

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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

Samih 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

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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  
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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**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
Assistant professor  
**Latest degree**  
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**Other areas of specialty/work**

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+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