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 Snozelen 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

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Iran (Islamic Republic of)

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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 commitee of Mashhad University of medical science

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

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Razavi Khorasan

Postal code
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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 snozlen, 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 snozlen 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

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Sponsors / Funding sources

1

Sponsor

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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
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
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MSc student of geriatric nursing
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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