

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Effectiveness Biofeedback with Electrical Stimulation in Improving Patient with Sexual Dysfunction

Protocol summary

Study aim

Evaluation of the Effectiveness Biofeedback compared with Electrical Stimulation in Patient with Sexual Dysfunction

Design

Two arm parallel group Semirandomised trial .

Settings and conduct

Patient with Sexual Dysfunction who Visit Emam Reza Hospital, Tehran are divided in Semirandomized manner in Two Group Biofeedback and Electrical Stimulation and have Therapy for 12 session

Participants/Inclusion and exclusion criteria

Stress Incontinency and Sexual Dysfunction, married, No Existence History of Systemic and Psychollogic Illness, No Existence Pelvic Floor Surgery, Absence Pelvic Floor prolapse grade3,4, Absence Use of Psychoaffective drugs

Intervention groups

Two Groups of Biofeedback and Electrical Stimulation

Main outcome variables

Desire, Arousal, Lubrication, Orgasm, Satisfaction, Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039319N1**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **retrospective**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

Registration date

2018-05-09, 1397/02/19

Registrant information

Name

Behnaz Aalaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3824 1935

Email address

aalaie_behnaz@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness Biofeedback with Electrical Stimulation in Improving Patient with Sexual Dysfunction

Public title

Evaluation of the Effect Biofeedback and Electrical Stimulation in Sexual Dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Stress incontinency and Sexual Dysfunction married

Exclusion criteria:

No Existence Systemic and Psychologic Illness No existence History of Pelvic Floor surgery No existence Pelvic Organ Prolapse grade3,4 Absence Psychoaffective drugs use

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Actual sample size reached: **10**

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 committee of Aja University of Medical Sciences

Street address

Emam Reza Hospital, E,temadzadeh Ave, west Fatemi Ave, Tehran city

City

Tehran

Province

Tehran

Postal code

1411718546

Approval date

2018-02-25, 1396/12/06

Ethics committee reference number

IR.AJAUMS.REC.1396.106

Health conditions studied**1****Description of health condition studied**

Stress incontinency, Sexual Dysfunction

ICD-10 code

N81.2

ICD-10 code description

Incomplete uterovaginal prolapse

Primary outcomes**1****Description**

Sexual Dysfunction Score in FSFI Questionarie

Timepoint

Sexual Dysfunction Score at initial of therapy and 1,,3 monthes after intervention

Method of measurement

FSFI Questionarie

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Biofeedback

Category

Treatment - Other

2**Description**

Intervention group: Electrical Stimulation

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Behnaz Aalaie

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Dr Sharif Najafi

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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

Artesh 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**

Artesh University of Medical Sciences

Full name of responsible person

Behnaz Aalaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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

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

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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