Chronic pain experience in adults with Down syndrome, with and without dementia, and the relationship with cognitive functioning.

Published: 06-02-2012
Last updated: 27-04-2024

The first aim of the present study is to examine whether the pain experience in adults with Down syndrome (without dementia) differs from the pain experience in adults without intellectual disability, after correction for mentale age, comorbidity…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON39082

Source
ToetsingOnline

Brief title
Pain in adults with Down syndrome.

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Joint disorders
- Mental impairment disorders

Synonym
1) trisomy 21 or Down syndrome; 2) intellectual disabilities or mental retardation; 3) musculoskeletal disorders or impediment of joints

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: subsidiefondsen zoals Fonds NutsOhra en Fonds Verstandelijk Gehandicapten.

Intervention

Keyword: Cognition, Dementia, Down syndrome, Pain

Outcome measures

Primary outcome

Pain experience; difference in pain experience between control group, Down

syndrome, and Down syndrome with indications for dementia.

Pain experience (both groups) consists of parameters for

- intensity of pain

- affect of pain

- location of pain

- tactile perception of pain

- pain behaviour (observation of facial expressions and body movements)

Relationship between pain experience and cognitive functioning

(neuropsychological test battery) in Down syndrome without and with indications

for dementia.

Secondary outcome

Possible confounding variables that will be examined in both studies:

- psychiatric comorbidity ([hetero]anamnesis and medical file)

- physical comorbidity (medical file)

- medication (medical file)

The usefulness of a computer test to answer questions about pain experience

independently

Study description

Background summary

Only a few studies have been published about a clinical very relevant symptom with probably a high prevalence in intellectual disabilities: chronic pain. Compared to the healthy population, people with intellectual disabilities have a higher risk of developing musculoskeletal disorders. This is alarming, because adults without intellectual disabilities rate musculoskeletal disorders as very or extremely painful. Moreover, medical interventions for physical conditions such as surgery or physiotherapy are often painful. An effective treatment of these painful conditions requires a reliable pain assessment, which is hampered in intellectual disabilities due to communicative limitations, especially in those suffering from dementia. Impaired cognitive performances have been observed in chronic pain patients. This is important in intellectual disabilities, because the relationship between chronic pain and cognition has not been examined in this syndrome.

First, we will focus on adults with Down syndrome, because the neuropathology of this syndrome is familiar among which the brain areas that are involved in pain processing.

Study objective

The first aim of the present study is to examine whether the pain experience in adults with Down syndrome (without dementia) differs from the pain experience in adults without intellectual disability, after correction for mentale age, comorbidity and medication. Furthermore, we will examine whether the pain experience in adults with Down syndrome without dementia differs from the pain experience in adults with both Down syndrome and dementia, after correction for mentale age, comorbidity and medication

The second aim of the present study is to examine within the group persons with Down syndrome whether a relationship exists between chronic pain experience and cognitive functioning, and whether the presence of dementia changes the pain experience.

The ultimate aim of the project is implimentation of daily pain diagnostics in Dutch institutions for people with an intellectual disability, which we will realise by training the nursing staff in execution of this diagnostics and by

developing a computer test in such way that people with intellectual disabilities can regularly and independently indicate their pain.

Study design

Invasive, observational study.

Study burden and risks

Burden for subjects control group: in total 1.5 hours per subject

Burden for subjects with Down syndrome: in total 1.5 hours per subject
- The ApoE genotype will be determined by collecting saliva in the cheek pouches with Orogene sponge sticks (and subsequently analyse these swabs in the laboratory).
- The pain experience will be assessed in the subjects by means of 3 visual analogue scales and 3 tests for tactile perception. In the test for tactile perception, the subjects has to judge with eyes closed whether he/she feels on the inside of his/her forearms the blunt or sharp side of a Neuropen, a cold mental instrument and warm a warm mental instrument and when he/she feels 'von Frey hairs' with differential thickness. This whole procedure will be executed with greatest care. The measurements are standardised and quanitative, for example 25 degrees Celcius for the cold stimulus and 40 degrees Celcius for the warm stimulus.
- The cognitive functioning will be assessed by means of a test battery, which is developed for adults with intellectual disabilities. Furthermore, the nursing staff will complete a questionnaire for executive functions, because these functions are difficult to test on the subjects themselves.

Burden for Down syndrome subjects Computer Test: in total 1 hour per subject
- Questions are answered by means of a touch screen, keypad buttons, or mouse. It is investigated what works best. After a brief introduction about pain, the subject answers a few questions about the location of body parts, numbersona a ruler, and faces that express pain. This is the assessment of understanding. Then the subject answer whether he / she has any pain today (answer YES and NO). When "NO" is answered, then the test is automatically completed. When "YES" is answered, then the pain experience is further explored. The test automatically includes only the images that are understood in the comprehension test. The test ends automatically with a pain score as a percentage of the maximum score depending on the number of questions that are asked.
- In the test for understanding of sentences, the subject choose the accompanying picture of each sentence that is read aloud. In the test for vocabulary, he / she is asked to give the meaning of words. In the test for block patterns, he / she makes patterns with colored blocks during which the time is recorded. The tests for vocabulary and block patterns are increasingly difficult until a cut-off point is reached.

Burden for nursing staff: 60 minutes per subject in total
- Completing an observation list for pain behaviour (by prefer 2x: after test session and again 3 months later)
- Completing 3 questionnaires (executive functions, mental level, dementia)

Risks for subjects and nursing staff: none (a pin prick at the most).

Contacts

Public
Vrije Universiteit

Van der Boechorstraat 1
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit

Van der Boechorstraat 1
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Control group:
*aged 18 years or older
*the group is matched with Down syndrome group on age and sex
*speaking and understanding the Dutch language;Patient group:

*Down syndrome
*calendar age 18 years or older
*speaking and understanding the Dutch language
*indications of possible dementia (in half of the subjects; see §4.4 Sample size calculation)
*estimated IQ 35 or higher
*sufficient understanding of the tests for pain experience and the cognitive tests;We are interested in musculoskeletal disorders (e.g. arthrosis, hip abnormalities or degenerative cervical spine instability), but this is not a request. We are both interested in persons that report pain and in persons that do not complain about pain (especially that last group is relevant). Thus, a presumption of pain is not a request.

Exclusion criteria

Control group:
*diagnosis of intellectual disability
*age < 18 years
*diagnosis of dementia
*use of anticonvulsants or antipsychotics
*neurological conditions, e.g. tumors, strokes, or infarctions
*visual impairment to such a high degree that tests cannot be seen properly
*hearing loss to such a high degree that questions cannot be heard properly and sign language is known insufficiently
*major clinical psychopathology (e.g. major depression disorder);Pain medication and anti-inflammatory medication are not excluded, they will be statistically corrected. ;Patient group:
*moderately severe or severe dementia
*calendar age < 18 years
*estimated IQ<35 and/or incapacity to perform neuropsychological and pain measures
*use of anticonvulsants or antipsychotics
*presence of neurological conditions (tumors, hemorrhages, infarctions)
*visual impairment to such a high degree that tests cannot be seen properly
*hearing loss to such a high degree that questions cannot be heard properly and sign language is known insufficiently;Preferably, we exclude in the clinical group subjects with hypothyroidism, epilepsy, or major clinical psychopathology (e.g. major depression disorder). A low frequency or absence of complaining about pain is not an exclusion criterion! Pain medication and anti-inflammatory medication are not excluded, they will be statistically corrected.

Study design

Design

Study type:	Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2012
Enrollment:	315
Type:	Actual

Ethics review

Approved WMO Date:	06-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2013
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	NL33540.029.11