

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of systematic patient and family education in the psychiatric emergency room on the process of receiving mental health care services

Protocol summary

Study aim

Evaluating the effect of systematic patient and family education in the psychiatric emergency room on the process of receiving mental health care services

Design

A clinical trial with a control and experiment group, single-blind and randomized, a sample size of 100 and randomization method is simple randomization

Settings and conduct

This study is conducted in Emergency Department of Razi Hospital, Tabriz. Four weeks after inclusion, a telephone call was made to enrolled patients and questions were asked about intended variables. Then reported results from both groups were compared to estimate effect of the education on process of receiving health care after discharge from emergency room. The person who took the information by phone calls, is blinded to the assigned group of the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability and willingness to give informed consent
Exclusion criteria: Impaired conscientiousness
Absence of family members

Intervention groups

In this study, in the experimental group, a 15-minute educational session is provided for each patient. The content of the training includes the name of the disease/disorder, symptoms, etiology, possible treatments and its prognosis, which is provided by psychiatry residents of Department of psychiatry, Tabriz University of Medical Sciences will be provided.

Main outcome variables

Frequency of visits to the emergency room or clinic, the frequency of visits to treating doctor, referral to other specialists, medications and their use, Symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180928041165N1**

Registration date: **2018-12-03, 1397/09/12**

Registration timing: **retrospective**

Last update: **2018-12-03, 1397/09/12**

Update count: **0**

Registration date

2018-12-03, 1397/09/12

Registrant information

Name

Mehrdad Ghaemmaghami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3380 4486

Email address

mehrdad.ghaem25@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-10, 1397/02/20

Expected recruitment end date

2018-09-11, 1397/06/20

Actual recruitment start date

2018-06-06, 1397/03/16

Actual recruitment end date

2018-09-22, 1397/06/31

Trial completion date

2018-10-27, 1397/08/05

Scientific title

Evaluating the effect of systematic patient and family education in the psychiatric emergency room on the process of receiving mental health care services

Public title

Evaluating the effect of systematic education on the process of receiving mental health care services

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability and willingness to informed consent

Exclusion criteria:

Absence of family members Impaired consciousnesses

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Actual sample size reached: **115**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Simple Randomization Unit:

Individual Randomization Tool: Envelope Shuffling

Concealment: Simple

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients in the test and control groups are unaware of which group they are in, but they are aware of the existence of different study groups.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Razi Hospital, Sheykh Mohammad Khiyabani Ave, Elgoli, Tabriz Town

City

Tabriz

Province

East Azarbaijan

Postal code

5167846184

Approval date

2018-04-23, 1397/02/03

Ethics committee reference number

IR.TBZMED.REC.1397.096

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

2**Description of health condition studied**

Major depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

3**Description of health condition studied**

Conversion disorder

ICD-10 code

F44

ICD-10 code description

Dissociative and conversion disorders

4**Description of health condition studied**

Panic disorder

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

5**Description of health condition studied**

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

6**Description of health condition studied**

Alcohol related disorders

ICD-10 code

F10

ICD-10 code description

Alcohol related disorders

7**Description of health condition studied**

Opioid related disorders

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

8**Description of health condition studied**

Cannabis related disorders

ICD-10 code

F12

ICD-10 code description

Cannabis related disorders

9**Description of health condition studied**

Sedative related disorders

ICD-10 code

F13

ICD-10 code description

Sedative, hypnotic, or anxiolytic related disorders

10**Description of health condition studied**

Cocaine related disorders

ICD-10 code

F14

ICD-10 code description

Cocaine related disorders

11**Description of health condition studied**

Other stimulant related disorders

ICD-10 code

F15

ICD-10 code description

Other stimulant related disorders

12**Description of health condition studied**

Hallucinogen related disorders

ICD-10 code

F16

ICD-10 code description

Hallucinogen related disorders

13**Description of health condition studied**

Nicotine dependence

ICD-10 code

F17

ICD-10 code description

Nicotine dependence

14**Description of health condition studied**

Inhalant related disorders

ICD-10 code

F18

ICD-10 code description

Inhalant related disorders

15**Description of health condition studied**

Other psychoactive substance related disorders

ICD-10 code

F19

ICD-10 code description

Other psychoactive substance related disorders

Primary outcomes**1****Description**

Frequency of visits to the emergency room or clinic, frequency of visits to treating doctor, the referral to other specialists, medications and their use it, symptoms

Timepoint

Study of the variables before intervention and 4 weeks after the end of the intervention

Method of measurement

The questionnaire designed by the researcher

Secondary outcomes**1****Description**

change of symptoms

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Questionnaire designed by researcher and description of the patient's family

Intervention groups**1****Description**

In the intervention group, one session of "psycho-education" with predefined content will be provided. The content of this session includes: the name of the disease/disorder, symptoms, signs, etiology, possible treatments and the prognosis. This 15-minute , interactional session will be provided by psychiatry residents of Department of Psychiatry, Tabriz University of Medical Sciences.

Category

Other

2

Description

Control group: This group will receive the routine care and routine educational materials within the emergency room.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital of Tabriz

Full name of responsible person

Mahsa Raji

Street address

Razi Hospital, Sheykh Mohammad Khiyabani Ave,
Elgoli, Tabriz Town

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info@prazi.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Juyban

Street address

Tabriz University of Medical Sciences, Golgasht Ave,
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Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mehrdad Ghaemmaghami

Position

assitant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Razi Hospital, Sheykh Mohammad Khiyabani Ave,
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Phone

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Email

Mehrdad.ghaem25@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehrdad Ghaemmaghami

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehrdad Ghaemmaghami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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East Azarbaijan

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Email

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In this study, only data on changes in symptoms and the frequency of referral to an emergency room or clinic, the frequency of referral to treating doctor, referral to other professionals, medications and their use will be provided.

When the data will become available and for how long

one year after publication.

To whom data/document is available

Researchers working in academic and Scientific institutions

Under which criteria data/document could be used

research in the field of mental health services

From where data/document is obtainable

1-Library of Tabriz University of Medical Sciences 2-
Library of Razi Hospital in Tabriz 3- Contact the
mahsaraji90@gmail.com email address

What processes are involved for a request to access data/document

Contact with the corresponding author via email, and answer will be provided within 72 hours

Comments