Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Substanse 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.
City
Gorgan
Province
Golestan
Postal code
4916818933
Phone
+98 17 3252 3853
Email
Mkolbaadi483@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Vice president for Research and technology
Street address
Daneshjoo St.
City
Gorgan
Province
Golestan
Postal code
4914739975
Phone
+98 17 3215 3000
Email
Mkolbadi483@gmail.com
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
Street address
No. 7, 16 street, golshar blvd
City
Gorgan
Province
Golestan
Postal code
4916818933
Phone
+98 17 3252 3853
Fax
Email
Mkolbadi483@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Mehdi Pourasghar Arabi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
No. 7, 16 street, golshar blvd
City
Sari
Province
Mazandaran
Postal code
4916818933
Phone
+98 17 3252 3853
Fax
Email
Me_Pourasghar@yahoo.com

Person responsible for updating data

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
Street address
No. 7, 16 street, golshar blvd
City
Gorgan
Province
Golestan
Postal code
4916818933
Phone
+98 17 3252 3853
Fax
Email
Mkolbadi483@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
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 physitions
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