Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Examining the effectiveness of a remote educational intervention based on self-efficacy theory in reducing job burnout among healthcare workers with occupational low back pain

Protocol summary

Study aim

The effectiveness of distance education based on self-efficacy theory on reducing job burnout of employees with occupational back pain

Design

A controlled, single-blind, randomized, phase 3 clinical trial on 102 patients. A table of random numbers will be used for randomization.

Settings and conduct

The study will be conducted in the health center of Chalus city. The participants are the health workers of the centers. In the first phase, a cross-sectional study is conducted to describe the society, in which all people are examined by census. In the next phase, a sample of these people is selected and randomly assigned to two intervention and control groups. Then the electronic educational program will be designed and implemented for the intervention group. The study is one-sided blind, so that the researchers or the outcome assessors are not aware of the allocation of the study groups. The assignment of groups will be done by the coordinator.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Male and female health workers 2. Having non-specific back pain 3. Internet access and online services Exclusion criteria 1. Having any disease that prevents the person from participating in the study 2. Pregnancy 3. Having back pain with any pathological cause 4. Taking medicine to reduce back pain according to doctor's prescription

Intervention groups

The educational intervention will be implemented through social media for 5 days and a duration of one hour for the intervention group. After the end of the intervention, a weekly reminder message is sent to people through social media or SMS. The control group will not receive training.

Main outcome variables

Primary outcome: Job burnout Secondary outcome: Self-efficacy, Low back pain

General information

Reason for update

Acronym

RESET

IRCT registration information

IRCT registration number: **IRCT20230930059559N1**
Registration date: **2024-02-20, 1402/12/01**
Registration timing: **prospective**

Last update: **2024-02-20, 1402/12/01**
Update count: **0**

Registration date

2024-02-20, 1402/12/01

Registrant information

Name

Seyedeh Somayeh Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3565 2373

Email address

so.kazemi@mazumz.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-18, 1402/12/28

Expected recruitment end date

2024-04-16, 1403/01/28

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Examining the effectiveness of a remote educational intervention based on self-efficacy theory in reducing job burnout among healthcare workers with occupational low back pain

Public title
Remote Education based on Self-Efficacy Theory
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Male and female health workers Having non-specific back pain related to work for 12 weeks or more (based on the diagnosis of a physical medicine specialist) Internet access and online services
Exclusion criteria:
Having any disease that prevents the person from participating in the study Pregnancy Having back pain with any pathological cause Taking medicine to reduce back pain according to doctor's prescription
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
In the first phase, a cross-sectional study is conducted to describe the society, in which all people are examined. In the next phase, a sample of these people is selected and assigned to two intervention and control groups by a simple random method. For this purpose, first, the list of employees with personnel code and mobile number is received from the administrative affairs unit through the coordinator. The personnel code of all the selected people is written on the envelope and then placed in an opaque container. Then 88 envelopes are randomly selected from the container by a third party. The first envelope is considered for the intervention group, the second envelope for the control group, and so on until the 88th envelope, one for the intervention group and one for the control group. To ensure the concealment of the random allocation of the envelopes, the coordinator (outside the research team) blindly selects the envelopes from the non-transparent container.
Blinding (investigator's opinion)
Single blinded
Blinding description
Researchers or outcome assessors are unaware of study group allocation. A person as a coordinator will assign the groups randomly based on the personnel code.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Moalem Square, Moalem Ave., Ayatollah Taleghani Ave., Research and Technology Deputy Building
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2023-12-18, 1402/09/27
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1402.102

Health conditions studied

1

Description of health condition studied
Job burnout
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Job burnout
Timepoint
Baseline and 3-months follow up
Method of measurement
Maslach Burnout Inventory

Secondary outcomes

1

Description
Self-efficacy
Timepoint
Baseline and 3-month follow up
Method of measurement
General Self-Efficacy Scale-GSE

2

Description
Low Back Pain
Timepoint
Baseline and 3-month follow up
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Prior to implementing the intervention, an educational program is designed based on self-efficacy theory and pre-tested. For the pre-testing, the educational program will be provided to two health education specialists, two orthopedic specialists, and ten healthcare workers for content and execution assessment. If needed, feedback from individuals and experts will be incorporated into the program, and the final file will be prepared for presentation. The educational content includes a general section, ergonomic principles, back stretching and strengthening exercises, self-efficacy and ways to enhance it, job fatigue and its factors, coping strategies with job fatigue. In the next stage, the educational intervention will be delivered through social media for 5 days, with a duration of one hour per day for the target group. After the intervention ends, a weekly reminder message will be sent to individuals through social media or text messages. The impact of the educational program will be evaluated three months after the intervention.
Category
Behavior

2

Description
Control group: Will not receive training. After the three-month follow-up and at the end of the project, the educational content will be provided to the control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health and treatment network of Chalous
Full name of responsible person
Seyedeh_Somayeh Kazemi
Street address
Imam Khomeini Street, Salamat Street
City
Chalous
Province
Mazandaran
Postal code
4661619373
Phone
+98 11 5222 1462
Email
so.kazemi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram Ebrahimnejad
Street address
Moalem Square, Moalem Ave., Ayatollah Taleghani Ave., Research and Technology Deputy Building
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Postal code
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Phone
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Email
so.kazemi@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
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
Mazandaran University of Medical Sciences
Full name of responsible person
Seyedeh_Somayeh Kazemi
Position

Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Km 18 of Khazarabad Road, Complex of University of Medical Sciences of the Prophet
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Person responsible for scientific inquiries

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Position
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Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Assistant Professor
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Health Promotion
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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
No - There is not 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
All personal data of participants can be shared after de-identification.
When the data will become available and for how long
The access period starts immediately after the results are printed.
To whom data/document is available
Researchers working in academic and scientific institutions and people working in industry.
Under which criteria data/document could be used
In the case of using the results of the study or designing an educational intervention in similar studies.
From where data/document is obtainable
via the corresponding author's email. Seyedeh somayeh Kazemi (somayeh.kazemi7@gmail.com)
What processes are involved for a request to access data/document
Contact the corresponding author by email and send it within ten working days.
Comments