Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectivness of Intensive Short term Dynamic Psychotherapy on tension headache cases.

Protocol summary

Study aim
Evaluating the effectiveness of Intensive Short term Dynamic Psychotherapy on tension headache cases
Design
Clinical trial, with control and experimental groups, parallel, single blind, randomized, on 15 patients. Block randomization method is used for randomization
Settings and conduct
Place of the study: internal neurology clinic of Rasool Akram Hospital, Tehran. Study population: people suffering from tension headaches referred to the internal neurology clinic of Rasool Akram Hospital in Tehran.
Participants/Inclusion and exclusion criteria
Inclusion criterion: Having a tension headache based on neurologist diagnosis. Non-inclusion criterion: being affected by severe physical illness
Intervention groups
Intervention groups: Intensive Short term Dynamic Psychotherapy based on Jon Fredrickson will be used. Control groups: They do not receive any intervention.
Main outcome variables
Tension Headache

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221101056370N1**
Registration date: **2023-07-21, 1402/04/30**
Registration timing: **retrospective**

Last update: **2023-07-21, 1402/04/30**
Update count: **0**
Registration date
2023-07-21, 1402/04/30

Registrant information

Name
Zahra Ahmadvand
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
2021-09-23, 1400/07/01
Expected recruitment end date
2022-03-03, 1400/12/12
Actual recruitment start date
2021-09-23, 1400/07/01
Actual recruitment end date
2022-04-22, 1401/02/02
Trial completion date
2023-02-01, 1401/11/12

Scientific title
Effectivness of Intensive Short term Dynamic Psychotherapy on tension headache cases.

Public title
Effectivness of Intensive Short term Dynamic Psychotherapy on tension headache.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having tension headache based on the neurologist diagnosis Having at least an average IQ at least Diploma education age between 18-50 year old
Exclusion criteria:
Having a significant physical illness based on the interview Having a severe psychiatric disorder according

to the fifth edition of the Diagnostic and Statistical Manual Illnesses DSM-5

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **15**

Actual sample size reached: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Restricted Randomization method of block randomization will be used. The number of samples assigned to each study groups become equal and in this study, we will have blocks of size 4. Random allocation software is used that this random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method. Allocation concealment is also used, which is the method used to execute a random sequence on study participants. In such a way that the assigned group is not known before the individual is assigned. Using Sequentially numbered, sealed, opaque envelopes, each random sequence created is recorded on a card. And the cards are placed in the envelopes respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Evaluator and statistical analysts are blind to the research process. The statistical analyst is blind to the belonging of the data to the experimental and control group of the research so that the data analysis is done without bias.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences; next to Milad Tower; Hemat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.IUMS.REC.1400.439

Health conditions studied

1

Description of health condition studied

Tension headache

ICD-10 code

G44.2

ICD-10 code description

Tension-type headache

Primary outcomes

1

Description

Headache score in International Classification of Headache Disorders (ICHD-II)

Timepoint

before the intervention, last session, 2months after the intervention

Method of measurement

Second International Classification of Headache Disorders (ICHD-II)

Secondary outcomes

1

Description

The symptom of emotion regulation

Timepoint

before the intervention, last session, 2months after intervention

Method of measurement

Gross and John emotional regulation

2

Description

the symptom of state- trait of Anger

Timepoint

before the intervention, last session, 2months after intervention

Method of measurement

Staxi questionnaire

3

Description

the Symptom of Anxiety

Timepoint

before the intervention, last session, 2months after intervention

Method of measurement

Beck anxiety inventory (BAI)

Intervention groups

1

Description

Intervention group: In this group, short-term psychodynamic therapy based on John Frederickson's model is used. In this protocol, the therapist changes the way of emptying anxiety in the body, improves the patient's capacity to observe emotions, anxiety and defenses internally.In this format, the therapist gradually calls out emotions so that the problems that the patient has with anxiety, backward defenses or self-observation capacity appear. At the same moment, the therapist strengthens the patient's capacity and then, again, gradually calls up the feeling.

Category

Treatment - Other

2

Description

Control group: Participants do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran institute of psychiatry

Full name of responsible person

Zahra Ahmadvand

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Sponsors / Funding sources

1

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Position

Research deputy of Iran university of medical science

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable