

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of Psychoeducational Intervention about Immune Health on Perceived Physical and Psychological Health Among Working Women at Damanhour University/Egypt: A Randomized Controlled Trial

Protocol summary

Study aim

Assess the Effect of Psychoeducational Intervention about Immune Health on Perceived Physical and Psychological Health Among Working Women

Design

A randomized controlled trial, single-blind, case and control groups, pre-post intervention measurement.

Settings and conduct

It will be conducted in five colleges affiliated with Damanhour University, Egypt.

Participants/Inclusion and exclusion criteria

Adult women working in the selected colleges for at least one year before initiating the study and enthusiastic to participate in this study

Intervention groups

The investigators will assess the women's educational needs and their past and current immune and health status by completing the pre-test. They will construct the content of the psycho-educational intervention with multimedia-assisted materials. Topics will include relationship between physical and psychological health, definition, importance, and types of physical and psychological immunity, chronic fatigue syndrome and its relationship with psychological health status, and the role of lifestyle activities control and self-efficacy in improving immunity, exploring the symptoms and sources of stress and how to manage by using effective coping techniques: breathing exercises, relaxation techniques, sleep hygiene, social activities, and maintaining self-control over lifestyles. They will receive ten Face-to-Face psychoeducational sessions. During the first month, two sessions/week, while during the second month, one session/two weeks. Digital supporting and motivating messages were delivered. Post-test will be after 3 months.

Main outcome variables

Physical health: participants' perceived physical immune

status, health lifestyles, and personal control status measured by self-reported scales. Psychological health: participants' perceived psychological immunity status, stress, and fatigue levels measured by self-reported measures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051555N5**

Registration date: **2023-12-30, 1402/10/09**

Registration timing: **retrospective**

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

Registration date

2023-12-30, 1402/10/09

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

2023-12-01, 1402/09/10

Expected recruitment end date

2023-12-30, 1402/10/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Psychoeducational Intervention about Immune Health on Perceived Physical and Psychological Health Among Working Women at Damanhour University/Egypt: A Randomized Controlled Trial

Public title
Effect of Psychoeducational Intervention about Immune Health on Perceived Physical and Psychological Health Among Working Women at Damanhour University: A Randomized Controlled Trial

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Adult women working in the selected colleges for at least one year before initiating the study
Exclusion criteria:
Unwillingness to participate in this study

Age
From **20 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **172**

Randomization (investigator's opinion)
Randomized

Randomization description
The target group for this study will be women working in the selected colleges. They were selected using a cluster sampling technique (five colleges). - A purposive sample of five colleges from Damanhour University will be selected based on having the highest number of female workers (Education, nursing, commerce, literature, and agriculture colleges) according to the latest data available from the university statistical center. - A list will be created with the whole eligible female workers. - The lottery system will be deployed by placing all the workers' names in a hat and then randomly selecting our sample without looking. -Seventy percent of the female workers from each college will be recruited using the proportional allocation technique. - Then they will be equally and randomly assigned to the intervention and comparison groups using a simple random method (Lottery method).

Blinding (investigator's opinion)
Single blinded

Blinding description

The investigator who conducted the statistical analysis will not engaged in the overall data collection process. The investigators who will collect the data enter them into the SPSS program using hidden codes from the analyzer. After finishing the data analysis process using predetermined codes, they will contacted to interpret the codes of both groups: intervention group "A" and comparison group "B."

Placebo
Not used

Assignment
Parallel

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

Damanhour

Postal code

22511

Approval date

2023-11-10, 1402/08/19

Ethics committee reference number

10-11-01-2023 EC

Health conditions studied

1

Description of health condition studied

Immunity and psychological health

ICD-10 code

F43.8

ICD-10 code description

Other reactions to severe stress

Primary outcomes

1

Description

perceived physical immune status

Timepoint

Before and 3 months after the intervention

Method of measurement

Immune Status Questionnaire (ISQ)

2

Description

perceived psychological immunity

Timepoint

Before and 3 months after the intervention

Method of measurement

Psychological-Immunity Scale (PIS)

3

Description

Perceived Stress level

Timepoint

Before and 3 months after the intervention

Method of measurement

Perceived Stress Scale (PSS)

4

Description

perceived fatigue level

Timepoint

Before and 3 months after the intervention

Method of measurement

Fatigue Assessment Scale (FAS)

5

Description

perceived level of Health Lifestyle and Personal Control

Timepoint

Before and 3 months after the intervention

Method of measurement

Health Lifestyle and Personal Control Questionnaire (HLPCQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: composed of 88 women who will receive the preplanned intervention. They will receive a total of ten Face-to-Face psychoeducational sessions. The average duration for each session will be 40-50 minutes and will be arranged at the convenience of the working women in each college with adequate meeting space and needed arrangements. During the first month, eight sessions will be delivered, two sessions per week, while during the second month, one session will be conducted every two weeks. In between the sessions, digital supporting, motivating, and follow-up messages will be delivered through the created WhatsApp group on a day-to-day basis. Finally, the follow-up will be accomplished after 3 months (posttest to guarantee that the women maintained the learned activities and information by comparing the posttest results with the pretest results.

Category

Behavior

2

Description

Control group: They will be 88 women who will receive nothing. They initially will complete the pre-test and then the post-tests after 3 months, identically to the intervention group. In the end, they will receive the same educational content and assisted materials to preserve their moral and ethical rights and extend the benefits.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Five colleges affiliated with Damanhour university
Egypt

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

samihareda93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Damanhour University- Faculty of Nursing

Full name of responsible person

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Street address

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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

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 of community health nursing
Latest degree
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Other areas of specialty/work
Public Health/Community Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
After publication 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
Scientific-ranked health journal
What processes are involved for a request to access data/document
None
Comments
None