

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

Isfahan

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

Street address
Mahmood Abad-Esfahan
City
Esfahan
Province
Isfahan
Postal code
84197-17716
Phone
+98 31 3361 3111
Email
mghafouri92@yahoo.com

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
City
Esfahan
Province
Isfahan
Postal code
84197-17716
Phone
+98 31 3361 3111
Email
mghafouri92@yahoo.com

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
Other areas of specialty/work
Health Promotion
Street address
Hezar jarib Ave
City
Esfahan
Province
Isfahan
Postal code
84197-17716
Phone
+98 31 3361 3111
Email
mghafouri92@yahoo.cim

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mozhgan Ghafouri
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Health Promotion
Street address
Department of Health education and promotion,
school of Health, Isfahan University of Medical
Sciences, Hezar Jerib Street
City
Esfahan
Province
Isfahan
Postal code
84197-17716
Phone
+98 31 3792 3244
Email
mghafouri92@uahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mozhgan Ghafouri
Position
MSc Student
Latest degree
Bachelor
Other areas of specialty/work
Health Professional
Street address

Department of Health education and promotion,
school of Health, Isfahan University of Medical
Sciences, Hezar Jerib Street

City

Esfahan

Province

Isfahan

Postal code

8419717716

Phone

+98 31 3792 3244

Email

mghafouri92@yahoo.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

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