Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

An investigation of the effectiveness of remote intervention monitoring signals to prevent the recurrence of disease in individuals with severe psychiatric disorders

Protocol summary

Study aim
Investigate the effectiveness of remote intervention monitoring signals to prevent the recurrence of disease in individuals with severe psychiatric disorders

Design
A clinical trial with the control group. with parallel groups of simple randomization on 52 patients. A sealed envelope is used for randomization.

Settings and conduct
Men and women departments of Sina Junghan Psychiatric Hospital. Education of warning signs of relapse and weekly telephone follow-up after discharge for the patient and his caregiver in the experimental group

Participants/Inclusion and exclusion criteria
Entry requirements: Definitive diagnosis of severe psychiatric disorder by a psychiatrist Conscious consent of the patient's legal guardian or primary caregiver for participation in the research The patient should be between 20 and 45 years old The absence of mental retardation and epilepsy Having minimum literacy by the patient and the guardian Living in the same house with the guardian or the primary caregivers The patient should not be a candidate for maintenance in long-term rehabilitation centers Non-entry conditions: The patient or caregiver should declare their unwillingness to continue cooperation during the research. The psychiatric patient and caregiver do not respond to the researcher's calls for three consecutive weeks.

Intervention groups
The basis of this study is teaching the warning signs of disease recurrence in severe psychiatric patients to them and their caregivers during hospitalization and the weekly contact of the researcher with them after discharge and completing the patient and family checklist. This study is divided into two experimental and control groups, In the control group people were not trained and followed up after the weekly discharge.

Main outcome variables
Relapse prevention; adherence to treatment; Regular medication use

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220702055343N1**
Registration date: **2022-07-17, 1401/04/26**
Registration timing: **prospective**

Last update: **2022-07-17, 1401/04/26**
Update count: **0**

Registration date
2022-07-17, 1401/04/26

Registrant information

Name
Mona Ehsani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
An investigation of the effectiveness of remote intervention monitoring signals to prevent the recurrence of disease in individuals with severe psychiatric disorders

Public title
An investigation of the effectiveness of remote intervention monitoring signals to prevent the recurrence of disease in individuals with severe psychiatric disorders
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of severe psychiatric disorder by a psychiatrist, based on the criteria of the fifth diagnostic and statistical manual of mental diseases (DSM5), and its inclusion in the patient's medical record conscious consent of the patient's legal guardian for them and the patient's participation in the research conscious consent of the main caregiver of the patient in cases where the primary caregiver of the patient is someone other than their legal guardian The psychiatric patient should be between 20 and 45 years old The absence of mental retardation and epilepsy based on the opinion of the psychiatrist and the contents of the patient's medical record Having at least reading and writing literacy by the person with psychiatric disease and guardian Living in the same house with the guardian or primary caregivers (family members of the patient) participating in this research The patient should not be a candidate for maintenance in long-term rehabilitation centers
Exclusion criteria:
The patient or caregiver should declare their unwillingness to continue cooperation during the research. The psychiatric patient and caregiver do not respond to the researcher's calls for three consecutive weeks.
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done in an accessible and consecutive way over time. At the beginning of the study, patients of the experimental and the control groups equalize in terms of variables such as the type and duration of the disease. The method of selecting intervention and control group patients will be random. In this way, as the number of patients, envelopes containing a number are considered. Once the patient is selected to enter the study, the number inside one of the random envelopes indicates the patient group. An even number means the patient is in the intervention group and an odd number means the patient is in the control group. In this way, the researcher does not know beforehand which group the patient will fall into.
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 the University of Social Welfare and Rehabilitation Sciences
Street address
University of Social Welfare and Rehabilitation Sciences, Koodakyar Ave., Daneshjo Blvd., Evin
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2022-06-16, 1401/03/26
Ethics committee reference number
IR.USWR.REC.1401.052

Health conditions studied

1

Description of health condition studied
Severe psychiatric diseases such as: schizophrenia, bipolar, major depression
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The number of relapses
Timepoint
3 months
Method of measurement
through the number of psychiatric hospital readmissions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 26 patients with severe psychiatric disorders admitted to Sina Psychiatric Hospital of Juneghan who meet the criteria for entering the study. These people and their caregivers, after obtaining conscious consent from the guardian and the main caregiver and informed consent from the patient, are trained on the warning signs of relapse. After discharge, we contact the patient and their caregiver weekly, and the checklist of the patient and the family is completed regarding the status of warning signs and how to take the medicine and adhere to the treatment.

Category

Prevention

2

Description

Control group: 26 patients with severe psychiatric disorders admitted to Sina Psychiatric Hospital of Juneghan who meet the criteria for entering the study. These people and their caregivers are placed in the control group after obtaining conscious consent from their main guardian and caregiver and informed consent from the person himself after randomization of the sealed envelope, and they are not trained, and there is no follow-up after weekly discharge.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Psychiatric Hospital of Joneghan

Full name of responsible person

Mona Ehsani

Street address

Five kilometers from Joneghan-Shahrekord road. Sina Psychiatric Hospital of Joneghan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr. Masoud Falahi Khoshknab

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2nd floor, Farabi building, University of Social Welfare and Rehabilitation Sciences, Koodakyar Ave., Daneshjoo Blvd., Evin, Tehran

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Mona Ehsani

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Social Services

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Not applicable
Title and more details about the data/document
After the end of the research, the data related to the main outcome and the data related to the conscious consent of the patients and their family and the checklists will be published in the form of a master's thesis in social work.
When the data will become available and for how long
The access period is from January of 2023.
To whom data/document is available
Researchers working in university and scientific institutions and psychiatric hospitals
Under which criteria data/document could be used
Study and use in researches
From where data/document is obtainable
Scientific research officer
What processes are involved for a request to access data/document
The request email should be sent to the scientific officer
Comments