

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The impact of education on anxiety and social adjustment of parents of children with Corona

Protocol summary

Study aim

The impact of education on anxiety and social adjustment of parents of children with Corona

Design

The clinical trial with the control group will be a simple double-blind randomization

Settings and conduct

Hazrat Ali Asghar Hospital

Participants/Inclusion and exclusion criteria

Entry requirements Children aged 4 to 18 years
Knowledge of the type of child disease No stressful event other than the child's illness during the past year
Absence from attending similar training sessions and classes Phone access No entry conditions Lack of access to the phone

Intervention groups

In the training intervention group, 4 sessions per week, one 45-minute session will be done by phone and online. Items such as how the disease occurs, the factors that cause its symptoms and complications, treatment of the disease, the need for treatment of the disease, lifestyle changes, the need for preventive activities such as masking, use of alcohol spray, quarantine, Avoid touching contaminated surfaces and avoid getting lost with friends and relatives and follow proper nutrition tips. Advise to manage calm and stress caused by corona. Be receptive and listen. Support the child. Provide a suitable environment during quarantine. Ask for help from support centers if needed. Have a flexible but regular daily schedule to teach your child to keep a safe distance. Have family coordination at home

Main outcome variables

Anxiety and social adjustment

General information

Reason for update

Acronym

کرونا

IRCT registration information

IRCT registration number: **IRCT20141216020344N7**

Registration date: **2021-04-29, 1400/02/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-29, 1400/02/09**

Update count: **0**

Registration date

2021-04-29, 1400/02/09

Registrant information

Name

Hamidreza Khoshnezhad Ebrahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7787 2189

Email address

khoshnezhad.hr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-22, 1400/02/02

Expected recruitment end date

2021-08-28, 1400/06/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of education on anxiety and social adjustment of parents of children with Corona

Public title

The impact of education on anxiety and social adjustment of parents of children with Corona

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

No stressful event other than the child's illness during the past year
Absence from attending similar training sessions and classes
Phone access
Knowledge of the type of child disease
Lack of care for another patient at home

Exclusion criteria:

Lack of parental cooperation

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.IUMS.REC.1400.005

Health conditions studied

1

Description of health condition studied

coronavirus

ICD-10 code

J12.82

ICD-10 code description

Pneumonia due to coronavirus disease

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Beck Anxiety Questionnaire

2

Description

Social adjustment

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Bell Social Adjustment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In the intervention group, training 4 sessions per week, a 45-minute session will be done by phone and online. Items such as how the disease occurs, the factors that cause its symptoms and complications, treatment of the disease, the need for treatment of the disease, lifestyle changes, the need for preventive activities such as masking, use of alcohol spray, quarantine, Avoiding touching contaminated surfaces and avoiding losing with friends and relatives and following proper nutrition tips, and social support in the emotional dimension means giving the participant ample opportunity to worry tools and actively listen to his / her words and communication. It will be right with his family.

Category

N/A

2

Description

Control group: Control group: In the control group, only routine ward care is performed
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital in Tehran

Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Street address

Tehran, Modares Highway, after Mirdamad Bridge,
Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar
Children's Hospital

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2222 2045

Email

khoshnezhad.hr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran
University of Medical Sciences

City

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Phone

+98 21 86701

Email

admins@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric Emergency Medicine

Street address

Tehran, Modares Highway, after Mirdamad Bridge,
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Position

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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

Data is encrypted in order to make individuals'
identifiable and confidential

When the data will become available and for how long

From the end of sampling to 6 months after the
publication of the article

To whom data/document is available

University Ethics Committee, Project Arbitration
Committee, Article Arbitration Committee and other
researchers

Under which criteria data/document could be used

Perform systematic review or meta-analysis by
mentioning the document

From where data/document is obtainable

Dr. Hamidreza Khoshnezhad Ebrahimi

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

After submitting the application via academic email, we
will provide the information files to the individuals within
a maximum of one week.

Comments