Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Quaid 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., Ferdawsi 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 Building., Razi St., Ferdawsi St.

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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 Heydarieh 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
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Full name of responsible person
mohammad namazi nia

Position
Member of the faculty of Torbat Heydarieh University of Medical Sciences

Latest degree
Subspecialist

Other areas of specialty/work
Nursery

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Email
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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