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The Healthy Eating, Aerobic and Resistance Training in Youth (HEARTY) trial

Submission date	Recruitment status
22/06/2007	No longer recruiting
Registration date	**Overall study status**
22/06/2007	Completed
Last Edited	**Condition category**
20/02/2019	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00195858

Protocol serial number
MCT-71979

Study information

Scientific Title
A single-centre, four-arm, randomised parallel trial of healthy eating, aerobic exercise and resistance training to reduce percent body fat in overweight or obese adolescents

Acronym
HEARTY

Study objectives
1. Reduction in percent body fat will be larger in diet and aerobic exercise and diet and resistance exercise than diet-only controls at post-treatment, and the combined aerobic and resistance training will be superior to either aerobic or resistance training alone in reducing percent body fat at post-treatment
2. The combined resistance and aerobic group will show greater improvements in percent body fat, body composition, and physiological and psychosocial function at post-treatment and 10-months follow-up
3. Groups that include resistance training will produce greater psychosocial changes and better adherence than aerobic training alone at post-treatment and follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Board of the Ottawa Hospital, December 2004
2. CHEO Research Ethics Board, 01/03/2005

Primary study design
Interventional

Study design
Single-centre four-arm randomised parallel trial with outcome assessor and study investigator blinding

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Sedentary post-pubertal overweight or obese youth aged 14 - 18 years

Interventions
After a four-week supervised low-intensity exercise run-in period to test compliance, 292 adolescents with BMI greater than or equal to 85th percentile for age and gender will be randomised in equal numbers to one of four arms:
1. Diet and aerobic exercise
2. Diet and resistance exercise
3. Diet and combined aerobic and resistance exercise
4. Diet-only control

The intervention will last 16 weeks, with a follow-up assessment at six-months post-treatment (11-months post-randomisation).

Intervention Type
Behavioural

Primary outcome(s)
Amended 24/02/2009:
Percent body fat measured using Magnetic Resonance Imaging (MRI) at six months (end of intervention).

Initial information at time of registration:
Percent body fat measured using Magnetic Resonance Imaging (MRI) at six months post treatment measured at six months post treatment/12 months post randomisation.

Key secondary outcome(s)
1. Resting energy expenditure (indirect calorimetry)
2. Lean body mass (DEXA)
3. Waist circumference
4. Important non-traditional CHD risk factors:
4.1. LDL particle diameter
4.2. Plasma insulin
4.3. Apoprotein B
4.4. C-reactive protein
5. Traditional metabolic CHD risk factors:
5.1. HDL-C
5.2. LDL-C
5.3. Triglycerides
5.4. Total/HDL cholesterol ratio
5.5. Blood pressure
5.6. HbA1c
5.7. Fasting and two-hour glucose
6. Effects on psychosocial adjustment will also be examined, including health related:
6.1. Quality of life (Pediatric Quality of Life Inventory™ [PedsQL™] - adolescent version)
6.2. Body image (Body Esteem Scale)
6.3. Mood (Profile of Mood States)
6.4. Self-esteem (Rosenberg self-Esteem Scale)

Completion date
31/08/2011

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 14 to 18 years
3. Tanner stage IV or above
4. Body mass index (BMI) greater than or equal to 95th percentile for age, and gender (http://www.cdc.gov/growthcharts),
AND/OR
greater than or equal to 85th percentile for age/gender with any of:
4.1. Fasting glucose greater than or equal to 6.0 fasting
4.2. Two-hour plasma glucose 7.8 - 11 mmol/L after 75 G oral glucose (impaired glucose tolerance)
4.3. Fasting triglycerides greater than 1.7 mmol/L
4.4. Fasting plasma insulin greater than 105 pmol/L
4.5. High density lipoprotein-cholesterol (HDL-C) less than 0.9 mmol/L
4.6. Low density lipoprotein-cholesterol (LDL-C) greater than 3.0 mmol/L
4.7. Total cholesterol/HDL-C greater than 90th percentile
4.8. First-degree relative with type 2 diabetes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
14 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. Participation during the previous four months in a regular program of exercise or aerobic sports greater than or equal to two times per week for at least 20 minutes per session
2. Diabetes mellitus
3. Body weight over 159 kg, and/or BMI greater than 45 kg/m^2, exceeding capacity of dual energy X-ray absorptiometry (DEXA) and computed tomography (CT) machines
4. Use of any performance-enhancing medication
5. Use of any medication or herbal supplement that is likely to affect body composition, lipids or glucose metabolism
6. Significant weight change (increase of greater than or equal to 10%, or decrease greater than or equal to 5% of body weight during the two months before enrolment)
7. Uncontrolled hypertension: blood pressure (BP) greater than 150 mmHg systolic or greater

than 95 mmHg diastolic BP in sitting position
8. Activity restrictions due to disease: unstable cardiac or pulmonary disease, significant arthritis
9. Other illness judged by the patient or study physician to make participation in this study inadvisable
10. Unwillingness/lack of availability to attend exercise and/or nutrition sessions at scheduled times and locations
11. Significant cognitive deficit resulting in inability to understand or comply with instructions
12. Pregnancy at the start of the study, or intention to become pregnant in the next year
13. Inability to communicate in English or French
14. Unwillingness of subject and/or parent/guardian to sign informed consent

Date of first enrolment
01/05/2005

Date of final enrolment
31/08/2011

Locations

Countries of recruitment
Canada

Study participating centre
Foothills Medical Center
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Sponsor information

Organisation
Ottawa Hospital Research Institute (OHRI) (Canada) - formerly Ottawa Health Research Institute

ROR
https://ror.org/03c62dg59

Funder(s)

Funder type
Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-71979)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/09/2018	20/02/2019	Yes	No