Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

Designing Caregiver Centered Program Based on Dunn’s Sensory Processing Model, and Defining Its Efficacy on Functional Disability and Behavior Dimensions in People with Dementia

Protocol summary

Study aim
Designing caregiver centered program based on Dunn’s sensory processing model, and defining its efficacy on Functional Disability and Behavior Dimensions in people with Dementia

Design
Randomized Clinical trial with control group, with parallel groups, double-blind, randomized

Settings and conduct
It will be performed in Alzheimer's Association of Iran. Participants and assessor in this study are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Dementia diagnosis based on medical records of patients and approved by DSM-V criteria Presence of at least one pattern of sensory processing disorders processing intervention program. No other psychiatric disorders. caregivers must dominate to Persian. MMSE Twenty -Three and Up for Caregivers (to determine caregivers' ability to apply sensory processing interventions). exclusion criteria: A patient with other types of dementia. The patient does not have any of the sensory processing disorders. A patient with other psychiatric disorders.

Intervention groups
The intervention group will receive interventions in two sessions of group caregiver training and several individual training sessions. After the group training sessions, the therapist will meet with each of the caregivers during which training intervention strategies will be associated with each of the sensory processing disorder patterns. Training methods will include a review of the Sensory Processing Disorder Model and clear and concise explanations of intervention strategies associated with the Disorder Pattern and guidance on applying these strategies to suit the context and context of the place of residence. The control group will receive routine occupational therapy interventions, including cognitive exercises, daily life activities training, etc.

Main outcome variables
Behavior, Functional Disability, Caregiver Burden

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191105045337N1**
Registration date: **2020-10-11, 1399/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-11, 1399/07/20**
Update count: **0**

Registration date
2020-10-11, 1399/07/20

Registrant information

Name
Masoome Zaree

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Designing Caregiver Centered Program Based on Dunn’s Sensory Processing Model, and Defining Its Efficacy on Functional Disability and Behavior Dimensions in People with Dementia

Public title
The Effect of Educational Program of Sensory Processing strategies on Behavior and Functional Disability of people with Dementia
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Dementia diagnosis based on medical records of patients and approved by DSM-V criteria by psychiatrist or neurologist (Alzheimer's or vascular type of dementia). Presence of at least one pattern of Sensory Processing disorders based on the Adolescent /Adult Sensory Profile. The severity of dementia will be determined after pilot test of the sensory processing intervention program. No other psychiatric disorders. caregivers must dominate to Persian. MMSE Twenty-Three and Up for Caregivers (to determine caregivers' ability to apply sensory processing interventions).
Exclusion criteria:
A patient with other types of dementia. The patient does not have any of the Sensory Processing disorders. A patient with other psychiatric disorders.
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were randomly divided into control and treatment groups. A simple randomization method will be used. Randomization based on a single sequence of random allocations is called simple randomization. A simple randomization of the most common methods used implement a random process. In this way there is a high probability of equal distribution of individuals assigned to each group, especially in studies with a small sample size. However, according to the probable hypothesis, with increasing the sample size, this inequality is greatly reduced. A table of random numbers will be used for randomization. The table of random numbers is a set of numbers that are produced without a specific pattern or order and in a completely random way. To use a random number table, the researcher first determines how to read the numbers (eg, top, bottom, left, or right). The second prerequisite is the researcher's consideration of numbers for different groups (for example, even numbers for intervention group and individual numbers for control group). The researcher then touches one of the numbers and moves in one of the predetermined directions, record the numbers and assign them to different groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants (caregivers of people with dementia) and assessor (responsible for data collection and outcome assessors) are blind. In this way, caregivers who are the main participants fall into two groups. Both groups receive training brochures on sensory processing strategies. In addition, both the intervention group and the control group have routine treatments. But in the intervention group, in addition to the above, caregivers also benefit from training sessions related to caregiver-specific sensory processing strategies. In this way, the participants are blind to the treatment and control group. The assessor (responsible for data collection and outcome assessor) is also kept blind to the information of the treatment and control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Fifth Floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway between Chamran and Sheikh Fazlollah, Tehran, Iran
City
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Province
Tehran
Postal code
1449613545
Approval date
2019-12-01, 1398/09/10
Ethics committee reference number
IR.IUMS.REC.1398.876

Health conditions studied

1

Description of health condition studied
Dementia, vascular Dementia, Alzheimer Disease
ICD-10 code
F01
ICD-10 code description
Dementia

Primary outcomes

1

Description
Behavior
Timepoint
before intervention and 1, 2 , 4 weeks after intervention
Method of measurement
Adolescent / Adult Sensory Profiles are designed to examine Behavioral responses to daily sensory experiences for individuals 11 years and older (Dunn and Brown, 2001). Items in this tool are organized according to the categories of sensory processing: taste/ smell, motion (vestibular/ deep), vision, tactile, level of activity and hearing. Item components (60 items) provide information about quadrants (low registration, sensory seeking, sensory sensitivity, sensory avoidance) based on Dunn's sensory processing model, sensory processing classifications, neural threshold continuum (above/ Bottom) and self-regulation strategies (passive / active).

2

Description
Functional Disability
Timepoint
before intervention and 1, 2 , 4 weeks after intervention
Method of measurement
The Disability Assessment of Dementia was designed to measure Functional ability in dementia in 1999 by Gelinas et al. This scale is based on the WHO Health Model. BADL, IADL, and Cognitive Skills, including starting, planning, organizing, and applying them effectively, are assessed at this scale. In total, it consists of 40 items, 17 items related to BADL and 23 items to IADL, which summarize the individual's performance over the past two weeks through a brief interview with the caregiver. Scoring items includes answers to yes: 1, no: 2 and useless. This scale was evaluated in 2016 by Soltani et al. And its validity and reliability were evaluated. Internal consistency was 0.78 for this scale and 0.99 for test-retest and test-retest reliability values.

3

Description
Burden of Care
Timepoint
before intervention and 1, 2 , 4 weeks after intervention
Method of measurement
The Burden of Care questionnaire for people with dementia is a 29-item scale designed in 2010 to assess the burden of care in Iran with respect to cultural context, test-retest reliability and internal consistency reliability of this scale were 0.94, respectively. And 0.97 reported.

Secondary outcomes

1

Description
cognition of dementia patients
Timepoint
before intervention and 1, 2 , 4 weeks after intervention
Method of measurement
The Montreal Cognitive Assessment Scale measures short-term memory, visual and spatial ability, executive performance, verbal fluency, and verbal abstraction task. The sensitivity of this scale was also reported in those with mild cognitive impairment 0.9 and those with Alzheimer's 100%. The Persian version of this scale was developed in 2010 by Amsaki and colleagues in people with Parkinson's disease. Internal consistency was 0.77 and sensitivity was 0.85.

Intervention groups

1

Description
Intervention group: The Intervention group will receive interventions in two sessions of group caregiver training and several sessions of individual training. Group training sessions: During these sessions, the therapist will use the designed training guide to describe the nervous system stimulation threshold, the arousal state (high response to low response), and the sensory processing pattern and analyze the behavioral problems of dementia patients. In these sessions, the therapist will encourage caregivers to address patients' behavioral problems and participate in group interactions. The therapist will transfer knowledge and make information meaningful to caregivers by explaining how these patterns affect people's daily activities, explaining how the environment and activities are adapted, and expressing self-regulatory strategies (calming and alert activities). Individual training sessions: After the group training sessions, the therapist will meet with each of the caregivers during which training interventions strategies will be developed for each of the sensory processing disorder patterns. Training methods include a review of the sensory processing disorder pattern and clear and concise explanations of intervention patterns related to the disorder pattern (using educational slides, brochures, videos, etc.) and guidance on applying these strategies to suit the context and context of the place of residence.
Category
Rehabilitation

2

Description
Control group: This group receives routine occupational therapy interventions. These interventions include cognitive interventions, sensory-motor interventions that performed by a therapist at the Alzheimer's Association. In this group, patients receive interventions in the form of regular sessions by the therapist.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Dementia and Alzheimer Association

Full name of responsible person
Masoumeh Salehi

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Iran Dementia and Alzheimer Association, Next to the Municipality of District 6, the beginning of the exit to Sattari North, Basij square, between phase 1 and 2, Ekbatan town, Tehran

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Afsoon Hasani Mehraban

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Participants' personal data (All information including main or sub-information) is shared, although all data can be shared after people have not been identified.
When the data will become available and for how long
It will be available six months after the release of the results.
To whom data/document is available
Researchers working at academic and scientific institutions and those working in dementia-related medical centers can apply for the data.
Under which criteria data/document could be used
The use of datas for treatment, counseling, etc... to caregivers or people with dementia is allowed in scientific and medical centers.
From where data/document is obtainable
1. Dr. afsoon hasani mehraban: email address: afsoonmehraban@hotmail.com 2. Dr. laleh lajevardi: email address: laleh23275@yahoo.com 3. masoome zaree: email address: masoomezaree@gmail.com
What processes are involved for a request to access data/document
1. Refer to one of the three people introduced via email or in person 2. Confirmation of the identity of the client by the team members 3. Specifying the purpose of the data request, For what purposes and for what purpose it will be used. 4. After reviewing the above, it will be provided to the applicant.
Comments