

Behavioural response of Individuals With Down's syndrome During a dental treatment

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Primary Objective: Analyse the behavioural response of individuals with Down's syndrome directly after a painful dental stimulus and compare this with video-analysed behaviour. Secondary Objective(s): 1) Determine which observational scale can...

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

Summary

ID

NL-OMON38348

Source

ToetsingOnline

Brief title

Response of Individuals With Down's syndrome During dental treatment

Condition

- Other condition
- Chromosomal abnormalities, gene alterations and gene variants

Synonym

Down's syndrome

Health condition

Downsyndroom

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam

Source(s) of monetary or material Support: instelling waar onderzoekers werkzaam zijn

Intervention

Keyword: behaviour, dentistry, Down's syndrome, pain

Outcome measures

Primary outcome

The participants will all have a different mental level. Which will probably mean they will all react in a different way.

The primary study outcomes are the pain-scores of the dentist, the dental assistant and the patient.

Secondary outcome

The pain behaviour will be assessed using different observation scales:

- 1) 3 behaviours from the Facial Action Coding system
- 2) Non-communicating Pain Checklist for adults
- 3) Numeric pain scale
- 4) Comfort scale

Study description

Background summary

A lack of research has limited our understanding of the prevalence and experience of pain and its longterm implications for individuals with developmental disabilities. Little research is done to describe the way in which individuals with Down's syndrome express and communicate pain. The dental setting provides the opportunity to observe these individuals during a potentially painful dental stimulus.

Study objective

Primary Objective:

Analyse the behavioural response of individuals with Down's syndrome directly after a painful dental stimulus and compare this with video-analysed behaviour.

Secondary Objective(s):

1) Determine which observational scale can be used to reliably and accurately assess pain during a dental treatment with individuals with Down's syndrome.

2) Determine the inter-analyst reliability of the two independent analysts who analyse the video's.

3) Compare the response of individuals with Down's syndrome on a aversive dental treatment with the response on a painful dental treatment (anaesthesia injection or mechanical removal of calculus) to indicate behavioural expression related to pain.

Study design

The participants will be videotaped during their dental treatment. These video's will be assessed using different pain-observation scales to assess the painbehaviour of the participants.

Directly after the potential painful stimulus (dental injection) the participants will be asked how much pain they had. Furthermore, the dentist and the dental assistant will give a score on how much pain they thought the participant felt.

Afterwards, the scores of the different observation scales will be compared with each other and with the scores given by the clinicians. Also the inter-rater reliability will be assessed and the validity of the different scales by comparing the scores of a painful with a non-pain stimulus.

Study burden and risks

Not applicable

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

Individuals 18 years or older with Down's syndrome.

Exclusion criteria

Individuals with Down's syndrome younger than 18 years.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 15-11-2010
Enrollment: 50
Type: Actual

Ethics review

Approved WMO
Date: 17-05-2010
Application type: First submission
Review commission: METC Isala Klinieken (Zwolle)
Approved WMO
Date: 08-10-2012
Application type: Amendment
Review commission: METC Isala Klinieken (Zwolle)

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	NL28326.075.10