

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

Golpayegan

**Province**

Isfahan

**Postal code**

8177746674

**Phone**

+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

**Street address**

Hezar Jarib street, Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**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**

Hezar Jarib Street, Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3668 0048

**Email**

sh.clinicalpsy@gmail.com

## 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

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib Street.,

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3668 0048

**Email**

fatemehzargar@gmail.com

## 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

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3668 0048

**Email**

sh.clinicalpsy@gmail.com

## 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**