Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of educational intervention based on the theory of planned behavior on the use of masks in workers

Protocol summary

Study aim
Determining the effect of educational intervention based on the theory of planned behavior on the use of masks in the workers of Isfahan's Atlas Flour Factory.

Design
The study group was composed of 50 employees of Isfahan Atlas Company. One of the shifts of this factory was 25 people randomly selected by drawing method as intervention group and other shifts as control group.

Settings and conduct
The location of the study is Isfahan's Atlas of flour. In a census method, 50 workers in two shifts of 25 people were enrolled. One of the shifts was randomly selected as the intervention group and the other shifts as control group. In the three stages before, immediately and after the intervention, the participants completed the questionnaire. The intervention was conducted in four educational sessions.

Participants/Inclusion and exclusion criteria
Entry conditions include having at least one year of work experience at the flour mill؛ the satisfaction of participating in the study and having a physical health. Failure to enter is also a lack of consent from the company in the study.

Intervention groups
The intervention designed in this study was to investigate the effect of an educational process using the Planning Behavior Theory on the behavior of the use of Masked workers in the flour mill, which target groups receive educational interventions and ultimately their impact on the control group is examined. .

Main outcome variables
Promoting safety behaviors; increasing the use of masks; reducing respiratory problems

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181121041717N1**
Registration date: **2018-12-23, 1397/10/02**
Registration timing: **retrospective**

Last update: **2018-12-23, 1397/10/02**
Update count: **0**

Registration date
2018-12-23, 1397/10/02

Registrant information

Name
Mozhgan Ghafouri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3361 3111

Email address
mghafouri92@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2017-11-01, 1396/08/10

Actual recruitment start date
2017-10-23, 1396/08/01

Actual recruitment end date
2017-11-01, 1396/08/10

Trial completion date
2018-04-21, 1397/02/01

Scientific title
The effect of educational intervention based on the theory of planned behavior on the use of masks in workers

Public title
The effect of educational intervention on the behavior of using mask workers
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having a job record of at least one year at the factory; Having physical health; and Satisfaction of the company in the study.
Exclusion criteria:
Dissatisfaction with the company in the study.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization-Picking groups in a draw
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar jarib Ave
City
Esfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2017-11-11, 1396/08/20
Ethics committee reference number
IR.MUI.REC.1396.3.789

Health conditions studied

1

Description of health condition studied
Prevention of respiratory problems
ICD-10 code
J00-J99
ICD-10 code description
Diseases of the respiratory system

Primary outcomes

1

Description
Beliefs and attitudes related to safe behaviors
Timepoint
Before the intervention, immediately and 3 months after educational intervention
Method of measurement
Researcher-made Questionnaire

Secondary outcomes

1

Description
The use of masks
Timepoint
Before the intervention, immediately and 3 months after educational intervention
Method of measurement
Researcher-made Questionnaire

Intervention groups

1

Description
Intervention group: Educational interventions related to safety behavior in 4 sessions
Category
Behavior

2

Description
Control group: No educational intervention
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Atlas Flour Factory
Full name of responsible person
Mozhgan Ghafouri

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Mahmood Abad-Esfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ahmad Movahedian Attar
Street address
Department of Health education and promotion, school of Health, Isfahan University of Medical Sciences, Hezar Jerib Street
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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
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Esfahan University of Medical Sciences
Full name of responsible person
Mozhgan Ghafouri
Position
Master student
Latest degree
Bachelor
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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
No - There is not 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data on primary and secondary outcome will be shared in the form of a spss file

When the data will become available and for how long
The access period will be from December 2018

To whom data/document is available
Researchers of academic institutions

Under which criteria data/document could be used
The researcher will give the data to other researchers for scientific use only.

From where data/document is obtainable
Send an e-mail to mghafouri92@yahoo.com

What processes are involved for a request to access data/document
People who want the data, send your request by e-mail to the above address. The researcher, after consulting the research team, sends the data to them, if they agree.

Comments