

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of Hypnotherapy, Cognitive-Behavioral therapy (CBT) and Cognitive-Behavioral Hypnotherapy (CBH) treatment on Resilience, Sleep quality, Sexual satisfaction and Physical symptoms in women with Fibromyalgia syndrome

Protocol summary

Study aim

Determining the effectiveness of Cognitive_Behavioral Hypnotherapy treatment on Sleep quality, Resiliency, Sexual satisfaction and Physical symptoms in women with Fibromyalgia Syndrome
Determining the effectiveness of Cognitive_Behavioral therapy on Sleep quality, Resiliency, Sexual satisfaction and Physical symptoms in women with Fibromyalgia Syndrome
Determining the effectiveness of Hypnotherapy treatment on Sleep quality, Resiliency, Sexual satisfaction and Physical symptoms in women with Fibromyalgia Syndrome

Design

Clinical trial with 3 intervention groups and 1Control group with Parallel group on 12 patients that were randomly distributed among 4 group which contained 3 persons.

Settings and conduct

In this research, the dependent variable is measured several times during the baseline phase and treatment phase. For the measurement of baseline at least 3 times measurement is necessary. In this way before performing the independent variable, the dependent variable should be measured since 20 days before performance to the exact day of introductory session. The results must be compared with each other.

Participants/Inclusion and exclusion criteria

Enter: Not receiving coherent psychological therapies.
Married women between at least 20 to 60 years old
Diploma degree at least Agreement of the patient for the research and signature of consent form
Do not enter: Having Psychotic disorder
Single ones Less than 20 and above 60 years old

Intervention groups

First group: Hypnotherapy_based intervention
Second group: Intervention based on Cognitive_Behavioral

therapy
Third group: Intervention based on Cognitive_Behavioral Hypnotherapy treatment
Forth group: Control without intervention

Main outcome variables

Resiliency, Sleep quality, Sexual Satisfaction, Physical Symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191130045558N1**

Registration date: **2020-08-02, 1399/05/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-02, 1399/05/12**

Update count: **0**

Registration date

2020-08-02, 1399/05/12

Registrant information

Name

Mahdieh Kolbadinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3252 3853

Email address

mkolbadi483@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-26, 1399/05/05
Expected recruitment end date
 2020-08-05, 1399/05/15
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison of the effectiveness of Hypnotherapy, Cognitive-Behavioral therapy (CBT) and Cognitive-Behavioral Hypnotherapy (CBH) treatment on Resilience, Sleep quality, Sexual satisfaction and Physical symptoms in women with Fibromyalgia syndrome

Public title
 Comparison of the effectiveness of Hypnotherapy, Cognitive-Behavioral therapy (CBT) and Cognitive-Behavioral Hypnotherapy (CBH) treatment on Resilience, Sleep quality, Sexual satisfaction and Physical symptoms in women with Fibromyalgia syndrome

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Not receiving coherent psychological therapies. Married women Age 20 to 60 Having a minimum level of diploma education Patient consent to participate in the study and sign a written consent No Psychotic disorder No substance abuse No serious medical illnesses; Includes severe liver and kidney failure Not having serious thoughts of self harm and debtors Not having Antisocial personality disorder
Exclusion criteria:
 Serious thoughts of harming yourself and others Having severe liver and kidney failure Having Antisocial Personality disorder Substance abuse Having Psychotic Disorders Single women Less than 20 and above 60 years old Under diploma degree

Age
 From **20 years** old to **60 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **12**

Randomization (investigator's opinion)
 Not randomized

Randomization description

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 Committe of Aliabad Katool Azad University

Street address

Univesity Blvd, Azad University

City

Ali Abad Katool

Province

Golestan

Postal code

49417-93451

Approval date

2020-07-22, 1399/05/01

Ethics committee reference number

IR.IAU.AK.REC.1399.013

Health conditions studied

1

Description of health condition studied

Hypnotherapy, Cognitive Behavioral Therapy ,Cognitive Behavioral Hypnotherapy, Resiliency, Sleep Quality, Sexual Satisfaction,Physical Symptoms, Fibromyalgial syndrome

ICD-10 code

M79.7

ICD-10 code description

Fibromyalgia

Primary outcomes

1

Description

Physical Symptoms

Timepoint

20 days before therapy, after 2nd, 4th, 6th, 7th and 8th therapy sessions, follow up 1 and 3 months after the end of therapy

Method of measurement

Paul and Enrit Physical Symptoms Questionnaire

2

Description

Resiliency

Timepoint

20 days before therapy, after 2nd, 4th, 6th, 7th and 8th therapy sessions, follow up 1 and 3 months after the end of therapy

Method of measurement

Conner and Davidson Resiliency Questionnaire

3

Description

Sleep Quality

Timepoint

20 days before therapy, after 2nd, 4th, 6th, 7th and 8th therapy sessions, follow up 1 and 3 months after the end of therapy

Method of measurement

Peterzburg Sleep Quality Questionnaire

4

Description

Sexual Satisfaction

Timepoint

20 days before therapy, after 2nd, 4th, 6th, 7th and 8th therapy sessions, follow up 1 and 3 months after the end of therapy

Method of measurement

Roshan Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Hypnotherapy is performed in 8 sessions per week, one session of 60 minutes which will be hold individually.

Category

Treatment - Other

2

Description

Second Intervention group: Cognitive_Behavioral Therapy is performed in 8 sessions per week, one session of 60 minutes which will be hold individually.

Category

Treatment - Other

3

Description

Third Intervention group: Cognitive-Behavioral Hypnotherapy is performed in 8 sessions per week, one session of 60 minutes which will be hold individually.

Category

Treatment - Other

4

Description

Control group: Without intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Aghaee Rheumatology Clinic

Full name of responsible person

Dr. Mehrdad Aghaee

Street address

No. 14, Edalat st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Vice president for Research and technology

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Grant name

Grant code / Reference number

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

No

Title of funding source

Azad uiversity of Gorgan

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

Islamic Azad University

Full name of responsible person

Mahdieh Kolbadinejad

Position

Phd student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Position

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Other areas of specialty/work

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

the whole research

When the data will become available and for how long

3month after published

To whom data/document is available

psychologists psychiatrists phsyitions

Under which criteria data/document could be used

for scientific researches

From where data/document is obtainable

mkolbadi483@gmail.com

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

researcher's corresponding e.mail:

Mkolbadi483@gmail.com

Comments