Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Cognitive Behavioral Therapy on Psychological Distress and its impact on Marital Adjustment and Quality of Life among Infertile Women.

Protocol summary

Study aim

Aim of this study is to assess the effectiveness of Cognitive Behavioral therapy on psychological distress of infertile women. Further objectives of study are to determine its impact on marital adjustment and quality of life of infertile women.

Design

This will be experimental study with one control and one experimental group. Each group will be comprised on 20 participants. participants will be parallel randomized in to each group.

Settings and conduct

This randomized study will be conducted on 40 infertile women of South Punjab Pakistan and intervention will be applied in hospital named "The Moeen Infertility center". To screen out the depression, anxiety and among infertile women DASS-42 items will be used similarly scale named as FertiQoL will be used to assess the quality of life of infertile women and Revised Dyadic adjustment scale will be used to assess marital adjustment in infertile women. At first primary assessment will be performed in two groups and then again, tests will be performed immediately after intervention like wise after one moth of intervention all questionnaires will be applied to follow up.

Participants/Inclusion and exclusion criteria

1.All diagnosed infertile women from South Punjab Pakistan age range 20 to 40 years will be included in this study. All women must be skilled in reading and writing.
2. Women who are other then South Punjab Pakistan and are above age 40 years will be excluded from study.

Intervention groups

Participants in intervention group will receive 8 sessions of culturally adapted Cognitive behavioral therapy. Each session will be comprised on 180 minutes once in a week.

Main outcome variables

Improvement in level of Psychological distress (depression and anxiety) marital adjustment and quality of life of infertile women by using Culturally adapted cognitive behavioral therapy will be the main outcome of the study.

General information

Reason for update

Acronym

N/A

IRCT registration information

IRCT registration number: **IRCT20221205056720N1**
Registration date: **2023-02-06, 1401/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-06, 1401/11/17**
Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Sarwat Sultana

Name of organization / entity

The Islamia University of Bahawalpur

Country

Pakistan

Phone

+92 62 2502025

Email address

fa19e1pa001@iub.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-27, 1401/11/07

Expected recruitment end date
2023-02-27, 1401/12/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Cognitive Behavioral Therapy on Psychological Distress and its impact on Marital Adjustment and Quality of Life among Infertile Women.

Public title
Effectiveness of Cognitive Behavioral Therapy on Psychological Distress and its impact on Marital Adjustment and Quality of Life among Infertile Women.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All diagnosed married infertile women belong to South Punjab Pakistan aged 20 to 40 years will be included in this study. All women must be skilled in reading and writing. Infertile women who had been trying to conceive for between 1 to 2 years will be included in this study.
Exclusion criteria:
The infertile women above age of 40 years will be excluded from this study. Women who can not read or write will excluded from sample of the study. Infertile women who are not taking any infertility treatment will be excluded from this study.
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In the random sampling process of infertile women in two groups of intervention and control, random allocation software for clinical trials will be used.
Blinding (investigator's opinion)
Triple blinded
Blinding description
N/A
Placebo
Not used
Assignment
Parallel
Other design features
Total 40 participants will be the part of this study. Participants will be divided into two groups in which 20 participants will be the part of experimental group and whereas 20 participants will be the part of control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of The Islamia University of Bahwalpur
Street address
Baghdad ul Jadeed Road Bahwalpur
City
Bahawalpur
Postal code
63100
Approval date
2022-10-06, 1401/07/14
Ethics committee reference number
92629255065

Health conditions studied

1

Description of health condition studied
Infertility related Psychological distress
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Marital Adjustment
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Quality of Life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
To assess the effectiveness of Culturally adapted Cognitive Behavioral Therapy to decrease the level of psychological distress of infertile women.
Timepoint
Before the intervention, immediately after the intervention and 6 weeks after the intervention
Method of measurement
Depression Anxiety and Stress Scale

2

Description
To assess the impact of applying Culturally adapted Cognitive Behavioral Therapy on marital adjustment among infertile women.
Timepoint
Before the intervention, immediately after the intervention and 6 weeks after the intervention
Method of measurement
Dyadic Adjustment Scale

3

Description
To assess the impact of applying Culturally adapted Cognitive Behavioral Therapy on Quality of llife among infertile women.
Timepoint
Before the intervention, immediately after the intervention and 6 weeks after the intervention
Method of measurement
FertiQol Scale

Secondary outcomes

1

Description
To assess the other demographic variables that cause psychological distress among infertile women
Timepoint
Before the intervention, immediately after the intervention and 6 weeks after the intervention
Method of measurement
Demographic sheet

Intervention groups

1

Description
Intervention group: This group will receive culturally adopted cognitive behavior therapy to decrease their psychological distress and to assess its impact on marital adjustment and quality of life. Culturally adopted cognitive behavior therapy is a dialogue written exercises based therapy that is comprised on eight sessions . All subjects of experimental group will receive one session in a week that will be comprised on 120 minutes. After completing eight sessions of psycho therapy post assessment will be conducted to assess the effectiveness. Follow up will be taken after two months of post assessment.
Category
Other

2

Description
Control group: This group will receive only placebo treatment that will be based on counselling and dialogues discussions between control group participants and therapist.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sohail infertility centre Bahawalpur
Full name of responsible person
Dr Sohail Chuadary
Street address
Sohail Infertility Centre Noor Mahal Road Bahawalpur
City
Bahawalpur
Postal code
063100
Phone
+92 62 2500271
Email
sitc.gynae@hotmail.com
Web page address
https://oladoc.com/pakistan/bahawalpur/h/sitc-hospital/6314

2

Recruitment center
Name of recruitment center
Moeen Infertility Centre Bahawalpur
Full name of responsible person
Dr Anjum Saboohi
Street address
Moeen infertility centre near rafi qamar road Bahwalpur
City
Bahawalpur
Postal code
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Phone
+92 62 2502335
Email
anjum.saboohi@gmail.com
Web page address
https://www.mybahawalpur.com/doctors/dr-anjum-saboohi/

3

Recruitment center
Name of recruitment center
All infertility centres of Bahawalpur
Full name of responsible person
Dr Asiya Manzoor
Street address
Bahawalpur Pakistan
City
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Postal code
063100

Phone
+92 926 2282736
Email
itsyasirumair@gmail.com
Web page address
https://oladoc.com/pakistan/bahawalpur/ivf-consultant

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Islamia University of Bahwalpur
Full name of responsible person
Professor Dr Masood Nadeem
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Baghdad ul Jadded Road Bahawalpur IUB town The Islamia University of Bahawalpur
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Grant name
The Islamia University of Bahawalpur
Grant code / Reference number
Not applicable
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Islamia University of Bahwalpur
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
The Islamia University of Bahawalpur
Full name of responsible person
Sarwat Sultana
Position
PhD Scholar
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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Person responsible for updating data

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Other areas of specialty/work
Psychology
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Postal code

63100

Phone

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Email

sarwatsultana88@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 data will be shared by hiding subject's identity

When the data will become available and for how long

Data will be available three months after recording the results

To whom data/document is available

Data will be available for researchers and students of social sciences

Under which criteria data/document could be used

The use of documentation in all scientific and research measures is permitted . In order to submit a request for access to data they must be students and researchers of the relevant field

From where data/document is obtainable

Data can be obtained by requesting through this given email that is written below. fa19e1pa001@iub.edu.pk

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

Students and researchers who will be interested to reutilize the data or any documents will send an email with some important details about the purpose of why they need data and it will be sent to them according to the need.

Comments

N/A