Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Mindful Self-Compassion Therapy on Mental Fatigue, Emotion Regulation, and Self-Critical Rumination in Nurses with Job Burnout

Protocol summary

Study aim
Determining the effectiveness of Mindful Self-Compassion therapy on fatigue, emotional regulation, and self-critical rumination in nurses with burnout

Design
This clinical trial study is a controlled, parallel-group, unblinded, and randomized (sealed envelope) study. It was conducted on 30 nurses working in Aftab and Parsian hospitals who scored at least 66 on the burnout questionnaire. It includes a control group and an intervention group that participate in mindfulness self-compassion therapy sessions, and then the results of the questionnaire are evaluated.

Settings and conduct
30 eligible people are randomly placed in two experimental and control groups (15 people). Both groups will complete a pre-test; the experimental group will receive 8 sessions of mindful self-compassion therapy and 1 session of retreat (165 minutes), while the control group will receive no treatment. Finally, both groups will complete a post-test.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Minimum score of 66 on the Maslach and Jackson Burnout Inventory (1981); Meeting burnout diagnostic criteria according to ICD-11 and structured clinical interview; No concurrent psychiatric disorder (DSM-5); No concurrent acute or chronic physical illness; Not receiving any other psychological treatment simultaneously; Exclusion Criteria: Nurses with less than one year of work experience

Intervention groups
Control group: 15 eligible nurses who complete the research questionnaires as a pre-test but do not receive any treatment. Intervention group: 15 eligible nurses who, after the pre-test, participate in 8 sessions of mindfulness self-compassion therapy based on the Neff and Grammer(2013)protocol and1 session of retreat for165 minutes.

Main outcome variables
Mental Fatigue, Emotional Regulation, Self-Critical Rumination

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250709066425N1**
Registration date: **2025-08-14, 1404/05/23**
Registration timing: **prospective**

Last update: **2025-08-14, 1404/05/23**
Update count: **0**

Registration date
2025-08-14, 1404/05/23

Registrant information

Name
Maedeh Safdari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-12, 1404/06/21

Expected recruitment end date
2025-11-11, 1404/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Mindful Self-Compassion Therapy on Mental Fatigue, Emotion Regulation, and Self-Critical Rumination in Nurses with Job Burnout

Public title

The effectiveness of mindfulness self-compassion therapy on Mental Fatigue, Emotional Regulation, and Self-Critical Rumination

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining a minimum score of 66 to diagnose burnout from the Maslach and Jackson (1981) questionnaire Having the necessary criteria for diagnosing burnout according to (ICD-11) based on a structured interview with a clinical psychologist Absence of diagnosable psychiatric disorders based on diagnostic criteria (DSM-5) and concurrent absence of acute physical illness No concurrent chronic physical illnesses Not receiving any other psychological treatment at the same time

Exclusion criteria:

Nurses with less than one year of work experience

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Experimental and control groups: After selecting the sample, in the next step, people are divided into experimental and control groups using a random method. How to perform randomization: First step: After selecting the voluntary sample, all selected people are placed on a list (numbers from 1 to 30 are assigned to people). Second step: From these people, using a random method using sealed and opaque (numbered) envelopes, people are divided into two experimental groups and a control group. Each person randomly selects an envelope and is divided into the corresponding group.

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

Research Ethics Committees of Islamic Azad University - Varamin-Pishva Branch

Street address

Islamic Azad University, Varamin–Pishva Branch, Naghsh-e Jahan Town, Pishva County, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

7489533817

Approval date

2025-06-10, 1404/03/20

Ethics committee reference number

IR.IAU.VARAMIN.REC.1404.033

Health conditions studied

1

Description of health condition studied

Burn-out

ICD-10 code

Z73.0

ICD-10 code description

Burn-out

Primary outcomes

1

Description

Mental Fatigue

Timepoint

Pre-intervention and Post-intervention

Method of measurement

Mental Fatigue Questionnaire Johnson et al. 2010

2

Description

Emotion Regulation

Timepoint

Pre-intervention and Post-intervention

Method of measurement

Emotion Regulation Questionnaire Cross and John 2003

3

Description

Self-Critical Rumination

Timepoint

Pre-intervention and Post-intervention

Method of measurement

Self-Critical Rumination Questionnaire Smart et al. 2016

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 15 participants who meet the inclusion criteria and score at least 66 on the Maslach and Jackson 1981 Burnout Questionnaire will be randomly assigned to the control group. They will complete the Mental Fatigue, Emotion Regulation, and Self-Critical Rumination Questionnaire; however, no treatment will be administered to this group.

Category

Behavior

2

Description

Intervention group: 15 participants who meet the inclusion criteria and score at least 66 on the Maslach and Jackson 1981 Burnout Questionnaire will be randomly assigned to the intervention group. They will complete the psychological fatigue, emotional regulation, and self-critical rumination questionnaires as a pre-test, then undergo 8 sessions of mindfulness-based self-compassion therapy based on the Neff and Grammer (2013) method, as well as 1 session of seclusion, each session lasting 165 minutes. After completing the sessions, they will complete the psychological fatigue, emotional regulation, and self-critical rumination questionnaires as a post-test.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Aftab Eye Hospital

Full name of responsible person

Mahmoud Jabbarvand

Street address

Aftab Eye Hospital, Opposite Javanmardan Park, After Kan Bridge, Hemmat Expressway (West), Tehran, Iran

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2

Recruitment center

Name of recruitment center

Parsian Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Azad University, South Tehran Branch

Full name of responsible person

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7th Floor, Islamic Azad University, South Tehran Branch Building, Corner of Azarshahr St. and Iranshahr St., Karimkhan Zand St., Tehran, Iran

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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

Azad University, South Tehran Branch

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

Islamic Azad University

Full name of responsible person

Maede Safdari

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for updating data

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and the main outcome results of the research can be shared after de-identification and preserving the privacy of individuals.

When the data will become available and for how long

Data can be made available 4 months after the results are published and after personally identifiable information is removed.

To whom data/document is available

The study data and documentation will be available to researchers and scholars working at reputable academic and scientific institutions.

Under which criteria data/document could be used

Research data and documentation may be used for scientific and research purposes. Users must undertake

to keep non-identifiable data confidential.

From where data/document is obtainable

f you need data, please contact maedesafdari7878@gmail.com

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

After receiving and reviewing the request from the researcher, a response will be provided as soon as possible.

Comments