

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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 be 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 Bahawalpur

Street address

Baghdad ul Jadeed Road Bahawalpur

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 life 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 psychotherapy 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-hospita/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 Bahawalpur

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

Bahawalpur

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 Bahawalpur
Full name of responsible person
Professor Dr Masood Nadeem
Street address
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 Bahawalpur

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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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Professor Dr Masood Nadeem

Position

PhD Scholar

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Baghdad ul Jadded Road Bahawalpur IUB town The Islamia University of Bahawalpur

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Email

sarwatsultana88@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The Islamia University of Bahawalpur

Full name of responsible person

Professor Dr Masood Nadeem

Position

Ph.D scholar

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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 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