Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of physical activity intervention on mood, marital satisfaction, sexual self-concept and serotonin and adrenaline levels in women consumer birth control pills

Protocol summary

Study aim

1. Comparison the mean score of the Mood and Sexual Function Scale in women taking birth control pills 2. Comparison the mean score of sexual self-concept and marital satisfaction in women taking birth control pills 3. Comparison the average score of physical activity in women taking birth control pills 6. Comparison the mean laboratory of serotonin level in women taking birth control pills 7. Comparison the mean laboratory of adrenaline level in women taking birth control pills

Design

The randomized controlled trial .Study is not blind. The sample size was based on the probability of the first type error was α = 0.05 and the second type error was β = 0.2, and considering the 10% drop, a total of 70 people (35 in each group) were selected.

Settings and conduct

Individuals are randomly selected based on the list in 6 health centers. The data of this study are analyzed by descriptive tests, correlation, regression, paired t-test.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age under 45 years Minimum fifth grade education Consumer of oral contraceptive pills Lack of orthopedic problems and mood disorders Exclusion criteria: Absence of more than 2 sessions in the sports program Stop taking birth control pills Foot injury and immobility during the study

Intervention groups

Sports intervention: Explain aerobic physical activity. The practical exercises are performed as follows: 3 sessions of aerobic exercise per week (warm-up, basic, cooling movements). The duration of training in the first and second weeks is equal to 35-40 minutes, in the third and fourth weeks to 45-40 minutes and in the fifth and sixth weeks to 45-55 minutes. For the control group, periodic routine care will be performed.

Main outcome variables

Changes in mood, marital satisfaction, sexual self-concept, serotonin and adrenaline levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180918041066N1**
Registration date: **2022-02-01, 1400/11/12**
Registration timing: **prospective**

Last update: **2022-02-01, 1400/11/12**
Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

Maryam Changizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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mrs.changizi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-02, 1400/11/13

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of physical activity intervention on mood, marital satisfaction, sexual self-concept and serotonin and adrenaline levels in women consumer birth control pills

Public title

The effect of physical activity intervention on mood, marital satisfaction, sexual self-concept, serotonin and adrenaline levels

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women referred and covered by the Comprehensive Health Service Cente Ager under 45 years Minimum fifth grade literacy Consumer of oral contraceptive pills Lack of orthopedic problems and mood disorders

Exclusion criteria:

Absence of more than 2 sessions in the sports program، Stop taking birth control pills ، Foot injury and immobility during the study

Age

To **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the urban health centers and 6 helth centers are randomly selected . Individuals are randomly selected based on the list of names in health centers .For random allocation using the 4-block method using random allocation software, subjects are divided into 2 groups of control and case.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Abadan School of Medical Sciences

Street address

Deputy of Education and Research, Next to Ayatollah Jami International Airport, Airport Square, Abadan, Iran

City

Abadan

Province

Khouzestan

Postal code

6313833177

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.ABADANUMS.REC.1400.105

Health conditions studied

1

Description of health condition studied

Psychological changes of birth control pills consumption

ICD-10 code

Z30.41

ICD-10 code description

Encounter for surveillance of contraceptive pills

Primary outcomes

1

Description

sexual self-concept,Mood (emotional state), marital satisfaction (assessing the happiness and stability of a marriage), serotonin or 5-hydroxytryptamine level (a monoamine with an important role in regulating the neurotransmitter of the neuro-hormonal system, adrenaline level.

Timepoint

Data will be collected before the intervention (pre-test) and 3 months after the intervention (post-test).

Method of measurement

Mood Questionnaire: Persian version of Bromez Mood status Questionnaire, Women's Sexual Function Scale (Questionnaire), Sexual Self-Concept (Questionnaire), Marital Satisfaction Questionnaire (Questionnaire), Short Form Physical Activity (IPAQ) (Questionnaire), Sertonin and Adrenaline (Blood test)

Secondary outcomes

1

Description

There study has no secondary consequence variable

Timepoint

zero

Method of measurement

No measurement

Intervention groups

1

Description
Intervention group: They will receive a sports activity program for several weeks. Before the study, a blood sample is measured to determine the levels of the hormones serotonin and adrenaline, and 3 months after the study, it will be re-evaluated along with other variables.

Category
Behavior

2

Description
Control group: For this group, periodic care related to the contraceptive pill user is performed

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Center ,Abadan .Iran

Full name of responsible person
maryam changizi

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Next to the Emergency Medical Center, Station no 10. Bahar St, Abadan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Abadan University of Medical Sciences

Full name of responsible person
Dr. Esmat Radmanesh

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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
Abadan 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
Abadan University of Medical Sciences

Full name of responsible person
Maryam changizi

Position
Employee of Health Deputy, Abadan, Iran

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available