

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of "Nursing Process Based on the Nursing Diagnoses, Nursing Interventions Classifications and Nursing Outcomes Classifications" Training, on the Patient Safety in Psychiatric Wards

Protocol summary

Study aim

To assess the effect of diagnoses, interventions and nursing outcomes on the nursing care related to patient safety in psychiatric wards

Design

Clinical trial with Control and Experimental Groups, Factorial, Double-blind, randomized allocation

Settings and conduct

In a clinical trial, 80 nurses working in Roozbeh Hospital were choosed and randomly assigned in two groups, control and experimental. The intervention of the study is training of signs, symptoms and etiology of important phenomena in psychiatric wards to select the correct nursing diagnoses and interventions in order to achieve the desired nursing outcomes. Nursing documented reports were reviewed and analyzed

Participants/Inclusion and exclusion criteria

Participants: Nurses working in Roozbeh hospital
Psychiatric wards Inclusion Criteria - Written and informed consent to participate in the research - Minimum of Bachelor's degree in Nursing - Work in psychiatric wards as a Clinical Nurse Exclusion criteria - Refuse to continuing of corporation in the research - Transfer from psychiatric hospital to another center during the study period

Intervention groups

The study groups consist of two experimental and control groups. The intervention conducts in the experimental group, while control group receives no intervention

Main outcome variables

Improvement in the Nursing care related to Patient safety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170917036237N2**

Registration date: **2018-10-01, 1397/07/09**

Registration timing: **retrospective**

Last update: **2018-10-01, 1397/07/09**

Update count: **0**

Registration date

2018-10-01, 1397/07/09

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3374 2587

Email address

b-saatchi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of "Nursing Process Based on the Nursing Diagnoses, Nursing Interventions Classifications and Nursing Outcomes Classifications" Training, on the

Public title

Effect of Nursing Diagnoses Training on the Patient Safety

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Written and informed consent to participate in the research Having at least a Bachelor's degree in Nursing Employment in Psychiatric ward as a Clinical Nurse

Exclusion criteria:

Reject to continue participation in the research Transfer or resign from psychiatric hospital to another center during the study period

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected by convenient sampling method, and assigned randomly by blocked randomization to experimental and control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in this study are Nurses working in psychiatric wards. The researcher of this study has the role of educator in collecting information and analysis of the results, and is unaware of the implications of this study.

Placebo

Not used

Assignment

Parallel

Other design features

The study samples are nurses working in psychiatric wards, so there is no patient-choosing in this study

Secondary Ids

empty

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

Joint Committee of Ethics of Nursing and Midwifery Faculty with Faculty of Rehabilitation Tehran Uni

Street address

School of Nursing and Midwifery, Tohid Sq, Tehran, Iran

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Postal code

1419733171

Approval date

2017-06-20, 1396/03/30

Ethics committee reference number

IR.TUMS.FNM.REC.1396.2697

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

Nursing care related to Patient Safety

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Nursing care related to patient safety

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

Questionnaire designed by researcher, to measure the frequency of using nursing Diagnoses, Interventions and Outcomes

Secondary outcomes

empty

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

Intervention on the intervention group, conducted during the four sessions of two-hour training courses, two months, and they will be taught by the researcher in the Roozbeh Hospital. The training includes training NANDA-I nursing diagnosis, Nursing Intervention Classification (NIC), and NANDA-I classification of nursing outcomes (NOC). The Safety/Protection domain has nursing diagnoses in six classes of infection, physical harms, violence, physical hazards, defensive processes and body thermoregulation, along with each of these diagnoses, interventions and related nursing outcomes will be taught too. The research intervention focused on teaching signs, symptoms and etiology of the common phenomena in the psychiatric wards to choose nursing

diagnoses related to needs and problems of the patient, and choosing nursing interventions to achieve short, medium and long term outcomes.

Category

Other

2**Description**

Control group: no intervention, conducted on this group

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roozbeh Hospital

Full name of responsible person

Babak Saatchi

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No. 606, District 11, South Kargar St, Tehran, Iran

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Web page address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammadali Sahrayian

Street address

Central Organization of the University, 6th floor of Research and Technology Department, Ghods St, Keshavarz Blvd, Tehran, Iran

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Web page address

http://vcr.tums.ac.ir/index.jsp?fkeyid=&siteid=22&pageid=203

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Babak Saatchi

Position

Student of Psychiatric Nursing MSc

Latest degree

Bachelor

Other areas of specialty/work

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Street address

Unit 3, No 8, Khazeie Alley, Fereshteh Ave, Azarbaijan St, Navvab, Tehran, Iran

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Babak Saatchi

Position

Master Student of Psychiatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic and Occupational data of the studied samples

When the data will become available and for how long

At the time thesis defended

To whom data/document is available

The project executives, and the rest of the people are subject to the permission of the main executor of the project

Under which criteria data/document could be used

Obtain permission by expressing the purpose of using documentation and data from the project executives

From where data/document is obtainable

Contact with this Email address: b-saatchi@razi.tums.ac.ir

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

Contact project executives and obtaining access permissions

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Babak Saatchi

Position

Student of Psychiatric Nursing MSc

Latest degree

Bachelor

Other areas of specialty/work

Psychiatric Nursing

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