Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Oct 2026

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

Protocol summary

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.

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

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.

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.

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.

Main outcome variables
Safety education; Safe behaviours; Unsafe behaviours; Petrochemical workers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170515033981N2**
Registration date: **2018-06-19, 1397/03/29**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-19, 1397/03/29**
Update count: **0**

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

Registrant information

Name
Azita Zahiri Harsini

Name of organization / entity
Tarbiat Modares University

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Iran (Islamic Republic of)

Phone
+98 21 8288 4546

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azitazahiri@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

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

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

Public title
Promoting workers' safe behaviours

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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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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Email
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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
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Person responsible for updating data

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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