Nutrition the Unrecognized Determinant for Alzheimer's Disease (NUDAD-L)

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To identify modifiable dietary risk factors for AD,by comparing three patientpopulations in nutritional intake, energy needs, body composition, physical activity and functioning of smell and taste.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Observational invasive

Summary

ID

NL-OMON46227

Source
ToetsingOnline

Brief title
NUDAD-L

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer's disease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Alzheimer's disease, nutrition, nutritional status, smell and taste

Outcome measures

Primary outcome

Nutritional intake in patients with AD, in comparison with subjects with subjective cognitive decline or MCI.

Secondary outcome

Determining changed energy needs and body composition in patients with (pre-dementia) AD compared to healthy people and patients with advanced AD.

Identifing altered eating behaviour in terms of olfactory and gustatory functioning, food preferences and satiety as determinants of altered food intake in patients with (pre-dementia) AD compared to healthy people and patients with advanced AD.

Establishing relationships between nutritional intake and energy needs & body composition, and nutritional biomarkers.

Pospectively validating panel of nutritional markers and relate them to measures of nutritional intake, energy requirements and body composition.

Relating these markers to in*vivo measures of AD pathology (i.e. MRI, CSF biomarkers for AD, APOE status, EEG).

Study description

Background summary

AD has been coined one of the grand challenges of the current century. In 2015, over 46.8 million people worldwide (260,000 in the Netherlands) suffered from

dementia, with annual costs estimated at US$ 818 billion. The WHO predicts the number of people with dementia to triple to 131.5 million by 2050.The G8 have recently made dementia a top priority, as currently, no cure for AD exists.

AD develops gradually over many years. The first brain changes (i.e. amyloid deposition) can be detected up to 20 years prior to onset of the clinical syndrome of dementia. As the disease progresses, tau pathology develops and neuronal injury occurs, eventually leading to memory impairment, global cognitive decline, and dementia. The predementia clinical stages of subjective cognitive decline and MCI offer a unique window for preventive intervention. The promise of preventive strategies has recently been illustrated by the finding that incidence numbers seem to rise less rapidly than anticipated, probably due to improved treatment of vascular risk factors, and a growing body of evidence suggest that nutritional status is a major, often unrecognized determinant for cognitive decline and AD. So far it remains unclear whether cognitive decline alters behavioural aspects of food intake, or whether AD pathology results in altered energy needs and body composition that result in altered nutritional status, or both.

Study objective

To identify modifiable dietary risk factors for AD,by comparing three patientpopulations in nutritional intake, energy needs, body composition, physical activity and functioning of smell and taste.

Study design

NUDAD-L is a prospective cohort study, representing a sub-cohort of NUDAD-XL. We will include patients who have visited our diagnostic screening. The duration of follow-up will be three years.

Study burden and risks

Before inclusion, all patients have been screened at the VUmc Alzheimer center, including comprehensive neuropsychological testing, MRI, EEG, and collection of blood, DNA and CSF for research purposes. When patients participate in NUDAD-L, they will undergo additional blood sampling, taste and smell testing, fill out several questionnaires on food preferences, food intake, physical activity, appetite, hunger and satiety, and they will have their energy expenditure measured by indirect calorimetry. At two years follow-up, we will repeat Fasting blood sampling, the olfactory and gustatory function tests and the 3 day food diary which will be filled out in advance at home. At the visit patients will receive material to sample their feces at home. This sample can be send to us. These measurements will take about 1 hour and will be scheduled on the same day as their regular second clinical follow-up appointment. In addition, patients will be invited for three annual follow-up visits (visit

medical doctor and neuropsychologist). The risks associated with participation are negligible and follow-up is organized in much the same way as our routine clinical follow-up.

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

Label of either subjective cognitive decline, Mild Cognitive Impairment or Alzheimer's Disease
Signed informed consent projects P2005_160, P2000_211 (SCD: also SCIENCe P2014-019)
Age * 50 years
MMSE*19

Exclusion criteria

Individuals who are considered medically unstable (assessed by physician)
Insufficient knowledge of Dutch language
Major psychiatric disorder, such as psychosis, schizophrenia, severe personality disorder or depression with vital signs, abuse of alcohol or other substances
Neurological disorder such as Parkinson*s disease, symptomatic stroke, mental retardation
Having a history of other neurological disorders known to influence smell and/or taste
Acquired Immune Deficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV)
Having a severe food allergy
Having a severe disease of the digestive tract, such as celiac disease, Crohn*s disease, active ulcerative colitis, short bowel syndrome
Having a severe metabolic disorder, such as phenyl ketonuria
A recent diagnosis of cancer or being actively treated for cancer (excluding basal cell carcinoma of the skin)
Having a current upper respiratory infection or severe COPD (known GOLD 3 or 4)
Being a regular smoker
In MCI and AD patients: unavailability of a study partner to assist with the participation of NUDAD-L in patients with dementia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2016
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	13-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL55116.029.15