

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The Effect Of multi-sensorial Environment (Snoezelen Therapy) On The Care Dependence Of The Elderly With Parkinson Disease.

#### Protocol summary

##### Study aim

Determining the effect of Snoezelen therapy on the care dependence of the elderly with Parkinson's.

##### Design

Clinical trial has two groups of intervention and control, with parallel groups, single blind, randomized with blocking on 70 patients. Randomization site is used for randomization.

##### Settings and conduct

This two-group randomized clinical trial study will be performed on 70 elderly people with Parkinson's disease referred to vertical neurology clinics who are willing to participate and meet the inclusion criteria. The samples are randomly divided into control and intervention groups. Before the intervention, the questionnaire will be filled in. Patients enter the room in groups of three. Then the intervention of Snoezelen begins. The olfactory stimulant of mint essential oil is spread in the environment. Then we play the visual and auditory stimulus. Thus, they receive stimuli for 25 minutes, and in the last 5 minutes, the auditory and visual stimuli are turned off and they only take deep breaths.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: desire to participate in the study; age over 60 with Parkinson's in the first and second stages; lack of cognitive problem with MMSE tool; absence of severe disturbances in the senses of smell, sight and hearing in the examination; not having an active mental illness. Exclusion criteria: unwillingness to participate in further study; death; absence from 1 session out of 8 sessions of Snoezelen therapy; change of disease stage to end stage; incidence of cognitive impairment; activation of mental disorder.

##### Intervention groups

In addition to medication and the center's standard training, the intervention team receives olfactory, visual, and auditory stimuli in the snooze rooms.

##### Main outcome variables

Psychological and physical dimensions of care

dependence

#### General information

##### Reason for update

##### Acronym

MSE

##### IRCT registration information

IRCT registration number: **IRCT20220209053981N1**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

##### Registration date

2022-02-24, 1400/12/05

##### Registrant information

##### Name

Fatemeh Yousefli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3763 3377

##### Email address

youseflif992@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-12, 1400/11/23

##### Expected recruitment end date

2022-04-02, 1401/01/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The Effect Of multi-sensorial Environment (Snoezelen Therapy) On The Care Dependence Of The Elderly With Parkinson Disease.

**Public title**

The effect of multi-sensory stimuli on dependence on the elderly caregiver

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Elderly desire to participate in the study Elderly people over 60 with Parkinson's in the first and second stages Lack of cognitive problems with MMSE tools Absence of severe disturbances in the senses of smell, sight and hearing in the examination No active mental illness

**Exclusion criteria:**

Reluctance to participate in further study Participant's death Absence from 1 session out of 8 sessions of Snoezelen therapy Change the disease stage to end stage Incidence of cognitive impairment Activation of mental disorder

**Age**

From **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling is available. Members are then randomized based on blockchain. This method is used to avoid significant imbalances in the number of participants assigned to each group. Block randomization ensures that no significant imbalance is established between groups at any time during randomization, and at certain points the number of participants in each group is equal. For this method, the volume of each block must first be determined.(Example of a quadruple block). Then write a list of blocks and assign numbers to them ((1)AABB - (2)ABAB -(3)ABBA -(4)BBAA -(5) BABA -(6) BAAB ) Then select random numbers between one and 6 (Eg 1 4 5, etc.) and finally specify the treatment allocation list based on previous random numbers (AB AABB-BBAA-BABA-). The method of four random blocks (AABB, ABAB, BBAA, BABA,) which have been prepared using the Randomization site will be used to assign research units to two groups. The blocks will be prepared before sampling begins. Random sequences will be stored in closed-door envelopes until sampling.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, participants were randomly grouped and blinded. Participants become blind, so that people have no knowledge of the group to which they are assigned.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethical committee of Mashhad University of medical science

**Street address**

Faculty of Nursing and Midwifery Mashhad, Ebn Sina St., Doctora Blvd..

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Approval date**

2022-02-10, 1400/11/21

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1400.088

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

Parkinson's disease

**ICD-10 code**

G20

**ICD-10 code description**

Parkinson's disease

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

Care dependency score changes

**Timepoint**

At the beginning of the study before the intervention and after 8 sessions (8 weeks)

**Method of measurement**

Care Dependence Questionnaire

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: After determining the research units and preparing the snow room, the researcher will be fully acquainted with the snow room, the available equipment and how they work. After the researcher is fully acquainted with snoozlen, the patients of the intervention group will be present in the hospital environment after coordination on the days of periodic visits or with the coordination and request of the patient. Patients then enter the room in groups of three. Preparations before starting Snoozelen: To reduce distraction and focus more, the cell phone should not be used in the room environment and we ask participants to turn off their cell phones and if they need a hygienic service or may be in If they need a session, be sure to go before starting the intervention. Before starting, we explain the snoozelen steps to the participants and answer any questions we may have, as well as reassuring them that they can leave the room whenever they want, thus showing them that they are completely on the environment. They have control. Now the intervention of snoozlen begins. The olfactory stimulant of essential oil (5 drops of mint and one to two drops of water from Nicochemical Company) We spread the essential oil burning device in the environment and ask the participants to close their eyes and take four breaths 1-4-2 (2 seconds of inhalation) , 4 seconds of respiratory arrest, 1 second of exhalation) to reduce anxiety. Then we play the visual and auditory stimulus (a relaxing clip selected in consultation with a neurologist). During the broadcast, the researcher pays attention to each person's reaction and is recorded in the researcher's observation checklist (for example, the clip of the first session fascinated or disliked participant A). Thus, receiving 25 minutes of stimuli and the last 5 minutes of auditory and visual stimuli are turned off and the participant focuses again on the olfactory stimulus, and we ask the patient to breathe 1-4-2 again and to express his opinion and expectations. Tell the first session. Finally, we thank the participants and end the meeting. Each session provides them with different visual and auditory stimuli. After 8 sessions, the care dependency questionnaire is completed again.

#### Category

Rehabilitation

### 2

#### Description

Control group: Members of this group receive standard care only under the supervision of their physician and complete the care dependency questionnaire scale twice in 8 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Qaeem hospital

##### Full name of responsible person

Seyyed Mahdi Hasani

##### Street address

Ahmadabad Blvd, Mashhad, Razavi Khorasan Province

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99199-91766

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##### Email

b.ghaem@mums.ac.ir

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Fatemeh Haji Abadi

##### Street address

Ebn Sina Ave, Doctora Blvd

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##### Province

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##### Web page address

<https://nurse.mums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Yousefli

**Position**

MSc student of geriatric nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Najmeh Valizade

**Position**

Associate professor

**Latest degree**

Ph.D.

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Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Yousefli

**Position**

MSc of geriatric nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Only data related to the main outcome can be shared.

**When the data will become available and for how long**

6 months later print results

**To whom data/document is available**

Only researchers working in scientific institutes can access this data.

**Under which criteria data/document could be used**

Responsible author for the purpose of research in connection with this treatment

**From where data/document is obtainable**

Responsible author: valizadehn@mums.ac.ir First author: farnazyousefli98 @ gmailcom

**What processes are involved for a request to access data/document**

After approving the title and getting the code of ethics and conducting the necessary studies with the research team, it will be sent to the applicant.

**Comments**