Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Development and evaluation of the effectiveness of cognitive readiness on stress reactivity, physiological health parameters, optimal decision making and brain wave patterns

Protocol summary

Study aim
develop a cognitive readiness protocol and evaluate its effectiveness on reactivity to stress, physiological health indicators, optimal decision making and brain wave patterns.

Design
Clinical trial with control group, single blind, randomized, on 40 people. The rand function of Excel software was used for randomization

Settings and conduct
Senior military officers who will participate in the three-month period of cognitive readiness improvement plan. This course will be implemented in one of the military centers located in Tehran. Participants will be randomly assigned to two experimental and control groups (probably 20 people in each group). It should be noted that due to the implementation of the research in a military environment and also due to the commitments made to maintain confidentiality, the exact location and some of the demographic characteristics of the participants will not be disclosed.

Participants/Inclusion and exclusion criteria
Entry criteria: 30-40 years old, desire and informed consent to participate in the research Exclusion criteria: presence of mental disorders such as depression, PTST, ASD, tic disorders, anxiety disorders / presence of physical problems and diseases, including history of trauma and Head injury or the presence of brain tumors, severe sweating, skin diseases, especially on the scalp, cardiovascular and respiratory diseases / the presence of disabilities or sensory disorders that affect learning or taking tests, such as visual impairment, hearing problems Difficulty in hand movements, inability or difficulty in standing in a balanced manner

Intervention groups
The experimental group includes people who undergo 72 sessions of cognitive preparation training The control group includes people who will not receive cognitive training

Main outcome variables
stress reactivity; physiological health parameters; optimal decision making; brain wave patterns

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161213031398N2**
Registration date: **2022-12-21, 1401/09/30**
Registration timing: **prospective**

Last update: **2022-12-21, 1401/09/30**
Update count: **0**

Registration date
2022-12-21, 1401/09/30

Registrant information

Name
Ahmad Ali Naji

Name of organization / entity
Semnan University

Country
Iran (Islamic Republic of)

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+98 21 7730 8591

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-13, 1402/02/23

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and evaluation of the effectiveness of cognitive readiness on stress reactivity, physiological health parameters, optimal decision making and brain wave patterns

Public title

effectiveness of cognitive readiness

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious consent to participate in research Age between 30 to 40 years

Exclusion criteria:

Having mental and physical disorders High blood pressure and high blood fats Sight and hearing problems

Age

From **30 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

People volunteering to participate in the research are randomly assigned to two experimental and control groups. In this regard, a number is assigned to all the people and the people of two groups are determined by drawing lots. In this way, in simple randomization with this method, the numbers related to all sample people are first written on sheets and then placed inside the container; Then, half of the cards are drawn from the container. The removed cards are placed in the experimental group and the remaining cards are placed in the control group. Then, if the two groups were equal in terms of demographic characteristics, the assignment ends, and if not, the above process is repeated until the equality of the two groups is achieved.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants are fully aware of the research objectives in their group, but they do not know which group they are in (experimental or control) and they are kept unaware of the research objectives in the other group. Also, A and B codes are sent to the analyst for intervention and control groups so that he does not know about the type of groups. Blinding of the outcome assessor will be ensured by his lack of knowledge about the allocation group of patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Semnan University Of Medical Sciences and Health Services

Street address

Semnan Province, Semnan City, Basij Boulevard, University of Medical Sciences and Healthcare Services

City

Semnan

Province

Semnan

Postal code

35147-99442

Approval date

2022-11-28, 1401/09/07

Ethics committee reference number

IR.SEMUMS.REC.1401.204

Health conditions studied

1

Description of health condition studied

Anxiety and stress

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

stress reactivity

Timepoint

1 and 50 days, pre-test and post-test

Method of measurement

stress reactivity questionnaire

2

Description
Physiological health indicators include body mass index (BMI), body fat index (BF), blood serum cholesterol (BSC) and systolic and diastolic blood pressure.
Timepoint
1 and 50 days, pre-test and post-test
Method of measurement
Calculating the ratio of weight to the square of height, the ratio of height and waist circumference per meter, taking 100 cc of blood, digital blood pressure monitor

3

Description
Optimal decision making using strategic management simulation
Timepoint
1 and 50 days, pre-test and post-test
Method of measurement
Using a computer simulator for 50 minutes and recording scores from reactions and decisions

4

Description
Recording of brain waves from the QEEG recording device
Timepoint
1 and 50 days, pre-test and post-test
Method of measurement
Recording of four waves of delta, theta, alpha, and beta in 19 regions of the brain

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: cognitive readiness training during 72 sessions with the headings of cognitive readiness (definition and explanation of cognitive readiness, necessity, goals and expectations, definition of skills, knowledge and insight as the main factors of cognitive readiness), situational awareness (teaching concepts related to three levels of awareness situational awareness, statement of theories of situational awareness, investigation of factors enhancing situational awareness, investigation of factors hindering situational awareness, practical exercises of situational awareness, exercise of assessing situational awareness, exercise of mindfulness with situational awareness). Metacognitive skills (step-by-step training of concepts related to metacognition. Training of cognitive strategies such as summarizing topics, taking notes and practicing retelling of content. Training of planning strategies. Training of monitoring control strategy, techniques for controlling the effectiveness of activities, searching for reasons, questioning oneself for control. self, training to adjust reaction time to social actions, training strategy including adjustment, modification or change of cognitive and emotional strategy). Problem solving skills (teaching theoretical basics based on the seven-step method). Creative thinking (teaching theoretical concepts, examining the stages of creative thinking, examining the characteristics of creative people, brainstorming technique, lotus blossom technique)
Category
Behavior

2

Description
Control group: Without effective intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
A military center in Tehran
Full name of responsible person
Ahmad Ali Naji
Street address
Block 22, Hijab St., Hakimieh, Tehran, 3rd floor, Unit 6
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Isaac Rahimian Boogar
Street address
Mahdishahr Faculty of Psychology and Educational Sciences, Darband, Mahdishahr, Semnan,
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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

Semnan 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

Semnan University

Full name of responsible person

Isaac Rahimian Boogar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Mahdishahr Faculty of Psychology and Educational Sciences, Darband, Mahdishahr, Semnan,

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the military example, I do not intend to detail the data

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Due to the type of research sample, it is not possible to publish individual data, but after the end of the research,

the findings and data analysis will be presented in writing.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutions or military centers who intend to conduct research on the protocol of cognitive preparation can benefit from the documents.

From where data/document is obtainable

Ahmad Ali Naji, aanaji1242@gmail.com

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

1. Sending the request to the responsible person 2. Review of the applicant's proposal and research plan 3. Examining the documents and consulting with the present professors

Comments