

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

study of The effect of a self-care program based on Orem's theory on the performance and quality of life of schizophrenic patients

Protocol summary

Summary

The aim of this study was to improve the performance and quality of life of patients with schizophrenia. This is a two-group clinical trial, three-step, and one-blind clinical trial. In this study, 70 people with schizophrenia who are eligible for inclusion in the study are selected through simple random sampling in two groups of test and control. At least two years of history of schizophrenia and having criteria for discharge and the ability to attend educational sessions are the most important criteria for entering this study, if for any reason, patients have more than two absenteeism sessions. The data gathering tool was a questionnaire on the quality of life of schizophrenic patients and general performance that was completed by the two groups in three stages before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072835350N1**

Registration date: **2017-08-23, 1396/06/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-23, 1396/06/01

Registrant information

Name

Sara Khalatbari Zamanpour

Name of organization / entity

College of Nursing and Midwifery, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3663 8424

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-10-02, 1396/07/10

Expected recruitment end date

2017-12-01, 1396/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study of The effect of a self-care program based on Orem's theory on the performance and quality of life of schizophrenic patients

Public title

The effect of self-care program based on Orem's theory on the performance and quality of life of schizophrenic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Criteria for entering the study: 1. Have at least 2 years of history of chronic schizophrenia. 2. Have a willingness to participate in the research. 3-Minimum age for participation in the research is 18 years and maximum 50 years. (Jahansari et al., 2011) 4. Be able to communicate and read and write in Persian. 5-Examples have the ability to understand the content provided in the training classes (according to the psychiatrist's approved insight) and have the consent to participate in

the study. (Jansari et al., 2011) 6. The selected samples are admitted to hospital and have criteria for discharge (criteria for returning to society) according to the psychiatrist. 7. Confirmation of the diagnosis of schizophrenia by a psychiatrist based on DSM-5 criteria in the chronic phase of the disease. (Jansari et al., 2011) 8. Do not have drug addiction and do not treat psychosocial drugs. 9. Do not have participated in any training project in this area before. 10. Do not have physical features that cause a functional impairment. Exit criteria: 1-The inability of a regular company to attend meetings (having more than two meetings absent) 2. The patient does not want to continue cooperation in educational sessions. 3. Suicide or death during the study. 4. The occurrence of stressful events in divorce and suicide is such that the level of their stress and anxiety according to the Holmes table and Rahe to patients during the study is more than 150.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Isfahan University of Medical Sciences, College of Nursing and Midwifery

Secondary trial Id

IR.MUI.REC.1396.3.210

Registration date

1396-01-03, 777/01/-806

Ethics committees

1

Ethics committee

Name of ethics committee

College of Nursing and Midwifery, Isfahan University of Medical Sciences

Street address

Azadi Square, Hezarjarib street

City

Esfahan

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

396210

2

Ethics committee

Name of ethics committee

College of Nursing and Midwifery, Isfahan University of Medical Sciences

Street address

Azadi Square, Hezarjarib street

City

Esfahan

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

396210

3

Ethics committee

Name of ethics committee

College of Nursing and Midwifery, Isfahan University of Medical Sciences

Street address

Azadi Square, Hezarjarib street

City

Esfahan

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

396210

Health conditions studied

1

Description of health condition studied

Schizophrenia disorder

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Overall performance

Timepoint

Before the intervention, one month later and three months after the intervention

Method of measurement

Secondary outcomes

1

Description

Quality of Life in Schizophrenic Patients

Timepoint

Before the intervention, one month later and three months after the intervention

Method of measurement

The quality of life questionnaire for schizophrenic patients

Intervention groups

1

Description

The researcher will set up his intervention program based on the Orem-based self-care plan and will act as a supportive educational intervention in eight 90-minute sessions, twice a week for patients with schizophrenia, who have criteria Clearance and Eligibility.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Specialized and Advanced Hospital

Full name of responsible person

Sara Khalatbari Zamanpour(Researcher)

Street address

Bozorg Mehr Bridge, Mashhagh Third Street, Arghavani Blvd.

City

Esfahan

2

Recruitment center

Name of recruitment center

Noor Medical Center and Ali Asghar (AS)

Full name of responsible person

Sara Khalatbari Zamanpour(Researcher)

Street address

Imam Hussein Square, Ostandari Square

City

Esfahan

3

Recruitment center

Name of recruitment center

Ayatollah Madras Medical Center

Full name of responsible person

Sara Khalatbari Zamanpour(Researcher)

Street address

18 km of Esfahan Road, Najaf Abad, at the beginning of Goldschat

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

College of Nursing and Midwifery, Isfahan University of Medical Sciences

Full name of responsible person

Sara Khalatbari Zamanpour

Street address

Azadi Square, Hezarjarib street

City

Esfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

College of Nursing and Midwifery, Isfahan 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

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Saeed Pahlavanzade

Position

Master of Psychiatric Nursing, Faculty Member of Department of Psychiatric Nursing, Faculty of Nursi

Other areas of specialty/work

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Position

nursing expert

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Position

nursing expert/ Student of Master of Psychiatric Nursing

Other areas of specialty/work**Street address**

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Web page address

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