

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Impact of web-based patient safety training to nursing managers on patient safety culture in nurses

#### Protocol summary

##### Study aim

Determining the impact of web-based patient safety training to nursing managers on patient safety culture in nursing staff

##### Design

two arm parallel group semi-experimental study with 2 control and intervention group of 100 head nurses (each 50) selecting hospitals (Imam Khomeini in one group, Sina and Shariati in another group) through simple dice sampling method selecting head nurses through available sampling method selecting nursing staff (nurses and nursing assistants) through Table of random sampling

##### Settings and conduct

Interview with Head nurses and nursing staff of Imam Khomeini, Shariati and Sinai hospitals and inviting them. After obtaining Informed consent, links of classes and questionnaire will be sent to. CCU, ICU, Dialysis and other wards like internal medicine, surgery, etc., are included in the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a management position at least 6 months and not participating in a similar management course for head nurses having at least a nursing bachelor's degree, having a certificate of nursing assistant, access to a smartphone or computer, willingness to participate in the study. Exclusion criteria: Changing the management post.

##### Intervention groups

Intervention group: educational content with weekly updates during 6 sessions of 30-40 minutes is presented only to head nurses of the intervention group during 6-12 weeks. The platform is in the educational system of the university. The pre-test before the first session and the post-test 2 and 6 weeks later will be taken from all participants. Control group: They do not receive any training, they only do the pre-test and post-test at the beginning and end of the training period of the intervention group.

#### Main outcome variables

Age! gender! education level! working experience in hospital! time and duration of having management position! patient safety education. patient safety culture

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170827035918N3**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

##### Registration date

2023-12-09, 1402/09/18

##### Registrant information

##### Name

zahra sajadi monfared

##### Name of organization / entity

Tehran University of Medical sciences/ Students\ Scientific Research Center (SSRC)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21889891614

##### Email address

zahrasajedi75@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-22, 1402/10/01

##### Expected recruitment end date

2024-04-20, 1403/02/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Impact of web-based patient safety training to nursing managers on patient safety culture in nurses

**Public title**

Impact of web-based patient safety training to nursing managers on patient safety culture in nurses

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Head nurses: having the management position for at least 6 months, having at least a bachelor's degree, not participating in a similar management course, access to a smartphone or computer, willingness to participate in the study  
Nursing staff/nurses: Having at least a bachelor's degree for nurses, including the title of nurse in their employment order, working as a nurse in hospital wards, access to a smartphone or computer, willingness to participate in the study  
Nursing staff/nursing assistants: Having a certificate of nursing assistant, including the title of nursing assistant in their employment order, working as a nursing assistant in hospital wards, access to a smartphone or computer, willingness to participate in the study

**Exclusion criteria:**

Changing the management post

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

selecting hospitals (Imam Khomeini in one group, Sina and Shariati in another group) through simple dice sampling method selecting nursing staff (nurses and nursing assistants) through Table of random sampling

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

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

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

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Tehran University of Medical Sciences, Keshavarz Blvd

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Tehran

**Postal code**

1467664961

**Approval date**

2023-11-18, 1402/08/27

**Ethics committee reference number**

IR.TUMS.FNM.REC.1402.163

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

No diseases

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

Patient safety culture

**Timepoint**

Before intervention. 2 and 6 weeks after intervention

**Method of measurement**

Hospital Survey on Patient Safety Culture

**Secondary outcomes**

empty

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

Intervention group: Individuals who join the intervention group receive the following training. The content is a combination of relevant sections on patient safety in nursing and management textbooks, patient safety culture questionnaires, clinical guidelines provided by the World Health Organization, and the literature review. The training includes patient safety and its culture,

communication and feedback regarding errors, organizational learning, teamwork, error reporting, risk assessment and management, drug adverse effects and interactions, infection control, nursing leadership and safety leadership, and managerial support for patient safety. The training is presented to the head nurses intervention group only in six 30-40 minute sessions over a period of 6-12 weeks through media. The electronic content is prepared under the supervision of the research team and will be controlled by nursing management group of the nursing and midwifery faculty members as well as the virtual education group of the university. The potential platform is in the university's educational system. Each individual has their own password and access code. After logging into their personal page, each person have access to the content of the session they need. The educational content cannot be downloaded and individuals have online access to it. The educational content of each session is updated weekly. A message is sent each week as reminder and motivation. Individuals are given two weeks to study the content of each session. It should be noted that the content of the next session is only accessible only if they answer the questions at the end of each session. Head nurses can this opportunity to ask their question. Pre-test is taken before starting the first session, and post-test is taken two weeks and six weeks after providing the training from all participants (head nurses and nursing staff).

**Category**

N/A

**2**

**Description**

Control group: people who allocate to control group receives no training. They are just asked to do pre and post tests at the beginning and end of training in intervention group,

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shariati hospital

**Full name of responsible person**

zahra sajedimonfared

**Street address**

Shariati Hospital, Jalal Al Ahmad Three Roads, North Kargar St, Tehran, Tehran Province

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**2**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital Complex

**Full name of responsible person**

zahra sajedimonfared

**Street address**

Tehran Province, Tehran, at the end of Keshavarz Boulevard, Imam Khomeini Hospital Complex

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imamhospital@tums.ac.ir

**3**

**Recruitment center**

**Name of recruitment center**

Sina hospital

**Full name of responsible person**

Zahra Sajedimonfared

**Street address**

Sina Hospital, Hassan Abad Square, Imam Khomeini Street, Tehran, Tehran Province

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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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**

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**

Zahra Sajedimonfared

**Position**

Master student of Nursing Management

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact**

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Tehran University of Medical Sciences

**Full name of responsible person**

Nahid Dehghan Nayeri

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

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**Position**

Master student of Nursing Management

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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**

No - There is not 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**

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

make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals.

**When the data will become available and for how long**

Start access after printing the results

**To whom data/document is available**

No limitation.

**Under which criteria data/document could be used**

The data can be used to plan empowerment programs for nurses and nursing managers.

**From where data/document is obtainable**

zahrasajedi75@gmail.com zahra sajedi

nahid.nayeri@gmail.com nahid dehghan nayeri

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

Sending an email to the responsible author is enough.

**Comments**