# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 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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Shahroud University of Medical Sciences and Health Services, Hafte Tir Square, Shahroud, Iran.
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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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**Phone**
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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 scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

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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**