

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Isfahan

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 sessions of acceptance and commitment 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 willingness 3- 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

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8177746674

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+98 31 5742 3033

Email

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

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Hezar Jarib street, Isfahan University of Medical Sciences

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7346181746

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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

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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

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

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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