Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Investigating the effectiveness of Narrative experiences online intervention using both qualitative and quantitative methods in patients with first episode of psychosis

Protocol summary

Study aim

Effectiveness of Narrative experiences online intervention in patients with first episode of psychosis using two methods of qualitative and quantitative data analysis

Design

The current study includes an experimental group and a control group, which are selected by random replacement. The sample in each group consists of 15 people, and the initial differences between the subjects are analyzed by the statistical methods of covariance analysis, control, and then with two quantitative (Mancova) and qualitative (thematic/reflective-narrative) methods.

Settings and conduct

The place of collecting patients' narratives is Razi, Rouzbeh and Iran Psychiatric Hospital in Tehran, and their registration and storage is also done in compliance with ethical principles and obtaining informed consent by completing the form in writing. Narratives are conducted with the help of semi-structured and unstructured interviews, picture cards and questionnaires.

Participants/Inclusion and exclusion criteria

he selection of the sample is done based on the entry and exit criteria by conducting a clinical interview, completing questionnaires and demographic information by the main researcher.

Intervention groups

The experimental group intervention consisted of a password-controlled online link that presented narratives of mental health recovery. In the present study, narratives are obtained through interviews with schizophrenia patients in the remission phase. First, these recorded narratives are selected by the recovery story feature list tool, and after ethics committee approval, they are made available online to the experimental groups. Also, access to the main intervention is provided for the control group after the end of the treatment phase. In fact, patients in the control group will receive the usual treatment (drug therapy).

Main outcome variables

Narratives of patients with the first episode of psychosis

General information

Reason for update

Modification of the intervention title

Acronym

NEON

IRCT registration information

IRCT registration number: **IRCT20230405057823N1**
Registration date: **2023-07-30, 1402/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-26, 1402/07/04**
Update count: **4**

Registration date

2023-07-30, 1402/05/08

Registrant information

Name

maryam amini fasakhoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4470 2905

Email address

amini.maryam329@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Narrative experiences online intervention using both qualitative and quantitative methods in patients with first episode of psychosis

Public title

Investigating the effectiveness of Narrative experiences online intervention in patients with first episode of psychosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

These patients must be in their first episode of psychosis and have not experienced or reported any history of diagnosis and treatment of schizophrenia in the past. No history of mood disorders No history of taking Antipsychotic drugs No drug abuse Failure to diagnose severe learning and mental disabilities and medical or neurological diseases that cause symptoms of psychosis. The criteria for entering the sample with the first episode of schizophrenia are: meeting the conditions based on the criteria of DSM-5-TR and the duration of the diagnosis period of at least 6 months Failure to diagnose mental disability or dementia, acute symptoms of psychosis and severe restlessness, communication and language problems that prevent interviews.

Exclusion criteria:

Lack of access or support to access the Internet through a personal computer or mobile device People experiencing crisis cannot participate in research.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, after selecting the subjects by targeted sampling in qualitative studies, we will then randomly assign people to two groups of experimental and control. To do this, we give the subjects number 1 to 30 and after we put them in a container, we remove two numbers each time and one in the experimental group and one in the group We put control. As such, the subjects of both groups are selected. In this study, there is no blind maker, and after the intervention, the control groups of the control group use several treatment sessions.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Making a treatment application based on the defined algorithm

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti of Medical Sciences

Street address

Second Floor, Building No. 2, Shahid Beheshti University of Medical Sciences, Shahid Arabi Street, Student Blvd, Shahriari Square, velenjak, Tehran

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tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.SBMU.MSP.REC.1401.699

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

The schizophrenic disorders are characterized in general by fundamental and characteristic distortions of thinking and perception, and affects that are inappropriate or blunted. Clear consciousness and intellectual capacity are usually maintained although

Primary outcomes

1

Description

Lived experiences

Timepoint

Before the start of the intervention and the end of the intervention (qualitative part)

Method of measurement

Semi-structured interview, unstructured interview and picture cards

Secondary outcomes

1

Description

Mental health trust scale

Timepoint

Week 1, 12 and 52 (quantitative part)

Method of measurement

Questionnaire

2

Description

Quality of Life

Timepoint

Week 1, 12 and 52 (quantitative part)

Method of measurement

Questionnaire

3

Description

Hope

Timepoint

Week 1, 12 and 52 (quantitative part)

Method of measurement

Questionnaire

4

Description

Psychotic attachment

Timepoint

Week 1, 12 and 52 (quantitative part)

Method of measurement

Questionnaire

5

Description

Personal recovery

Timepoint

Week 1, 12 and 52 (quantitative part)

Method of measurement

Questionnaire

6

Description

Life events

Timepoint

Week 1, 12 and 52 (quantitative part)

Method of measurement

questionnaire

Intervention groups

1

Description

Experimental group: receiving the intervention of online narrative experiences The Online Narrative Experiences Intervention is a large-scale research study running from 2017 to 2023 that seeks to recruit participants who are current users of any mental health service and mental health workers to design and test a clinical intervention based on recovery narratives. Made to help. The study team collects stories from a wide range of sources, focusing on the stories of people whose voices are rarely heard by mainstream culture, and brings them together to form the world's largest online repository of mental health recovery stories. They then make these stories available to others to see, hear and read about the NEON intervention and evaluate in a randomized controlled trial whether people benefit from the neon intervention or not. They will also investigate whether access to these stories can improve the way mental health workers support people with Psychosis. Assessments at weeks 1, 12, and 52 are required for clinical analysis. Also, follow-up assessment at 104 weeks is not required; Because at the end of the intervention, the results are subjected to qualitative analysis in addition to quantitative analysis.

Category

Rehabilitation

2

Description

Control group: no treatment

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Hospital

Full name of responsible person

Maryam Amini Fasakhoudi

Street address

Razi Psychiatry Training Center, Shahid Rostgar Blvd., Taghi Abad Road, Shahreri

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2

Recruitment center
Name of recruitment center
Roozbeh Psychiatric Hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Iran Psychiatric Hospital
Full name of responsible person
Maryam Amini Fasakhoudi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Vice President of Research and Technology, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Arabi Street, Chamran Highway
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti University of Medical Sciences-100 million toman sponsorship of product-oriented theses
Proportion provided by this source
25
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
Shahid Beheshti University of Medical Sciences
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Position
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
The publication program is related to the printing of the article
When the data will become available and for how long
2 years
To whom data/document is available
Only the researchers of the present study
Under which criteria data/document could be used
Analysis and interpretation
From where data/document is obtainable
Principal investigator
What processes are involved for a request to access data/document
Research researchers are in contact with each other
Comments