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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

Submission date 06/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/09/2006	**Overall study status** Completed	
Last Edited 01/11/2016	**Condition category** Circulatory System	

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