Clinical Trial Protocol
Iranian Registry of Clinical Trials
08 Dec 2021

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 کرونایک

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
139914040

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

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
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
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1919816766
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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
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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
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, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital
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Person responsible for scientific inquiries

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Full name of responsible person
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Latest degree
Specialist
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Person responsible for updating data

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Specialist
Other areas of specialty/work
Pediatric Emergency Medicine
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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