologist or psychiatrist 12) No psychotropic drugs use

Intervention groups

Multi-sensory stimulation (olfactory, visual and auditory stimulation) will be administered three days a week (even days) for four weeks, each session will be 25 minutes. Auditory stimulation will be performed by using relaxed and wordless music playback by Dan Gibson, visual stimulation using nature images, and olfactory stimulation using aromatherapy with lavender essential oil. Patients in the other group (aromatherapy group) will

receive only aromatherapy with lavender essential oil.

Main outcome variables

anxiety, depression and well-being

General information

Reason for update

Acronym

مقایسه ی تاثیر تحریکات چند حسی و رایحه درمانی با اسطوخودوس بر اضطراب، افسردگی و احساس خوب بودن سالمندان همودیالیزی

IRCT registration information

IRCT registration number: **IRCT20170611034454N4**

Registration date: **2019-12-03, 1398/09/12**

Registration timing: **prospective**

Last update: **2019-12-03, 1398/09/12**

Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name

Ehteram Sadat Ilali

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of multi-sensory stimulation intervention and aromatherapy inhalation with lavender essential oil on anxiety, depression and well-being in the elderly undergoing hemodialysis

Public title

Comparison the effect of multi-sensory stimulation intervention and aromatherapy with lavender essence on anxiety, depression and well-being in the elderly undergoing hemodialysis

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Chronological age 60 and older Alertness and ability to communicate (ability to answer questions) Normal cognitive status based on abbreviated mental test (AMT) (score 7 and above) Mild to moderate anxiety (score 16-10) Mild to moderate depression (score 5-11) Having a hemodialysis history at least 6 months and at least 3 hemodialysis sessions per week Having sensory health of hearing, sight and smell No allergies to lavender odor No alcohol use and no opioid or No experience of any event that may cause increasing mental pressure on a person (death of a spouse or other family member, divorce, serious illness and other adverse events) 6 months ago No participation in the anxiety and depression classes concurrently or not being consulted with a psychologist or psychiatrist No psychotropic drugs (sedatives/ hypnotics/ antidepressants/ anti-anxiety) use

Exclusion criteria:

Incidence of allergy to perfume during intervention Candidate for Kidney Transplant Having other Neuropsychiatric Disorders Absence of more than three sessions at the time of intervention Lack of interest to music withdrawal or unwillingness to Continue to study die

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation of the samples to the two groups will be blocking. The blocking is done with random allocation software and 11 quadruple blocks are

generated with the software then samples with inclusion criteria are assigned to each of the multi-sensory stimulation or aromatherapy groups accordingly. To hide the random allocation, 44 non-transparent envelopes (for the sake of clarity of envelope content) were prepared, and each random sequence generated was recorded on a card and the cards were inserted in the envelope respectively. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the envelope door is glued and placed in a box, respectively. At the time the participants begin to register, based on the order of entry of the eligible participants into the study, one of the envelopes, respectively, opened and the assigned group of the participant is revealed.

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 Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences (Vice chancellor for research), Moallem Square

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2019-11-17, 1398/08/26

Ethics committee reference number

IR.MAZUMS.REC.1398.1151

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

2

Description of health condition studied

Depression

ICD-10 code

F32.9

ICD-10 code description

Depressive episode, unspecified

3

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Dialysis (renal) NOS

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention, at the end of the second and fourth weeks after the intervention and one week after the intervention

Method of measurement

Geriatric Anxiety Inventory (GAI)

2

Description

Depression

Timepoint

Before the intervention, at the end of the second and fourth weeks after the intervention and one week after the intervention

Method of measurement

Geriatric Depression Scale (GDS)

3

Description

Well-being

Timepoint

Before the intervention, at the end of the second and fourth weeks after the intervention and one week after the intervention

Method of measurement

Well-being Index (WHO-5-P)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 2: Multi-sensory stimulation

intervention will include three types of stimulation in the form of auditory, visual and olfactory stimulation that will be performed in the hemodialysis ward of Sari Dialysis Center during hemodialysis on elderly patients undergoing hemodialysis. Auditory stimulation will be performed using relaxing and unassuming music playing with the sound of nature from Dan Gibson's collection of relaxing music songs with the sound of nature (birds singing, water sounds). Visual stimulation will be done using nature images (video slide shows and audio playback via a laptop (15-inch Lenovo E-ideapad 330 and headphones). Auditory and visual stimulation will be performed simultaneously for 10 minutes, then the elderly will rest for 5 minutes, and for 10 minutes the olfactory stimulation (aromatherapy) will be performed so that patients in the multi-sensory stimulation group will inhale the lavender essential oil. The patients of the multi-sensory stimulation groups will inhaled lavender essential oil that is diluted with almond oil in a ratio of 1:20 (5% lavender essential oil), both produced by Barij Essence Pharmaceuticals and are ISO 9001 certified and ISO/IEC 17025 certified. Patients receive lavender inhalation three days a week, alternately on Saturdays, Mondays, and Wednesdays for 4 weeks. So that a cotton ball impregnated with 3 drops of lavender essential oil at a concentration of 5% (diluted with sweet almond oil at a ratio of 1:20) adheres to the patient's collar and is asked to sit for 10 minutes to breathe normally. People are also asked not to use any perfume or cologne or other fragrance before or during the intervention. Finally, in the multi-sensory stimulation group, the three-week multi-sensory stimulation intervention will be performed on a daily basis in the even days (Saturday, Monday, Wednesday) for four weeks. Each session will last a total of 25 minutes.

Category

Rehabilitation

2

Description

Intervention group 2: Patients in the aromatherapy group will inhale the almond oil diluted with sweet almond oil for a period of 10 minutes in a ratio of 1:20 (5% lavender essential oil) that are produced by Barij Essence Pharmaceutical Company, it has ISO 9001 quality certified and ISO/IEC 17025 standard. Patients receive lavender inhalation three days a week, alternately on Saturdays, Mondays, and Wednesdays for 4 weeks in the same way as aromatherapy in the multi-sensory stimulation group and will not receive visual and auditory stimuli.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrvand Dialysis Center

Full name of responsible person
Azar Jafari-Koulaei
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Sari 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

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable