

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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

Patient Safety in Psychiatric Wards

**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

**City**

Tehran

**Province**

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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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**Email**

hosp\_roozbeh@tums.ac.ir

**Web page address**

http://roozbehhospital.tums.ac.ir/

**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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tums@tums.ac.ir

**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**

Psychiatric Nursing

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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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