

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 45 3352 2247

Email address

m.zare@khalums.ac.ir

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

City

Ardabil

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

Street address

Hafez Street

City

Ardabil

Province

Ardabil

Postal code

5614614615

Phone

+98 45 3371 4902

Email

zaremaryam119@gmail.com

2

Recruitment center

Name of recruitment center

Digestive Disease Research Center (DDRC)

Full name of responsible person

Maryam Zare

Street address

30 Tir Street

City

Ardabil

Province

Ardabil

Postal code

5614614615

Phone

+98 45 3326 2925

Email

zaremaryam119@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

WHO Eastern Mediterranean Regional Office

Full name of responsible person

Farhad Pourfarzi

Street address

daneshgah street

City

Ardabil

Province

Ardabil

Postal code

56189-85991

Phone

+98 45 3352 2247

Email

zaremaryam119@gmail.com

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

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Daneshgah Street

City

Ardabil

Province

Ardabil

Postal code

56189-85991

Phone

+98 45 3352 2247

Email

zaremaryam119@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Maryam Zare

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Daneshgah Street

City

Ardabil

Province

Ardabil

Postal code

56189-85991

Phone

+98 45 3352 2247

Email

zaremaryam119@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Maryam Zare

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Daneshgah Street

City

Ardabil

Province

Ardabil

Postal code

56189-85991

Phone

+98 45 3352 2247

Email

zaremaryam119@gmail.com

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