

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparing the effectiveness of online Balint group and pharmacotherapy with Selective Serotonin Reuptake Inhibitors in Coronavirus anxiety in healthcare workers.

Protocol summary

Study aim

Comparing the effectiveness of online Balint group and pharmacotherapy with Selective Serotonin Reuptake Inhibitors in Coronavirus anxiety in healthcare workers

Design

This non-inferiority trial has two randomized not-blinded parallel intervention groups (target intervention Vs standard treatment). Randomization will be done in alternate allocation method according to the order of enrollment. The calculated study population is 30 (fifteen in each arm). Data will be analyzed per-protocol.

Settings and conduct

The research team will be centered in 5th Azar Hospital, Gorgan, Iran. Visits will be done by two psychiatrists through phone calls. Balint groups will be managed by a certified leader and co-leader in the Skype application.

Participants/Inclusion and exclusion criteria

All the healthcare workers in hospitals aging 18 to 59 who have been in contact with COVID-19 patients and suffering from Coronavirus anxiety. These subjects should be able to participate in online Balint sessions or use SSRIs according to the study protocol. They should not have a history of previous psychiatric illness.

Intervention groups

After being visited by two psychiatrists through phone-calls and recruiting, subjects will fill in the study questionnaires including demographics, Corona Disease Anxiety Score, and Connor-Davidson Resilience Score. Then they will be randomly allocated to the intervention groups including Balint or pharmacotherapy. Balint groups will be held online in Skype application for 8 to 10 sixty-minute sessions and the pharmacotherapy group will receive oral Sertraline tablets (starting with 50 mg/day and increased if needed according to the patient's symptoms and tolerance). Following the 4-week intervention period, subjects will again answer the questionnaires.

Main outcome variables

Corona Disease Anxiety Score (CDAS) and Connor-Davidson and Resilience Score (CD-RISC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047023N1**

Registration date: **2021-01-26, 1399/11/07**

Registration timing: **retrospective**

Last update: **2021-01-26, 1399/11/07**

Update count: **0**

Registration date

2021-01-26, 1399/11/07

Registrant information

Name

Hossein Mohaddes Ardabili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3700 2202

Email address

myhhoo@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

2020-06-09, 1399/03/20

Actual recruitment end date

2020-08-20, 1399/05/30

Trial completion date

2020-09-18, 1399/06/28

Scientific title

Comparing the effectiveness of online Balint group and pharmacotherapy with Selective Serotonin Reuptake Inhibitors in Coronavirus anxiety in healthcare workers.

Public title

Comparing the effectiveness of online Balint group and SSRIs in Coronavirus anxiety

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hospital Healthcare workers who have been in contact with COVID-19 patients No history of previous psychiatric illness Ability to use Skype application and participate in online sessions Written consent for participating in the study Diagnosis of illness anxiety after being evaluated by two psychiatrists

Exclusion criteria:

No further interest in continuing the study More than 3 absent Balint sessions No medication compliance

AgeFrom **18 years** old to **59 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **40**Actual sample size reached: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Subjects will be allocated according to the order of enrollment. The first patient to fulfill the inclusion criteria will be assigned to the Balint group, the second patient to the pharmacotherapy group, and the allocation will be continued in this way.

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 Golestan University of Medical Sciences

Street address

Ethics Committee office, Deputy of research and technology of Golestan University of Medical Sciences, Central Library building, beginning of Shast-Kala road

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.GOUMS.REC.1399.020

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

Illness anxiety disorder

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes**1****Description**

score in Corona Disease Anxiety Scale (CDAS)

Timepoint

At the beginning of study (before intervention) and after 4 weeks

Method of measurement

Corona Disease Anxiety Scale (CDAS)

Secondary outcomes**1****Description**

Score in Connor-Davidson resilience scale

Timepoint

At the beginning of study (before intervention) and after 4 weeks

Method of measurement

Connor-Davidson resilience scale

Intervention groups

1

Description

First Intervention group: Participating in 5 to 10 session of Online Balint Group

Category

Behavior

2

Description

Second Intervention group: Standard pharmacological treatment with a drug from Selective Serotonin Reuptake Inhibitors (SSRIs) started from low-dose and increased if needed during follow-up

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5th Azar Hospital

Full name of responsible person

Najmeh Shahini

Street address

5th Azar Hospital, 5th Azar St.

City

Gorgan

Province

Golestan

Postal code

4917763681

Phone

+98 17 3115 3365

Email

Najmeh.shahini@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Honarvar

Street address

Deputy of research and technology of Golestan University of Medical Sciences, Central Library building, beginning of Shast-Kala road

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 1654

Fax

Email

mrhonarvar@goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Golestan 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

Golestan University of Medical Sciences

Full name of responsible person

Najmeh Shahini

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

5th Azar Hospital, 5th Azar St.

City

Gorgan

Province

Golestan

Postal code

4917763681

Phone

+98 17 3115 3365

Email

Najmeh.shahini@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Najmeh Shahini

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

5th Azar Hospital, 5th Azar St.

City

Gorgan

Province

Golestan

Postal code

4917763681

Phone

+98 17 3115 3365

Email

Najmeh.shahini@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Mohaddes Ardabili

Position

Psychiatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Ibne Sina psychiatric hospital, Horre Ameli street,
BouAli square

City

Mashhad

Province

Razavi Khorasan

Postal code

9195983134

Phone

+98 51 3700 2202

Fax

Email

Myhhoo@gmail.com

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

After issuing appropriate permission from Golestan University of Medical Sciences all recorded data can be shared anonymously.

When the data will become available and for how long

6 months after publishing the results of the study in research journals.

To whom data/document is available

All the researchers and scientific institutes can access our data.

Under which criteria data/document could be used

All the researchers and scientific institutes should mention why and how they want to use the data in their request. Moreover, distributing further results needs new permission from the corresponding person.

From where data/document is obtainable

Written formal requests should be emailed to Dr. Najmeh Shahini using the below email address:
Najmeh.shahini@gmail.com 5th Azar Hospital, 5th Azar St., Gorgan, Iran Phone Number: 00981731153365

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

After receiving formal data access requests, it should be evaluated and approved by the research team and deputy of research at Golestan University of Medical Sciences.

Comments