ISRCTN10416750 https://doi.org/10.1186/ISRCTN10416750

Effect of physical exercise on treadmill in women with polycystic ovary syndrome

Submission date
24/07/2018

Recruitment status
No longer recruiting

Registration date
14/08/2018

Overall study status
Completed

Last Edited
01/09/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Polycystic ovary syndrome (PCOS) is a common condition that leads to hyperandrogenism (excess male sex hormones) and other hormone alterations, increased weight and waist-to-hip ratio (WHR), behavioural changes such as sexual dysfunction, anxiety and dperession, and a reduced quality of life. Physical exercise is one of the ways to reduce these effects of PCOS. However, there have been no studies that have evaluated the effects of exercise on sexual function in women with PCOS.
This study aims to look at the effects of continuous and intermittent aerobic exercise on hormones, metabolism, body measurements such as weight and WHR, sexual function, quality of life, depression and anxiety, and telomere length (part of human chromosomes, the length of which affect how we age) in women with PCOS.

Who can participate?
Women with PCOS aged 18-39 years old with a BMI of 18-39.9 kg/m² who do not participate in regular exercise

What does the study involve?
Participants will be randomised into 3 groups - CAT, IAT and control.
The CAT group will be asked to perform 40-60 minutes of continuous physical aerobic training on a treadmill 3 times per week for 16 weeks.
The IAT group will be asked to perform 40-60 minutes of intermittent physical aerobic training on a treadmill 3 times per week for 16 weeks.
The control group will not perform any exercise.
At the start of the study and after 16 weeks of training, all 3 groups will be assessed on their sexual function and depression/anxiety by questionnaire. Blood samples will be taken to assess metabolic, hormonal and genetic changes, and weight, height, WHR and BMI will be measured using standard techniques. Additionally, participants will undergo X-rays to determine body fat.

What are the possible benefits and risks of participating
The possible benefit of participating is that exercise may lead to improvements both physically and mentally. There is a possible minor risk of discomfort during blood collection or breathlessness during physical training.

Where is the study run from?
Ribeirão Preto Medical School, University of São Paulo, Brazil

When is the study starting and how long is it expected to run for?
July 2014 to October 2018

Who is funding the study?
State Research Support Foundation of São Paulo (FAPESP) (Brazil)

Who is the main contact?
Professor Rosana Maria dos Reis
romareis@fmrp.usp.br

Contact information

Type(s)
Scientific

Contact name
Mr VICTOR RIBEIRO

ORCID ID
https://orcid.org/0000-0001-8753-7975

Contact details
Ribeirão Preto Medical School (FMRP), USP
Av. Bandeirantes, 3900, Monte Alegre
RIBEIRÃO PRETO
Brazil
14049-900

Type(s)
Scientific

Contact name
Mrs ROSANA REIS

ORCID ID
https://orcid.org/0000-0001-9631-4167

Contact details
Ribeirão Preto Medical School (FMRP), USP
Av. Bandeirantes, 3900, Monte Alegre
Ribeirão Preto
Brazil
14049-900

Type(s)
Scientific

Contact name
Mrs GISLAINE KOGURE

ORCID ID
https://orcid.org/0000-0002-2860-846X

Contact details
Ribeirão Preto Medical School (FMRP), USP
Av. Bandeirantes, 3900, Monte Alegre
Ribeirão Preto
Brazil
14049900

Additional identifiers

Protocol serial number
RBR/78qtwy

Study information

Scientific Title
Effect of continuous and intermittent aerobic physical training in women with polycystic ovary syndrome

Acronym
Effect of physical exercise in women with polycystic ovary syndrome

Study objectives
Continuous and intermittent aerobic physical training improves anthropometric, endocrine, metabolic, and inflammatory parameters of body composition, telomere length, epigenetics, sexual function, quality of life, anxiety and depression and body image in women with polycystic ovary sundrome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the University Hospital (UH), Ribeirao Preto Medical School, University of Sao Paulo, 26/08/2014, 9640/2014

Study design
Interventional open three-arm randomized controlled parallel trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Polycystic ovary syndrome (PCOS)

