

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effectiveness of metallization-based therapy and emotion-regulated therapy based on the Gross process model on self-compassion and resilience in Critical Care Unit Nurses

Protocol summary

Study aim

The aim of this study is to evaluate the effectiveness of psychotherapy-based therapy and emotion regulation therapy on resilience and self-compassion variables in nurses of intensive care units of Tehran hospitals.

Design

Quasi-experimental study with two experimental groups and one control group, with pre-test and post-test. 45 nurses in three groups (15 in the psychotherapy-based treatment group, 15 in the emotion-based therapy group and 15 in the control group). The test groups each receive eight separate 90-minute sessions. The control group does not receive any therapeutic intervention as a control. First, they are selected in a targeted manner and then placed in three groups in a random allocation by the online random number generation program.

Settings and conduct

This study lasts for 60 days (8 weeks) from the beginning of July 1401 to the end of September. Sample research of nurses in special wards (Imam Khomeini Hospital, Shariati, Tehran Heart Hospital and Bank Mellii) will be in Tehran. Finally, 45 nurses are divided into three groups.

Participants/Inclusion and exclusion criteria

Bachelor and senior nurse nurse in CCU or ICU / 22-50 years / in Tehran hospitals / consent to participate in research / lack of physical disability or debilitating disease. absence in 2 sessions / non-cooperation during work and not completing questionnaires / having a debilitating illness.

Intervention groups

1- Mentalization therapy intervention taken from Batman and Funagi treatment protocol 2- Therapeutic intervention of emotion regulation training based on emotion regulation therapy protocol of Gross model. 3. The control group does not receive any therapeutic intervention as a control.

Main outcome variables

In this study, training sessions are expected to improve self-compassion and resilience in nurses working in intensive care units.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055024N1**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Soheila Salmanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 7935

Email address

soheilasalmanian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of metallization-based therapy and emotion-regulated therapy based on the Gross process model on self-compassion and resilience in Critical Care Unit Nurses

Public title

Comparison of the effectiveness of mentalization and emotion regulation in the level of self-compassion and resilience of nurses

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Bachelor and senior nurse of the special ward working in the CCU or ICU consent to participate in research and lack of physical disability or incapacitated disease (in the age range of employees, 22-50 years) in Tehran hospitals,

Exclusion criteria:

Exclusion criteria are: the person is absent for 2 sessions or more, does not cooperate during work and does not complete questionnaires has a debilitating illness.

Age

From **22 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with statistical software through the website (<https://www.Randomization.com>) was used online for random allocation. (One of the accepted methods of random sequence generation is the use of web randomization. It is available to researchers for free.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

The present study is a quasi-experimental study with two experimental groups and one control group. The statistical population of nurses working in intensive care units of educational and medical centers affiliated to Tehran University of Medical Sciences in 1401, of which 45 people in three groups are randomly assigned. in this research. Nurses are divided into three groups (15 people in the group based on mentalization therapy, 15

people in the group based on emotion regulation therapy and 15 people in the control group). The test groups each receive eight 90-minute sessions separately. Data collection tools are self-compassion and resilience scale questionnaires.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Islamic Azad University- Falavarjan Branch

Street address

Gol e narges residency complex - apartment no 22A - building no 47 - Albirz alley - Seyed mofidi st (koohsar area) - Darakeh - Tehran - iran

City

Tehran

Province

Tehran

Postal code

1939614484

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.IAU.FALA.REC.1400.057

Health conditions studied**1****Description of health condition studied**

Self-compassion / resilience

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Score of 26-choice self-compassion questionnaire. Self-Compassion Questionnaire: The Self-Compassion Questionnaire includes 26 items and 6 components of self-compassion, self-judgment, human sharing, isolation, awareness or extreme awareness and imitation in a 5-point Likert scale from strongly disagree = 1 to strongly agree = 5 is scored. The six components of self-kindness (5 articles), self-judgment (5 articles), human sharing (4 articles) against isolation (4 articles) and mindfulness (4 articles) against extreme imitation (4 articles) have been formulated. The higher the score the higher the level of compassion shown. Articles 1, 4, 8, 9, 11 and 12 are also scored in reverse. Reliability of Compassion Questionnaire Alpha coefficient for overall score of 0.91 scale

Timepoint

The interventions are held in the form of one-and-a-half-hour weekly sessions for 8 sessions continuously. Compassion measurement sections are performed as pre-test (before intervention) and post-test (after intervention).

