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

Submission date	Recruitment status	Prospectively registered	
22/06/2007	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
22/06/2007	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
20/02/2019	Nutritional, Metabolic, Endocrine		

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Ron Sigal

#### Contact details

7th floor, North Tower Foothills Medical Center 1403 29 Street NW Calgary Alberta Canada T2N 2T9 +1 (0)403 944 2783 rsigal@ucalgary.ca

#### Type(s)

**Public** 

#### Contact name

Ms Penny Phillips

#### Contact details

-

\_

Canada

+1 (0)613 738 8400 ext. 81959 pphillips@ohri.ca

#### 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

#### Study design

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

#### Primary study design

Interventional

#### 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

Αll

#### 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<sup>2</sup>, 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

Alberta Canada

T2N 2T9

# 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, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, 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
Participant information shee	Participant information sheet	11/11/2025	11/11/2025 No	Yes