

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Surveying the effect of a Web-based Health information intervention in care performance, burden, knowledge and attitude of family caregivers of people with dementia in Kerman and evaluation of their satisfaction

Protocol summary

Study aim

This study aim is evaluating the efficacy of a Web-based health information program for informal caregivers of patients with dementia through a pilot unblinded randomized controlled trial

Design

randomised trial with control group, unblinded intervention and outcome assessment

Settings and conduct

for selecting participants, researcher refer the neurologists offices in Kerman city, Iran and samples are select based on inclusion criteria. Then the pre-test will be taken from both groups and after that practitioners are divided into two groups randomly. in next part through designed websites information mainly on the implications of this disease, its symptoms, behavioral changes, stress management for caregivers and how to take care, will be present during 2 months (12 sessions) and in forms of text, slides, pictures and videos. all information approve by a neurologist. After the intervention, post-test comes into action and results will be analyzed using descriptive and inferential statistic.

Participants/Inclusion and exclusion criteria

inclusion criteria; personally responsible for patient care (the care was his/her responsibility); to have access to a computer with Internet connection, ability to work with Internet exclusion criteria: continue participation, assign patient care to other people were our exclusion criteria, and patients death.

Intervention groups

We recruit and randomize 50 informal caregivers of patients with dementia in Kerman, Iran. They either receive the Web-based intervention and usual care for 2 months (experimental group, n=25) or only usual care (control group, n=25). Caregivers' perceived knowledge, care burden, attitude and care function were measure at baseline and at the end of the program

Main outcome variables

knowledge care burden attitude care function

General information

Reason for update

this trial updating because: 1- update the sampling date: The sampling took longer than originally mentioned due to the drop in the number of samples before starting the intervention. because most of them canceled their cooperation. 2- double blinded changed to un blinded because double blinded did not apply in web interevention.

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052828121N1**
Registration date: **2017-02-26, 1395/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-31, 1398/10/10**

Update count: **1**

Registration date

2017-02-26, 1395/12/08

Registrant information

Name

Simin Salehi Nejad

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kerman University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date

2017-05-22, 1396/03/01

Trial completion date

2017-11-11, 1396/08/20

Scientific title

Surveying the effect of a Web-based Health information intervention in care performance, burden, knowledge and attitude of family caregivers of people with dementia in Kerman and evaluation of their satisfaction

Public title

Effect of information intervention in care performance, burden, knowledge and attitude of family caregivers of people with dementia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: consent to participate in research; caregiver is personally responsible for patient care (the care of his responsibility); internet access (at least twice a week); understanding and ability to work with Internet; interested in receiving information on this disease.

Exclusion criteria: unwillingness to continue to cooperate; escrow patient care to other people; patient death.

Exclusion criteria:**Age**

From **15 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Stratified randomization method was used. By attempting to eliminate heterogeneity of the groups before random allocation by classifying two variables; age and the number of hours in day caring for care recipient

Blinding (investigator's opinion)

Not blinded

Blinding description**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, Somayeh intersection, In front of the Besaat clinic,

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2016-08-20, 1395/05/30

Ethics committee reference number

IR.KMU.REC.1395.185

Health conditions studied**1****Description of health condition studied**

Dementia in Alzheimer disease

ICD-10 code

F00

ICD-10 code description

Alzheimer disease is a primary degenerative cerebral disease of unknown etiology with characteristic neuropathological and neurochemical features. The disorder is usually insidious in onset and develops slowly but steadily over a period of several years

2**Description of health condition studied**

Vascular dementia

ICD-10 code

F01

ICD-10 code description

Vascular dementia is the result of infarction of the brain due to vascular disease, including hypertensive cerebrovascular disease. The infarcts are usually small but cumulative in their effect. Onset is usually in later life

3**Description of health condition studied**

Dementia in other diseases classified elsewhere

ICD-10 code

F02

ICD-10 code description

Cases of dementia due, or presumed to be due, to causes other than Alzheimer disease or cerebrovascular disease. Onset may be at any time in life, though rarely in old age

Primary outcomes

1

Description

Care burden

Timepoint

At the beginning and 2 months after intervention

Method of measurement

Questionnaire

2

Description

Care performance

Timepoint

At the beginning and 2 months after intervention

Method of measurement

Questionnaire

3

Description

Knowledge

Timepoint

At the beginning and 2 months after intervention

Method of measurement

Questionnaire

4

Description

Attitude

Timepoint

At the beginning and 2 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Through designed websites information mainly on the implications of this disease, its symptoms, behavioral changes, stress management for caregivers and how to take care will be present during 2 months (12 sessions) and in forms of text, slides, pictures and video all information which approved by a neurologist.

Category

Other

2

Description

The participants of control group received no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurologists office

Full name of responsible person

Neurology Specialist

Street address

haft bagh highway

City

Kerman

Province

Kerman

Postal code

7616911320

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Email

mirc.kmu@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kerman, University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

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Somayeh intersection, In front of the Besaat clinic

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7619813159

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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

Vice Chancellor for Research, Kerman, 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

2**Sponsor****Name of organization / entity**

Medical Informatics Resaerch Center

Full name of responsible person

Dr. Reza Khajouei

Street address

Unit 212, 2nd floor, Institute for Future Studies in Health, Kerman University of Medical Sciences, Haft Baghe Alavi Highway

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Phone

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Email

mirc.kmu@gmail.com

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

Yes

Title of funding source

Medical Informatics Resaerch Center

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**

Kerman Medical Informatics Resaerch Center

Full name of responsible person

Simin Salehi Nejad

Position

MS.c

Latest degree

Master

Other areas of specialty/work**Street address**

No. 212, 2nd floor, Institute for Future Studies in Health, Kerman University of Medical Sciences, Haft Baghe Alavi Highway, Kerman, Iran

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Province

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Phone

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Fax**Email**

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

Kerman Faculty of Management and Health Informatics

Full name of responsible person

Mohammad Aazami

Position

Ph.D of library and information sciences

Latest degree

Ph.D.

Other areas of specialty/work

medical librarian and information sciences

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Kerman

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Fax**Email**

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

Kerman Medical Informatics Resaerch Center

Full name of responsible person

Simin Salehi Nejad

Position

MS.c

Latest degree

Master

Other areas of specialty/work**Street address**

No. 212, 2nd floor, Institute for Future Studies in Health, Kerman University of Medical Sciences, Haft Baghe Alavi Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

Iran

Phone

+98 34 3132 5418

Fax

Email

s_salehi@kmu.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

the primary outcome measure only

When the data will become available and for how long

starting results 6 months after publication

To whom data/document is available

Patient and caregiver data will not be available for anybody

Under which criteria data/document could be used

Only use the results of the study in future studies

From where data/document is obtainable

email: s_salehi@kmu.ac.ir

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

Undecided

Comments