Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparision the Effectiveness of Counseling based on two models of PLISSIT and BETTER on Sexual function and Sexual self-disclosure of women after childbirth

Protocol summary

Study aim

Comparision of the effectiveness of sexual couseling based on PLISSIT and BETTER models on sexual function and sexual self-disclosure of women after childbirth

Design

A total of 80 women with score 28 or less than 28 in FSFI questionnaire between 4weeks to 6 months after chilldbirth randomly divided into two groups of PLISSIT and BETTER by table of random numbers.

Settings and conduct

A total of 80 women with history of sexual problem between 4weeks to 6 months after chilldbirth, will be randomized into one of the groups. subjects were allocated to each group ofPLISSIT and BETTER randomly by Table of random numbers. First group will receive PLISSIT model and BETTER model will be implemented for the second group. Both groups will participate in two sessions. All enrolled subjects will be assessed for demographic characteristics, sexual function, sexual self-disclosure, stress, depression and anxiety.Not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Giving a written consent; Having literacy; Being iranian and living in Mashhad; Having a single child in recent pregnancy; Age 20-45 years; Married and having an intact marriage; Participate in study from 4weeks to 6 months after delivery; Having sex sfter delivery; Score 28 or less than in FSFI questionnaire; Do not have chronic medical history that affect on sexual function; Term pregnancy.Exclusion criteria: Alcohol and other form of drug abuse; Severe mental disorder; Participate in sexual educational sessions outside the study enviroment; Taking medications that affect sexual function in woman or her husband; Prostatic and sexual dysfunction in husband; Postpartum complications inrecent delivery; History of surgical procedures or pelvic radiotherapy.

Intervention groups

PLISSIT model (Permission, Limited Information, Specific Suggestions, Intensive Therapy):The subjects in this group will receive five 60-90 minute therapy sessions.St1: Permission; client freely talks about her sexual concerns. Permission also is given to those non-problematic sexual behaviors which subject has already experienced. St2: Limited Information; therapist provides patient with limited information about the given problem. St3: Specific Suggestions; specific recommendations are offered enabling patient to manage her sexual problems. The fourth stage: Intensive Therapy; psycho-sexual therapy is performed by the researcher or Co-I psychiatrist.BETTER treatment model:The subjects in this group will receive five 60-90 minute therapy sessions.BETTER model include 6 steps.St1: Bring up;the counselor simply speaks to the client about sexual issues and tells them that he can talk quite comfortable. In fact, this step is to give the client a chance to talk about sexual issues and identify her attitudes. St2: Explain; The consultant explains the importance and impact of sexual issues on quality of life, and also tells the reader that it is completely free to talk about this. It helps to normalize sexual discourse and reduce feelings of shame.St3: TELL; The consultant assures the client that she will provide all his information to solve her problem. St4:Time; The counseling time is determined on the basis of the patient's preference. St5: Educate; The counselor will educate the patient about the complications of childbirth, the effects of childbirth on sexual matters.St6: Record; Interventions and therapeutic outcomes are recorded.At the end one month after the last sessions, the degree of sexual self-disclosure and sexual function score Sex is measured.

Main outcome variables

sexual function; sexual self-disclosure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170430033718N3**
Registration date: **2018-03-07, 1396/12/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-07, 1396/12/16**
Update count: **0**

Registration date

2018-03-07, 1396/12/16

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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karimifr941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-11, 1396/06/20

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision the Effectiveness of Counseling based on two models of PLISSIT and BETTER on Sexual function and Sexual self-disclosure of women after childbirth

Public title

Comparison the Effectiveness of counseling based on PLISSIT and BETTER models on sexual function and sexual self-disclosure of women after childbirth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Giving a written consent Having literacy Being iranian and living in Mashhad Having a single child in recent pregnancy Age 20 t0 45 years Married and having an intact marriage Participate in study from 4 week to 6 months after delivery Having sex after delivery Score 28 or less than 28 in FSFI questionnaire Do not have chronic medical history that affect on sexual function Term pregnancy

Exclusion criteria:

Alcohol and other form of drug abuse Severe mental disorder Participate in sexual educational sessions outside the study enviroment Taking medications that affect sexual function in woman or her husband Prostatic and sexual dysfunction in husband postpartum complications in recent delivery History of surgical procedures or pelvic radiotherapy

