Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity

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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.
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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
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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
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

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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