Pain in adults with Down syndrome.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21264

Source
NTR

Health condition

Pain
Down syndrome
Cognition
Dementia

Pain
Down syndrome
Cognition
Dementia

Sponsors and support

Primary sponsor: Performer: VU university, Department of Clinical Neuropsychology, The Netherlands.
Main investigator: Nanda de Knegt (MSc.)Doctoral thesis supervisors: prof. dr. Scherder and prof. dr. Evenhuis.

METC permission: submitted in May 2011, in progress.
Source(s) of monetary or material Support: Fonds NutsOhra
Fonds Verstandelijk Gehadicapten
Possibly: Innovatiefonds Zorgverzekeraars

Intervention

Outcome measures

Primary outcome

The main study parameters are:

1. The difference in pain experience between the control group and Down syndrome group;

2. The difference in pain experience between Down syndrome adults without versus with indications for dementia;

3. The difference in the relationship between pain and cognitive functioning comparing Down syndrome adults without versus with dementia;

4. The difference in pain experience, cognitive functioning, and the relationship between pain experience and cognitive functioning comparing Down syndrome adults without versus with ApoE e4 allele.

Secondary outcome

N/A

Study description

Background summary

This will be the first clinical study in which the pain experience is examined in adults with Down syndrome, compared with a control group and divided into the presence and absence of indicated dementia. Also, this is the first study in which the relationship between pain experience and cognitive functioning is exmined in persons with Down syndrome.

Country: The Netherlands.

Study objective

Necessity:

A study on chronic pain in persons with Down syndrome is clinical relevant for 5 reasons:

1. The neuropathology of Down syndrome without and with dementia affects pain-related gray and white matter, which may alter pain experience;

2. The prevalence of age-related painful conditions is increasing in Down syndrome due to increase in estimated life expectancy;

3. Persons with Down syndrome may suffer from more painful conditions than controls do;

4. The sensory-discriminative aspect of pain appears to be abnormal in Down syndrome;

5. The relationship between cognitive functioning and pain may be altered by the presence of apolipoprotein E4 (ApoE4) in Down syndrome without and with dementia.

Aim:

To study the relationship between pain experience and cognitive functioning in adults with Down syndrome, with and without dementia. To compare pain experience between adults with Down syndrome and subjects of a control group.

Hypotheses:

1. Adults with Down syndrome will report an increased pain experience compared to the control group;

2. In Down syndrome adults with dementia, pain experience will be further increased compared to Down syndrome adults without dementia;

3. Chronic pain experience will relate negatively to cognitive functioning in Down syndrome adults (without and with dementia);

4. The ApoE e4 allele is negatively associated with cognitive functioning in Down syndrome.

Study design

Measurements will be performed in total during 45 minutes (one visit) with the control subjects and 180 minutes (several visits to prevent exhaustion) with the Down syndrome subjects.

Intervention

Control group and clinical group:

The pain perception in the subject will be studied using self-reported visual analogue scales, an observation list for pain behavior, and a test for tactile perception. The self-report scales and observation lists are administred at rest and after physical examination.

During the physical examination, the client is requested by the researcher to imitate movements with joints (neck, shoulders, elbows, wrists, fingers, back, legs and jaw). In this way, we examine whether joint pain occurs.

In the test for vital sensibility, the subject is asked to judge with eyes closed whether his/her forearms are touched with a sharp or blunt edge of a Neuropen (cautiously), a hot or cold metal roller (carefully) is placed and when (at which thickness) a nylon hair is used.

Only clinical group (Down syndrome):

The ApoE genotype will be determined by striking a cotton swab along the buccal mucosa (and subsequent analysis in the laboratory).
Cognitive functioning will be investigated using a neuropsychological test battery (NETOL).
A caretaker of the subject will observe pain behavior in three situations (at rest / during an active moment of care / chewing), but the client will not be instructed during these observations.
The level of intellectual disability will be assessed by using a short test for logical reasoning (performed by subjects), a questionnaire for adaptive functioning (SRZ, completed by caretakers), and results of an intelligencetest from the personal file. Indications for dementia will be assessed by asking the caregiver to complete a dementia questionnaire (DVZ or DSDS) and by a short heteroanamnesis about indications for dementia (and pain). The scores of the SRZ and the DVZ/DSDS will be compared with data from previous completements of the same questionnaire in the care center.

Contacts

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Eligibility criteria

Inclusion criteria

Control group: N= 105

1. Aged 18 years or older;

2. One or several musculoskeletal disorders, e.g. arthrosis, hip abnormalities or degenerative cervical spine instability. Prevalence and type of musculoskeletal disorders in control group are matched with Down syndrome group, hence the musculoskeletal disorders are not always required;

3. Matched with Down syndrome group on age and sex.

Patient group: N= 210 (N= 105 without dementia and N= 105 with dementia)

1. Down syndrome;

2. Calendar age 18 years or older;

3. Screening of dementia (in half of the subjects; N= 105);

4. Estimated IQ 35 or higher;

5. Sufficient understanding of the tests for pain experience and the cognitive tests;

6. We are interested in musculoskeletal disorders (e.g. arthrosis, hip abnormalities or degenerative cervical spine instability), but this is not a request;

7. We are both interested in persons that report pain and in persons that doe not complain about pain (expecially that last group is relevant). Thus, a presumption of pain is not a request.

Exclusion criteria

Control group:

1. Diagnosis of intellectual disability;

2. Age < 18 years;

3. Diagnosis of dementia or incapacity to understand neuropsychological and pain measures;

4. Use of antiepileptic or antipsychotic;

5. Neurological conditions, e.g. tumors, strokes, or infarctions;

6. Visual impairment to such a high degree that tests cannot be seen properly;

7. Hearing loss to such a high degree that questions cannot be heard properly and sign language is known insufficiently;

8. Major clinical psychopathology (e.g. major depression disorder).

Patient group:

1. Moderately severe or severe dementia;

2. Calendar age < 18 years;

3. Estimated IQ<35 and/or incapacity to perform neuropsychological and pain measures;

4. Use of anticonvulsants or antipsychotics;

5. Presence of neurological conditions (tumors, hemorrhages, infarctions);

6. Visual impairment to such a high degree that tests cannot be seen properly;

7. Hearing loss to such a high degree that questions cannot be heard properly and sign language is known insufficiently.

Preferably, we exclude subjects with hypothyroidism, epilepsy, or major clinical psychopathology (e.g. major depression disorder). Pain medication and anti-inflammatory medication are not excluded, they will be statistically corrected.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	315
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL2769
NTR-old	NTR2909
Other	METC VU Medical Center : 2011/134
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A