

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of sharing experiences in virtual support group on compassion fatigue and resilience of family caregivers of disabled elderly

Protocol summary

Study aim

Determining the effect of sharing experiences in virtual support group on the compassion fatigue and resiliency of family caregivers of disabled elderly

Design

Randomized controlled clinical trial with a parallel group design; with a sample size of 50 disable elderly caregivers

Settings and conduct

In this study, elderly patients referred to the clinic and neurosurgical departments of Ghaem and Imam Reza (AS) hospitals in Mashhad that have informed consent to participate in the study, will be assessed for disabilities. The primary caregiver of the elderly with moderate or severe disability who are met inclusion criteria of the study, include to the study. There will be no blinding in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have informed consent to participate in the study (elderly and caregiver); Over 60 years old (elderly); Moderate or severe disability according to the WHO-DAS II scale (elderly); Giving care at home (elderly). Non-inclusion criteria: have major physical problems or problems under treatment (caregiver); being a member of other related support groups (caregiver); receiving money for providing care (caregiver)

Intervention groups

Intervention group: In the first session: Introducing the research plan; the second session: finding the most basic problems of these caregivers in caring for the elderly through the brine storming; then adding them to a group on a virtual network and sharing their experiences each week on one of the issues (up to eight weeks) . Control group: Only the introduction of the research plan.

Main outcome variables

Fatigue compassion; Resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200118046173N1**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Fatemeh Esmaelzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

esmaeilzadehf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-05-04, 1399/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of sharing experiences in virtual support group on compassion fatigue and resilience of family caregivers of disabled elderly

Public title

The effect of sharing experiences on compassion fatigue and resilience of family caregivers of disabled elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Have informed consent to participate in the study (elderly and caregiver) Over 60 years old (elderly) Moderate or severe disability according to the WHO-DAS II scale(elderly) Giving care at home (elderly) Giving care from family members (elderly) Being a member of the family of an elderly person (caregiver) Being the primary caregiver means spending the most time with the elderly among the other caregivers (caregiver) Take care of the elderly for at least three months (caregiver) Being literate (caregiver) Being able to participate in virtual social groups or use the Internet (caregiver)

Exclusion criteria:

have major physical problems or problems under treatment (caregiver) being a member of other related support groups (caregiver) receiving money for providing care (caregiver)

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects will be divided into control and intervention groups using permuted block method. The permuted block method is one of the random allocation methods in which each block is selected as the number of groups studied. There are two blocks AB and BA in this study. Randomly one of the blocks will be selected. If the first block selected is AB, the first is assigned to group A and the second to group B. And this process continues until all the samples are allocated. The value of this method is that the two study groups will have equal numbers. All steps are performed using Random Allocation software.

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 Mashhad University of Medical Sciences

Street address

Nursing and midwifery school; Ebne Sina street; Doctora intersection

City

Mashhad

Province

Razavi Khorasan

Postal code

9175776965

Approval date

2019-12-31, 1398/10/10

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.088

Health conditions studied

1

Description of health condition studied

Fatigue compassion

ICD-10 code

ICD-10 code description

2

Description of health condition studied

resilience

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fatigue compassion

Timepoint

At the beginning of study and after the intervention

Method of measurement

by using of fatigue compassion questionnaire

2

Description

Resilience

Timepoint

At the beginning of the study and after intervention

Method of measurement

by using the resilience questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first session, the researcher will introduce the research for both intervention and control groups and inform them about the general principles of care for the disabled elderly as well as discuss home care problems. The second session, which is dedicated to the intervention group, will focus on finding the most basic problems for these caregivers in the care of the elderly through the brain storming. The intervention group will then join a virtual group in one of the virtual networks, sharing their experiences each week on one of the problems posed. And this process will be continued for up to eight weeks, depending on the number of problems encountered during the thought session.

Category

Lifestyle

2

Description

Control group: The control group will attend the first session at the beginning of study . If intervention will be effective, they will also be added to the virtual support group after ending the intervention and will be shared the results and summary of study discussions.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Dr Fatemeh Tara

Street address

Ahmadabad street

City

Mashhad

Province

Razavi Khorasan

Postal code

91766-99199

Phone

+98 51 3840 0001

Email

b.ghaem@mums.ac.ir

Web page address

<https://quaem.mums.ac.ir/chairman-and-managing-do-mains/about-the-head>

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Ali Khorsand Vakilzadeh

Street address

Imam Reza hospital, Imam Reza square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

b.Imamreza@mums.ac.ir

Web page address

<https://emamreza.mums.ac.ir/index.php/hoze-riasat/2014-07-06-04-24-47>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Seyed Mohammad Hosein Bahreini Toosi

Street address

In front of Daneshgah NO.18, Daneshgah street

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Province

Razavi Khorasan

Postal code

91357345

Phone

+98 51 3841 3007

Email

presidentoffice@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Fatemeh Esmaelzadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after making people unidentifiable

When the data will become available and for how long

after publishing of finding

To whom data/document is available

other researcher

Under which criteria data/document could be used

nothing

From where data/document is obtainable

responsible researcher

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

Email to responsible researcher

Comments