Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Oct 2026

Evaluating of Health Improvement Program in Caregivers of Patients with Schizophrenia based on Watson’ Theory

Protocol summary

Study aim
Health Improvement in caregivers of patients with scizophrenia

Design
This study will be a randomized clinical trial with a four-group solomon design, involving 72 participants, each group with 18 participants. In this way, after selecting the individuals who meet eligibility criteria, the allocation of participants to two groups will be done by simple randomization using a table of random numbers. Again, in the same way, each group's individuals are assigned to the intervention and control groups. The per-test will be held for the intervention group1 and control group1. Intervention groups will receive intervention program in addition to routine care. During the study, the control groups will receive only regular care. In the end, the post-test will be performed for all four groups.

Settings and conduct
Individual counseling- EbneSina psychiatric Hospital in Shiraz, Affiliated to Shiraz University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Participants are caregivers of patients with schizophrenia; inclusion criteria: Over 18 years old, Main family caregiver of patients with schizophrenia for at least one year; Exclusion criteria: Unable to understand the study procedures; Under treatment for mental illnesses.

Intervention groups
Intervention group1: include five sessions of 1.5 to two hours of individual counseling with aiming identifying and satisfying the health needs; Intervention group 2: five sessions of 1.5 to two hours of individual counseling with aiming identifying and satisfying the health needs. Control group1: will receive routine care during the study; Control group 2: receive routine care during the study.

Main outcome variables
Outcomes will include improving well-being and reducing the burden of care in caregivers of patients with schizophrenia.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111105008011N2**
Registration date: **2021-04-11, 1400/01/22**
Registration timing: **prospective**

Last update: **2021-04-11, 1400/01/22**
Update count: **0**

Registration date
2021-04-11, 1400/01/22

Registrant information

Name
shahpar Bagheri

Name of organization / entity
Shiraz university of medical sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-06-21, 1400/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating of Health Improvement Program in Caregivers of Patients with Schizophrenia based on Watson' Theory

Public title
Evaluating of Health Improvement Program in Caregivers of Patients with Schizophrenia based on Watson' Theory

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Over 18 years old Main family caregiver of patients with schizophrenia for at least one year

Exclusion criteria:
Unable to understand the study procedures Under treatment for mental illnesses

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
First, we will contact individuals who meet eligibility criteria from whose information is recorded in the psychiatric center. We will invite 72 people to a briefing session and obtaining informed consent. (the number of participants has been calculated with the Med-calc statistical software with 80% power and 5% error and considering a possible drop of 20%). In the next step, we will consider a cod for each person. Then, for a simple random assignment with a random number table, participants are divided into two groups (by starting sampling from a point on the right side of a line of the table based on a random sequence such as even and odd numbers). Again, the two groups will randomly be divided into intervention and control groups (Solomon four-group design). In this way, we will have four groups of 18 people (two intervention groups and two control groups).

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 Shiraz University of Medical Sciences

Street address
School of Nursing and Midwifery, Nemazee Square, Zand St.

City
Shiraz

Province
Fars

Postal code
71936-13119

Approval date
2019-06-09, 1398/03/19

Ethics committee reference number
IR.SUMS.REC.1398.574

Health conditions studied

1

Description of health condition studied
Caregivers of schizophrenia patients

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Well-being

Timepoint
Before and four weeks after the intervention

Method of measurement
Caregiver well-being Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The intervention program includes 5 sessions of 1.5 to two hours of individual counseling in 5 weeks. Session 1: Aiming to improve self-awareness by teaching mindfulness, self-reflection, and time diary; Session 2: Identifying and Satisfying Psychological needs by training: Stress Management, Problem Solving; Session 3: Identifying and meeting physical needs: self-care and lifestyle promotion; Session 4: Identifying and Satisfying family and social communication needs:

teaching communication skills, promote coexistence; Session 5: Management of schizophrenia. The participant is required to record her/his experiences and performance in the worksheet. The worksheets will be reviewed and given feedback in the next session.

Category

Lifestyle

2

Description

Intervention group 2: The intervention program includes 5 sessions of 1.5 to two hours of individual counseling in 5 weeks. Session 1: Aiming to improve self-awareness by teaching mindfulness, self-reflection, and time diary; Session 2: Identifying and Satisfying Psychological needs by training: Stress Management, Problem Solving; Session 3: Identifying and meeting physical needs: self-care and lifestyle promotion; Session 4: Identifying and Satisfying family and social communication needs: teaching communication skills, promote coexistence; Session 5: Management of schizophrenia. The participant is required to record her/his experiences and performance in the worksheet. The worksheets will be reviewed and given feedback in the next session.

Category

Lifestyle

3

Description

Control group 1: During the study, control group will receive only routine care. After the study, the intervention program will be provided to the control group.

Category

Lifestyle

4

Description

Control group 2: During the study, control group will receive only routine care. After the study, the intervention program will be provided to the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebnesina Hospital

Full name of responsible person

Shahpar Bagheri

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Hafez street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Deputy of research, Shraz University of Medical Sciences

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Shahpar Bagheri

Position

Nursing PhD Student

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

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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
Yes - There is 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
Yes - There is 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
IPD, Analysis, Clinical trial study report
When the data will become available and for how long
From one month after the end of the study
To whom data/document is available
Researchers and Clinical Practitioners
Under which criteria data/document could be used
For clinical and research use
From where data/document is obtainable
Ladan Zarshenas
What processes are involved for a request to access data/document
By request, explanation and sending via email
Comments