

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effectiveness of occupational therapy technology added to drug therapy compared to drug therapy alone among elderly people with dementia and their caregivers

Protocol summary

Study aim

1. Determine the effectiveness of occupational therapy in the elderly with dementia and their caregivers
2. Determine the cost-effectiveness (economic evaluation) of occupational therapy in the elderly with dementia

Design

Clinical trial with control group, triple blind, randomized (blocks of size 4). 100 patients were divided into four intervention and control groups and received intervention between August and October 2019.

Settings and conduct

After randomization and assignment of patients in each group, the elderly with dementia received a 12-week occupational therapy intervention (2 sessions 1 hour per week) at home. Caregivers also received 12 weeks of intervention and occupational therapy counseling at home and at the Brain & Cognitive or Yas Clinic in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 65 and older; Neurologist's diagnosis based on DSM-IV criteria for dementia. Non-inclusion criteria: Relatively severe and severe dementia; The patient's unwillingness and cooperation to intervene

Intervention groups

Intervention group 1: Elderly patients with dementia who receive occupational therapy with drug therapy. Control group 1: Elderly patients with dementia who receive only medication. Intervention group 2: Caregivers of demented elderly who receive occupational therapy interventions and counseling. Control group 2: caregivers of demented elderly who do not receive occupational therapy interventions and counseling.

Main outcome variables

Patients: Patient Recognition Rate (ACE-R), Mini Mental State Examination score, Patient Balance Test (BERG) score. Caregivers: Depression, Anxiety, Caregiver burden, Life Balance Inventory, Loneliness Management

Social and Emotional Adult (SALSA) and Time Management

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191027045253N1**

Registration date: **2020-05-01, 1399/02/12**

Registration timing: **retrospective**

Last update: **2020-05-01, 1399/02/12**

Update count: **0**

Registration date

2020-05-01, 1399/02/12

Registrant information

Name

Marjan Ghandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 3374 4307

Email address

m.ghandi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2019-09-20, 1398/06/29

Actual recruitment start date

2019-10-06, 1398/07/14

Actual recruitment end date

2019-11-05, 1398/08/14
Trial completion date
2019-12-20, 1398/09/29
Scientific title
Evaluation of the effectiveness of occupational therapy technology added to drug therapy compared to drug therapy alone among elderly people with dementia and their caregivers

Public title
Effectiveness of occupational therapy in dementia patients and their caregivers

Purpose
Health service research
Inclusion/Exclusion criteria

Inclusion criteria:
Age over 65 years Neurologist's diagnosis based on DSM-IV criteria for dementia Patients should be kept at home by official carers

Exclusion criteria:
Relatively severe and severe dementia Patient's unwillingness and no cooperation to intervene

Age
From **65 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **120**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly assigned to the intervention (12 sessions of home therapy over 6 weeks) and control group (routine care without any occupational therapy), using the randomized block design (block of size four).

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants were divided into two groups: Group I and II: Elderly with Dementia and Control and Group III and IV: Informal caregivers of patients with Dementia and Control. Group I and II: Dementia Patients: Due to the intervention at home and pre and post tests at home, subjects were blinded to the intervention or control group. Group 3 and 4: Unofficial caregivers of dementia: Although pre and post tests were performed in the clinic and of course occupational therapy was also performed at home for the group, the subjects were blinded to what group they were in and They didn't know which group they were in. Occupational Therapy Intervention Providers: Given that pre and post-patient testing was performed by someone else, and we have used 4 different occupational therapists to intervene in this

study, the intervention providers provided information on the patient's status at which stage of the disease were uninformed and did only the intervention and remained blind until after the analysis of the intervention.

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman

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Kerman

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Postal code

7616913555

Approval date

2019-10-08, 1398/07/16

Ethics committee reference number

IR.KMU.REC.1398.329

Health conditions studied

1

Description of health condition studied

Dementia

ICD-10 code

F03.90

ICD-10 code description

Unspecified dementia without behavioral disturbance

Primary outcomes

1

Description

Patient's cognition

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Addenbrooke's Cognitive Examination

2

Description

Cognitive evaluation of patients

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Mini-Mental State Examination

3

Description

Patient Balance

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

BERG Balance Scale

4

Description

Depression in patients with dementia

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Beck Depression Inventory ii

5

Description

Anxiety in caregivers of patients with dementia

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Beck Anxiety Inventory

6

Description

Caregiver Burden

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Caregiver Burden

7

Description

The life balance structure of caregivers

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Life Balance Inventory

8

Description

Social and emotional loneliness of caregivers

Timepoint

Before the intervention and 6 weeks after the start of

occupational therapy

Method of measurement

Social and Emotional Loneliness Scale for Adults

9

Description

Time management of caregivers

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Time Management Questionnaire

Secondary outcomes

1

Description

Social skills

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Disability Assessment For Dementia

2

Description

Motor Abilities

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Timed "Up & Go" (TUG), Ten Meter , Chairstand, Barthel , Allen

3

Description

Quality of Life

Timepoint

Before the intervention and 6 weeks after the start of occupational therapy

Method of measurement

Euro QoL- 5 Dimension (in patients) AND World Health Organization Quality of Life-BREF (in Caregivers)

Intervention groups

1

Description

Intervention group 1: Elderly with dementia to reduce cognitive impairment and increase motor skills for 6 weeks (12 one-hour sessions, 2 times a week) by occupational therapist, occupational therapy intervention to enhance cognitive skills, enhance daily life skills, they received reinforcement and facilitation of motor skills at home.

Category

Rehabilitation

2

Description

Control group 1: Elderly patients with dementia who received only medication. This group performed the relevant tests (before) and was again taken after 6 weeks of testing.

Category

N/A

3

Description

Intervention group 2: Informal caregivers received 12 sessions of occupational therapy on how to treat patients with dementia and raise awareness about the cause of patients' behavioral problems and provide adaptive strategies to better perform the caregiver role and also to restore caregiver balance. These 12 sessions were performed as the first 5 sessions in the clinic, 2 sessions at the patient's home, 4 sessions via telephone counseling and the last session again in the clinic.

Category

Rehabilitation

4

Description

Control group 2: caregivers of patients with dementia who did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and Cognition Clinic

Full name of responsible person

Marjan Ghandi

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No.18, Block 11, Ekhlas alley, Hooshmand street, Qods boulevard, Dolatabad, Tehran

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Recruitment center

Name of recruitment center

Aging Medicine Clinic of Iran University of Medical Sciences

Full name of responsible person

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Recruitment center

Name of recruitment center

Jasmine Daily Rehabilitation Clinic

Full name of responsible person

Marjan Ghandi

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Recruitment center

Name of recruitment center

Arman Shayan Daily Rehabilitation Clinic

Full name of responsible person

Marjan Ghandi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Reza Dehnavieh

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Mostafa Almasi Doughaee

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr. Malat Akbarfahimi

Position

Associate Professor

Latest degree

Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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Assistant Professor

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Ph.D.

Other areas of specialty/work

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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

Not applicable

Title and more details about the data/document

Information on the main outcome, which is the purpose of the trial, will be shared for use in future studies.

When the data will become available and for how long

6 months after analyzing and publishing the results

To whom data/document is available

Researchers and health policy makers

Under which criteria data/document could be used

To be used in research and through citation studies

From where data/document is obtainable

marjanghandi89@gmail.com

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

After receiving the email, if reviewed and with the agreement of Kerman University of Medical Sciences, it will finally be emailed after 10 days.

Comments