Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Impact of collaborative care model on care burden and resilience of family caregivers of mentally ill patients

Protocol summary

Summary

The aim of this clinical trial study is to determine of the impact of collaborative care model on care burden and resilience of family caregivers of mentally ill patients. Among the study population consist of family caregivers of mentally ill patients who hospitalize in Shahid Rajaiee mental Hospital of Yasuj, 64 families will select and the caregivers have a main role in care giving and their score of care burden questionnaires will at least 47 will enrolled the study. After the introduction of the researcher and explanation about objectives of the study, the informed consent is obtained. Then researcher applied for need assessment of these families and following, demographic questionnaire, Novak and Guest's care burden questionnaire (1989) and Sixbey's family resilience assessment scale (2005) were completed by objects. The test group divided to groups contain 8 to 10 families and educational plan based on data analysis of the first stage (pre- intervention) will be conducted on experimental group whereas the control group will not receive any training at this time. This educational program led to the identification of resource, needs and weaknesses in different dimension and include 4 levels of motivation, preparation, engagement and evaluation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060622580N1**
Registration date: **2015-07-31, 1394/05/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-31, 1394/05/09

Registrant information

Name

Mohammad Zoladl

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology of Yasuj University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-06-19, 1394/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of collaborative care model on care burden and resilience of family caregivers of mentally ill patients

Public title

Impact of collaborative care on care burden and resilience

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age range of 15 to 75 years old; have literacy in educational status; have a main role in care giving; have not any diagnosed mental illness; the score

of family care burden questionnaires will at least 47; completion of written informed consent and exclusion criteria will : Withdraw from the study when the research objects want ; lack of cooperation ; incomplete returned questionnaires; Immigration; no appropriate participation in training sessions after entering the study

Age
From **15 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Yasuj University of Medical Sciences

Street address
Deputy of research and technology, Yasuj University of Medical Science, Shahid Motahari Blvd., Yasuj, Iran

City
Yasuj

Postal code

Approval date
2015-02-22, 1393/12/03

Ethics committee reference number
9301200312

Health conditions studied

1

Description of health condition studied
Family care burden in families of mental ill paient

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Care burden

Timepoint
At the begining of study

Method of measurement
Novak and Guest care-giver burden inventory-1989

2

Description
Resillience

Timepoint
At the begining of study

Method of measurement
Sixbeyfamily resillience questionnaire-2005

Secondary outcomes

1

Description
Care burden

Timepoint
A month after manipulation (collaborative care model)

Method of measurement
Novak and Guest care-giver burden inventory-1989

2

Description
Resillience

Timepoint
A month after manipulation (collaborative care model)

Method of measurement
Sixbey family resillience questionnaire-2005

Intervention groups

1

Description
Collaborative care model in experimental group

Category
Behavior

2

Description
No manipulation but they will give Routine care

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaiee Hospital

Full name of responsible person

Street address

Shahid Rajaiee Hospital, Imam Hossein Square, Yasuj, Iran

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research and technology of Yasuj University of Medical Sciences

Full name of responsible person

Dr. Mehdi Akbartabar Touri

Street address

Research manager office, Deputy of research and technology, Yasuj University of Medical Science, Shahid Motahari Blvd, Yasuj, Iran

City

Yasuj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of research and technology of Yasuj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Zoladl

Position

PhD of psychiatric nursing- Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Aminollah Haghgoo

Position

Ms student of Psychiatric nursing

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty