

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Exploration of Experiences of Caregivers in patient with Demance's disease , Developing Educational Masseges &Determining Effect Of Intervetion According to PLST Model On Promotion Of Care Process.Mixed Method Study

Protocol summary

2019-01-11, 1397/10/21

Study aim

Effect Of Intervention According to Progressively Lowered Stress Threshold Model On Promotion Of Care Process.

Design

the controlled clinical trial enrolled between October 2016 and September 2018 and followed for one month.according to the similar study, the sample size 38 people the available is in this group.

Settings and conduct

Alzheimer's Elderly Care Center in Isfahan

Participants/Inclusion and exclusion criteria

Having experience or being in the care of the elderly with dementia, Ability to communicate in expressing experiences, Interested in clear expression

Intervention groups

The number of training sessions for the intervention group is 2 consecutive . about 3 hours

Main outcome variables

Increasing the Control of Challenging Behaviors in Patients with Dementia , improving the performance of caregivers of patients with dementia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180421039370N1**

Registration date: **2019-01-11, 1397/10/21**

Registration timing: **retrospective**

Last update: **2019-01-11, 1397/10/21**

Update count: **0**

Registration date

Registrant information

Name

Fatemeh Raeesi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 7805

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exploration of Experiences of Caregivers in patient with Demance's disease , Developing Educational Masseges &Determining Effect Of Intervetion According to PLST Model On Promotion Of Care Process.Mixed Method Study

Public title

Effect Of Intervetion According to PLST Model On Promotion Of Care OF Elderly with Demance's Disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly dementia caregivers with who have been diagnosed for at least one year

Exclusion criteria:

1. The lack of cooperation in study 2- lack of desire to participate in training sessions over a one meeting

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

Actual sample size reached: **38**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of isfehan University of Medical Sciences

Street address

isfehan University of Medical Sciences, Hezarjarib Blvd

City

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Province

Isfehan

Postal code

73461-81746

Approval date

2016-06-18, 1395/03/29

Ethics committee reference number

IR.MUI.REC.1395.3.204

Health conditions studied

1

Description of health condition studied

improvement of Dementia care process

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Increased control of the challenging behaviors of patients with dementia

Timepoint

3 month

Method of measurement

questionnaire from qualitative study

Secondary outcomes

1

Description

improvement of caregivers of demantia patient

Timepoint

3 month

Method of measurement

researcher made questionnaire

Intervention groups

1

Description

The number of training sessions for the intervention group is 2 consecutive. The time frame will be about 3 hours (two consecutive days) and the goal is that the intervention group (caregivers), based on this model, has methods of communication and dealing with behaviors. Learn the patient's challenging, ongoing care process. In fact, with this intervention, he takes care of management and care planning, as well as on dementia, probable prevention, illness, methods of self-efficacy and many other skills provided in the form of systematic(based on PLST model) tables. This study administrated without control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadeghie & White Rainbow Elderly Nursing Home in Isfahan

Full name of responsible person

Shakiba Zahed

Street address

University of Technology Square, Amin Abad Blvd,

Sadeghie Elderly Care Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo

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Hezar Jarib Ave, Isfahan University of Medical Sciences

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shakiba Zahed

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Family Health

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Person responsible for scientific inquiries

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Other areas of specialty/work

Health Promotion

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Isfahan-Hezar Jarib- Isfahan University of Medical Science- Behdasht Campus

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

Result of Intervention on Caregiver in PLST Model

When the data will become available and for how long

6 Month After

To whom data/document is available

Medical Stuff and Researchers

Under which criteria data/document could be used

Educational Contents

From where data/document is obtainable

Department of Health Education & Promotion Isfahan

University of Medical Sciences, Isfahan, Iran

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

Department of Health Education & Promotion Isfahan

University of Medical Sciences request

Comments