Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

لاتین Influence of two regular physical activity interventions on sexual dysfunction and steroid level in female patients with major depressive disorders and undergoing a treatment with SSRIs – randomized interventional study

Protocol summary

Study aim
Influence of physical activity on sexual dysfunction due to SSRIs in female patients with major depressive disorders

Design
randomized ,double blind ,parallel, Clinical trials with control group

Settings and conduct
After a thorough screening and once a participant is randomized, she completes a brief questionnaire on habitual sexual activity and sexual dysfunction. Thereafter, at baseline, participants complete a series of questionnaires on sexual dysfunction, depression, sleep, psychological functioning, and physical activity. In parallel, experts blind to participants' group allocation rate participants' symptoms of depression. Further, blood samples are taken to assess steroids.Such an assessment is repeated at week 6, and week 12 (end of the study). Additionally, at week 3 and week 9, participants rate their sexual dysfunction, depression and sleep complaints.

Participants/Inclusion and exclusion criteria
1. Female, Age between 18 and 50 years, major depressive disorders, SSRI-induced sexual dysfunction,Willing and able to comply with the study conditions,Continuous treatment with an SSRI, Signed written informed Exclusion criteria: 1. Other psychiatric disorders such as bipolar disorders, anxiety disorders, post-traumatic stress disorders, or personality disorders. 2. Pregnant or intending to get pregnant during the period of the study, or breastfeeding; 3. Serious physical impairments such as injuries, surgery recently only recently accomplished, or accidents; 4. Currently under further treatments such as regular physical activity, neuromodulation, or psychotherapy

Intervention groups
Intervention 1: Endurance training Intervention 2: Coordinative training Control: without training

Main outcome variables
sexual dysfunction, Steroids level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090304001743N16**
Registration date: **2020-05-29, 1399/03/09**
Registration timing: **prospective**

Last update: **2020-05-29, 1399/03/09**
Update count: **0**

Registration date
2020-05-29, 1399/03/09

Registrant information

Name
Mohammad Haghighi

Name of organization / entity
Research Center for Behavioral Disorders and Substance Abuse, Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01
Expected recruitment end date
2021-03-19, 1399/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
لاتین Influence of two regular physical activity interventions on sexual dysfunction and steroid level in female patients with major depressive disorders and undergoing a treatment with SSRIs – randomized interventional study

Public title
لاتین Influence of two regular physical activity interventions on sexual dysfunction and steroid level in female patients with major depressive disorders and undergoing a treatment with SSRIs
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Major depressive disorders characterized by trained psychiatrists and clinical psychologists based on DSM-5 criteria SSRI-induced sexual dysfunction, diagnosed by an accurate clinical interview based on DSM-5 criteria Signing a written consent 18-50 years old
Exclusion criteria:
Pregnancy or intention to conceive during the study period or breastfeeding other psychiatric disorders
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is performed with the software randomization.com, generating at random 3 x 15 assignments/tickets. A psychologist not further involved in the study prepares the 3 x 15 tickets and puts them each in a sealed envelope. All 45 envelopes are put in an opaque box and stirred. Once an envelope is drawn, it is put aside.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients in two groups experience different physical activities, and one group will not be active.Therefore,researcher and the clinical caregiver are not aware of the group experience . The investigator of the outcome is also unaware of the group experience .
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Fahmideh Bulvar.Mahdieh street
City
Hamadan
Province
Hamadan
Postal code
65178
Approval date
2020-05-22, 1399/03/02
Ethics committee reference number
IR.UMSHA.REC.1399.218

Health conditions studied

1

Description of health condition studied
medication induced sexual dysfunction
ICD-10 code
F13.981
ICD-10 code description
Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic or anxiolytic-induced sexual dysfunction

Primary outcomes

1

Description
Sexual dysfunction
Timepoint
Before the intervention,3,6,9,12 weeks after the intervention
Method of measurement
Female Sexual Function Index score

2

Description
steroid level in blood
Timepoint
Before the intervention,12 weeks after the intervention
Method of measurement
level of Estrogen,Progesterone, testosterone,Cortisol in Blood

Secondary outcomes

1

Description
Emotion Regulation
Timepoint
Before the intervention, 6,12 weeks after the intervention
Method of measurement
emotional competencies inventory

2

Description
Social activity
Timepoint
Before the intervention, 6,12 weeks after the intervention
Method of measurement
Social Adaptation Self-evaluation Scale

3

Description
Depressive symptoms
Timepoint
Before the intervention,3, 6,9,12 weeks after the intervention
Method of measurement
Beck Depression Inventory-Fast Screen

4

Description
Hypomania
Timepoint
Before the intervention, 6,12 weeks after the intervention
Method of measurement
Hypomania Check List 32

5

Description
Insomnia
Timepoint
Before the intervention,3, 6,9,12 weeks after the intervention
Method of measurement
Insomnia Severity Index

6

Description
Physical activity
Timepoint
Before the intervention, 6,12 weeks after the intervention
Method of measurement
International Physical Activity Questionnaire (IPAQ).

Intervention groups

1

Description
Intervention group: endurance training,30-45 min in duration,for 12 consecutive weeks and consists of three weekly. After 5 min of warming-up and stretching, participants exercised for 25-35min on treadmill, exercise bicycles or walking/jogging over ground. Participants are encouraged to keep the pace during the intervention, though, they were allowed to pause individually for 1-2min. After the intervention, it follows a cooling down of 5min. At the end of a session, participants should have the feeling to be slightly exhausted, but not severely exhausted
Category
Treatment - Other

2

Description
Intervention group: Coordinative training,30-45 min in duration,for 12 consecutive weeks and consists of three weekly.After 5 min of warming up, exercises focus on coordinative training such as balancing on a small bar, mirroring and imitating movements of others (such as dancing steps), balancing balls, ‘football-tennis’, balancing with closed eyes on a rope on the floor and similar exercises. At the end of a session, participants should have the feeling to be slightly exhausted, but not severely exhausted . Cooling down lasts for about 5min.
Category
Treatment - Other

3

Description
Control group: with out training
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Mohammad Haghighi
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Dibaj street, Farshchian Hospital

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Mohammad Haghighi
Position
Professor of Psychiatry
Latest degree
Subspecialist
Other areas of specialty/work
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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