Understanding and objectively measuring paratonia in persons with dementia: a surface electromyography approach

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON51656

Source
ToetsingOnline

Brief title
Surface EMG to measure paratonia in dementia

Condition

- Movement disorders (incl parkinsonism)

Synonym
heightened muscle tone, Paratonia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: Dementia, Electroencephalography, Electromyography, Paratonia

Outcome measures

Primary outcome

The primary outcome measure is muscle activity, derived from EMG, during active and passive movements. Outcome measures are root mean square, co-contraction index, corticomuscular coherence and corticokinetic coherence.

Secondary outcome

- Cognitive function as measured with the Montrial Cognitive Assessment

- Physical function as measured with the Timed-Up-And-Go test

Study description

Background summary

Although dementia is mostly associated with deterioration in cognitive function, movement disorders are also involved in dementia. Paratonia is a movement disorder in people with dementia that is characterized by increased muscle tone during passive movements proportional to the stimulus applied and deteriorates with increased severity of dementia. The increased resistance during passive movements can ultimately result in countermovements, severely impacting daily functioning of people with dementia.

Despite their impact, movement disorders in people with dementia receive surprisingly littel attention. Diagnosis of paratonia relies on subjective questionnaires completed by health care providers. However, indirect evidence suggests that paratonia results from disinhibition of the frontal cortex. Based on these data, one can argue that paratonia can be objectively measured using non-invasive electrophysiological techniques.

Study objective

Because experimental evidence suggested the possibility to measure paratonia

through muscle activity, the primary aim of this study is to develop an objective non-invasive tool based on surface electromyography (sEMG) to quantify the presence and severity of paratonia in people with AD.

Secundairy aims:
- To examine the relationship between paratonia and cognitive and physical function.
- To identify possible underlying neuromuscular mechanisms associated with paratonia.

Study design

We will measure the participants' cognitive and physical function. To quantify paratonia, participants are asked to (let) perform active and passive movements at three different speeds and under two different attention-conditions. During these movements, participants' muscle- and brain-activity will be measured using electromyography and electroencephalography, respectively.

Study burden and risks

Overall, the risks associated with the proposed study are minimal. Participants can experience muscle fatigue as a result of the repeating conditions/trials. However, participants are continuously supervised and repeatedly asked whether they are doing fine. Breaks between conditions can be prolonged if necessary. As the experiment is non-therapeutic, the experiment has no direct benefits for the participants. However, all assessments are non-invasive and will be performed according to established guidelines. Moreover, the study consists in only one session. As such, we consider the risks of the current study negligible and the burden for the participants minimal. The proposed group of participants and patients is essential to achieve our research goals. That is, paratonia is a motor disorder that is specific for patients with dementia and its severity increases with advancements in the disease.

Contacts

Public
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
Groningen 9700AD FA23
NL
Scientific
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
Groningen 9700AD FA23
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For healthy participants:
- Age in one of the following categories: 18-30y, 40-55y, >65y
- Intact cognitive function (MOCA > 26)

For patients:
- Diagnosed mild cognitive impairment (CDR score 0.5), mild dementia (CDR score 1), moderate dementia (CDR score 2) or severe dementia (CDR score 2).
- Able to sit independently.

Exclusion criteria

For healthy participants:
- a history of neurological problems (e.g., CVA, epilepsy or PD) or peripheral nerve problems.
- Intake of medication that substantially affects the functioning of the nervous system in the three months prior to the experiment. This includes psychotropic medication (ATC codes N03A, N05A, N05B, N05C, N06A, N06B), anti-migraine and analgesics.

For patients:
-The participant has experienced intercurrent diseases that negatively affected cognitive and motor function.
- The participant has a fever at the time of the experiment.

- The participant is deliriant.
- The participant is terminally ill (i.e., life expectancy < 2 weeks according to the attending physician).
- People with primary vascular dementia, Lewy Body / Parkinson dementia and fronto-temporal dementia based on chart diagnosis.
- Intake of medication that substantially affects the functioning of the nervous system in the three months prior to the experiment. This includes psychotropic medication (ATC codes N03A, N05A, N05B, N05C, N06A, N06B), anti-migraine and analgesics.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2023
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO

Date:	08-03-2023
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
ClinicalTrials.gov	NCT05606445
CCMO	NL81562.042.22