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
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**
- ۵۳۵۴۱۶۹۴۴

**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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Province
Tehran
Postal code
1919816766
Phone
+98 21 86701
Email
adminsite@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, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital
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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
Professor
Latest degree
Specialist
Other areas of specialty/work
Pediatric Emergency Medicine
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Person responsible for updating data

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Full name of responsible person
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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
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