

Changes in salt perception as a result of a long-term salt reduced diet

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The primary objective is to investigate if a salt-reduced diet leads to an increased reward response when exposed to lower salt concentrations in food.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35225

Source

ToetsingOnline

Brief title

Salt

Condition

- Other condition
- Heart failures
- Vascular hypertensive disorders

Synonym

salt perception and salt preference

Health condition

preferentie voor zout

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: NWO/STW, Campina, Danone Vitapole, Friesland Nutrition, TI Food and Nutrition, Unilever

Intervention

Keyword: Perception, Reward, Salt, Sensitivity

Outcome measures

Primary outcome

Brain activity in reward area's

Saltiness preference (subjective ratings)

Secondary outcome

Sensitivity for saltiness, measured by:

-threshold NaCl

-Supra threshold subjective ratings of NaCl in water

Desire-to-eat salty foods (subjective ratings)

Study description

Background summary

Worldwide, the daily sodium intake is too high and this leads to an increased blood pressure and thereby an increased prevalence of cardiovascular disease. A reduction of sodium in foods results in a decrease in saltiness, which is often associated with a less palatable taste. In humans, the perception and preference for salt is learned by experience rather than by physiological factors. Preference for saltiness can change by repeated exposure, as shown before. A salt-reduced diet may increase the reward response in the brain when exposed to low salt concentrations in food and may increase the taste sensitivity to saltiness.

Study objective

The primary objective is to investigate if a salt-reduced diet leads to an increased reward response when exposed to lower salt concentrations in food.

Study design

An intervention that consists of a 13-week diet of 2 g dietary sodium a day. The intervention will be compared with a control (normal, their habitual diet).

Intervention

Intervention: 2 g dietary sodium a day during 13 weeks
Control: Normal, habitual, diet

Study burden and risks

Burden participants:

- inclusion questionnaire
- 6X taste tests (taste and rate food and salty solutions)
- 6X computertask (rate desire-to-eat salty products visually on computer screen)
- 6X tongue scraping (non-invasive)
- 4X MRI-scan (questionnaires before scanning, 30 minutes in scanner)
- (-5 X blood pressure measurements for control group)
- (-5 x 24h urine for control group)

The taste tests and computer tasks will take place within the same session and take app 45 minutes together. MRI-scans are separate and will take 45 minutes. The time of the burden is 76,5 hours in total, spread out over 15 weeks. This research is non therapeutic to participants. The risks associated with participation is negligible and the burden is considered as low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for the intervention group of the *Salt* study:

- Participation in the Ka/Na-trial
 - Willing to participate in the *Salt* study;
- Inclusion criteria for the control group of the *Salt* study:
- Drop-outs of Ka/Na-trial due to a too low blood pressure (SBP < 130 mm Hg)

Exclusion criteria

Exclusion criteria intervention and control group of the "Salt" study (only for MRI measurements, there are no exclusion criteria for sensory tests):

- Having a contra-indication to MRI scanning:
(claustrophobia, epilepsy, serious physical or mental illnesses, pacemakers and defibrillators, intraorbital or intraocular metallic fragments, difficulties eating and or swallowing)

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO	
Date:	24-01-2012
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	
Date:	24-04-2012
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22606
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39002.081.11
OMON	NL-OMON22606