

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Effect of Interactive Digital-based Psychoeducational Intervention about COVID-19 on Knowledge, Fear, and Anxiety among Secondary School Students

Protocol summary

Covid-19 related knowledge, fear, and anxiety

Study aim

Investigate the effect of interactive digital-based psychoeducational intervention about COVID-19 on knowledge, fear, and anxiety among secondary school students

Design

A quasi-experimental (one group pre/posttest), a multistage random technique in the selection of the schools and classes then a convenient sample from students (200 participants), followed for two months.

Settings and conduct

This one group pre-posttest study will be conducted virtually using multi-media digital-based educational intervention methods for the students selected from the randomly chosen four governmental secondary schools (2 boys schools and 2 girls schools).

Participants/Inclusion and exclusion criteria

Inclusion criteria: - both sexes, possessed a smart mobile phone/computer and an internet connection, Willing to participate in the study Exclusion criteria: the presence of either visual or auditory problems and psychological or mental disorders

Intervention groups

The intervention group (200 students) will receive the psychoeducational intervention for six consecutive months. The total sample will be divided into six subgroups (30-35) where four sessions on Zoom will be conducted for every subgroup with a total of 24 sessions for the whole sample. WhatsApp will be used for fostering daily communication with the students either in written format or using audio messages. Emails will be used for delivering the PowerPoint, educational videos, and graphics. Then after 2 months, the post-test will be conducted to evaluate the effectiveness of the trial. The study will be conducted from the beginning of November 2021 to May 2022

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051555N2**

Registration date: **2021-10-30, 1400/08/08**

Registration timing: **prospective**

Last update: **2021-10-30, 1400/08/08**

Update count: **0**

Registration date

2021-10-30, 1400/08/08

Registrant information

Name

Samiha Hamdi

Name of organization / entity

Dmanhour University, Faculty of Nursing

Country

Egypt

Phone

+20 45 3538264

Email address

samihareda93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-10, 1400/08/19

Expected recruitment end date

2021-12-10, 1400/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Interactive Digital-based Psychoeducational Intervention about COVID-19 on Knowledge, Fear, and Anxiety among Secondary School Students

Public title
Effect of Interactive Digital-based Psychoeducational Intervention about COVID-19 on Knowledge, Fear, and Anxiety among Secondary School Students

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Both sexes Possessed a smart mobile phone/computer and internet connection Willing to participate in the study
Exclusion criteria:
Visual or auditory problems Psychological or mental disorders

Age
From **14 years** old to **19 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's committee of the Faculty of Nursing-Damanhour University

Street address

Damanhour, Elbehira, Governorate, Egypt

City

Damahour

Postal code

22511

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

08-09-03-2021 EC

Health conditions studied

1

Description of health condition studied

Corona virus related anxiety and fear

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

COVID-19 knowledge

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Self-report knowledge questionnaire

2

Description

COVID-19 related fear

Timepoint

Before intervention and 2 months after intervention

Method of measurement

COVID-19 fear scale (adopted from Ahorsu et. Al, 2020)

3

Description

COVID-19 related anxiety

Timepoint

Before intervention and 2 months after intervention

Method of measurement

COVID-19 anxiety scale - A screening tool for dysfunctional anxiety associated with the coronavirus crisis (Lee 2020)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention will be conducted according to the following phases: I. Needs assessment Phase: The study instrument will be entered to the Google form spreadsheet. A WhatsApp group will be created to share the link with the students for the pre-

post-test. A pre-test will be completed to evaluate the students' knowledge about COVID-19 and the associated level of fear and anxiety to address insufficiencies to be deemed during the construction of the psychoeducational intervention. It is also will be used as baseline data for comparison with the post-test. II. Planning phase: interactive digital-based psychoeducational intervention about COVID-19 will be developed by the researchers according to the following steps: -a. Setting objectives • General objective: Improve the students 'knowledge about COVID-19 and alleviate fear and anxiety from COVID-19: • Specific objectives: - Identify the COVID-19 pandemic-List the possible signs and symptoms of COVID-19- Discuss the preventive measures against Coronavirus infection-Explain the main complications of COVID-19 and its treatment- Conceptualize the COVID-19 related fear and anxiety and their causes- Mention symptoms linked to fear and anxiety and their alleviating measures -Demonstrate different relaxation techniques-Apply different ways to reduce fear and anxiety of COVID-19 b. Preparation of the content and presentation methods: The content will be designed by the researchers to cover all the predetermined objectives. It will be developed based on a review of relevant recent literature about COVID-19. It will contain information about the COVID-19 definition, possible signs and symptoms, modes of transmission, preventive behaviors and vaccination, complications, and treatment. In addition to the definition of COVID-19 related fear and anxiety, possible signs, and symptoms, causes, and different relaxation techniques and alleviating measures.- Numerous interactive digital-based methods will be developed to present the content as a WhatsApp group, enlisting the students' Emails, and Zoom meetings. In addition to, PowerPoint presentation, animated graphics, and educational videos- Implementation Phase:-The fieldwork will be spanned for six consecutive months starting from November 2021to May 2022. The total sample will be divided into six subgroups (30-35) where four sessions on Zoom (about 35-40 minutes) will be conducted for every subgroup with a total of 24 sessions for the whole sample. The WhatsApp group will be employed for fostering daily communication with the students either in written format or using audio messages. Emails will be used for delivering the PowerPoint, educational videos, and graphics. IV- Evaluation Phase. The posttest will be conducted after three months from implementing the intervention, with the aim of comparing the results with the baseline data from the pretest to assure the fulfillment of the study aim.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

secondary school in Damanhour city

Full name of responsible person

Samiha Hamdi Sayed Ramadan

Street address

Damanhour, Elbehira, Governorate, Egypt

City

Damahour

Postal code

22511

Phone

+20 45 3311679

Email

nursing.of.damanhour@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Damanhour University- Faculty of Nursing

Full name of responsible person

Ebid Abd Elaty Saleh

Street address

Damanhour, Elbehira, Governorate, Egypt

City

Damahour

Postal code

22511

Phone

+20 45 3344206

Email

Ebeed.saleh@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Damanhour University- Faculty of Nursing

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

Damanhour University- Faculty of Nursing

Full name of responsible person

Samiha Hamdi Sayed Ramadan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing
Street address
Damanhour, Elbehira, Governorate, Egypt
City
Damahour
Province
Elbehira Governorate
Postal code
22511
Phone
+20 45 3311679
Email
samihareda93@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Damanhour University- Faculty of Nursing
Full name of responsible person
Samiha Hamdi Sayed Ramadan
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursing
Street address
Damanhour, Elbehira, Governorate, Egypt
City
Damahour
Province
Elbehira Governorate
Postal code
22511
Phone
+20 45 3311679
Email
samihareda93@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Damanhour University- Faculty of Nursing
Full name of responsible person
Samiha Hamdi Sayed Ramadan
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work

Nursing
Street address
Damanhour, Elbehira, Governorate, Egypt
City
Damahour
Province
Elbehira Governorate
Postal code
22511
Phone
+20 45 3311679
Fax
+20 45 3538264
Email
samihareda93@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Clinical Study Report

Yes - There is 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

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

Title and more details about the data/document

Published research report that contains all the findings of the study.

When the data will become available and for how long

within one year and will be available long life

To whom data/document is available

for public

Under which criteria data/document could be used

for scientific use and public education

From where data/document is obtainable

None

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

none

Comments

none