

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of family-centered empowerment model on stress, anxiety and family satisfaction in patients with Covid-19

Protocol summary

Study aim

The effect of family-centered empowerment model on stress, anxiety and family satisfaction in patients with Covid-19

Design

Clinical trial with control group, with parallel groups, Two blind, randomized, with a sample size of 30

Settings and conduct

209/5000 In the intervention group, a family-based empowerment model that includes 4 empowerment training sessions (2 45-minute sessions per week) will be held. This model includes four steps of perceived threat, problem solving, educational participation, and evaluation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having coronavirus. Non-Inclusion conditions: 1-Not willing to continue research.

Intervention groups

This study will be performed on the families of patients with Covid-19 disease referred to the 9th Di Torbat Heydariyeh Hospital. Two complementary groups, then in the intervention group, family-based empowerment model, which will include 4 empowerment training sessions (2 45-minute sessions per week). This model includes four steps of perceived threat, problem solving, educational participation and evaluation. The focus will be on college classes.

Main outcome variables

stress

General information

Reason for update

The end date of sampling was recorded.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180429039463N2**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-04, 1400/02/14**

Update count: **1**

Registration date

2020-04-10, 1399/01/22

Registrant information

Name

mohammad namazinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5222 5280

Email address

namazinm951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-04-21, 1399/02/02

Actual recruitment start date

2020-04-01, 1399/01/13

Actual recruitment end date

2020-07-25, 1399/05/04

Trial completion date

2020-07-31, 1399/05/10

Scientific title

The effect of family-centered empowerment model on stress, anxiety and family satisfaction in patients with Covid-19

Public title

The Impact of Family-Based Empowerment Model on Stress, Anxiety and Satisfaction

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
39/5000The patient has coronavirus.
Exclusion criteria:
Do not want to participate in research

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **70**

Randomization (investigator's opinion)
N/A

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

دانشگاه های علوم پزشکی ایران

Street address

Torbat Heydariyeh University of Medical Sciences
Building., Razi St., Ferdaws St.

City

Torbat Heydarieh

Province

Razavi Khorasan

Postal code

95196-33787

Approval date

2020-03-17, 1398/12/27

Ethics committee reference number

IR.THUMS.REC.1398.060

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

stress

Timepoint

Stress will be measured once before the first intervention and once after the last intervention session.

Method of measurement

Doss Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Family-Based Empowerment Model, which will include four empowerment training sessions (2 45-minute sessions per week).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nohome day Hospital, Torbat Heydarieh University of Medical Sciences

Full name of responsible person

محمد نمازی نیا

Street address

Torbat Heydariyeh University of Medical Sciences
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Email

mnamazi99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Dr Hasann Azhdari Zarmehri

Street address

Torbat Heydariyeh University of Medical Sciences

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azhdarizarmehri1@thums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Torbate-Heidaria 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

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

mohammad namazi nia

Position

Member of the faculty of Torbat Heydariyeh University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Member of the faculty of Torbat Heydariyeh University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

mohammad namazi nia

Position

Member of the faculty of Torbat Heydariyeh University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Nursery

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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

Information about the main consequence after being unidentified will be shared

When the data will become available and for how long

Start the access period 6 months after Publish results

To whom data/document is available

Everyone

Under which criteria data/document could be used

The results obtained in this study can be used without restriction by researchers.

From where data/document is obtainable

Referring to Torbat Heidarieh Nursing and Midwifery Faculty

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

After sending the email to the person responsible for the response process begins.

Comments