

# 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)

##### Phone

+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

**City**

Kerman

**Province**

Kerman

**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

##### **Street address**

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

##### **City**

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## 2

#### **Recruitment center**

##### **Name of recruitment center**

Aging Medicine Clinic of Iran University of Medical Sciences

##### **Full name of responsible person**

Marjan Ghandi

##### **Street address**

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## 3

#### **Recruitment center**

##### **Name of recruitment center**

Jasmine Daily Rehabilitation Clinic

##### **Full name of responsible person**

Marjan Ghandi

##### **Street address**

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## 4

#### **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

**Street address**

Medical University Campus, Kerman University of Medical Sciences, at the beginning of Haft-Baghe Alavi Highway, Kerman,

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rdehnavi@gmail.com

**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**

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

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Malat Akbarfahimi

**Position**

Associate Professor

**Latest degree**

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**Other areas of specialty/work**

Occupational Therapy

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

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Reza Goodarzi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Economy

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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**