

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigating the effect of education based on protection motivation theory on preventive behaviors of Covid 19 in food industry employees.

Protocol summary

Study aim

Determining the effect of education based on motivation protection theory on preventive behaviors of Covid-19 in food industry employees

Design

A randomized, single-blind randomized controlled clinical trial was performed on 208 participants who were selected by stepwise cluster sampling.

Settings and conduct

Intervention in the field of Covid-19 infection prevention training in food industry workers in the factories of the intervention group is done in person and presentation of educational texts based on motivation protection theory. Then the result of the intervention on the behavior of employees in both experimental and control groups, before, after and 3 months after the intervention will be determined and analyzed. When entering information into the software, the information identifying the intervention and control group is hidden so that the analyst is kept blind to their findings.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have a primary or secondary education level Have at least 6 months of work experience and insurance Conscious consent to participate in the study
Exclusion criteria: Leaving the factory during the study
Death of the person being studied
Absence of more than one session in the training class
Dissatisfaction with continued cooperation during the study
Incomplete completion of questionnaires

Intervention groups

Educational intervention to improve the preventive behaviors of Covid-19 for the experimental group is performed in the intervention factories. During the intervention, the control group did not receive training. But after the intervention, the educational package is provided to the control group.

Main outcome variables

Perceived self-efficacy Perceived response efficiency
Perceived vulnerability Perceived intensity Perceived

response cost

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200811048362N1**

Registration date: **2022-05-21, 1401/02/31**

Registration timing: **prospective**

Last update: **2022-05-21, 1401/02/31**

Update count: **0**

Registration date

2022-05-21, 1401/02/31

Registrant information

Name

Mehrsadat Mahdizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3189 2206

Email address

mahdizadehtm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Secondary ids
Scientific title Investigating the effect of education based on protection motivation theory on preventive behaviors of Covid 19 in food industry employees.	empty
Public title The effect of education on preventive behaviors of covid-19	Ethics committees
Purpose Education/Guidance	<u>1</u>
Inclusion/Exclusion criteria Inclusion criteria: Having a level of junior high school and higher Have at least 6 months of work experience and insurance Conscious consent to participate in the study Exclusion criteria: Leaving the factory during the study Cognitive and psychological diseases Dissatisfaction with continued cooperation during the study	Ethics committee Name of ethics committee Ethics committee of Mashhad University of Medical Sciences Ethics Committee Street address No. 16, Daneshgah Street, School of Health. Postal Code: 9137673119 City Mashhad Province Razavi Khorasan Postal code 9137673119 Approval date 2021-12-18, 1400/09/27 Ethics committee reference number IR.MUMS.REC.1400.333
Age No age limit	Health conditions studied
Gender Both	<u>1</u>
Phase N/A	Description of health condition studied COVID-19 ICD-10 code U10.9 ICD-10 code description Multisystem inflammatory syndrome associated with COVID-19, unspecified
Groups that have been masked Data analyser	Primary outcomes
Sample size Target sample size: 104	<u>1</u>
Randomization (investigator's opinion) Randomized	Description Score of preventive behaviors of COVID-19 Timepoint Before the intervention - immediately after the intervention - 3 months after the intervention Method of measurement questionnaire
Randomization description Cluster sampling is used for sampling. First, one of the types of food industry is selected from two types of protein-dairy and non-protein food industries. In the next step, 4 factories are randomly selected from a food industry group so that the factories are homogeneous in terms of working conditions, demographic characteristics of the employees; Randomly selected by lottery method from 4 selected factories, 2 factories are allocated to the experimental group and 2 factories to the control group. Finally, the study sample will be selected from the list of employees in each factory in a simple random way using a table of random numbers to participate in the study.	Secondary outcomes
Blinding (investigator's opinion) Single blinded	<u>1</u>
Blinding description With single-blinded method, the study analyzer is kept blind to the information of the intervention and control groups by assigning an unspecified title (for example, groups 1 and 3).	Description Scores of structures of motivation protection theory. Timepoint Before the intervention - immediately after the intervention - 3 months after the intervention Method of measurement Researcher-made questionnaire
Placebo Not used	
Assignment Parallel	
Other design features	

Intervention groups

1

Description

Intervention group: First, a descriptive study is performed to determine the factors related to the preventive behaviors of Quid-19. In the second stage, intervention studies of before and after type are performed with a randomized control group that the training is based on the theory of motivation protection on preventive behaviors of Quid-19 for food industry employees. Training program between 6 to 8 sessions; 5 face-to-face sessions (each session lasts 60 minutes) will be held over a period of 6 weeks. The educational content will be in the form of pamphlets, tracts, educational videos and slides, multimedia and will be completed in 3 stages: researcher-made questionnaire before training, immediately after training and 3 months after training. And the data is analyzed with SPSS software to measure the impact of the training method.

Category

Behavior

2

Description

Control group: Control group do not receive training program. In this group, the questionnaires are completed by the participants at the same time with the intervention group in three stages before the intervention, immediately and 3 months after the intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Food production factories in Chenaran industrial town

Full name of responsible person

Mehrsadat Mahdizadeh

Street address

No. 16, Daneshgah St., School of Health

City

Mashhad

Province

Razavi Khorasan

Postal code

9137673119

Phone

+98 51 3819 2206

Fax

+98 51 3852 2775

Email

mahdizadehtm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayyur Mobarehan

Street address

No. 16, Daneshgah Street, Ghoreyshi, Mashhad, Korasan Razavi.

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Phone

+98 51 3841 2081

Fax

+98 51 3841 3006

Email

mahdizadehtm@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mehrsadat Mahdizadeh

Position

Assistant Profesor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

No. 16, Daneshghah street, School of health, Mashhad, Khorasan Razavi.

City

Mashhad

Province

Razavi Khorasan
Postal code
9137673119
Phone
+98 51 3891 2206
Email
mahdizadehtm@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mehrsadat Mahdizadeh
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
No. 16, Daneshgah street, School of health,
Mashhad, Khorasan Razavi.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137673119
Phone
+98 51 3189 2206
Email
mahdizadehtm@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mehrsadat Mahdizadeh
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
No 16. Daneshgah street, Mashhad, Khorasan-
Razavi.
City

Mashhad
Province
Razavi Khorasan
Postal code
9137673119
Phone
+98 51 3189 2206
Email
mahdizadehtm@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Upon completion of the study, Results will be provided to the applicant organizations.

When the data will become available and for how long

1402 and later.

To whom data/document is available

Managers of food industry factories selected as intervention and control groups and Mashhad University of Medical Sciences.

Under which criteria data/document could be used

Formal request of factory managers of intervention and control group.

From where data/document is obtainable

Mehrsadat Mahdizadeh- School of health, Mashhad University of Medical Sciences.

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

Written request to the Vice Chancellor for Research of Mashhad University of Medical Sciences or the researcher in charge of science with the following email address: mahdizadehtm@mums.ac.ir

Comments