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The initial selection of samples was a multistage cluster. From the five health centers of Mashhad, two comprehensive health services were selected randomly (centers number 1 and 3). Then, among the centers of health center number one, two centers (one in city and the other is the margin) through the lottery. For the health center number three, we also work the same way. Of the 4 centers selected (2 centers are in the margin area and 2 centers in the non-marginal area of Mashhad) we select one health center by lottery, which collects 4 base stations. Of all 4 centers and 4 bases, 10 eligible samples are selected as unpredictable. In order to prevent the exchange of information, Participants in centers and sub-bases receive counseling in two different ways.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

subjects were allocated to each group of intervention and control randomly by Table of random numbers. First group will receive PLISSIT model and BETTER model will be implemented for the second group. Both groups will participate in two sessions. All enrolled subjects will be assessed for demographic characteristics, sexual function, sexual self-disclosure, stress, depression and anxiety.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraishy Building,

University St

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Razavi Khorasan

Postal code
9137913199

Approval date
2017-08-02, 1396/05/11

Ethics committee reference number
IR.MUMS.REC.1396.160

Health conditions studied

1

Description of health condition studied
sexual function

ICD-10 code
F52.9

ICD-10 code description

Primary outcomes

1

Description
Sexual Function

Timepoint
Before intervention and 4 weeks after intervention

Method of measurement
female sexual function index

2

Description
Sexual self-disclosure

Timepoint
Before intervention and 4 weeks after intervention

Method of measurement
Hurlbert Sexual Self-disclosure questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: First, the FSFI and DASS-21 questionnaires and the Hulbert sexual self-disclosure questionnaire are measured by the individuals and the sexual function, sexual self-disclosure, and the degree of anxiety, depression and stress.PLISSIT model (Permission, Limited Information, Specific Suggestions, Intensive Therapy):The subjects in this group will receive five 60-90 minute therapy sessions. Sessions 1, 2 are all adapted from the PLISSIT treatment model including four therapeutic stages. St1: Permission; client freely talks about her sexual concerns. Permission also is given to those non-problematic sexual behaviors which subject has already experienced. St2: Limited Information; therapist provides patient with limited information about the given problem. St3: Specific Suggestions; specific recommendations are offered enabling patient to manage her sexual problems. The fourth stage: Intensive Therapy; psycho-sexual therapy is performed by the researcher or Co-I psychiatrist. All subjects will be provided the two therapy sessions even if they might not need to receive intensive therapy. Researcher will be in contact with the subjects regularly to avoid missing follow up as well as addressing their concerns related to the therapy. Interventions for the subjects will be free of charge. One month after the last session, sexual self-disclosure and sexual function are re-measured.

Category
Other

2

Description
Intervention group2: Intervention group1: First, the FSFI and DASS-21 questionnaires and the Hulbert sexual self-disclosure questionnaire are measured by the individuals and the sexual function, sexual self-disclosure, and the degree of anxiety, depression and stress. BETTER model(Bring up,Explain,Tell,Time,Educate,Record). The subjects in this group will receive five 60-90 minute therapy sessions. Sessions 1, 2 are all adapted from the BETTER treatment model including six therapeutic stages. St1: Bring up; In the first step, the counselor simply speaks to the client about sexual issues and tells them that he can talk quite comfortable. In fact, this step is to give the client a chance to talk about sexual issues and identify her attitudes. St2: Explain; The consultant explains the importance and impact of sexual issues on quality of life, and also tells the reader that it is completely free to talk about this. It helps to normalize sexual discourse and reduce feelings of shame.St3: TELL; The consultant assures the client that she will provide all his information to solve her problem. St4:Time; The counseling time is determined on the basis of the patient's preference. Since rebuilding sex is a continuous process, the counselor should be available to address the concerns and respond to the patient's questions. St5: Educate; The counselor will educate the patient about the complications of childbirth, the effects of childbirth and lactation on sexual matters, so that her concerns go away. The counselor must be familiar with the client's knowledge of how to deal with sexual problems in order to correct misconceptions about proximity to delivery. St6: Record; Assessments, interventions and therapeutic outcomes are recorded. In order to prevent samples from falling and respond to their health problems, the researcher will frequently contact with the individuals during the visits. At the end one month after the last session, the degree of sexual self-confidence and performance score Sex is measured again.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Emamt comprehensive Health Services Center

Full name of responsible person
Dr Motahari

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28 Emamt, Emamat Blvd

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2

Recruitment center

Name of recruitment center
Ahmadi comprehensive Health Services Center

Full name of responsible person
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3

Recruitment center

Name of recruitment center
Valiasr comprehensive Health Services Center

Full name of responsible person
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4

Recruitment center

Name of recruitment center
Emam Hadi comprehensive Health Services Center

Full name of responsible person
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5

Recruitment center

Name of recruitment center
Banafshe health center

Full name of responsible person
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6

Recruitment center

Name of recruitment center
Sina health center

Full name of responsible person
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7

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Name of recruitment center
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8

Recruitment center
Name of recruitment center
Sanaii health center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
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Full name of responsible person
Farzaneh karimi
Position
Midwifery Master, Student
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available