ISRCTN97865321 https://doi.org/10.1186/ISRCTN97865321

Finding the Optimal Resistance Training Exercise for type 2 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
14/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] 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

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Additional identifiers

Protocol serial number
#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)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

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(s)
Measured at baseline and 6 months:
1. HbA1c
2. Maximal aerobic power (VO2 max)

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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, The Toronto Rehabilitation Institute, Rehabilitation Institute of Toronto, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration