

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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 $\alpha = 0.05$ and the second type error was $\beta = 0.2$, 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)

Phone

+98 61 5332 9306

Email address

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

Street address

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

City

Abadan

Province

Khouzestan

Postal code

6318663659

Phone

+98 61 5338 4004

Email

abadan@domain.ac.ir

Web page address

<https://healthcenter.abadanums.ac.ir/portal/home/?276127/%D9%85%D8%B1%DA%A9%D8%B2-%D8%A8%D9%87%D8%AF%D8%A7%D8%B4%D8%A-A-%D8%A2%D8%A8%D8%A7%D8%AF%D8%A7%D9%86>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abadan University of Medical Sciences

Full name of responsible person

Dr. Esmat Radmanesh

Street address

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

City

Abadan

Province

Khouzestan

Postal code

6313833177

Phone

+98 61 5326 5361

Fax

Email

abadan@aums.ac.ir

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

Street address

Deputy of Health, street no.15, Ahmedabad, Abadan, Iran

City

Abadan

Province

Khouzestan

Postal code

6316794194

Phone

+98 61 5332 9313

Email

mrs.changizi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Welfare Organization, Abadan, Iran

Full name of responsible person

Kefaiat salmanian

Position

employee

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Razi St , Shahid Montazeri Blvd, Abadan, Iran

City

Abadan

Province

Khouzestan

Postal code

6316794132

Phone

+98 61 5322 8630

Email

kefayat.salmaniyan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Abadan University of Medical Sciences

Full name of responsible person

Maryam changizi

Position

Employee of Abadan Health Deputy, Abadan, Iran.

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Deputy of Health, Street no.15, Ahmadabad, Abadan, Iran

City

Abadan

Province

Khouzestan

Postal code

6316794194

Phone

+98 61 5332 9313

Email

mrs.changizi@yahoo.com

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