

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Screening of psychiatric disorders in patients with Covid 19 and Psychological intervention in mental health of the patients in comparison with control group in Imam Hossein hospital

Protocol summary

Study aim

To investigate the effectiveness of telephone-delivered treatment for psychological disorders of COVID-19 survivors in Tehran, the capital of Iran.

Design

Non-randomized- non blinded clinical trial of telephone-delivered psychological intervention, with control group, (parallel group on 91 patients who are diagnosed as having psychological issues after primary screening)

Settings and conduct

The refereed patients to Imam Hossein hospital who are diagnosed with psychological problems are divided in two groups. Before and after the intervention the outcome variables are assessed.

Participants/Inclusion and exclusion criteria

Screening part: COVID-19 survivors who will refer to a Imam Hossein hospital in Tehran. Intervention part: Those who are diagnosed as having psychological issues will participate in this part. Those who want to receive psychological intervention will belong to case group and those who doesn't will be in control group.

Intervention groups

In intervention group telephone base intervention perform for 2 to 5 sessions(one to two sessions per week) and if the patient need more intervention refers to out patients clinic. In control group: the patients don't receive telephone base interventions but they will refer to outpatient clinic if they want.

Main outcome variables

We are measuring the mental health pre and post intervention with using the GHQ questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210930052638N1**

Registration date: **2021-10-12, 1400/07/20**

Registration timing: **prospective**

Last update: **2021-10-12, 1400/07/20**

Update count: **0**

Registration date

2021-10-12, 1400/07/20

Registrant information

Name

Roya Roya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7755 1023

Email address

roya832003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Screening of psychiatric disorders in patients with Covid 19 and Psychological intervention in mental health of the patients in comparison with control group in Imam

Public title

The effectiveness of telephone based psychological services to COVID-19 survivors in Tehran, Iran

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

In screening part: COVID-19 survivors who were referred to a referral teaching hospital In intervention part: case group : patients suffering from psychological issues and want to receive psychological intervention and in control group patients suffering from psychological issues and don't want to receive psychological intervention

Exclusion criteria:

Those who refuses mental health screening

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **91**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Shahid Beheshti University of Medical Sciences

Street address

Madani Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2020-06-28, 1399/04/08

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Depression, anxiety, post traumatic stress disorder

ICD-10 code

Z64

ICD-10 code description

Problems related to certain psychosocial circumstances

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

The mental health scored assessed by GHQ

Timepoint

Before intervention and at the end of intervention

Method of measurement

Those with psychological problems (in both case and control groups) the General Health Questionnaire(GHQ) fill out and compares the score changes

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

The score of satisfaction from telephone follow up measuring by a researcher design questionnaire

Timepoint

At the end of the study

Method of measurement

At the end of the study the satisfaction from telephone follow up measure by using researcher design a Likert questionnaire

Intervention groups**1****Description**

Intervention group: They receive telephone psychological intervention such as (Behavioral activation, problem solving, thought control, stress management and other related techniques) one or two times per week for 20 to 30 minutes. Psychiatric services are available to all patients who have a psychiatric disorder

Category

N/A

2**Description**

Control group: The patients who have the psychological problem and don't want to participate in telephone psychological intervention. They receive a brief psychoeducation and they can use psychiatric services if

they want. They are told that their mental health status will be assessed at the end of the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Medical center, Tehran, Iran

Full name of responsible person

Roya Vaziri Harami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roya Vaziri Harami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Latest degree

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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

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

In case of IPD briefly describe what specific participant data sets are to be shared (e.g., all collected deidentified IPD, IPD collected for the primary outcome measure only, etc)

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

This only available for people working in academic institutions

Under which criteria data/document could be used

To use for scientific and therapeutic purposes

From where data/document is obtainable

Imam Hossein Medical center, Tehran ,Iran- Rooya Vaziri-roya832003@yahoo.com

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

All the applicants can mail through the hospital address or email address with subject to the aim of their request will access to the data or documents within three days

Comments