Method of measurement

The Compassion Questionnaire consists of 26 items and 6 components in a 5-point Likert scale from strongly disagree = 1 to strongly agree = 5. The higher the score the higher the level of compassion shown. Articles 1, 4, 8, 9, 11 and 12 are also scored in reverse.

2

Description

25-item resilience questionnaire score. Resilience Scale: Connor and Davidson Resilience Questionnaire is 25 items. Examination of descriptive indicators of resilience scores showed that the minimum score is 18 and the maximum score is 94. In this questionnaire, each item is scored on a Likert scale between zero (completely incorrect) and five (completely correct). To get the total score of the questionnaire, the total score of all the questions is added together. This score will range from 0 to 100. The higher the score, the more resilient the respondent will be, and vice versa. This questionnaire has been studied to assess the resilience factors in people at risk of substance abuse and the resilience of Connor and Davidson with Cronbach's alpha has been reported as 0.89.

Timepoint

The interventions are held in the form of one-and-a-half-hour weekly sessions for 8 sessions continuously. Resistance measurement sections are performed as pre-test (before intervention) and post-test (after intervention).

Method of measurement

The Resonance Scale of the Connor & Davidson Resilience Questionnaire is 25. Each item is scored on a Likert scale between zero (completely incorrect) and five (completely correct). To get the total score of the questionnaire, the total score of all the questions is added together. This score will range from 0 to 100. The higher the score, the more resilient the respondent will be, and vice versa.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group of mentalization-based therapy: Mentalization-based therapy is one of the psychological therapies. According to the treatment protocol set by Batman and Funagi, it is performed in 8 sessions of 90 minutes in the form of psychological counseling sessions. Has been described as the ability of a person to understand or explain his or her behavior or

that of others, and is based on the school of object relations and attachment theory. Interpret, infer, imagine, simulate, recall, reflect and predict.

Category

Behavior

2

Description

Intervention group 2: Emotion regulation therapy: Emotion regulation therapy is one of the psychological therapies, which is based on the Gross process model. This protocol is performed in 8 sessions of 90 minutes in the form of psychological counseling sessions. Recognizing emotion and motivating situations, differentiating the performance of different types of emotions, information about different dimensions of emotion and short-term and long-term effects of emotions, identifying the level of emotional vulnerability in the individual, problem-solving strategy training, interpersonal skills (dialogue, expression and conflict resolution) Stopping rumination and worrying, as well as identifying miscalculations and their effects on emotional states, identifying the extent and manner of using the inhibition strategy and examining its emotional consequences (exposure, training to express emotion, modifying behavior by changing environmental enhancers, Emotion relief training, relaxation, and reverse practice) and ultimately the application of skills learned in natural environments outside of the treatment session.

Category

Behavior

3

Description

Control group: The control group did not receive training.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Shariati Hospital, Tehran Heart Hospital and Bank Melli Hospital

Full name of responsible person

Sheida Jabalameli

Street address

Gol e narges residency complex - apartment no 22A - building no 47 - Albirz alley - Seyed mofidi st (koohsar area) - Darakeh - Tehran - iran

City

Tehran

Province

Tehran

Postal code

۱۹۳۹۶۱۴۴۸۴

Phone

+98 21 2264 7935

Email

soheilasalmanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

, Islamic Azad University Of Najafabad

Full name of responsible person

Mehdi Rafiei

Street address

Gol e narges residency complex - apartment no 22A - building no 47 - Albirz alley - Seyed mofidi st (koohsar area) - Darakeh - Tehran - iran

City

Tehran

Province

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1939614484

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Email

soheilasalmanian@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

, Islamic Azad University Of Najafabad

Proportion provided by this source

100

Public or private sector

Private

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

Sheida Jabalameli

Position

Department of Psychology, Najafabad Branch, Islamic Azad University, Najafabad, Iran

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Gol e narges residency complex - apartment no 22A -

building no 47 - Albirz alley - Seyed mofidi st (koohsar area) - Darakeh - Tehran - iran

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Phone

+98 21 2264 7935

Email

soheilasalmanian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sheida Jabalameli

Position

Assistant Professor, Department of Psychology, Najafabad Branch, Islamic Azad University, Najafabad,

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Phone

+98 21 2264 7935

Email

soheilasalmanian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sheida Jabalameli

Position

Assistant Professor, Department of Psychology, Najafabad Branch, Islamic Azad University, Najafabad,

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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