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Effects of a Nordic Diet on cardiovascular risk factors

Submission date	Recruitment status	[ ] Prospectively registered
24/11/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/12/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/12/2009	Circulatory System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U-07-009

Study information

Scientific Title
Effects of a Nordic Diet on cardiovascular risk factors in hypercholesterolemic subjects: a randomised controlled trial

Acronym
NORDIET

Study objectives
The aim of the study was to investigate the effects of a Nordic diet on cardiovascular risk factors in mildly hypercholesterolemic subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee in Uppsala approved on the 19th of December 2007 (ref: North D U-07-009 Dnr 2007/328)

Study design
Randomised controlled parallel-group study with voluntary free-living subjects

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular risk factors

Interventions
Intervention Group - The Nordic Diet:
The nutrient profile of the Nordic Diet (ND) was based on Nordic nutrition recommendations 200423 and inspired by the Mediterranean diet, Portfolio diet, DASH diet and NCEP. The food profile was based on typical foods consumed in the Nordic countries and the nutrient profile is comparable to that of the Mediterranean diet, including LDL-C lowering foods.

Control group - care as usual.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Change in plasma LDL-C after 6 weeks

Secondary outcome measures
Change in:
1. Other blood lipids and apolipoproteins
2. Blood pressure
3. Insulin sensitivity (fasting insulin and homeostatic model assessment insulin resistance [HOMA-IR])

Overall study start date
20/12/2007

Completion date
15/05/2008

Eligibility

Key inclusion criteria
1. Men and women between 25 and 65 years of age
2. Healthy as assessed by a physician
3. Body mass index (BMI) greater than or equal to 20 and less than or equal to 31 kg/m^2
4. Plasma low density lipoprotein cholesterol (LDL-C) greater than or equal to 3.5 mmol/l
5. Haemoglobin (Hb) greater than or equal to 120 g/l for women and greater than or equal to 130 g/l for men

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
88

Key exclusion criteria
1. Participation in a clinical study within 90 days prior to screening visit and throughout the study
2. Use of lipid lowering drugs two months prior screening and throughout the study
3. Blood pressure greater than 145/85 mmHg
4. Use of products or supplements fortified with plant sterols, omega-3, omega-6 or omega-9 fatty acids within 3 weeks prior to baseline visit
5. Allergy to certain foods
6. Weight-loss diets or drugs
7. Special diets (e.g. vegan and gluten free)
8. Pregnant or lactating

Date of first enrolment
20/12/2007

Date of final enrolment
15/05/2008

Locations

Countries of recruitment
Sweden

Study participating centre
Clinical Nutrition and Metabolism
Uppsala
Sweden
751 85

Sponsor information

Organisation
University of Uppsala (Sweden)

Sponsor details
Clinical Nutrition and Metabolism
Department of Public Health and Caring Sciences
Uppsala Science Park
Uppsala
Sweden
751 85

Sponsor type
University/education

Website
http://www.uu.se

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Industry

Funder Name
The Cerealia Foundation R&D (Sweden)

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