

Dose-Responses to EXercise TRaining: a randomised controlled four year trial on the effects of regular physical exercise and diet on endothelial function, atherosclerosis and cognitive function

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| Submission date 06/09/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 13/09/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 01/11/2016 | Condition category Circulatory System | <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Dose-Responses to EXercise TRaining: a randomised controlled four year trial on the effects of regular physical exercise and diet on endothelial function, atherosclerosis and cognitive function

Acronym

DR's EXTRA

Study objectives

1. Regular aerobic or resistance exercise causing an energy expenditure of 1000 - 1500 kcal/wk (4.2 - 6.3 MJ/wk) reduces the risk of developing metabolic syndrome and type two diabetes, attenuates inflammation, improves endothelial function, diminishes the progression of atherosclerosis, and decreases the risk of cognitive impairment, without additional benefit from higher exercise energy expenditures.
2. Regular aerobic or resistance exercise enhances Nitric Oxide (NO) bioavailability as a consequence of the down-regulation of the modified RiboNucleic Acid (mRNA) of inducible NO Synthase (iNOS), and this effect can be seen as an improved Flow-Mediated Dilatation (FMD) of the brachial artery.
3. Regular aerobic exercise generates muscle specific InterLeukin-6 (IL-6), which induces an anti-inflammatory response by elevating the levels of anti-inflammatory cytokines, reflected by lowering of high sensitivity C-Reactive Protein (hsCRP), and seen as improved FMD of the brachial artery.
4. Regular aerobic or resistance exercise enhance the levels of mitochondrial proteins and further enhance the expression of metabolic genes during acute exercise and thereby improves insulin sensitivity and glucose tolerance.
5. Low saturated fat, high unsaturated fat, high fiber diet, enriched with omega-3 fatty acids, attenuates inflammatory reaction by down-regulating the mRNA of iNOS and Heat Shock Protein HSP72 thereby improving endothelial function, diminishing the progression of atherosclerosis, and decreasing the risk of cognitive impairment.
6. Combined exercise and diet intervention is more powerful for attenuation of inflammatory reaction, improving endothelial function, diminishing the progression of atherosclerosis, and decreasing the risk of cognitive impairment than exercise or diet alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Joint ethics committee of Kuopio University and Kuopio University Hospital

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Endothelial function, atherosclerosis

Interventions

Participants are randomly allocated into:

1. Control group
2. Aerobic exercise
3. Resistance exercise
4. Diet
5. Combined aerobic exercise and diet
6. Combined resistance exercise and diet

Intervention Type

Behavioural

Primary outcome measure

Changes in:

1. Atherosclerosis
2. Endothelial function
3. Cognitive function

Secondary outcome measures

Changes in:

1. Inflammatory status
2. Metabolic risk factors
3. Cardiovascular risk factors

Overall study start date

15/01/2003

Completion date

15/09/2010

Eligibility

Key inclusion criteria

A random population sample of the citizens in Kuopio, aged 55 to 74 years at the time of recruitment

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

1500

Key exclusion criteria

Conditions that inhibit safe engagement in prescribed exercise training, malignant diseases and other conditions preventing co-operation, as judged by the research physicians.

Date of first enrolment

15/01/2003

Date of final enrolment

15/09/2010

Locations**Countries of recruitment**

Finland

Study participating centre

Kuopio Research Institute of Exercise Medicine

Kuopio

Finland

FIN-70100

Sponsor information**Organisation**

Ministry of Education (Finland)

Sponsor details

PO Box 29

Helsinki

Finland

00023

Sponsor type

Government

Website

<http://www.minedu.fi>

ROR

<https://ror.org/02w52zt87>

Funder(s)

Funder type

Government

Funder Name

Ministry of Education in Finland (Finland) (refs: 125/722/2003; 116/722/2004; 134/627/2005)

Funder Name

Academy of Finland (Finland) (refs: 102318;104943)

Alternative Name(s)

Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Finland

Funder Name

Kuopio University Hospital (Finland) (refs: 13/2002; 24/2004)

Alternative Name(s)

Kuopio University Hospital, KYS

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Finland

Funder Name

Diabetes Research Foundation (Finland)

Funder Name

European Union (Belgium) - partner in EXGENESIS consortium (ref: EU 005272)

Funder Name

Sydäntutkimussäätiö

Alternative Name(s)

Finnish Foundation for Cardiovascular Research

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Finland

Funder Name

Paivikki and Sakari Sohlberg Foundation (Finland)

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|----------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/07/2010 | | Yes | No |
| Results article | prediabetic states results | 01/07/2012 | | Yes | No |
| Results article | results | 01/07/2012 | | Yes | No |
| Results article | results | 14/11/2014 | | Yes | No |
| Results article | results | 01/04/2015 | | Yes | No |
| Results article | results | 01/11/2015 | | Yes | No |