

Polarized exercise training improves cardiometabolic health

Submission date 12/06/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/06/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/10/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Being obese or overweight and having poor cardiorespiratory capacity (ability of the heart and lungs to deliver oxygen around the body and remove carbon dioxide during exercise) are independent risk factors linked with development of long-term diseases and death. It is well known that having a high cardiorespiratory capacity can improve obesity-related diseases such as type 2 diabetes, high cholesterol and high blood pressure. It is well known that exercising more has the ability to improve cardiorespiratory capacity and metabolic health (chemical processes in the body) in obese patients, however the best form of training is not known. The aim of this study is to compare the effects of a high intensity exercise programme, a moderate intensity endurance exercise programme and a polarized training (80% high intensity, 20% low intensity) programme to find out which is best able to improve cardiorespiratory capacity and metabolism in obese women.

Who can participate?

Overweight/obese adult woman aged between 20-40 years.

What does the study involve?

Participants are randomly allocated to one of four groups. Those in the first group do not do any extra exercise during the 12 weeks of the study. Those in the second group take part in moderate intensity endurance training, which involves 45-50 minute sessions of cycling exercise at a constant speed three times a week for 12 weeks. Those in the third group take part in high intensity exercise, which involves three training sessions a week for 12 weeks. These sessions involve four sets of four bouts of very high intensity cycling, with two minutes of active recovery (slow cycling) between bouts and four minutes of passive recovery (sitting or back pedaling) between sets. Those in the fourth group take part in three sessions of polarized training a week for 12 weeks. This involves 30 minutes of cycling exercise at a constant speed with two sets of three bouts of high intensity cycling for 60 seconds, with two minutes of active recovery between bouts and 4 minutes of passive recovery between sets. Participants in all groups must attend 80% of the sessions in order to finish the study. At the start of the study and then again after 12 weeks, all participants undergo a number of medical tests to measure their cardiorespiratory capacity.

What are the possible benefits and risks of participating?

The expected benefits are improved cardiorespiratory and metabolic health outcomes compared with participants included in control group. Possible risks are limited to minor injuries or discomfort during the training process.

Where is the study run from?

The University of Concepción (Chile)

When is the study starting and how long is it expected to run for?

May 2015 to December 2015

Who is funding the study?

The University of Concepción (Chile)

Who is the main contact?

Professor Hugo Cerda Kohler

hugo.cerda@gmail.com

Contact information

Type(s)

Scientific

Contact name

Prof Hugo Cerda Kohler

Contact details

Universidad de Chile

Independencia 1027

Santiago

Chile

8380453

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2016-PI215136015-1.0IN

Study information

Scientific Title

Greater reductions in cardiometabolic risk factors in overweight and obese young women with polarized training

Study objectives

Polarized training induce greater adaptive responses compared to endurance or high intensity interval training in obese and overweight female patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethical Committee at the Universidad de Concepción (University of Concepción), ref: 2016-PI215136015-1.0IN

Study design

Single-centre four-arm randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

Participants are randomly allocated to one of four groups using SPSS Statistics Software.

Control group: Participants do not participate in any formal physical activity.

Moderate-intensity endurance training group: Participants take part in 36 supervised cycling sessions spread over 12 weeks (3 sessions/week). These sessions involve 45-50 minutes of cycling exercise with a constant cadence (70-80 rpm) at 95% of pVT1.

High intensity interval-training group: Participants take part in 36 supervised cycling sessions spread over 12 weeks (3 sessions/week). These sessions consist of four sets of four bouts of 60 second cycling exercise at 90% pVO₂max, with 2 minutes of active recovery between bouts (~30-40 W) and four minutes of passive recovery (i.e., sitting or backward pedaling in the cycle-ergometer) between sets. This prescription remained consistent for every training session.

Polarized training group: Participants take part in 36 supervised cycling sessions spread over 12 weeks (3 sessions/week). These sessions consist of 30 minutes of cycling exercise with a constant cadence (70-80 rpm) at 95% of pVT1; plus 2 sets of 3 bouts of 60s cycling exercise at

100% pVO₂max, with 2 minutes of active recovery between bouts (~30-40 W) and 4 minutes of passive recovery (i.e., sitting or backward pedaling in the cycle-ergometer) between sets.

To be included in the analysis, the participants have to attend at least 80% of the training sessions. Nutritional intake is not standardized, but all the participants are instructed to maintain their normal dietary habits throughout the course of the study. In order to maintain the intensity prescribed, the overall rating of perceived exertion and heart rate is obtained at the end of all training sessions. If one of these variables decreased over two consecutive training sessions, the power output is increased by 5-10 watts. Participants in all groups are followed up after 12 weeks.

Intervention Type

Other

Primary outcome measure

Cardiorespiratory capacity is assessed through a maximal incremental test on a cycle-ergometer and gas exchange recorded continuously with a portable breath-to-breath gas analyzer at baseline and 12 weeks.

Secondary outcome measures

1. Blood lactate concentration is measured using a standard enzymatic lactate analyzer at baseline and 12 weeks
2. Heart rate is measured during exertion using a cardiac monitor at baseline and 12 months
3. Perceived exertion (RPE) is measured immediately after exercise using the ten-point Borg scale at baseline and 12 weeks
4. Body composition (total body and regional estimates of bone mass, bone mineral density, fat mass, lean mass, and fat percentage) is measured using dual X-ray absorptiometry (DXA) at baseline and 12 weeks
5. Whole body insulin sensitivity was assessed using an oral glucose tolerance test and the Quantitative Insulin Sensitivity Check Index (QUICKI) at baseline and 12 weeks
6. Insulin resistance is estimated using the Homeostasis Model of Assessment of Insulin Resistance (HOMA-IR) at baseline and 12 weeks

Overall study start date

01/05/2015

Completion date

04/12/2015

Eligibility

Key inclusion criteria

1. Age between 20 and 40 years
2. Female.
3. Body mass index (BMI) between 27 and 40 kg/m²
4. Physically inactive (i.e. less than 2 hours of physical activity/week)
5. Non-diabetic
6. Able to be enrolled in a high-intensity exercise training program

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

After sign a written-informed consent, 52 eligible young women were enrolled in the intervention

Key exclusion criteria

1. Hypertension, cardiovascular or respiratory disease
2. Acute or chronic inflammatory diseases
3. Digestive system surgery
4. Thyroid hormone replacement
5. Antidepressants consumption
6. Pregnancy
7. Recent participation (i.e. less than two months) in training or diet interventions

Date of first enrolment

03/08/2015

Date of final enrolment

28/08/2015

Locations**Countries of recruitment**

Chile

Study participating centre

Universidad de Concepción

Concepción

Chile

4440000

Sponsor information**Organisation**

University of Concepción

Sponsor details

Juan Antonio Coloma 0201

Los Ángeles

Chile
4440000

Sponsor type
University/education

ROR
<https://ror.org/0460jpj73>

Funder(s)

Funder type
University/education

Funder Name
Universidad de Concepción

Alternative Name(s)
University of Concepcion, UdeC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Chile

Results and Publications

Publication and dissemination plan
Planned publication in PLOS ONE

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

18/09/2018

Yes

No