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Diabetes Aerobic and Resistance Exercise (DARE) trial

Submission date	Recruitment status
05/09/2005	No longer recruiting
Registration date	**Overall study status**
05/09/2005	Completed
Last Edited	**Condition category**
27/01/2010	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

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00195884

Protocol serial number
MCT-44155

Study information

Scientific Title
Effects of aerobic exercise, resistance exercise, or both in type 2 diabetes: a randomised trial

Acronym
DARE

Study objectives
To assess the impact of exercise training (aerobic exercise, resistance exercise, combined aerobic and resistance exercise) versus a sedentary waiting list control on glycaemic control (as reflected in reduced haemoglobin A1c [HbA1c]), body composition (weight, body mass index [BMI], waist circumference, total body fat, visceral and subcutaneous abdominal fat, mid-thigh muscle cross-sectional area), lipids (Apo-B, Apo-A1, Apo-B/A1 ratio, low density lipoprotein (LDL) particle diameter, high-sensitivity C-reactive protein) and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Loeb Health Research Institute at the Ottawa Hospital approved on the 25th March 1999

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Aerobic and resistance exercise training versus none.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in haemoglobin A1c (HbA1c) between baseline and end of the 6-month supervised exercise period. HbA1c is a reflection of the mean blood glucose over the previous 2 - 3 months.

Key secondary outcome(s)
1.Change in health related quality of life
2. Nontraditional cardiovascular risk factors: Apo-B, Apo-A1, high-sensitivity C-reactive protein, LDL particle diameter, estimated insulin resistance
3. Blood pressure

4. Lipid concentrations
5. Body composition (weight, BMI, waist circumference, total body fat, visceral and subcutaneous abdominal fat, mid-thigh muscle cross-sectional area), lipids (Apo-B, Apo-A1, Apo-B /A1 ratio, LDL particle diameter, high-sensitivity C-reactive protein)
6. Resting metabolic rate

Completion date
31/03/2005

Eligibility

Key inclusion criteria
1. Type 2 diabetes mellitus as defined by the 1998 CDA guidelines
2. Male or female, treated with diet and/or oral agents (no insulin), aged 40 - 70 years, HbA1c 0.066 - 0.099

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participation during the previous 6 months in a regular program of exercise or aerobic sports greater than or equal to 2 times/week for at least 20 minutes per session, or in any resistance training during the previous 6 months
2. Insulin therapy, or uncontrolled hyperglycaemia (HbA1c greater than 0.099). Insulin therapy is an exclusion criterion because it would render Homeostasis Model Assessment (HOMA) insulin sensitivity calculation invalid.
3. Changes in medications for diabetes in the 2 months prior to enrolment, or for blood pressure (BP) or lipids in the 1 month prior to enrolment
4. Significant weight change (increase or decrease of greater than or equal to 5% of body weight during the 2 months before enrolment)
5. Significant renal disease: serum creatinine greater than or equal to 200 mEq/1 or proteinuria greater than 1 g/24 hours
6. Uncontrolled hypertension: blood pressure (BP) greater than 160 mmHg systolic or greater than 95 mmHg diastolic BP in a sitting position
7. Restrictions in physical activity due to disease: intermittent claudication, severe peripheral neuropathy or active proliferative retinopathy, unstable cardiac or pulmonary disease, disabling stroke, severe arthritis
8. Significant cognitive deficit resulting in inability to understand or comply with instructions
9. Other illness judged by the patient or study physician to make participation in this study inadvisable

10. Pregnancy at the start of the study, or intention to become pregnant in the next two years
11. Inability to communicate in English or French
12. Unwillingness to sign informed consent

Date of first enrolment
01/04/2001

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
Canada

Study participating centre
7th floor, North Tower
Calgary, Alberta
Canada
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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-44155) funding for all remaining subjects

Funder Name
Canadian Diabetes Association (Canada) - funding for first 28 subjects

Funder Name
University of Ottawa Interfaculty Grant (Canada) - funding for energy expenditure measurement on first 28 subjects

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/09/2007		Yes	No