Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 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 an 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
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Iran (Islamic Republic of)
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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 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
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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
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Postal code
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Approval date
2019-11-19, 1398/08/28
Ethics committee reference number

IR.SUMS.REC.1398.1026

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

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.

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Province

Fars

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Email

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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

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

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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 theintervention 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.Zackeriyan (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