Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Bushehr University of Medical Sciences
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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

1

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; Rishehr 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

1

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

1

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)

2

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)

3

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
Street address
Vice chancellor for research, Bushehr University of medical sciences, Rishehr avenue, Sabzabad avenue, Bushehr
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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 scientific inquiries

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Associate professor

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Other areas of specialty/work
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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