ISRCTN59775422 https://doi.org/10.1186/ISRCTN59775422

Resistance Exercise in Already-active Diabetic Individuals (READI)

Submission date
22/06/2007

Recruitment status
No longer recruiting

Registration date
22/06/2007

Overall study status
Completed

Last Edited
20/02/2019

Condition category
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)
NCT00410436

Protocol serial number
MCT-80682

Study information

Scientific Title
Resistance Exercise in Already-active Diabetic Individuals (READI): a multicentre, two arm, randomised parallel trial

Acronym
READI

Study objectives
Primary hypothesis:
In type one diabetic individuals who already engage in regular aerobic exercise, adding a six-month resistance training program will result in improved glycaemic control as reflected in reduced HbA1c compared to aerobic training alone.

Secondary hypotheses:
In type one diabetic individuals who already do regular aerobic exercise, adding a six-month resistance training program will have favourable effects on body composition, non-traditional and traditional Cardiovascular Disease (CVD) risk factors, and quality of life versus aerobic exercise alone (note: sample size was calculated solely based on having adequate statistical power for the primary outcome).

Exploratory research questions without a-priori hypotheses:
1. What is the incremental effect of resistance training on insulin requirements and frequency of hypoglycaemia?
2. Do changes in glycaemic control, body composition, or quality of life during the resistance training intervention predict exercise participation during the subsequent six months?
3. How cost-effective is it to add the resistance training program?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Board of the Ottawa Hospital, Ottawa, Ontario (Canada), 08/07/2005, ref: 2005301-01H
2. Research Ethics Board of the Children's Hospital of Eastern Ontario, Ottawa, Ontario (Canada), 25/07/2005, ref: 05/30E

Study design
Multicentre two-arm randomised parallel trial with study investigator, personnel involved in insulin adjustment, and outcome assessor blinded

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 1 diabetes mellitus

Interventions
Intervention:
Resistance exercise training, three times per week, beginning with one to two sets of eight exercises at moderate intensity, high repetition training and progressing to three sets, eight repetitions of eight exercises at 8RM for 22 weeks. Subjects will continue performing aerobic exercise at the same volume, duration and intensity as they did at baseline.

Control:
Waiting-list control, subjects will continue performing aerobic exercise at the same volume, duration and intensity as they did at baseline; they will not perform any resistance training activity for 22 weeks.

Intervention Type
Behavioural

Primary outcome(s)
HbA1c at the end of the six-month supervised exercise period, adjusted by Analyses of Covariance (ANCOVA) for HbA1c at randomisation, measured at baseline, 1 month, 3 months, 6 months and 12 months.

Key secondary outcome(s))
1. Body composition, baseline and six months
2. Non-traditional CVD risk factors measured at one month (pre-randomisation) and six months:
2.1. Low density lipoprotein (LDL) particle diameter
2.2. Apolipoprotein B (Apo-B)
2.3. Apolipoprotein A1 (Apo-A1)
2.4. Apo-B/Apo-A1 ratio
2.5. Urinary albumin to creatinine ratio
2.6. Serum C-reactive protein
2.7. Free fatty acids (FFA)
3. Traditional metabolic CVD risk factors, measured at baseline, 1 month (pre-randomisation), and at 3, 6, and 12-months:
3.1. High density lipoprotein (HDL) cholesterol
3.2. LDL cholesterol
3.3. Triglycerides
3.4. Total/HDL cholesterol ratio
3.5. Systolic and diastolic blood pressure
4. Quality of Life, baseline, 1 month (pre-randomisation), 3, 6, and 12 months:

4.1. Diabetes-Specific Quality of Life scale
4.2. Medical Outcomes Study Short Form-36
4.3. EuroQol EQ-5

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Type one diabetes mellitus as defined by the 2003 Canadian Diabetes Association (CDA) guidelines with duration greater than or equal to one year, requiring insulin therapy starting within one year of diagnosis and continuously thereafter
2. Male or female, aged greater than or equal to 16 years, HbA1c 0.066 - 0.099 (normal non-diabetic range 0.040 - 0.060)
3. Habitual performance during the previous four months of aerobic exercise greater than or equal to three times per week, including at least 90 minutes per week of vigorous aerobic exercise (of sufficient intensity to cause sweating, e.g., jogging, soccer, basketball, racquet sports), and/or greater than or equal to 150 minutes per week of aerobic exercise of at least moderate intensity (e.g., brisk walking, moderate-paced bicycling) but no resistance training. Subjects must agree to maintain their habitual volume and intensity of aerobic activity during run-in and intervention periods, minimising variation due to seasons, but they will be permitted to vary specific exercises chosen
4. Willingness and ability to work closely with the study physicians, nurse and dietician and follow their recommendations for insulin therapy and adjustments of diet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participation during the previous four months in any resistance training
2. Hypoglycaemia unawareness, or severe hypoglycaemia requiring assistance from another person within the previous three months
3. "Brittle" diabetes, characterised by frequent and unpredictable hypoglycaemia (even if not requiring assistance from others) and hyperglycaemia
4. 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
5. Known or suspected clinically significant gastroparesis
6. Body mass index greater than 35 kg/m^2, or weight greater than 147 kg (exceeding capacity of dual energy X-ray absorptiometry [DEXA] or computed tomography [CT] scanners)
7. Fasting serum c-peptide greater than or equal to 0.2 nmol/l

8. Increase or decrease of greater than or equal to 5% of body weight during the previous two months
9. An expected requirement within the subsequent six months for medications (other than insulin) that will affect glucose metabolism (e.g., corticosteroids)
10. If age is less than 18 years, linear growth of greater than or equal to 1 cm during the previous year
11. Significant renal disease: serum creatinine greater than or equal to 200 mEq/l or proteinuria greater than 1 g/24 hours
12. Uncontrolled hypertension: blood pressure (BP) greater than 150 mmHg systolic or greater than 95 mmHg diastolic in a sitting position
13. Other illness, judged by the patient or investigators to make participation in this study inadvisable
14. Cognitive deficit resulting in inability to understand or comply with instructions
15. Pregnancy at the start of the study, or intention to become pregnant in the next year
16. Inability to communicate in English or French
17. Ischaemic alectrocardiogram (ECG) changes during baseline maximal cardiopulmonary stress test, unless subsequently cleared for participation by a cardiologist after appropriate investigation
18. Low aerobic fitness: aerobic fitness more than 15% below the mean for age and gender, based on baseline maximal treadmill exercise test. This criterion is included in order to reduce likelihood of candidates entering the trial by exaggerating their habitual activity. Very few people engaging in regular aerobic activity would have such low treadmill performance
19. Unwillingness to sign informed consent

Date of first enrolment
01/10/2006

Date of final enrolment
31/10/2010

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-80682)

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	01/03/2015	20/02/2019	Yes	No