

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Investigating the impact of using a health assessment mobile application on clinical judgment and medical errors in trauma patient assessment

#### Protocol summary

##### Study aim

Investigating the impact of using a health assessment mobile application on medical errors in the assessment of trauma patients

##### Design

The study will be conducted as a clinical trial with a control group, with parallel groups, one-sided blind, with the participation of 80 patients hospitalized due to trauma. Randomization will be done using white and black colored cards.

##### Settings and conduct

Trauma patients referring to the medical education centers of Shahid Beheshti University of Medical Sciences, if they are eligible, will be included in the study and will be randomly assigned to intervention and control groups using colored cards. This study will be performed in a blind way. In this way, researcher A will do the evaluation and error checking will be done by researcher B, who will be unaware of the allocation of groups. Also, the data analyst will not know about the grouping of the participants

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: hospitalization due to trauma,  
Exclusion criteria: not having a smart phone

##### Intervention groups

In the intervention group, the patient's assessment is checked with the help of the status assessment software. In this software, the assessment steps are done in order and step by step, and it guides the evaluator like a guide and reminds the evaluator of points at each step, and in the control group, the evaluation will be done without the help of the software and in the usual way.

##### Main outcome variables

Increasing accuracy in the evaluation of trauma patients and reducing the occurrence of medical errors in the evaluation of patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210131050189N7**

Registration date: **2023-12-14, 1402/09/23**

Registration timing: **prospective**

Last update: **2023-12-14, 1402/09/23**

Update count: **0**

##### Registration date

2023-12-14, 1402/09/23

##### Registrant information

##### Name

Raziyeh Ghafouri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3335 4520

##### Email address

ghafouri@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-21, 1402/09/30

##### Expected recruitment end date

2024-02-19, 1402/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the impact of using a health assessment mobile application on clinical judgment and medical errors in trauma patient assessment

#### Public title

Impact of using a health assessment mobile app on medical errors

#### Purpose

Diagnostic

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Having a smart phone Hospitalized due to trauma

##### Exclusion criteria:

Reluctance to use mobile application for initial assessment after hospitalization

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Before starting the research, 40 white color cards and 40 black cards will be prepared. All the cards will be placed in an envelope, then the cards will be taken out randomly and numbered from 1 to 80 in order of exit.

Each card will then be placed in a sealed envelope and its number will be written on the envelope. As each patient enters the study, a special envelope from number 1 to 80 will be opened for him. If the card is white, the participant will be assigned to the intervention group, and if the card is black, the participant will be assigned to the control group.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The evaluation of patients is done by researcher A, and the evaluation of errors that occurred in the evaluation is checked by the researcher. Also, the data analyst will not know the type of intervention

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2023-10-23, 1402/08/01

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.152

### Health conditions studied

#### 1

#### Description of health condition studied

Trauma

#### ICD-10 code

F43.10

#### ICD-10 code description

Post-traumatic stress disorder, unspecified

### Primary outcomes

#### 1

#### Description

Reducing the occurrence of medical errors in the evaluation of patients

#### Timepoint

Upon arrival to a month after discharge

#### Method of measurement

Re-hospitalization and error in evaluation based on 28 errors

### Secondary outcomes

empty

### Intervention groups

#### 1

#### Description

Intervention group: In the intervention group, the patient's assessment is checked with the help of the status assessment software. In this software, the evaluation steps are done in order and step by step, and it guides the evaluator like a guide and reminds the evaluator of points at each step.

#### Category

Diagnosis

**2**

**Description**

Control group: In the control group, the evaluation is done in the usual way

**Category**

Diagnosis

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Hossein Hospital, Tehran

**Full name of responsible person**

Raziyeh Ghafouri

**Street address**

Shahid Madani Street, Imam Hossein Square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 3000

**Email**

info@sbmu.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

(Ayatollah) Taleghani Educational Hospital

**Full name of responsible person**

Raziyeh Ghafouri

**Street address**

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

19839-63113

**Phone**

+98 21 2303 1100

**Email**

taleghani@sbmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zergj

**Street address**

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

19839-63113

**Phone**

+98 21 2243 9770

**Email**

Intl\_office@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Raziyeh Ghafouri

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

SBMU School of Nursing & Midwifery, Vali-Asr Avenue, Cross of Vali-Asr Avenue and Hashemi Rafsanjani (Neiaiesh) Highway, Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1996835119

**Phone**

+98 912 783 8896

**Email**

raziieghafouri@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Raziyeh ghafouri

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**SBMU School of Nursing & Midwifery, Vali-Asr Avenue,  
Cross of Vali-Asr Avenue and Hashemi Rafsanjani  
(Neiaiesh) Highway, Tehran.**City**

Tehran

**Province**

Tehran

**Postal code**

1996835119

**Phone**

+98 21 8820 2520

**Email**

raziehghafouri@gmail.com

**Province**

Tehran

**Postal code**

1996835119

**Phone**

0982188202520

**Email**

raziehghafouri@gmail.com

**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**

Yes - There is a plan to make this available

**Title and more details about the data/document**By email to the corresponding author  
raziehghafouri@gmail.com**When the data will become available and for how long**

After the publication of the article

**To whom data/document is available**

Academic researchers

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

More research

**From where data/document is obtainable**By email to the corresponding author  
raziehghafouri@gmail.com**What processes are involved for a request to access data/document**By email to the corresponding author  
raziehghafouri@gmail.com**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Raziyeh Ghafouri

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**SBMU School of Nursing & Midwifery, Vali-Asr Avenue,  
Cross of Vali-Asr Avenue and Hashemi Rafsanjani  
(Neiaiesh) Highway, Tehran.**City**

Tehran