

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparing the effectiveness of Balint group work and compassion focus group therapy on quality of life, burnout and psychosomatic syndrome in emergency department's nurses, Kowsar hospital, Semnan, 2022

Protocol summary

Study aim

This study aims to compare the effectiveness of two methods of group therapy on quality of life, burnout, and psychosomatic symptoms

Design

In a randomized, controlled clinical trial, phase 3 with pre and post-test, 33 nurses working in the emergency department are randomly assigned to three groups. For randomization, first 39 balls from number 1 to 39 are considered and then randomly divided into three equal groups, including group 1 (Balint), group 2 (compassion therapy) and group 3 (control) and then using a lottery container, the ball of each group was taken out and the intended sequence was recorded.

Settings and conduct

Nurses working in the emergency department in Semnan, will be assigned to intervention or control groups. Questionnaires for quality of life, Maslach burnout and psychosomatic criteria are filled and compared before and after intervention.

Participants/Inclusion and exclusion criteria

Nurses working in the emergency department with at least three years of experience will be enrolled in the study. Nurses who have a second job, with a physical or mental illness, or receive any psychotherapy are excluded.

Intervention groups

In the pre-test stage, quality of life, burnout and DCPR questionnaires are completed. For the first group, weekly Balint sessions are held for 8 weeks. The second group attended 8 weekly sessions of a group-based compassion-focused therapy approach and the control group completed the pre and post-test without any intervention, but waiting according to ethical principles. Finally, after three months, the questionnaires are refilled as post test and the scores are compared by pre-test scores.

Main outcome variables

Quality of life; burnout; psychosomatic symptoms.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N15**

Registration date: **2022-04-30, 1401/02/10**

Registration timing: **prospective**

Last update: **2022-04-30, 1401/02/10**

Update count: **0**

Registration date

2022-04-30, 1401/02/10

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of Balint group work and compassion focus group therapy on quality of life, burnout and psychosomatic syndrome in emergency department's nurses, Kowsar hospital, Semnan, 2022

Public title
Effectiveness of Balint group work and compassion focus group therapy on quality of life, burnout and psychosomatic syndrome in emergency department's nurses

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Job experience at least 3 years Nurses working in the emergency department
Exclusion criteria:
Having a second job Physical or mental illness Receiving any type of psychotherapy

Age
From **25 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **39**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, at first stage, 39 spheres from one to 39 are considered and following that will randomly assigned into three groups, including "1" (Intervention, Balint group) and group 2 (Intervention, compassion focus group) and group 3 (Control group), in this way, the first ball is assigned to the first group (Intervention, Balint group), the second ball to the second group (Intervention, compassion focus group) and the third ball to the third group (Control group), and the process is repeated and the intended sequence will be recorded.

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

Ethics committee of Medical Faculty, Mashhad University of Medical Sciences

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Azadi Square, Easter Entrance of Pardis

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Province

Razavi Khorasan

Postal code

9177948564

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.196

Health conditions studied

1

Description of health condition studied

Quality of life

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Burnout

ICD-10 code

Z73.0

ICD-10 code description

Burn-out

3

Description of health condition studied

Psychosomatic disorders

ICD-10 code

F45

ICD-10 code description

Somatoform disorders

Primary outcomes

1

Description

Quality of life

Timepoint

8 Weeks after intervention

Method of measurement

The World Health Organization's Quality of Life Questionnaire (WHOQOL-Bref)

2

Description

Burn-out

Timepoint

8 Weeks after intervention

Method of measurement

Maslach Burnout Inventory

3

Description

Psychosomatic disorder

Timepoint

8 Weeks after intervention

Method of measurement

Diagnostic Criteria for Psychosomatic Research (DCPR)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the first group, weekly Balint sessions are held for 8 weeks. Each session is 60-90 minutes. The group's leader is researcher and is the only one who can indirectly offer solutions and suggestions. In each session, participants express an emotional traumatic event which they experienced, put them at a crossroads, or have a mental repetition. A topic is selected from the topics and the narrator is asked to describe the situation and feelings at that time and the present moment. The members of the group are completely silent as long as the narrator speaks. After the narrator has spoken, he is asked to leave the group and sit and watch. The leader then asks the group members to talk about bodily feelings or similar experiences without any judgment and to ask the narrator questions for more information, the narrator has the right to answer or not. Finally, the leader concludes and indirectly suggests solutions to the narrator.

Category

Behavior

2

Description

Intervention group: For the second group, weekly sessions of compassion-focused group therapy are held for 8 weeks. The first session includes initial communication, pre-test, general principles of compassion therapy and distinguishing regret from compassion, conceptualizing of self-compassion education. The second session is mindfulness training along with physical examination and breathing exercises, being familiar with brain systems based on compassion, empathy training, training to make people understand that they feel they can handle the situation with a sympathetic attitude. The third session is becoming familiar with the characteristics of

people with compassion, feeling compassion for others, cultivating the feelings of warmth and kindness to oneself, developing the understanding that others also have flaws and problems in the face of self-destructive feelings and shame (cultivating a sense of human commonalities), teaching empathy. Fourth session: encouraging the subjects to self-knowledge and examine their personality according to educational topics; identifying oneself as a non-compassionate or compassionate person; identifying oneself as a person who values self-compassion, empathy and sympathy; developing a compassionate mind; applying exercises to oneself and others; teaching the physiotherapist metaphor, teaching forgiveness. Fifth session: Performing compassionate mind developing exercises; reviewing the previous session; being familiar and applying forgiveness, acceptance without judgment, teaching the metaphor of the flu, and teaching patience; teaching acceptance of issues; accepting the changes ahead; enduring difficult and challenging situations considering the changing nature of life and confronting with different challenges. Sixth session: creating compassionate images practically, teaching styles and methods of expressing compassion (verbal compassion, practical compassion, intermittent compassion, and continuous compassion); applying these methods in daily life and for spouse, children, parents, friends, teachers, and acquaintances; teaching the developing valuable and transcendent emotions. Seventh session: teaching writing compassionate letters for oneself and others, teaching daily registering and recording real situations based on compassion and individual's performance in applying this method in that situation. Eighth session: Training and practicing skills, reviewing and practicing the skills presented in previous sessions for helping subjects to confront different situations in different ways; final summarizing, and providing solutions to maintain and apply this therapeutic method in everyday life.

Category

Behavior

3

Description

Control group: The control group will participate in pre-test and post-test and will not receive any intervention during the research. But, based on ethical issues, control groups are placed on a waiting list for training, and after conducting research and obtaining results, a method that is more effective will be implemented on them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Educational, Research and Treatment Center

Full name of responsible person

Roza Salehian

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Position

Postdoctoral researcher

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Meshkat

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Roza Salehian

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Postdoctoral researcher

Latest degree

Ph.D.

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Psychology

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Person responsible for updating data

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Semnan University of Medical Sciences

Full name of responsible person

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Position

Researchman

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Anonymized data will be offered.

When the data will become available and for how long

After publishing of final report

To whom data/document is available

researcher who working in academic institutions

Under which criteria data/document could be used

Referees and competent people

From where data/document is obtainable

Contact with scientific responsible

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

After verifying the applicant's position

Comments