Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of acceptance and commitment therapy on concerns about infection, health, anxiety, psychological well being and quality of life in the family of patients with COVID-19.

Protocol summary

Study aim

The effect of acceptance and commitment therapy on concerns about infection, health, anxiety, psychological well being and quality of life in the family of patients with COVID-19

Design

A clinical trial with a control group, without blinding, randomized to phase 3 on 80 patients, with the function of Excel software for randomization.

Settings and conduct

People who have someone infected with Corona in their family are referred to the relevant expert in Isfahan health centers electronically or by phone. These individuals will be selected to participate in the study if they had a score higher than 40 in the Corona Anxiety Inventory. After obtaining informed consent, participants are divided into two groups , intervention and control. The control group will receive routine training.In the intervention group, in addition to regular training, acceptance and commitment therapy is also performed by a psychotherapist for two months at the health center of Golpayegan . Some of the tutorials will be provided through WhatsApp. All participants will complete the study questionnaires before the intervention and 2 months later.

Participants/Inclusion and exclusion criteria

The entry criteria include consent to participate in the study, the presence of a person with the disease of COVID-19 in the main family and the absence of serious psychiatric , medical illness and the absence of the disease of Covid-19.

Intervention groups

The intervention group receives routine training, necessary follow-ups, and training in the field of infection prevention methods and patient care, and in addition to routine training, acceptance and commitment therapy is also performed by a psychotherapist for two months.

Main outcome variables

concerns about infection; Health anxiety; Psychological well-being; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040974N5**
Registration date: **2022-08-04, 1401/05/13**
Registration timing: **prospective**

Last update: **2022-08-04, 1401/05/13**
Update count: **0**

Registration date

2022-08-04, 1401/05/13

Registrant information

Name

Fatemeh Zargar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2475

Email address

f.zargar@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of acceptance and commitment therapy on concerns about infection, health, anxiety, psychological well being and quality of life in the family of patients with COVID-19.

Public title
The effect of acceptance and commitment therapy on relatives of patients with COVID-19
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent for participation The presence of a person with COVID-19 in the main family No serious psychiatric illness based on a clinical psychiatric interview Absence of severe and chronic medical diseases
Exclusion criteria:
Having COVID-19 disease Having a serious medical illness
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
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
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib Street, Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
8177746674
Approval date
2020-09-01, 1399/06/11
Ethics committee reference number
IR.MUI.MED.REC.1399.441

Health conditions studied

1

Description of health condition studied
COVID-19 disease
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Score of health anxiety
Timepoint
Before the intervention and two months after the start of acceptance and commitment therapy
Method of measurement
Health Anxiety Scale

2

Description
Score of Corona Disease Anxiety
Timepoint
Before the intervention and two months after the start of acceptance and commitment therapy
Method of measurement
Corona Disease Anxiety Scale

3

Description
Score of quality of life
Timepoint
Before the intervention and two months after the start of acceptance and commitment therapy
Method of measurement
Quality of life scale (12 items)

4

Description
Score of psychological well-being
Timepoint
Before the intervention and two months after the start of acceptance and commitment therapy

Method of measurement
Ryff Psychological Well-being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
”Intervention group”:The 8 session’s of acceptance and committment therapy included:1- Training to use mindfulness in daily life, focusing on what is in your control and confirming your thoughts and feelings 2- body scans, sitting meditation, committed action, establishment of acceptance and willingness3- identifying resources such as disinfecting and distancing
Category
Lifestyle

2

Description
"Control group:" This group does not receive medical intervention, but the necessary follow-ups and training regarding Covid-19 and methods of prevention and medical treatment are provided over the telephone.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Golpayegan city health center
Full name of responsible person
Shokooh Shahidi
Street address
Golpayegan city health center, Golpayegan
City
Golpayegan
Province
Isfehan
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8177746674
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+98 31 5742 3033
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sh.clinicalpsy@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences
Street address
Hezar Jarib street, Isfahan University of Medical Sciences
City
Isfahan
Province
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Postal code
7346181746
Phone
+98 31 3668 0048
Email
researchmanager@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Shokooh Shahidi
Position
Health center employee
Latest degree
Master
Other areas of specialty/work
Family Health
Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Fatemeh Zargar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

Full name of responsible person
Shokooh Shahidi

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Health center employee

Latest degree
Master

Other areas of specialty/work
Family Health

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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
All data related to the questionnaires can be shared after unidentified individuals.

When the data will become available and for how long
Access period starts 2 months after the results are published

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Researchers and clinicians working in the private and public sectors will also have access to the data, subject to the approval of the center's top official.

From where data/document is obtainable
Golpayegan Health Center, Golpayegan, Shokooh Shahidi

What processes are involved for a request to access data/document
Within 10 days after submitting the request of the head of the center to the Vice Chancellor for Research and Technology of Isfahan University of Medical Sciences and approval of the said center

Comments