

# Feasibility study: Studying the effect of two healthy dietary patterns on physical and psychological symptoms

Published: 30-07-2015

Last updated: 19-04-2024

To study if it is feasible to conduct such a investigation in the future, I first want to search for 35 volunteers who are willing to follow the paleo diet during four weeks and the Dutch Consensus Diet during four weeks. After both periods of four...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON42408

### Source

ToetsingOnline

### Brief title

Feasibility dietary patterns

### Condition

- Other condition

### Synonym

mental health, physical symptoms, somatic complaints

### Health condition

lichamelijke en psychische klachten

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Psychiatrie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Anxiety, Depression, Diet, Somatic complaints

## Outcome measures

### Primary outcome

Feasibility: 1) time needed for recruiting 35 participants, 2) extent to which participants actually followed the guidelines, 3) percentage of participants that completed the study, and 4) representativeness of our study population compared to the Dutch population.

### Secondary outcome

Effect size on physical and psychological symptoms.

## Study description

### Background summary

A hunter-gatherer type diet, also called the paleo diet, consists of vegetables, fruit, meat, sea-food, eggs and nuts. It is a very popular diet not only among the general population, but also among dieticians and other health-care providers. A brief internet-search suggests that people do not only follow this diet to lose weight, but also, amongst other reasons, because it is suggested to reduce somatic as well a psychological complaints. Various studies have shown that hunter-gatherer type diets improve glucose regulation and lipid profile to a larger extent than other healthy diets such as Diabetes Diets, the Mediterranean diet and Consensus Diets (Boers et al., 2014; Johnsson et al., 2009; Masharani et al., 2015; Lindeberg et al., 2007). Up to today, researchers have not investigated the possible effects on physical and psychological symptoms. In the future, I want to investigate the effects of such a diet on physical and psychological symptoms.

### Study objective

To study if it is feasible to conduct such a investigation in the future, I first want to search for 35 volunteers who are willing to follow the paleo diet during four weeks and the Dutch Consensus Diet during four weeks. After both periods of four weeks I'll ask them to what extent they actually followed the diets, how hard it was to follow the diets and if they have suggestions for improving the instruction manuals. Next to feasibility, I also want to estimate effect of the paleo diet compared to the Dutch Consensus diet on physical and psychological complaints.

## **Study design**

Both dietary patterns are followed during four weeks. Two different short-term studies, respectively two and three weeks, showed a significant improvement in glucose regulation, cholesterol and blood-pressure (Boers et al., 2014; Masharani et al. 2015). The hypothesis is that the paleo diet improves physical and psychological symptoms within four weeks. Physical and psychological complaints will be measured using questionnaires.

## **Intervention**

Participants follow two dietary patterns during four weeks: The paleo diet and the Dutch Consensus Diet.

## **Study burden and risks**

There are no risks to participation in this study. Participants will need to invest some extra effort in preparing their food, specifically for following the paleo diet. Participants receive a manual for both diets including guidelines and recipes to ease following the diets. Filling out the questionnaires takes 1x 5 min and 2x 15 min.

## **Contacts**

### **Public**

Selecteer

Hanzeplein 1  
Groningen 9713GZ  
NL

### **Scientific**

Selecteer

Hanzeplein 1  
Groningen 9713GZ

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Being 18 years or older.

Good command of Dutch language.

Willing to follow both dietary patterns.

### Exclusion criteria

Having to eat a low-potassium diet.

Pregnancy.

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 23-09-2015  
Enrollment: 35  
Type: Actual

## Ethics review

Approved WMO  
Date: 30-07-2015  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL53798.042.15