Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of educational-treatment package based on psychological flexibility in burnout, quality of working life, work-family conflict and mental health of the care team working in medical centers for patients with COVID-19

Protocol summary

Study aim
Preparation of educational-therapeutic package based on psychological flexibility (based on acceptance) and evaluation of its effect on quality of work life, burnout and work-family conflict and mental health for the care team working in medical centers for patients with COVID-19

Design
A clinical trial with a control group, with one-way blind groups, randomized

Settings and conduct
This intervention is performed on the staff working in the corona care unit in a hospital unit on the intervention group.کار

Participants/Inclusion and exclusion criteria
Inclusion criteria 1- Working in medical centers for patients with COVID-19 2- Age between 23 and maximum 65 years; 3- Lack of physical and mental illness Output Criteria: 1- Dissatisfaction with continuing research. 2- The occurrence of any serious accident or complication that prevents the continuation of the study.

Intervention groups
Implement an educational-therapeutic package based on psychological flexibility on the intervention group And the control group will not intervene.

Main outcome variables
Quality of working life, burnout, work-family conflict, mental health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200413047052N1**
Registration date: **2020-05-07, 1399/02/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-07, 1399/02/18**
Update count: **0**

Registration date
2020-05-07, 1399/02/18

Registrant information

Name
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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-04, 1399/02/15

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of educational-treatment package based on psychological flexibility in burnout, quality of working life, work-family conflict and mental health of the care team working in medical centers for patients

with COVID-19

Public title
The effectiveness of educational-treatment package based on psychological flexibility in burnout, quality of working life, work-family conflict and mental health
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Working in medical centers for patients with COVID-19
Age between 23 and maximum 65 years
Exclusion criteria:
Dissatisfaction with continuing research. The occurrence of any serious accident or complication that prevents the study from continuing Having a specific physical and psychological illness
Age
From **23 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, to allocate members to control and intervention groups, first a cluster of four sections of a section was selected and in the selected section based on simple randomization using statistical software, randomization to allocate members to the intervention group and Control is done.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, people such as the clinical caregiver, the outcome assessor, the data analyst, the data safety and monitoring committee, and the researcher are unaware of which group the participant is in. Also, the selected participant in an intervention group learns about the implementation and duration of the intervention, but does not know the type of intervention.
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 St., Isfahan University of Medical Sciences and Health Services, School of Medicine
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8174673461
Approval date
2020-04-08, 1399/01/20
Ethics committee reference number
IR.MUI.MED.REC.1399.026

Health conditions studied

1

Description of health condition studied
the care team working in COVID-19 patients
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
Quality of work life score in Walton's questionnaire
Timepoint
Before and after the implementation of the educational-therapeutic package
Method of measurement
Walton's Work Quality of Life Questionnaire

2

Description
Mental Health Score in the General Health Questionnaire (GHQ)
Timepoint
Before and after the implementation of the educational-therapeutic package
Method of measurement
General Health Questionnaire (GHQ)

3

Description
Work-Family Conflict Score and Family-Work Conflict in the Work-Family Conflict Questionnaire
Timepoint

Before and after the implementation of the educational-therapeutic package

Method of measurement

the Work-Family Conflict Questionnaire

4

Description

The burnout score on the burnout questionnaire is gold

Timepoint

Before and after the implementation of the educational-therapeutic package

Method of measurement

Goldard's burnout questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention team will receive a training package based on psychologically developed flexibility for 8 two-hour sessions using educational facilities such as blackboards.This educational-therapeutic package is based on a qualitative research of the theoretical theory and has been prepared after interviewing and observing the treatment staff in the special sections of Corona and Codex based on psychological flexibility.

Category

Treatment - Other

2

Description

Control group: They will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid, Amin, Isa Ibn Maryam, Omid, Al-Zahra

Full name of responsible person

Amrolla Ebrahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Amrullah Ebrahimi

Position

Associate Professor

Latest degree
Specialist
Other areas of specialty/work
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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
Information on the main consequence
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Everyone
Under which criteria data/document could be used
Use for research and applied fields
From where data/document is obtainable
Send a request to seyedmhm74@gmail.com
What processes are involved for a request to access data/document
One week
Comments