Finding the Optimal Resistance Training Exercise for type 2 diabetes

Submission date	Recruitment status No longer recruiting	Prospectively registered	
14/01/2010		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
21/06/2010 Last Edited	Completed Condition category	☐ Results	
		Individual participant data	
21/06/2010	Nutritional, Metabolic, Endocrine	Record updated in last year	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Paul Oh

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers #19581

Study information

Scientific Title

Finding the optimal volume and intensity of resistance training exercise for type 2 diabetes: a randomised controlled trial

Acronym

The FORTE Study

Study objectives

A higher intensity, hypertrophic resistance training protocol added to aerobic training would lead to more marked improvements to glycaemic control and cardiovascular risk factors compared to lower intensity endurance training.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Toronto Research Ethics Board (REB) approved in February 2006 (ref: 19581)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

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

Type 2 diabetes

Interventions

Six months of aerobic and resistance training:

- 1. Aerobic training and minimal resistance training (usual care)
- 2. Aerobic training and high intensity resistance training
- 3. Aerobic training and low intensity resistance training

The intervention for all groups was 6 months. Following completion of the program, patients will not be followed-up.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Measured at baseline and 6 months:

- 1. HbA1c
- 2. Maximal aerobic power (VO2 max)

Secondary outcome measures

Measured at baseline and 6 months:

- 1. Fasting glucose
- 2. Insulin
- 3. Proinsulin
- 4. Blood lipid profile
- 5. Body composition (dual energy x-ray absorptiometry [DEXA])
- 6. Cytokines (interleukin-6 [IL-6], interleukin-1B [IL-1B], c-reactive protein [CRP])
- 7. Adipokines (tumour necrotising factor-alpha [TNF-alpha], adiponectin, leptin, leptin receptor)
- 8. Depressive mood (Center for Epidemiologic Studies Depression Scale [CESD])
- 9. Quality of life (Diabetes Quality of Life Clinical Trial Questionnaire [DSQLQ])
- 10. Nutrition intake

Overall study start date

01/05/2006

Completion date

31/03/2009

Eligibility

Key inclusion criteria

- 1. Adults aged greater than 18 years, either sex
- 2. Type 2 Diabetes
- 3. Participating in the Diabetes Exercise and Healthy Lifestyle Program of the Toronto Rehabilitation Institute

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

Key exclusion criteria

- 1. History of diagnosed cardiovascular disease
- 2. Contraindications to high intensity exercise participation:
- 2.1. Glaucoma
- 2.2. Retinopathy
- 2.3. Musculoskeletal limitations
- 2.4. Kidney disease
- 2.5. Balance impairments

Date of first enrolment

01/05/2006

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

Canada

Study participating centre Toronto Rehabilitation Institute

Toronto Canada M4G 1R7

Sponsor information

Organisation

Toronto Rehabilitation Institute (Canada)

Sponsor details

c/o Paul Oh, MD 347 Rumsey Road Toronto Canada M4G 1R7 1 416 597 3422 oh.pauldr@torontorehab.on.ca

Sponsor type

Research organisation

Website

http://www.torontorehab.on.ca/

ROR

https://ror.org/00mxe0976

Funder(s)

Funder type

Research organisation

Funder Name

Toronto Rehabilitation Institute (Canada)

Alternative Name(s)

Toronto Rehab, UHN Toronto Rehabilitation Institute, TRI

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Canada

Funder Name

Human Physiology Performance Laboratory (Canada)

Funder Name

Canadian Diabetes Association (Canada)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration