ISRCTN84550872 https://doi.org/10.1186/ISRCTN84550872

# Effects of a Nordic breakfast on cardiovascular risk factors.

| Submission date | Recruitment status |
| --- | --- |
| 04/12/2009 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 07/01/2010 | Completed |
| **Last Edited** | **Condition category** |
| 14/05/2014 | 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

**Protocol serial number**
North B U-08-017

## Study information

**Scientific Title**
Effects of a Nordic breakfast diet on risk markers for cardiovascular disease in healthy mildly hypercholesterolemic men and women.

**Acronym**

North B

## Study objectives
The aim of this study is to investigate if intake of a healthy Nordic breakfast may affect risk markers for cardiovascular disease in healthy mildly hypercholesterolemic men and women.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The study was approved by the regional ethic committee in Uppsala, on the 20th of January 2009 (ref: North B U-08-017, Dnr 2009/018)

## Study design
Randomised controlled parallel group intervention study

## Primary study design
Interventional

## Study type(s)
Prevention

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

## Interventions
The test breakfast will include: Porridge made of oat bran. Low fat milk or yoghurt. A choice of jam (blueberries or lingonberries). Whole grain bread. Margarine with high content of polyunsaturated fatty acids (19%). Something to put on the bread such as low fat meat or pickled herring or mackerel in tomato. Fresh fruit will also be included.

Outcomes after intake of a Nordic breakfast diet in comparison to ordinary foods in mildly hypercholesterolemic men and women, (LDL-cholesterol levels > 3.0 mmol/l) will be measured after 12 weeks. There will be no follow up beyond the end of the 12 week intervention.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
The effect on LDL-cholesterol will be measured at baseline, 6 and 12 weeks.

## Key secondary outcome(s))
The following will be measured at baseline, 6 and 12 weeks
1. HDL cholesterol
2. Total cholesterol
3. Triglycerides
4. High-Sensitivity C-Reactive Protein (HS-CRP)
5. Apolipoprotein A1 and B

6. Blood pressure
7. Sagittal abdominal diameter (SAG)
8. Hip
9. Waist
10. Glycated Haemoglobin (HbA1c)
The following will be measured at baseline and 12 weeks
11. Glucose response
12. Insulin sensitivity

### Completion date
30/01/2010

## Eligibility

### Key inclusion criteria
1. Slightly overweight and hyperlipidemic but otherwise healthy as assessed by the results of the screening laboratory tests and judged by medical staff
2. Age ≥ 25 and ≤ 67 years at visit 1
3. Body Mass Index (BMI) ≥ 25 and ≤ 35 kg/m2
4. LDL cholesterol ≥ 3.0 mmol/l
5. Haemoglobin (Hb) ≥ 120 g/l for women and ≥ 130 g/l for men
6. Signed written informed and biobank consents

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Participation in a clinical study with blood sampling within 90 days prior to screening visit and throughout the study.
2. Use of cholesterol lowering medication <3 months prior screening visit.
3. Blood pressure >155/95 (will be measured at visit 1 for inclusion).
4. Consumption of products or supplements fortified with plant sterols or omega-3 or omega-6 or omega 9- fatty acids within 3 weeks prior to the visit 1 and no consumption at all throughout the study.
5. Allergic to certain foods
6. Slimming or medically prescribed diet/medication or a special diet (vegan and gluten-free).
7. Not able to eat porridge for breakfast every day during 12 weeks
8. Not able to eat herring or mackerel for breakfast 3 days/week during 12 weeks
9. Pregnant or lactating or wish to become pregnant during the period of the study.
10. Lack of suitability for participation in the study for any reason as judged by the personnel at Good Food Practice (GFP) research clinic.

**Date of first enrolment**
01/06/2009

**Date of final enrolment**
30/01/2010

# Locations

**Countries of recruitment**
Sweden

**Study participating centre**
**Clinical Nutrition and Metabolism**
Uppsala
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751 85

# Sponsor information

**Organisation**
University of Uppsala (Sweden)

**ROR**
https://ror.org/048a87296

# Funder(s)

**Funder type**
Industry

**Funder Name**
Cerealia Foundation R&D (Sweden)

# Results and Publications

**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 | 01/02/2015 | | Yes | No |