

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of psychological preparation on the level anxiety before head and neck M.R.I in outpatients referred to Ahvaz Golestan hospital

Protocol summary

Summary

In a randomized clinical trial 66 patients who were referred to Ahvaz Golestan Hospital and candidated for head and neck M.R.I were selected. Aim of this study is to determine state and trait anxiety and compare them in intervention and control group. Participants should have the ability to communicate verbal Persian conversation and in case of dementia and the presence of major psychiatric disorders, they were excluded. A Eshpil Berg questionnaire for measuring level of anxiety was used and filled out by patients in 2 times. The first time when patients referred to M.R.I that represents the basic anxiety and the second time after intervention, before M.R.I. For the experimental group, after the questionnaire was completed in the first phase, psychological preparation was carried out for the patients. Information such as time of located in the MRI machine, the voice device, duration and amount of wait time for MRI. After that, their anxiety, information, and beliefs about M.R.I were assessed, the intervention was carried out in three areas: Information control, Cognitive and Behavioral control.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120920739N4**

Registration date: **2016-12-31, 1395/10/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-31, 1395/10/11

Registrant information

Name

Forouzan Behroozina

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3038

Email address

behrouzian-f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of psychological preparation on the level anxiety before head and neck M.R.I in outpatients referred to Ahvaz Golestan hospital

Public title

The effect of psychological preparation on the level anxiety before M.R.I

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 16-65 years; the language Farsi; the ability to communicate verbally; with no history of previous head and neck M.R.I; without inclusion M.R.I; a consent to enter the scheme. Exclusion criteria: the risk

of dementia: mental retardation: distinctive physical problems that interfere consultation; history of major psychiatric disorders: that the patients is not cooperative.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 66

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients based on 4-of permutation blocks randomly divided into two equal groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd.

City

Ahvaz

Postal code

Approval date

2016-07-09, 1395/04/19

Ethics committee reference number

IRAJUMS.REC.1395.216

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F40,F41,F

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

State Anxiety

Timepoint

Before Intervention - After Intervention

Method of measurement

Eshpil Berger Questionnaire

2

Description

Trait Anxiety

Timepoint

Before Intervention - After Intervention

Method of measurement

Eshpil Berger Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: A Spielberg questionnaire for measuring level of anxiety was used and filled out by patients in 2 times. The first time when patients referred to the M.R.I. that represents the basic anxiety and the second time after intervention and before M.R. After the questionnaire was completed in the first phase, psychological preparation was carried out for the patients before M.R.I. After their anxiety, information, and beliefs about M.R.I conduction were assessed, the intervention was carried out in three areas: Information control, Cognitive and Behavioral control (advantage of M.R.I and its positive point)

Category

Behavior

2

Description

To gauge the length of time it takes for cases, intervention is carried out regular information placed at the disposal of the control group and the intervention does not take place.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Fouroozan Behrouzian

Street address

Golestan hospital, Golestan Blvd.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Forouzan Behrouzian

Street address

Golestan Hospital, Golestan Blvd

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Ahvaz Jundishapur
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Frouzan Behrouzian

Position

Assistant Professor

Other areas of specialty/work

Street address

Ahvaz Golestan Hospital, Golestan Blvd, Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 3374 3038

Fax

Email

fbehrouzian@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mehrnaz Jalalian Larki

Position

Resident

Other areas of specialty/work

Street address

Ahvaz Golestan hospital, Golestan Blvd.

City

Ahvaz

Postal code

Phone

+98 619163115117

Fax

Email

jalalian.m@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mehrnaz Jalalian Larki

Position

Resident

Other areas of specialty/work

Street address

Ahvaz Golestan hospital, Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 619163115117

Fax

Email

jalalian.m@hotmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty