Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of a web-based education strategy on immunoglobulin G and M in the prevention of covid-19

Protocol summary

Study aim
Determining the efficacy of women's empowerment in predicting the consequences of COVID-19 disease

Design
This study will be conducted as a randomized clinical trial, single-blind. Study subjects will be divided into two intervention groups (152 people) and control (151 people) using the randomization method along with matching for age and BMI.

Settings and conduct
Samples were selected from health centers, clinical examinations and questionnaires were completed at the Gastrointestinal Diseases Research Center.Because of the nature of this study, only the analysts and evaluators were masked in group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Housewives aged between 30-60 years old, free of kidney disease and diabetes, mental and learning problems, visual and hearing problems, literate, have access to the Internet, and have a computer or smartphone. Exclusion criteria: pregnant or lactating people, who had positive Ig G or Ig M antibody titers for Covid-19 at the beginning and recovered patients.

Intervention groups
The current study aimed to provide four education sessions on mental health behavior and four training sessions on personal health behaviors, Physical activity, and healthy diet within 4 weeks (8 sessions). Each training session lasted one hour. The training sessions were conducted online using multimedia via the big blue button. A WhatsApp group was created for the intervention group, and they were informed of the class times. A training site was created . Codes were given to the intervention group.

Main outcome variables
Immunoglobulin G (IgG) and Immunoglobulin M (Ig M) antibodies titers Symptoms of COVID-19

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221228056969N1**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **retrospective**

Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date
2023-01-21, 1401/11/01

Registrant information

Name
Maryam Zare

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
2020-12-31, 1399/10/11

Expected recruitment end date
2022-06-02, 1401/03/12

Actual recruitment start date
2021-01-04, 1399/10/15

Actual recruitment end date
2021-08-16, 1400/05/25

Trial completion date
2023-01-22, 1401/11/02

Scientific title

The effect of a web-based education strategy on immunoglobulin G and M in the prevention of covid-19

Public title
Evaluation of the effectiveness of women's empowerment in predicting infected COVID-19 outcomes.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Housewives with an age range of 30-60years No renal disease or diabetes, mental and learning problems, vision, and hearing problems Has literacy Internet access Having a computer or smartphone
Exclusion criteria:
Pregnant women / intention to conceive or breastfeed Subjects with COVID-19 disease Subjects who are recovering of COVID-19
Age
From **30 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **303**
Actual sample size reached: **252**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants were randomized to the intervention group (n = 152) and the control group (n = 151) were assigned randomly, and random numbers were generated using Random Allocation Software (RAS), using block. Allocations were communicated to the groups by people other than the trial coordinator. The study groups were matched in terms of age and weight variables during a random assignment.
Blinding (investigator's opinion)
Single blinded
Blinding description
Because of the nature of this study, only the analysts and evaluators were masked in group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ardabil University of Medical Sciences
Street address
Daneshgah street
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Province
Ardabil
Postal code
56189-85991
Approval date
2020-08-11, 1399/05/21
Ethics committee reference number
IR.ARUMS.REC.1399.284

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
B97.2
ICD-10 code description
Coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Immunoglobulin G (IgG) and Immunoglobulin M (Ig M) antibodies titers
Timepoint
This study was conducted at three time points: baseline, post-intervention (4 weeks), and follow-up (12 weeks).
Method of measurement
enzyme-linked immunosorbent assay, using kits (ELISA; Pishtaz, Iran)

Secondary outcomes

1

Description
Symptoms of COVID-19 Diseases
Timepoint
baseline, post-intervention (4 weeks), and follow-up (12 weeks)
Method of measurement
the physician examined the participants' physical condition during the study and diagnosed symptoms of COVID-19 diseases.

2

Description
Mental Health Behavior score
Timepoint
baseline, post-intervention (4 weeks), and follow-up (12 weeks)

Method of measurement
the lifestyle for prevention of infectious diseases questionnaire (LSPIDQ)

3

Description
Stress and Anxiety score
Timepoint
baseline, post-intervention (4 weeks), and follow-up (12 weeks)
Method of measurement
the lifestyle for prevention of infectious diseases questionnaire (LSPIDQ)

4

Description
Personal and Public Health Behavior score
Timepoint
baseline, post-intervention (4 weeks), and follow-up (12 weeks)
Method of measurement
the lifestyle for prevention of infectious diseases questionnaire (LSPIDQ)

5

Description
physical activity behavior score
Timepoint
baseline, post-intervention (4 weeks), and follow-up (12 weeks)
Method of measurement
the lifestyle for prevention of infectious diseases questionnaire (LSPIDQ)

6

Description
healthy eating behavior score
Timepoint
baseline, post-intervention (4 weeks), and follow-up (12 weeks)
Method of measurement
the lifestyle for prevention of infectious diseases questionnaire (LSPIDQ)

7

Description
Average intake of macronutrients
Timepoint
baseline, post-intervention (4 weeks), and follow-up (12 weeks)
Method of measurement
24-hour dietary recall

8

Description
Physical activity score
Timepoint
baseline, post-intervention (4 weeks), and follow-up (12 weeks)
Method of measurement
the International Physical Activity Questionnaire (IPAQ)

Intervention groups

1

Description
Intervention group: The current study aimed to provide four education sessions on mental health behavior and four training sessions on personal health behaviors, Physical activity, and healthy diet within 4 weeks (8 sessions). Each training session lasted one hour. Both local psychologists and university professors provided training strategy programs in the fields of mental health behavior and personal health, healthy diet, and physical activity education. The training sessions were conducted online using multimedia via the big blue button, and questions and answers were conducted during the sessions to ensure the attendance of the participants. A WhatsApp group was created for the intervention group, and they were informed of the class times. A training site was created to make educational content available to the intervention group, including a home page, instructions, and offline classes. Access codes protected offline classes and instructions. On the site's offline classes section, the educational content of online classes was uploaded. Codes were given to the intervention group. After the training strategy, the intervention group was evaluated in terms of educational content. The contents of the sessions were developed based on a review literature search.
Category
Lifestyle

2

Description
Control group: The control group received routine training via mass and social media. After follow-up, the control group was provided with address training sites.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Care Centers
Full name of responsible person
Maryam Zare
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2

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Sponsors / Funding sources

1

Sponsor
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WHO Eastern Mediterranean Regional Office
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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
WHO Eastern Mediterranean Regional Office
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Foreign
Category of foreign source of funding
UN agencies and international organizations
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Maryam Zare
Position
Assistant Professor
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The dataset analyzed during the current study is not publicly available due to legal and ethical constraints. Public sharing of participant data was not included in the informed consent of the study. All inquiries about access to data should be sent to the corresponding author. All requests to access data will be handled in accordance with the Ethics Committee of the Faculty of Ardabil University of Medical Sciences.
When the data will become available and for how long
The dataset analyzed during the current study is not publicly available due to legal and ethical constraints.
To whom data/document is available
All inquiries about access to data should be sent to the corresponding author
Under which criteria data/document could be used
All inquiries about access to data should be sent to the corresponding author
From where data/document is obtainable
the corresponding author
What processes are involved for a request to access data/document
All requests to access data will be handled in accordance with the Ethics Committee of the Faculty of Ardabil University of Medical Sciences.
Comments