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Comparison of two modalities of aerobic training on health-parameters in adolescent obese

Submission date
12/02/2016

Recruitment status
No longer recruiting

Registration date
16/02/2016

Overall study status
Completed

Last Edited
15/02/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obese (very overweight) children are at a higher risk than thought of developing vascular disease (for example, atherosclerosis where the blood vessels become clogged up with fatty deposits). Vascular disease often leads to coronary heart disease, heart disease and stroke in later life. In the early stages of vascular disease, microvascular function (function of the small blood vessels) may be affected, leading, for example, to the walls of the blood vessels to stiffen or become thicker. Studies have not yet been able to show if microvascular function is affected in obese children. Despite the well-established health-related benefits of aerobic training in obese people, it is not clear yet what type and intensity of exercise works best for obese children. There is growing evidence to suggest that high-intensity interval training (HIIT) can be an effective alternative to the more traditional moderate continuous training (MCT). At present there is no information on whether HIIT might have a greater beneficial effect than MCT on the vascular function in obese people. The aims of the present study were to compare the microvascular function of obese and normal-weight adolescents and to determine the effects of three months of HIIT and MCT on microvascular function, body composition (percentage of fat, bone, muscle and water in the body), and aerobic fitness in obese adolescents.

Who can participate?
Obese adolescents aged 12-16 years and healthy normal weight adolescents aged 12-16 years.

What does the study involve?
First of all, all participants undergo a blood flow test. All obese adolescents have further tests including height, weight, body composition, fitness, microvascular function and metabolic profile (for example blood sugar levels and liver and kidney function via blood tests). The obese participants are then randomly allocated to one of two groups. Those in group 1 undergo a 3 month weight loss programme including diet and HIIT. Those in group 2 undergo a similar programme but with MCT. All obese participants undergo the same tests that they had at the start of the study after 3 months to assess its effects.

What are the possible benefits and risks of participating?
One potential benefit for obese adolescents taking part is that they have access to a supervised and well-controlled exercise training sessions that may help them to improve their level of fitness. A potential risk could be that severely obese adolescents may not be able to exercise.. All adolescents will have a complete medical check-up before starting the programme. Participants may be reluctant to have their blood taken for analysis but they can choose not to have one if they wish.

Where is the study run from?
Saint-Pierre University Hospital, Pediatric Institute (France)

When is the study starting and how long is it expected to run for?
January 2013 to June 2014

Who is funding the study?
Saint-Pierre University Hospital, Pediatric Institute (France)

Who is the main contact?
Professor Agnes Vinet

Contact information

Type(s)
Scientific

Contact name
Prof Agnes Vinet

Contact details
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84916

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Microvascular adaptations after moderate continuous and high-intensity interval-training in adolescents with severe obesity

Study objectives
We hypothesized that high-intensity interval-training induced better improvements in microcirculation function moderate continuous, i.e higher changes in peak cutaneous blood flow.

The aims of the study are:
1. To compare the microvascular phenotype of obese adolescents and normal-weight adolescents
2. To determine the effects of three months of high-intensity interval-training and moderate continuous training on microvascular function, body composition, metabolic markers and aerobic fitness in obese adolescents

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (SSR Institut-Saint-Pierre, Palavas-Les-Flots, France), 06/01/2013

Study design
Interventional non-randomised

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Obesity

Interventions
At the start of the study, the cutaneous microvascular function of all participants are assessed. Obese adolescents also undergo body composition, metabolic profile and aerobic fitness assessments. They then undergo a 3-months weight loss program consisting of diet and exercise training managed by a single-pediatric weight center. They are randomly allocated into one of 2 groups of exercise training: either high-intensity interval training (HIIT) or moderate continuous training (MCT) . They all receive an identical moderately hypocaloric diet with a daily energy deficit of 500 kcal. Only the exercise training program differ in both groups. Exercise training program consists of 3 supervised sessions per week during 3 months. MCT consists of 40 to 60 min at 60-70% of maximal heart rate and HIIT program consists of (4 to 6) x (2 min to 2 min 30s) periods at 90-95% of HRmax interspersed by 1 min 30s period at 55% of HRmax. They undergo

the same assessments at the start of the study at the end of the three month intervention period.

Intervention Type
Other

Primary outcome measure
Cutaneous blood flux (CBF) was determined by means of laser Doppler flowmetry (Periflux PF 5000, Perimed, Stockholm, Sweden) equipped with a thermostatic LDF probe (PF 481, Perimed, Stockholm, Sweden), on the volar surface of the right forearm. Assessed at baseline in obese adolescents and controls, and after 3 months of intervention only in obese adolescents.

Secondary outcome measures
1. Body composition, assessed only in obese adolescents at inclusion and after 3 months of intervention
2. Aerobic fitness (including the 20-meter shuttle run test), assessed only in obese adolescents at inclusion and after 3 months of intervention
3. Weight and height measurements were performed and body mass index (BMI) was calculated as weight in kilograms divided by height in squared meters (kg.m-2), at baseline and after 3 months of intervention
4. Body fat mass, abdominal and gluteal fat masses and lean body mass, assessed in only obese adolescents using dual-energy X-ray absorptiometry (DEXA), (QDR 2000 – Discovery, Hologic, Bedford, MA), at baseline and after 3 months of intervention
4. Plasma glucose, plasma insulin and lipid profile were assessed only in obese adolescents using fasting blood samples, at baseline and after 3 months of intervention

Overall study start date
04/01/2013

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Obese adolescents, male or female, aged 12-16 years, non-smokers, not taking any medications and without known cardiovascular or metabolic disease
2. Healthy normal-weight pubertal stage-matched adolescents

Participant type(s)
Mixed

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Minimum 12 subjects in each group (control and obese sub-groups of training)

Key exclusion criteria
1. Smokers
2. Adolescents who participated in extra-school sport activities more than 2h per week

Date of first enrolment
30/01/2013

Date of final enrolment
10/06/2014

Locations

Countries of recruitment
France

Study participating centre
Saint-Pierre University Hospital, Pediatric Institute (SSR pediatrique Institut-Saint-Pierre)
71 Av de l'Eveche de Maguelone
Palavas-les-Flots
France
34250

Sponsor information

Organisation
Saint-Pierre University Hospital, Pediatric Institute (SSR Institut St Pierre)

Sponsor details
371 Av de l'Eveche de Maguelone
Palavas-Les-Flots
France
34250

Sponsor type
Hospital/treatment centre

Website
http://www.institut-st-pierre.com/

ROR
https://ror.org/01q046q46

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Saint-Pierre University Hospital, Pediatric Institute (SSR Institut St Pierre)

Results and Publications

Publication and dissemination plan

Intention to publish date
15/08/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request