

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Designing and evaluation of educational program on safe behaviours in Petrochemical workers

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

In this research, the researcher will draw a conceptual model to design an educational intervention based on the mixed method design to promote workers' safe behaviours in the petrochemical industry in Mahshahr city, Iran and examine its impact.

Last update: **2018-06-19, 1397/03/29**

Update count: **0**

#### Registration date

2018-06-19, 1397/03/29

#### Design

This study is a randomized controlled trial (RCT) with community based and pragmatic control group, with parallel, two-blind, randomized groups.

#### Registrant information

##### Name

Azita Zahiri Harsini

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 4546

##### Email address

azitazahiri@modares.ac.ir

#### Settings and conduct

The research setting is Shahid Tandoogian petrochemical industry in Mahshahr city, Iran. The statistical population of present research is workers employed in Shahid Tondgoian petrochemical industry. Research Participants and safety officials are kept blind.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria are having more information on a topic, the concept or research questions. In addition, people will attend who are motivated to talk about the subject matter. Exclusion criteria are the reluctance of participants to continue to participate in the study and the lack of regular attendance at the training sessions.

#### Expected recruitment start date

2017-05-06, 1396/02/16

#### Expected recruitment end date

2019-03-11, 1397/12/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

The assignment of the samples to the studied groups (test and control groups) is done randomly, test group (88) and control group (88). Intervention will be performed in the test group.

#### Scientific title

Designing and evaluation of educational program on safe behaviours in Petrochemical workers

#### Main outcome variables

Safety education; Safe behaviours; Unsafe behaviours; Petrochemical workers

#### Public title

Promoting workers' safe behaviours

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170515033981N2**

Registration date: **2018-06-19, 1397/03/29**

#### Purpose

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Having work experience in the petrochemical industry at least two years. Participants' motivation to recount their experiences to the researcher

**Exclusion criteria:**  
The reluctance of participants to continue to participate in the study The lack of regular attendance at the training sessions

**Age**  
No age limit

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **176**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization method: Simple randomization Random unit: Individual Randomization tool: Statistical software Random allocation software

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Participants in research and safety department officials are kept blind.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
MeasureThis study is a Mixed Methods Research (MMR), in which the research methodology will be presented as follows:1- Qualitative research 2- Investigating the psychometric properties of the designed instrument to measure safe behaviours. 3- Randomised controlled trial (measuring the effect of educational intervention on promoting workers' safe behaviours).

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tarbiat Modares University

##### Street address

No. 7, Jalal, Al Ahmad Street, Tarbiat Modares University

##### City

Tehran

##### Province

Tehran

##### Postal code

14115111

##### Approval date

2017-01-18, 1395/10/29

##### Ethics committee reference number

IR.TMU.REC.1395.503

## Health conditions studied

### 1

#### Description of health condition studied

Injury and Unsafe Behaviours

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Safe behaviour score of the designed questionnaire based on conceptual model

#### Timepoint

Comparability between the two groups will be assessed at the baseline and 3 months after the intervention

#### Method of measurement

We will distribute a survey which will be designed by the researcher based on conceptual model constructs among workers in the petrochemical industry.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: workers through the designed educational intervention and training sessions directly through active education methods and engagement of workers such as group discussion, role play, modeling, problem solving, and indirectly through designing an educational software (multimedia) will be trained.

#### Category

Prevention

### 2

#### Description

The control group: The control group will not receive the intervention.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

The National Petrochemical Company

**Full name of responsible person**

Alireza Narimannejad

**Street address**

No. 104, North Sheikh Bahaie Ave, Molla Sadra St

**City**

Tehran

**Province**

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**Postal code**

193956896

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**Email**

narimannejad@nipc.net

**Web page address**

<http://www.nipc.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

The National Petrochemical Company

**Full name of responsible person**

Alireza Narimannejad

**Street address**

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narimannejad@nipc.net

**Web page address**

<http://www.nipc.ir/>

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

Yes

**Title of funding source**

The National Petrochemical Company

**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**

Industry

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Azita Zahiri Harsini

**Position**

Ph.D candidate

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

**Street address**

No. 7, Jalal, Al Ahmad Street, Tarbiat Modares University

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Azita Zahiri Harsini

**Position**

Ph.D candidate

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**Person responsible for updating data****Contact****Name of organization / entity**

Tarbiat Modares University

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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**

Not applicable

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

The total potential data can be shared after unidentifiable people

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

The start of the data access period will be 6 months after the results are printed.

**To whom data/document is available**

Data or other documentation will be available to researchers working in academic and scientific institutions and industry professionals.

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

Refer to the present study if you use data or other documents with following the principles of scientific ethics.

**From where data/document is obtainable**

Azita Zahiri Harsini, Tarbiat Modares University  
azitazahiri@modares.ac.ir +98 21 8288 4546 +98 912 098 8024

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

If requested for access to documents, one week after sending the request by email, appropriate action will be taken.

**Comments**