Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Effects of a Psychoeducational Intervention on Perceived Physical and Psychological Immunity, Stress, and Fatigue Among Working Women: An Open-Label Randomized Controlled Trial

Protocol summary

Study aim

Evaluate the effectiveness of a psychoeducational intervention on self-reported perceived physical and psychological immunity, health-promoting behaviors, personal control, stress, and fatigue among working women.

Design

An open-label, two-arm, parallel-group randomized controlled trial with blinded statistical analysis

Settings and conduct

Three 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

Participants' perceived physical immune status, health lifestyles, and personal control status measured by self-reported scales. Participants' perceived psychological immunity status, stress, and fatigue levels measured by self-reported measures.

General information

Reason for update

This update is requested to align the registry record with the final study protocol and the manuscript for publication. Specifically, we are updating the revised title statement requested by the journal, the target sample size to 160 to reflect our final sample size calculation (accounting for a 20% attrition rate), and the recruitment start date to July 2024 to reflect the actual timeline of the study. In addition, we are updating the ethical approval number and date and correcting the blinding status to 'Open label with blinded statistical analysis' to accurately reflect the trial design described in the manuscript.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051555N5**
Registration date: **2023-12-30, 1402/10/09**
Registration timing: **prospective**

Last update: **2026-09-17, 1405/06/26**
Update count: **1**

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
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samihareda93@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-07-01, 1403/04/11
Expected recruitment end date
2024-07-30, 1403/05/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of a Psychoeducational Intervention on Perceived Physical and Psychological Immunity, Stress, and Fatigue Among Working Women: An Open-Label Randomized Controlled Trial

Public title
Effects of a Psychoeducational Intervention on Perceived Physical and Psychological Immunity, Stress, and Fatigue Among Working Women: An Open-Label Randomized Controlled Trial
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Adult women (20 years or more) working in the selected colleges for at least one year before initiating the study Access to a smartphone with WhatsApp Ability to read and understand Arabic
Exclusion criteria:
Unwillingness to participate in this study Participation in another structured educational or psychological program during the study period Severe psychiatric illness requiring ongoing specialized treatment (as self-reported) Inability to attend the scheduled intervention sessions.
Age
From **20 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
A purposive selection of three colleges will be made based on their high number of female employees. Eligible participants from these colleges will be assigned identification numbers. A computer-generated random number sequence will be used to randomly allocate participants to either the intervention or control group in a 1:1 ratio. Allocation concealment will be ensured by using sealed, opaque, sequentially numbered envelopes prepared by an independent researcher not involved in participant recruitment or data collection. Each envelope will be opened sequentially only after a participant has provided informed consent, completed the baseline assessment, and been enrolled, minimizing the risk of selection bias.
Blinding (investigator's opinion)
Not blinded
Blinding description
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
2023-06-23, 1402/04/02
Ethics committee reference number
101-d-23-6-2023

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 80 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 30-40 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 support, 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 conducted 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 80 women who will receive nothing. They initially will complete the pre-test and then the post-test after 3 months, identically to the intervention group. At the end, they will receive the same educational content and support materials to preserve their moral and ethical rights and extend the benefits.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Three colleges affiliated with Damanhour university Egypt

Full name of responsible person

Samiha Hamdi Sayed Ramadan

Street address

Damanhour, Elbehira, Governorate, Egypt

City

Damahour

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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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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
Ph.D.
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
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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, it will be available for 5 years
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

Contacting the corresponding author

Comments

None