Pain in Dementia- Prevalence and Diagnostics

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43653

Source
ToetsingOnline

Brief title
Pain in Dementia

Condition

- Other condition
- Peripheral neuropathies
- Dementia and amnestic conditions

Synonym
ache, Alzheimers's disease, cognitive impairment, dementia, neuralgia, neuropathic pain, orofacial pain, pain, 'senility'

Health condition

pijn

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Alzheimer Nederland;Fund Nuts Ohra care subsidies;Osira Amstelring;Roomsch Catholijk Oude Armen Kantoor (RCOAK);SBOH;Stichting Henriëtte Hofje

Intervention

Keyword: cognition/behaviour, dementia, oral health care, pain

Outcome measures

Primary outcome

Dementia subtypes and grading of dementia, Pain, Cognition.

Secondary outcome

Neuropsychiatric symptoms, Qualitity of Life, Oral Health Status, Vital

Sensibility and Gnostic Sensibility, Autonomic responses.

Study description

Background summary

Recent years have seen a steadily increasing scientific interest in pain in elderly with dementia. Still, much remains unclear. The prevalence of pain in dementia is uncertain, as is the relation between pain and the different subtypes of dementia. In addition, the studies published so far often do not differentiate between the various types of pain e.g. acute vs chronic pain or nociceptive vs neuropathic pain. Finally, an often overlooked type of pain in research is orofacial pain, even though it is very likely that this type of pain is common in elderly with dementia, given their decreased ability to perform oral care.
Despite the apparent absence of studies differentiating between various types of dementia, distiguising between the various etiologies and the associated neuropathology is clinically highly significant. The presence of white matter lesions is an important part of the pathology and they are known to increase pain experience.
The two goals of this study are 1. to investigate the prevalence of pain in elderly with dementia and to examine the relationship between the most prevalent subtypes of dementia, i.e. AD, VaD, FTD and DLB, and specific types

of pain, e.g. nociceptive pain and (central) neuropathic pain. Another goal of the present study is to examine the relationship between specific types of pain, cognitive functioning, and the presence of neuropsychiatric symptoms in the various subtypes of dementia.

Study objective

Objectives:
1. To assess the prevalence of pain in elderly with dementia and to study the relationship between the various subtypes of dementia and the presence of specific types of pain(e.g. nociceptive pain, neuropathic pain, and orofacial pain).
2. To study the relationship between various types of pain and cognitive functioning in elderly with dementia.
3. To study the relationship between various types of pain and the presence of neuropsychiatric symptoms, and how this is related to the quality of life.

Study design

An observational, cross-sectional, and partially longitudinal cohort study. All participants will be asked about the presence and intensity of pain. If they are no longer able to communicate, observation and proxy rated scales will be utilized. In nursing homes, a pain observation scale with an emphasis on pain due to musculoskeletal disorders will be administered to the nurse or auxiliary nurse during morning care. When one of the the pain assessment methods produces a positive indication of pain, a physical examination will be performed with an emphasis on musculoskeletal pain and signs of neuropathic pain. Furthermore, all participants will receive a dental examination with special focus on possible causes of orofacial pain. Other measurements include medication use, cognitive functioning, ADL functioning, presence of neuropsychiatric symptoms and quality of life. If pain is present, a differential diagnosis will be made and this will be given as feedback to the attending physician. The effects of this feedback on the patients* treatment will be evaluated after three months

Study burden and risks

The risks of this study are negligible and the burden associated with participation is minimal.
If participants are unable to complete the questionnaires by themselves, a proxy-rated scale will be used.
Blood samples are part of standard practice at the COGA/BACO. Blood samples are taken by means of a venous puncture and minimal risk is expected.
Oral examination (comparable to standard oral examination) will be performed by a dentist with experience in the care for people with dementia and will be finished directly if the participant shows resistance to the examination.
Physical examination will be performed by a elderly care medicine trainee with

experience in examine people with dementia. The physical examination will be performed only if there are signals of the presence of pain based on the information from the questionnaires.
The participants could benefit from this study due to a better recognition of pain and more appropriate treatment, or they could benefit as a result of the oral examination en receive proper treatment for the oral conditions seen at examination.
In general patients with dementia could benefit from this study by gaining knowledge on the prevalence and diagnostics of pain in people with dementia.

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

dementia, MCI, subjective memory problems, aged > 60 years

Exclusion criteria

no dementia, aged < 60 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2014
Enrollment:	440
Type:	Actual

Ethics review

Approved WMO Date:	14-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	05-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2016
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	NL43861.029.13