

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Investigating the relationship between cognitive emotion regulation (CER) with cognitive performance through physiological indices and determining the appropriate characteristics of predictive stimulus of cognitive performance

#### Protocol summary

##### Study aim

determine the relationship between cognitive emotion regulation (CER) with cognitive performance and physiological indices

##### Design

a parallel pseudo randomized trial group design of 40 control room operators in Combined Cycle Power Plant. Based on the results of the CERQ questionnaire, individuals divided into appropriate and inappropriate groups and then each group, divided into control and intervention groups.

##### Settings and conduct

This research will be conducted on control room operators of Combined Cycle Power Plant. First the CERQ will be administered and based on the results people will be divided into appropriate and inappropriate groups in terms of cognitive emotion regulation ability. Then they will be invited to attend the DANA Brain Health Institute. Intervention group will encounter emotional stimuli and their physiological signals will be recorded simultaneously. Then their cognitive performance will be examined using CANTAB (Cambridge Neuropsychological Test Automated Battery) cognitive test. Control group will not experience any emotional stimuli and just their cognitive performance will be assessed.

##### Participants/Inclusion and exclusion criteria

Fars Combined Cycle Power Plant Control Room Staff, Being at least 24 years old, Having at least 4 years of work experience, No history of neurosurgery, No history of mental illness and related medications.

##### Intervention groups

intervention group: watch stimuli from emotional image bank (IAPS: International Affective Picture System)  
control group: no stimuli An emotional image bank known as IAPS was used for the intervention. This set includes heartbreaking and calming images, etc.

#### Main outcome variables

Cognitive performance (CANTAB), Physiological indices (Heart Rate, Respiration, Electromyography), Emotional stimulus profile predicts optimal cognitive performance (based on emotional coordinates)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191228045922N1**

Registration date: **2020-11-22, 1399/09/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-22, 1399/09/02**

Update count: **0**

##### Registration date

2020-11-22, 1399/09/02

##### Registrant information

##### Name

Zahra Ghanbari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3620 9751

##### Email address

ghanbari\_az@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

**Expected recruitment end date**

2020-12-21, 1399/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the relationship between cognitive emotion regulation (CER) with cognitive performance through physiological indices and determining the appropriate characteristics of predictive stimulus of cognitive performance

**Public title**

survey the relationship between cognitive emotion regulation (CER) with cognitive performance and physiological indices

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Fars Combined Cycle Power Plant Control Room Staff  
Being at least 24 years old  
Having at least 4 years of work experience

**Exclusion criteria:**

history of neurosurgery  
history of mental illness and related medications

**Age**From **24 years** old**Gender**

Male

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This research will be done in two phases. In the first phase, using the CER questionnaire, the state of cognitive regulation of emotion in the study group will be examined and individuals will be divided into two groups: appropriate and inappropriate from this perspective (people in the appropriate group use positive strategies to cognitively regulate their emotions in upsetting situations). Then, people in each group will form two subgroups (intervention and control) with the same number of members. Members of the intervention subgroup of both groups (appropriate and inappropriate)

will experience visual emotional stimuli (IAPS: International Affective Picture System) and will complete the SAM questionnaire, then they will be asked to take standardized cognitive function tests. It should be noted that physiological indicators are also recorded simultaneously. For members of the control subgroup in both groups (appropriate and inappropriate), the above steps will be performed, with this difference that emotional stimuli will not be displayed for the control group. In the second phase, the results of the first stage will be used to define the specifications of the capacity and excitability of the emotional stimulus that has led to the optimal performance, and based on that, and using related databases, the stimulus with the level of arousal and valence will be available. Then, taking into account the stimulus obtained as an intervention, the steps of measuring the physiological index and the performance measurement test will be performed.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Unit 3, Block 45, Sarvenaz residential complex, Golzar St, Golestan town, Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

7189883764

**Approval date**

2019-04-20, 1398/01/31

**Ethics committee reference number**

IR.TUMS.SPH.REC.1398.003

**2****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Unit 3, Block 45, Sarvenaz residential complex, Golzar St, Golestan town, Shiraz

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**Province**

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**Postal code**

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**Approval date**

2019-11-19, 1398/08/28

**Ethics committee reference number**

## Health conditions studied

### 1

#### Description of health condition studied

Cognitive Emotion Regulation (CER)

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

Cognitive Performance

#### ICD-10 code

#### ICD-10 code description

### 3

#### Description of health condition studied

Physiological Indices

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Cognitive Performance: Mental performance 1 hour after intervention.

#### Timepoint

in both control and intervention group, at the end of the experiment.

#### Method of measurement

computerized cognitive tests (Cambridge Neuropsychological Test Automated Battery: CANTAB).

### 2

#### Description

physiological indices: Heart rate, respiration and electromyography.

#### Timepoint

during the experiment.

#### Method of measurement

Polygraphy and HEG.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: IAPS. According to this concept that emotion has two main components of arousal and valence, it is necessary to determine these two components in emotion-oriented research. For this

purpose, a standard and global database is used, which includes a set of images that arousal and valence of them has been determined. This bank is called International Affective Picture System (IAPS). This emotional image pack contains 10 loaded block and 11 neutral block (neutral blocks will present between loaded blocks) and each block contains 13 images. Each image presents for 5 seconds.

#### Category

N/A

### 2

#### Description

Control group: without IAPS

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Combined Cycle Power Plant

##### Full name of responsible person

Zahra Ghanbari

##### Street address

Unit 3, Block 45, Sarvenaz residential complex, Golzar St, Golestan town, Shiraz

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##### Province

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##### Postal code

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##### Phone

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ghanbari\_az@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr.Seyyed Aboualfazl Zackeriyan

##### Street address

School of Public Health, Tehran University of Medical Sciences, Enqelab Square.

##### City

Tehran

##### Province

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##### Postal code

1417613151

##### Phone

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##### Email

szakerian@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

25

**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

**2**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.AliReza Choobineh

**Street address**

Ergonomics Department, school of Health, Razi Blvd.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Phone**

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**Email**

alrchoob@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

75

**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 Medical Sciences

**Full name of responsible person**

Zahra Ghanbari

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Ergonomics

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**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Zahra Ghanbari

**Position**

PhD Candidate

**Latest degree**

Master

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to

make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Part of data like the intervention effect can be shared.

**When the data will become available and for how long**

Access will be start 12 months after publications.

**To whom data/document is available**

Researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Contact people in charge of research.

**From where data/document is obtainable**

- Zahra Ghanbari (Ghanbari\_az@yahoo.com) -

Dr.A.Choobineh (alrchoob@yahoo.com)

Dr.S.A.Zackerian (szakerian@gmail.com)

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

The person should contact email addresses provided above. The minimum access time is estimated to be one month.

**Comments**