

Haalbaarheidsstudie: Onderzoek naar het effect van twee gezonde voedingspatronen op lichamelijke en psychische klachten.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24048

Source

Nationaal Trial Register

Brief title

Haalbaarheidsstudie voedingspatronen

Health condition

Psychological symptoms, physical symptoms, healthy diets, paleo diet

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: N.a.

Intervention

Outcome measures

Primary outcome

: Four aspects of feasibility will be studied. First, the amount of time needed to recruit 35

participants. Second, the percentage of participants that completes the study. Third, the extent to which the participants followed the two diets, Fourth, representativeness of our participants for the normal population.

Secondary outcome

Effect size on physical and psychological complaints.

Study description

Background summary

Different studies have shown that a hunter-gatherer type diet is effective in improving glucose regulation and lipid profile. This research focusses on the question of this type of diet also reduces the number of physical and psychological symptoms.

The main objective is to test feasibility of a cross-over study comparing the effect of two healthy diets on physical and psychological symptoms. The secondary aim is to estimate effect size. In this cross-over designed study, 25 individuals of 18 years or older from the normal population will be included. Each participant will eat according to the Dutch Consensus Diet during 4 weeks and according to the Palaeolithic Diet during 4 weeks. Four aspects of feasibility will be studied. First, the amount of time needed to recruit 35 participants. Second, the percentage of participants that completes the study. Third, the extent to which the participants followed the two diets, Fourth, representativeness of our participants for the normal population. Furthermore, we will estimate effect size on physical and psychological complaints.

Study objective

Different studies have shown that a hunter-gatherer type diet is effective in improving glucose regulation and lipid profile. I want to investigate if the hypothesis that this type of diet also reduces the number of physical and psychological symptoms can be proved.

Study design

At $t=0$ an intake questionnaire will be administered.

At $t=0$, $t=4$ and $t=8$ weeks a questionnaire about the physical and psychological complaints will be administered.

Every week a nutrition questionnaire will be administered.

Intervention

Each participant will eat according to the Dutch Consensus Diet during 4 weeks and according to the Palaeolithic Diet during 4 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years or older
- Good understanding and knowlegde of the Dutch language
- Being willing to follow both of the diets for four weeks.

Exclusion criteria

- Following a pottasium-restricted diet
- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	21-09-2015
Enrollment:	35
Type:	Anticipated

Ethics review

Positive opinion	
Date:	14-09-2015
Application type:	First submission

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
NTR-new	NL5391
NTR-old	NTR5492
Other	NL53798.042.15 : M15.177545

Study results