Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy a family- based psychological intervention program on spiritual happiness, marital satisfaction and migraine disorder syndrome couples

Protocol summary

Study aim
Evaluation of family-centered psychological intervention program on spiritual vitality, marital satisfaction and migraine disorder syndrome in married people

Design
Clinical trial with one control group and one intervention group, with parallel groups, designed for 30 patients, Simple randomization with a table of random numbers

Settings and conduct
This study is performed in patients with migraine in the subspecies pain clinic. In this study, blinding has not been done

Participants/Inclusion and exclusion criteria
The diagnosis of migraine disorders should be confirmed based on the clinical diagnosis of migraine in patients. Having a high school education Being between 40 to 55 years old Absence of a history of neurological disorders and a history of hospitalization in a psychiatric hospital No substance abuse Being married Willingness to cooperate

Intervention groups
1. In the experimental group, a family-centered psychological intervention program was implemented based on Lidl's family-centered therapy protocol. 2. The control group did not receive any therapeutic intervention as a witness of the research.

Main outcome variables
Spiritual vitality, marital satisfaction and migraine disorder symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220625055272N1**
Registration date: **2023-02-15, 1401/11/26**
Registration timing: **retrospective**
Last update: **2023-02-15, 1401/11/26**
Update count: **0**

Registration date
2023-02-15, 1401/11/26

Registrant information

Name
Negar Sheikhli

Name of organization / entity
University of Tehran Kish International Campus

Country
Iran (Islamic Republic of)

Phone
+98 21 3223 5011

Email address
sheikhlinegar34@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-21, 1401/05/30

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy a family- based psychological intervention program on spiritual happiness, marital satisfaction and migraine disorder syndrome couples

Public title
Developing and Effectiveness a family- based psychological intervention program on spiritual happiness, marital satisfaction and migraine disorder syndrome couples

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 40-50 years The diagnosis of migraine disorders should be confirmed based on the clinical diagnosis of migraine in patients. Not using other treatment psychotherapy programs and changing medications during the research Being married Willingness to cooperate No substance abuse
Exclusion criteria:
Psychological treatment in the last 6 months Severe mental disorder Failure to respond to the therapist for two weeks in a row participants suffering from other physical diseases
Age
From **40 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with random numbers in the group division Randomized allocation in clinical trial studies refers to randomly dividing participants into different groups. Randomizing gives each participant equal odds of being placed in each group. Forty migraine patients are selected randomly in the centers. The randomization tool is a random table of numbers in which the researcher moves the numbers right and downward on one of the numbers, finally recording the numbers and dividing them into two experimental groups of twenty people and determining the control group (twenty people) whose number has already been established.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Psychology and Educational Sciences, University of Tehran
Street address
Kish Campus: Mirmahna Blvd. - the beginning of Niayesh St. - Kish International Campus of Tehran University
City
Kish
Province
Hormozgan
Postal code
1358879331
Approval date
2022-06-05, 1401/03/15
Ethics committee reference number
IR.UT.PSYEDU.REC.1401.034

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine without aura [common migraine]

Primary outcomes

1

Description
Pain syndrome
Timepoint
Before an intervention, immediately after the intervention, 3 months after the end of intervention
Method of measurement
Pain Disability Index Questionnaire

Secondary outcomes

1

Description
Spiritual vitality
Timepoint
Before an intervention, immediately after the intervention, 3 months after the end of intervention
Method of measurement
Spiritual Vitality Scale (Afrooz, 2016)

2

Description
Marital satisfaction
Timepoint
Before an intervention, immediately after the intervention, 3 months after the end of intervention
Method of measurement
Marriage Satisfaction Questionnaire

Intervention groups

1

Description

Family-centered psychological interventions program by recognizing and respecting the existence of the family and promoting the competence and confidence of the family in taking care of themselves and the patient, and empowering the family to support the patient in the compromise with the care and treatment system, according to the focus of the education of the enhancing lifestyle Health and its maintenance, adherence to treatment, interpersonal communication, stress management and prevention of disease progression were compiled with the participation of the family and with a holistic approach. In the present study, after developing a package of family-oriented psychological interventions, this program was conducted in 8 sessions of 1.5-2 hours per week, with the educational participation of the spouse of the affected person and the affected person, and the transfer of information through educational booklets and audio CDs.) was done as a group.

Category

Behavior

2

Description

Control group: Only taking medication was prescribed by a neurologist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Pain Specialized Clinic

Full name of responsible person

Negar Sheikhli

Street address

Gilan province, Rasht, Golsar boulevard, Bint Al-Huda, between Amani and Zand dead end. Mehr Pain Specialized Clinic

City

Rasht

Province

Guilan

Postal code

1358879331

Phone

+98 34 4326 3329

Email

sheikhlinegar34@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Tehran

Full name of responsible person

Shirin Naderi

Street address

Kish Campus: Mirmahna Blvd. - the beginning of Niayesh St. - Kish International Campus of Tehran University

City

Kish

Province

Hormozgan

Postal code

13588784612

Phone

+98 34 1822 0795

Email

info@kiau.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Tehran

Proportion provided by this source

1

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

The University of Tehran

Full name of responsible person

Negar Sheikhli

Position

PhD student of Health Psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

پردیس کیش: بلوار میرمهنا - ابتدای خیابان نیایش - پردیس بین المللی کیش دانشگاه تهران

City

Tehran

Province

Guilan

Postal code

1358879331

Phone

+98 34 4326 3329

Email

sheikhlinegar34@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Tehran

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Person responsible for updating data

Contact

Name of organization / entity

The University of Tehran

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City

Rasht

Province

Guilan

Postal code

1358879331

Phone

009843263329

Email

sheikhlinegar34@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All related data to participants are shared after hiding patient's name.

When the data will become available and for how long

The period of access to the present research data will be available 6 months after publication of the research results in the form of research articles.

To whom data/document is available

The present study data will be available only to researchers working in the academic and scientific institutions.

Under which criteria data/document could be used

The output of statistical analysis will be available

From where data/document is obtainable

Applicants can apply for documentation and data via email at sheikhlinegar34@gmail.com

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

After completion of the research and publication of the extracted articles, it will be available for a maximum 6 months later.

Comments