

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Effect of Spiritual -Religious Care education on Ability , Spiritual Health and Caregiving burden of Family Caregivers of Elderly in Bushehr city, year 2020

Protocol summary

Study aim

Determining the effect of spiritual care on the ability, mental health and care burden of elderly family caregivers in Bushehr, 2020

Design

After selecting 80 target family caregivers and reviewing entry and exit criteria, individuals will be assigned to two test and control groups in parallel using a simple random method. G power 3.1.9.2 software will be used for randomization.

Settings and conduct

This study will be performed on elderly caregivers with disabilities in Bushehr.

Participants/Inclusion and exclusion criteria

Participants included 80 elderly home care workers with disabilities in Bushehr. These Muslim and Shiite caregivers are at least 18 years old, have a family relationship with an elderly person and his roommate. At least 6 months have passed since their care began, and they have been providing care for at least 40 hours a week. They do not have alcohol or drugs and do not have the experience of participating in educational programs on elderly care.

Intervention groups

Each of the two test and control groups will include 40 elderly home caregivers. And it will be done in 30 minutes in groups of 10. In the control group, they continue throughout their daily lives and will eventually receive an educational pamphlet.

Main outcome variables

The ability of caregivers, the spiritual health of caregivers and the care burden of caregivers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150529022466N16**

Registration date: **2020-06-28, 1399/04/08**

Registration timing: **prospective**

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

Registration date

2020-06-28, 1399/04/08

Registrant information

Name

Shahnaz Pouladi

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-10, 1399/05/20

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Spiritual -Religious Care education on

Ability , Spiritual Health and Caregiving burden of Family Caregivers of Elderly in Bushehr city, year 2020	
Public title	The effect of spiritual-religious care on the ability, mental health and care burden of elderly family caregivers.
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	Elderly care that depends on family members for at least one of its six daily activities (based on the six criteria of the ADL questionnaire). Has minimal literacy to read and write At least 6 months have passed since the beginning of their care Having a family relationship with an elderly person under care Being home with the elderly under care Provide at least 40 hours of care per week At least 18 years old Religion to Islam and adherence to Shiism
Exclusion criteria:	Taking psychiatric medications by the caregiver based on the person's self-expression Experience participating in a spiritual-religious education program for elderly care Drug or alcohol addiction based on one's self-expression
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	Target sampling will be performed. The research units will then be randomly assigned to the two test and control groups.The block randomization method will be used using quadruple blocks.G power 3.1.9.2 software will be used for randomization.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Bushehr University of Medical Sciences and Health Services
Street address	School of nursing and midwifery; Bushehr University of medical sciences; Rishahr avenue; Sabzabad avenue; Bushehr
City	Bushehr
Province	Boushehr
Postal code	7518759577
Approval date	2020-06-15, 1399/03/26
Ethics committee reference number	IR.BPUMS.REC.1399.042
Health conditions studied	
<u>1</u>	
Description of health condition studied	Ability , Spiritual Health and Caregiving burden of Family Caregivers of Elderly people with disabilities
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	Ability of caregiver
Timepoint	Before and a month after the start of the intervention
Method of measurement	Family Empowerment Questionnaire in Care of the Elderly Steel et al. (2013)
<u>2</u>	
Description	Spiritual Health of Caregivers
Timepoint	Before and a month after the start of the intervention
Method of measurement	Pollutzin and Ellison Spiritual Health Questionnaire (1982)
<u>3</u>	
Description	Caregiving burden of Caregivers
Timepoint	Before and a month after the start of the intervention
Method of measurement	Novak and Gost CBI Care Load Questionnaire (1989)
Secondary outcomes	empty

Intervention groups

1

Description

Intervention group: In the test group, the intervention will be of the spiritual care type based on Richards and Bergin's model based on the teachings of Islam. The treatment will be performed in 4 sessions, twice a week for one hour and 30 minutes each, in the educational classes of Farzanegan Association, by a person familiar with nursing and religious education and with groups of 10 people.

Category

Other

2

Description

Control group: In the control group, they will continue throughout their daily lives and will receive an educational pamphlet on spirituality and its various meanings at the end of the research process in order to observe ethical principles.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Deputy of Rehabilitation, Bushehr Welfare Organization

Full name of responsible person

Shahnaz Pouladi

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Bushehr, Imam Khomeini St., Fatemieh St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Khamisipour

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Vice chancellor for research, Bushehr University of medical sciences, Rishahr avenue, Sabzabad avenue,

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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

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Shahnaz Pouladi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

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