

# Folic Acid and Carotid Intima-media Thickness: a 3-year randomised controlled trial (RCT) examining the effects of folic acid supplementation on vascular disease

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>16/05/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>16/05/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>23/05/2022       | <b>Condition category</b><br>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

ClinicalTrials.gov (NCT)  
NCT00110604

**Protocol serial number**

## Study information

### Scientific Title

Folic Acid and Carotid Intima-media Thickness: a 3-year randomised controlled trial (RCT) examining the effects of folic acid supplementation on vascular disease

### Acronym

FACIT

### Study objectives

To determine if folic acid supplementation can slow down atherosclerotic progression, age-related cognitive decline and age-related hearing loss.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the local medical ethics committee

### Primary study design

Interventional

### Study design

Randomised, double blind, placebo controlled, parallel group trial

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Vascular disease

### Interventions

Three-year long daily (oral) supplementation with 0.8 mg folic acid versus placebo pill.

### Intervention Type

Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

Folic acid

### Primary outcome(s)

1. Change in mean carotid intima-media thickness
2. Change in maximum carotid intima-media thickness

### Key secondary outcome(s)

1. Change in carotid distension
2. Change in hearing levels (pure tone air conduction averages of 0.5, 1, and 2 kHz & 4, 6 and 8 kHz)
3. Cognitive performance at year three (cognitive domains: simple speed, cognitive flexibility, and memory; and information processing speed and semantic memory)
4. Inflammatory markers and haemostasis markers

**Completion date**

01/12/2004

## Eligibility

**Key inclusion criteria**

1. 50 - 70 years old
2. Men and post-menopausal women
3. Vitamin B12 greater than or equal to 200 pmol/l
4. Homocysteine greater than or equal to 13 umol/l

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Current use of vitamin supplements containing B vitamins
2. Hormone replacement therapy or lipid-lowering therapy

**Date of first enrolment**

01/09/1999

**Date of final enrolment**

01/12/2004

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Division of Human Nutrition  
Wageningen

Netherlands  
6700 EV

## Sponsor information

**Organisation**  
Wageningen Centre for Food Sciences (WCFS) (The Netherlands)

## Funder(s)

**Funder type**  
Research organisation

**Funder Name**  
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

**Funder Name**  
Wageningen Centre for Food Sciences (The Netherlands)

## Results and Publications

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

**IPD sharing plan summary**  
Not provided at time of registration

### Study outputs

| Output type                     | Details           | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|-------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |                   | 02/01/2007   |            | Yes            | No              |
| <a href="#">Results article</a> |                   | 20/01/2007   |            | Yes            | No              |
| <a href="#">Results article</a> |                   | 01/05/2011   | 23/05/2022 | Yes            | No              |
| <a href="#">Results article</a> |                   | 01/06/2011   | 23/05/2022 | Yes            | No              |
| <a href="#">Results article</a> | post hoc analysis | 06/04/2021   | 23/05/2022 | Yes            | No              |
| <a href="#">Study website</a>   | Study website     | 11/11/2025   | 11/11/2025 | No             | Yes             |