

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effectiveness of individual counseling based on ex-plissit and GATHER models on sexual function in women with a history of gestational diabetes during lactation

Protocol summary

Study aim

Comparison of the effectiveness of individual counseling based on ex-plissit and GATHER models on sexual function in women with a history of gestational diabetes during lactation

Design

A randomized controlled clinical trial with parallel groups, without blinding

Settings and conduct

KHorraramabad city, Selected clinics, Individual counseling in 2 weekly sessions

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Women with a history of gestational diabetes and currently controlled by diet 2) Breastfeeding 3) Sexual function has started 4) Recent term delivery is single and infant 5) At least 10 and up to 14 weeks postpartum 6) Having at least one problem Sexual 7) Exposure to stressful events during pregnancy and postpartum 8) Available within a month 9) No underlying illness, psychiatric medication and history of any genital surgery 10) At least one year of marriage 11) No participation in counseling and training programs during the past 6 months 12) No postpartum depression 13) No Vaginismus; Study: 1) lack of desire to continue to participate in the study, 2) absence in a maximum of one Azjlsat counseling 3) of something bad happening while studying 4) an addiction 5) Change Location 6) the loss of children 7) away from the wife 8) depression during the study

Intervention groups

Intervention group explissit model: two one-hour sessions of individual counseling per person weekly
Intervention group model: Two one-hour sessions of individual counseling per week

Main outcome variables

Desire; stimulation; orgasm; pain; moisture; sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191013045079N2**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **prospective**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

Registration date

2020-03-19, 1398/12/29

Registrant information

Name

hadis fattah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3340 6516

Email address

hadisfth@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of individual counseling based on ex-plissit and GATHER models on sexual function in women with a history of gestational diabetes during lactation

Public title

The effect of sexual function counseling on lactating women with a history of gestational diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A history of gestational diabetes and controlled by current diet Breastfeeding to the baby Sexual activity has begun Recent term labor and single baby Pass at least 10 and maximum 14 weeks of delivery Having at least one sexual problem (score less than 28 on the FSFI questionnaire) Lack of exposure to stressful events during pregnancy and postpartum Available over the next month No underlying disease, psychiatric drug use and history of any genital surgery At least one year of marriage Failure to participate in counseling and training programs during last 6 months No postpartum depression No vaginismus

Exclusion criteria:

Unwilling to continue participating in the study Failure to attend at least one consultation session Occurrence of an accident while studying Addiction Change of location Losing a baby Being away from your spouse Depression during the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 78

Randomization (investigator's opinion)

Randomized

Randomization description

Cluster sampling: According to the cluster sampling, 4 health centers are selected from 4 districts of KHorramabad city. Randomized Blocks Method: Randomly divided people into two groups of 39 for each counseling model

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 Arak University of Medical Sciences

Street address

Arak University of Medical Sciences., Alam Hoda Street., Shahid Shiroudi Street., Arak

City

Arak

Province

Markazi

Postal code

6819763383

Approval date

2020-02-02, 1398/11/13

Ethics committee reference number

IR.ARAKMU.REC.1398.300

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52.0

ICD-10 code description

Hypoactive sexual desire disorder

Primary outcomes

1

Description

Improve sexual function

Timepoint

Before intervention and 1 month after intervention

Method of measurement

FSFI Women's Sexual Functioning Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the first group, there are two individual counseling sessions based on the explissit model and weekly for one hour. The instruments used were posters, pamphlets and whiteboards. Before and after the intervention, one month after the end of the intervention, sexual function was measured and compared with the second group

Category

Rehabilitation

2

Description

Intervention group: For the second group, two individual counseling sessions based on the GATHER model are offered weekly for one hour. The instruments used were posters, pamphlets and whiteboards. Before and after the intervention, one month after the end of the intervention, sexual function was measured and compared with the first group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

KHorramabad Health Centers

Full name of responsible person

Hadis Fattah

Street address

Deputy of Health., Anushirvan Square

City

KHorramabad

Province

Markazi

Postal code

3814957558

Phone

+98 66 3323 9919

Email

Hadisfth@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

University complex of the Great Prophet., Sardasht

City

Arak

Province

Markazi

Postal code

6819767373

Phone

+98 66 3340 6516

Email

Hadisfth@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak University of Medical Sciences

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

Arak University of Medical Sciences

Full name of responsible person

Hadis Fattah

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

University complex of the Great Prophet., Sardasht

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3417 3503

Fax**Email**

hadisfth@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Katayoon Vakilian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Second Floor., Blue Wing Building., Prophet University Academic Complex., Sardasht

City

Arak

Province

Markazi

Postal code

6819767373

Phone

+98 86 3417 3503

Email

cattyv2002@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hadis Fattah

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

University complex of the Great Prophet., Sardasht

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3417 3503

Fax

Email

hadisfth@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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Main outcome information

When the data will become available and for how long

Access started from 1400

To whom data/document is available

public

Under which criteria data/document could be used

Send researcher an email

From where data/document is obtainable

Original author - Email

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

Confirmation of original author and supervisor

Comments