Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Impact of Balint Group on Mental Health of Healthcare Workers in Covid-19 Pandemic

Protocol summary

Study aim

Determining the extent of mental distress,avoidance,unwanted thoughts,hyperactivity,depression and anxiety in health workers while serving in the Covid-19crisis

Design

The research is a before and after quasi-experimental.After receiving the code of ethics, a virtual invitation message will be sent to people. Individuals enter the project after the initial interview,then the purpose is explained,written consent,and then research and demographic questionnaires are answered. They will then join the intervention groups.At the end of the course, individuals will answer the questionnaires again and the results will be analyzed by dependent t test.

Settings and conduct

intervention will be via Skype with 9 members, a leader and an assistant leader in 75 minutes per session ,three times a week. The members of the group will be between 8-12 people. If members request an individual meeting, it will be provided to them by the leader or assistant leader. Participants are from all groups that serve patients with or suspected of having coronary heart disease or caregivers of suspected and suspected individuals.

Participants/Inclusion and exclusion criteria

Working in health centers,Having Covid 19 or encountering Covid-19 patients,having diploma or higher,age between 20-50,Having the consent to participate in research, Not using psychiatric drugs and psychological therapies during the study not suffering from other acute or chronic disorders, problem in hearing or speaking

Intervention groups

This intervention will be performed as Balint group on health care workers, including physicians,nurses,midwives,interns,residents and crew. under a safe psychoanalytic environment, members narrate and process cases under guidance of a psychoanalyst leader,rethink their work through a group discussion.

Main outcome variables

Mental helplessness, avoidance, Unwanted thoughts, Anxiety, Depression, hyper-arousal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180502039508N2**
Registration date: **2021-09-08, 1400/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-08, 1400/06/17**
Update count: **0**

Registration date

2021-09-08, 1400/06/17

Registrant information

Name

Maedeh Parvizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86701

Email address

parvizimaedeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Balint Group on Mental Health of Healthcare Workers in Covid-19 Pandemic

Public title

The effect of balint group on psychological symptoms of health care workers during corona

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Working in health centers Having Covid 19 or encountering Covid-19 patients having diploma or higher age between 20-50 Having the consent to participate in research

Exclusion criteria:

using psychiatric drugs and psychological therapies during the study suffering from other acute or chronic disorders problem in hearing or speaking

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **55**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences and Health Services, Hafte Tir Square, Shahroud, Iran.

City

shahroud

Province

Semnan

Postal code

3614773955

Approval date

2020-12-23, 1399/10/03

Ethics committee reference number

IR.SHMU.REC.1399.145

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2

Description of health condition studied

Major depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Anxiety score in GAD-7 questionnaire

Timepoint

Before and after the intervention

Method of measurement

GAD-7 questionnaire

2

Description

Patient Health Questionnaire 9-Scale score

Timepoint

Before and after the intervention

Method of measurement

Patient Health Questionnaire 9-Scale

3

Description

Impact of Event Scale - Revised score

Timepoint

Before and after the intervention

Method of measurement

Impact of Event Scale - Revised questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Healthcare Workers
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahroud University of Medical Sciences
Full name of responsible person
Maedeh Parvizi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Hassan Emamian
Street address
Shahroud, Seventh Tir Square, Shahroud University of Medical Sciences and Health Services, Vice Chancellor for Research and Technology
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Email
vcr@shmu.ac.ir
Web page address
https://shmu.ac.ir/research/en
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Maedeh Parvizi
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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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

Yes - There is 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 the data is potentially shareable after unidentifying individuals.

When the data will become available and for how long

from 2022

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of published documents for scientific and therapeutic purposes is permitted after contacting the responsible author.

From where data/document is obtainable

parvizimaedeh@gmail.com

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

After receiving the email and reviewing the application, the information will be provided to the applicant within a week.

Comments