

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

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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

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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

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Azita Zahiri Harsini

Position

Ph.D candidate

Latest degree

Master

Other areas of specialty/work

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

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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
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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