Interventions
A randomisation stratified by BMI (<30 kg / m² and ≥ 30 kg / m²) was used using blocks of 15. Each block of 15 allocated 5 participants to Group I, 5 to Group II and 5 to Group III. The allocation group was placed into sequentially numbered sealed opaque envelopes that were grouped into blocks of 15. These blocks were picked up consecutively and separated depending on the participant's BMI at the time of inclusion. After the inclusion of the participant, the envelope was opened and the patient was allocated according to the contents of the envelope. 90 women with polycystic ovary syndrome (PCOS) will be placed randomly in three parallel groups.
Participants in Group I will perform continuous aerobic physical training in a treadmill with 40-60 minutes of workout during 16 weeks, 3 times per week.
Participants in Group II will perform intermittent aerobic exercise training in a treadmill with 40-60 minutes of workout during 16 weeks, 3 times per week.
Participants in Group III will be the placebo group and therefore will not receive any intervention.
The training protocol for the groups I and II will also have 5 minutes of heating and 5 minutes cool-down (50-60% of maximum heart rate). The intensity of the continuous aerobic physical training (Group I) and interval aerobic physical training (Group II) will be adjusted to provide the same volume of training for both groups. The intensity will be calculated using the formula 220 - age x % intensity, which is between 60 and 90%. Progressions of time as the intensity take place during the training, respecting the range of values mentioned above, as far as increased training volume.

Intervention Type
Other

Primary outcome(s)
Alterations in telomere content, analyzed by quantitative real time polymerase chain reaction (qPCR) at the baseline and after 16 weeks of physical training for all groups. The data are expressed in relative values of 2-CT in which it is expected a difference of 0.3 between the group.

Key secondary outcome(s))
Changes in the following were measured at the baseline and after 16 weeks of physical training for all groups:
1. Hormone concentrations and endocrine parameters, assessed by chemiluminescence
2. Body composition, assessed by absorptiometry method Dual Energy X-Ray absortiometry (DEXA), skin folds and bioelectrical impedance
3. Anthropometric indices
4. Epigenetic mechanisms, investigated by the Genome-Wide DNA methylation, X inactivation and the CAG repeat polymorphism within the androgen receptor gene
5. Quality of life, assessed using the Short Form 36 (SF-36) questionnaire
6. Anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS) questionnaire
7. Sexual function, assessed using the Female Sexual Function Index (FSFI)
8. Body image, assessed using the Body Shape Questionnaire (BSQ) and Figure Rating Scale (FRS)

Completion date
20/10/2018

Eligibility

Key inclusion criteria
1. Polycystic ovary syndrome
2. Aged 18-39 years
3. BMI 18-39.9 kg/m² (normal, overweight and obesity grades I and II)
4. Do not practice regular physical activity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
39 years

Sex
Female

Total final enrolment
87

Key exclusion criteria
1. Presence of systemic disease that contraindicate physical activity
2. Presence of disabling musculo-skeletal disorders
3. Use of drugs that interfere with the hypothalamic-pituitary-ovarian-axis
4. Use of hormonal contraceptives
5. Smoking
6. Pregnant
7. Not available to participate in all stages of the study

Date of first enrolment
05/11/2014

Date of final enrolment
15/04/2017

Locations

Countries of recruitment
Brazil

Study participating centre

Ribeirao Preto Medical School, University of Sao Paulo
Av. Bandeirantes, 3900, Monte Alegre
Ribeirão Preto-SP
Brazil
CEP: 14049-900

Sponsor information

Organisation
Faculty of Medicine of Ribeirão Preto

ROR
https://ror.org/00ey54k21

Funder(s)

Funder type
Not defined

Funder Name
Foundation for Research Support of the State of São Paulo

Funder Name
Coordination of Improvement of Higher Level Personnel

Funder Name
National Council for Scientific and Technological Development

Results and Publications

Individual participant data (IPD) sharing plan
The datasets analysed during the current study will be available upon request from romareis@fmrp.usp.br. The data can be made available with averages and standard deviations and final statistics after being published. In addition, the volunteers will not be identified, and the confidentiality of the information related to the participant's privacy will be maintained, as applied by the consent term of this study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2020	19/08/2021	Yes	No
Results article		27/10/2021	06/09/2023	Yes	No
Other publications	Secondary analysis	21/01/2024	01/09/2025	Yes	No