

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the effectiveness of exposure-based one-session with multi-session treatment on psychological symptoms, inflammatory-gene expression, and level of cytokines and hormones, in individuals with specific phobia.

Protocol summary

Study aim

Comparison of the efficacy of one-session with multi-session exposure therapy in reducing biological and psychological symptoms of a specific phobia disorder (Rat)

Design

Parallel therapeutic groups include a one-session and multi-session treatment. In each treatment group, 20 participants divided into 4 groups containing 5 individuals for group therapy. Participants are randomly divided into groups

Settings and conduct

The process consists of a baseline assessment stage in which biomarkers and psychological symptoms of subjects are assessed before any animal exposure. The exposure stage, which students are exposed with the rats on the basis of the protocol and then are guided for blood sampling and psychological assessments. The intervention stage, which students received either one-session or multi-session therapy, and a post-treatment evaluation stage that students will be treated in the same way as the second stage with the animal and the evaluations.

Participants/Inclusion and exclusion criteria

The population of the study includes female college students aged 18-35, who are afraid of rats. Inclusion criteria: 1- Ages 18-35 years 2. Having a BMI of 18-35 kg/m² 3- Stay in the Luteal phase 4. Having a specific (rat) phobia based on DSM-V criteria Exclusion criteria: 1 - A history of previous exposure to mice and rats 2- Using anti-anxiety, psychoactive, beta-blockers, hormonal, or contraceptive drugs 3- Smoking cigarette or tobacco 4. Having history of mental, cardiovascular, metabolic or chronic diseases

Intervention groups

The first group received one-session treatment, and the

second group received a four-session treatment for rat phobia.

Main outcome variables

Independent variable: One-session treatment; Multi-session therapy; Dependent variables: Psychological symptoms of rat phobia; IL-1 gene expression; Gene expression of Nfkb ; Serum cortisol; serum IL-6; blood pressure; pulse.

General information

Reason for update

Fixing errors in entering the start and end dates of the clinical trial. It should be noted that this study was a prospective study and sampling of clients was done after registration and approval of the clinical trial.

Acronym

IRCT registration information

IRCT registration number: **IRCT20171123037602N1**
Registration date: **2018-09-30, 1397/07/08**
Registration timing: **prospective**

Last update: **2020-05-11, 1399/02/22**

Update count: **1**

Registration date

2018-09-30, 1397/07/08

Registrant information

Name

Camellia Hemyari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-21, 1397/08/30

Expected recruitment end date
2019-07-03, 1398/04/12

Actual recruitment start date
2018-11-21, 1397/08/30

Actual recruitment end date
2019-05-20, 1398/02/30

Trial completion date
2019-05-20, 1398/02/30

Scientific title

Comparison of the effectiveness of exposure-based one-session with multi-session treatment on psychological symptoms, inflammatory-gene expression, and level of cytokines and hormones, in individuals with specific phobia.

Public title

Comparison of the effectiveness of one session and multi-session treatment in individuals with specific phobia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having Body Mass Index in the range of 18 to 35 kg/m²
Being at Luteal phase
Having a specific phobia disorder (mouse and rat) based on DSM-V criteria, using the ADIS-IV structured interview

Exclusion criteria:

History of a previous exposure to mice and rats
Using anti-anxiety, psychoactive, beta-blocker, hormonal or contraception drugs
Smoking cigarette or tobacco
Having the history of mental illness, cardiovascular, metabolic or other chronic diseases

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **3**

Three samples are taken from each person. At each turn, a blood sample, blood pressure test and psychological assessment by a questionnaire are performed.

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random number tables

Blinding (investigator's opinion)

Single blinded

Blinding description

Those that measure biological and psychological assessments and analyze the data are unaware of the treatment groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

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1985713834

Approval date

2017-11-21, 1396/08/30

Ethics committee reference number

IR.USWR.REC.1396.256

Health conditions studied

1

Description of health condition studied

Rat phobia

ICD-10 code

F40.21

ICD-10 code description

Animal type phobia

Primary outcomes

1

Description

Specific phobic disorder based on DSM-V diagnostic criteria

Timepoint

1- Baseline measurement 2- Pre-treatment measurement after facing with laboratory rat 3- Post-treatment evaluation after exposure to the animal

Method of measurement

In this study, an anxiety disorder interview (ADIS-IV) is used to diagnose the disorder.

2

Description

Fear of the rat based on mice phobia questionnaire

Timepoint

1- Baseline measurement 2- Pre-treatment measurement after facing with laboratory rat 3- Post-treatment evaluation after exposure to the animal

Method of measurement

The 18-point questionnaire for fear of mice (adapted from the Spider-Man's Questionnaire (FSQ), Szymanski, O'Donohue, 1995)

3

Description

Serum cortisol level

Timepoint

1- Baseline measurement 2- Pre-treatment measurement after facing with laboratory rat 3- Post-treatment evaluation after exposure to the animal

Method of measurement

Cortisol measurement by Enzyme-Associated Immunosorbent Assay

4

Description

The expression level of IL-1 β encoding gene in white blood cells

Timepoint

1- Baseline measurement 2- Pre-treatment measurement after facing with laboratory rat 3-Post-treatment evaluation after exposure to the animal

Method of measurement

The expression of this gene relative to a house keeping gene (such as beta-actin) is measured by the Real Time PCR method.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One-session cognitive-behavioral therapy for three hours in accordance with Ost's manual.

Category

Treatment - Other

2

Description

Intervention group: Exposure-based cognitive-behavioral therapy for specific phobia disorder includes 4 sessions of 2 hours based on Barlow protocol.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Camellia Hemyari

Position

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Latest degree

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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

No more information

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable