Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Investigating the effect of educational messages on the prevention of respiratory infectious diseases, with emphasis on Covid-19 based on the developed parallel process model, on risk control responses in diabetic middle-aged people

Protocol summary

Study aim
Evaluating the effect of educational messages containing response effectiveness, self-efficacy and perceived threat (perceived sensitivity/severity), risk control response, and fear control responses in diabetic middle-aged

Design
Clinical trial with one control group and two intervention groups, with parallel groups, one-way blind, randomized on 240 diabetic middle-aged people. All eligible individuals are arranged according to the national code, then three blocks are used, each block as Randomly, one is in the control group and the other two are in the intervention group and continue in the same way

Settings and conduct
This study was performed on 240 diabetic middle-aged people in Shahinshahr health centers, which were divided into two groups of intervention and control, in which 80 people are in each group.The receiver is unaware and the study is one-way blind

Participants/Inclusion and exclusion criteria
Entry requirements 1- Middle-aged (30-60 years) diabetic should be covered by selected health centers 2- Satisfaction for the company 3- Literacy 4- Persian language and citizen of Iran 5- Smart phone 6- Ability to use mobile smart phone 7- History of not being infected with Quid-19 Exit conditions 1- Not wanting to continue participating in the study 2- Leaving the area covered by the health center 3- Malfunction or lack of mobile phone access 4- Having any disease, which is not able to continue participating in the study

Intervention groups
Middle-aged two groups receive training messages based on the components of response effectiveness, self-efficacy, and perceived threat for 1 month (two training messages per week) via WhatsApp or Soroush channel. The control group did not receive a message and only training They routinely receive health personnel

Main outcome variables
Perceived Sensitivity & Intensity/Self-Efficacy/Response Efficiency/ Fear/Fear Control & Risk Control Response

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210609051525N1**
Registration date: **2021-06-29, 1400/04/08**
Registration timing: **retrospective**

Last update: **2021-06-29, 1400/04/08**
Update count: **0**

Registration date
2021-06-29, 1400/04/08

Registrant information

Name
Dena Ghafari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-26, 1400/04/05

Expected recruitment end date
2021-06-26, 1400/04/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of educational messages on the prevention of respiratory infectious diseases, with emphasis on Covid-19 based on the developed parallel process model, on risk control responses in diabetic middle-aged people

Public title
The effect of education on the prevention of acute respiratory disease
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Middle-aged (30-60 years) diabetics should be covered by selected health centers To be satisfied to participate in the study Be literate. Be Persian-speaking and Iranian citizens. Have a smart phone. Be able to use mobile phones to subscribe and use the content of WhatsApp and Soroush groups. Do not have a history of Quid 19
Exclusion criteria:
Reluctance to continue participating in the study Leaving the area covered by the selected health center, for any reason Mobile phone failure or lack of access Having any illness, in which the participant is unable to continue participating in the study
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
After obtaining the necessary permits, and ensuring the validity of the research tool, sampling will be done in such a way that initially diabetic middle-aged people in Shahinshahr will be considered. After reviewing the entry criteria, all eligible people are arranged according to the national code, then triple blocks are used in such a way that the first three national codes form a block, each of which is randomly one in the control group and two Others are in the intervention group and continue in the same way.
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
Faculty of Health, Isfahan University of Medical Sciences, Hezar Jerib St, Isfahan
City
isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-06-26, 1400/04/05
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.126

Health conditions studied

1

Description of health condition studied
Infectious respiratory diseases
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Diabetes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Response efficiency and perceived self-efficacy and threat (perceived severity and sensitivity
Timepoint
Before the intervention and one week after the intervention
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The first group of intervention: are middle-aged people who, based on the results of the pre-test, have a perceived threat score higher than average. They will. This group completes the questionnaires again one week after the intervention.
Category
Behavior

2

Description
The second group of intervention: are middle-aged people whose perceived threat score is lower than the average score. This group receives both messages related to perceived threat (perceived sensitivity / severity) and messages of response efficiency and self-efficacy for one month (They will receive two training messages per week via the virtual channel. This group completes the questionnaires again one week after the intervention.
Category
Behavior

3

Description
Control group: The group that is considered as a control group does not undergo any educational intervention by the researcher. Simultaneously with the first and second groups, post-test will be performed in this group as well. It should be noted that at the end of the study, in order to observe ethics in research, educational messages will be placed in the control
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahinshahr Health Center
Full name of responsible person
dr masud poor mehrab
Street address
9 west, taleghani, shahin shahr
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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dena ghafari
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable