

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Compiling of metacognitive analytical therapy protocol using intervention mapping and its effect on ego strength and reducing anxiety and depression of nurses involved with covid -19

Protocol summary

Study aim

The aim of this study was to develop an analytical metacognitive therapy protocol using intervention mapping and its effect on my ability and reduce anxiety and depression of nurses involved with Covid-19 patients.

Design

In the first stage, the intervention protocol is developed using cartography, in the second stage, the impact of the metacognitive analytical treatment protocol components is measured as an intervention for the nurse with the diagnosis of mild, moderate and severe depression.

Settings and conduct

The intervention is done for each person individually at Ali Bin Abi Talib Hospital in Zahedan.

Participants/Inclusion and exclusion criteria

The participant must have at least a nursing degree and at least one year of work experience, be at least 23 and at most 30 years old, not have a severe physical or psychological illness, not receive psychological services from another person, and be female.

Intervention groups

Three people will be selected with a diagnosis of mild, moderate and severe anxiety and depression, and the research objectives will be discussed in detail and the baseline test will be performed until the scores of the dependent variables are stable. Then analytical metacognitive therapy intervention is performed. During the intervention, a test will be performed for each participant after each treatment session (before the start of the next session). After the intervention, the last test will be taken with a maximum interval of one week.

Main outcome variables

Increase ego strength-Reduce anxiety-Reduce depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180705040356N1**

Registration date: **2023-04-19, 1402/01/30**

Registration timing: **prospective**

Last update: **2023-04-19, 1402/01/30**

Update count: **0**

Registration date

2023-04-19, 1402/01/30

Registrant information

Name

Rahim Shahbakhsh

Name of organization / entity

Tehran University of science and culture

Country

Iran (Islamic Republic of)

Phone

+98 21 4423 8171

Email address

rahimshabakhsh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Compiling of metacognitive analytical therapy protocol using intervention mapping and its effect on ego strength and reducing anxiety and depression of nurses involved with covid -19

Public title
Compiling of metacognitive analytical therapy protocol using intervention mapping and its effect on ego strength and reducing anxiety and depression of nurses involved with covid -19

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Having at least a bachelor's degree in nursing Having at least one year of work experience in different departments of Zahedan hospitals Having satisfaction and willingness to cooperate Being at least 23 years old and at most 30 years old Failure to report any other severe physical or psychological illness at the initial screening interview Not using the psychological services of another person at the same time Having a low score and a maximum of 40% of my ability questionnaire score being female
Exclusion criteria:
Anxiety and depression with psychotic features Severe disability in one of the five senses Severe mood swings

Age
From **23 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **3**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Single

Other design features
One type of intervention will be conducted on three groups of one person with mild, moderate and severe anxiety and depression

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Royan Research Institute - Academic Jihad

Street address

Royan Research Institute- NO 9- UNIT 10- Royan Alley- Hafez East St-Bani Hashem St- Resalat Highway- Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۶۱۹۶۸۱۵۱

Approval date

2021-04-12, 1400/01/23

Ethics committee reference number

IR.ACECR.ROYAN.REC.1401.010

Health conditions studied

1

Description of health condition studied

Mixed anxiety and depressive disorder

ICD-10 code

F41.2

ICD-10 code description

Mixed anxiety and depressive disorder

Primary outcomes

1

Description

Increase Ego strength score

Timepoint

7, 14, 21, 28, 35, 42, 49, 56, 62, 69, 75

Method of measurement

Makström Ego Strength Questionnaire

2

Description

Decreased anxiety score

Timepoint

7, 14, 21, 28, 35, 42, 49, 56, 62, 69, 75

Method of measurement

Beck anxiety questionnaire

3

Description

Decreasing the depression score

Timepoint

7, 14, 21, 28, 35, 42, 49, 56, 62, 69, 75

Method of measurement

Beck depression questionnaire

Secondary outcomes

1

Description

Increase my strength score

Timepoint

One week after each treatment session and one hour before the next treatment session, measurement will be done, which will be done eleven times in the process of implementing the protocol.

Method of measurement

Makström Ego Strength Questionnaire

2

Description

Decreased anxiety score

Timepoint

One week after each treatment session and one hour before the next treatment session, measurement will be done, which will be done eleven times in the process of implementing the protocol.

Method of measurement

Beck anxiety questionnaire

3

Description

Decreasing the depression score

Timepoint

One week after each treatment session and one hour before the next treatment session, measurement will be done, which will be done eleven times in the process of implementing the protocol.

Method of measurement

Beck depression questionnaire

Intervention groups

1

Description

Intervention group: Three people with the diagnosis of mild, moderate and severe anxiety and depression will be selected and a detailed discussion will be conducted regarding the objectives of the research and a baseline test will be performed until the scores of the dependent variables are stable. Then metacognitive analytic treatment intervention is performed. During the intervention for each participant, after each treatment session (before the start of the next session), the test will be administered. After the end of the intervention, the last test will be taken with a maximum interval of one week.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences

Full name of responsible person

Rahim Shahbakhsh

Street address

Unit8- Building 1- Varzesh Residential Complex- Alley 19- Enghelab Street

City

Zahedan

Province

Sistan-va-Balouchestan

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Email

Rahimshabakhsh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Science and Culture

Full name of responsible person

Musa Itharbakhsh

Street address

Tehran University of Science and Culture- Bahar Street - Shahid Qomoshi Street- Ashrafi Esfahani Boulevard.

City

Tehran

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Phone

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Email

info@usc.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Science and Culture

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

Tehran University of Science and Culture

Full name of responsible person

Ali Soleimani

Position

Assistant Professor, Department of Psychology,
Tehran University of Science and Culture

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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alisoleimani42@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Science and Culture

Full name of responsible person

Rahim Shahbakhsh

Position

Doctoral student of Clinical Psychology, Tehran
University of Science and Culture

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Science and Culture

Full name of responsible person

Rahim Shahbakhsh

Position

Doctoral student of Clinical Psychology, Tehran
University of Science and Culture

Latest degree

Master

Other areas of specialty/work

Psychology

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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

The research results will be available after publication.

When the data will become available and for how long

The data will be available from March 2024

To whom data/document is available

researchers

Under which criteria data/document could be used

For therapeutic and research purposes

From where data/document is obtainable

Science and Culture University Library

What processes are involved for a request to access data/document

By referring to the library of the University of Science
and Culture and submitting a request regarding the
research results

Comments