

Normal values of orofacial motor skills in children from 2 to 8 years

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The collection of data of the orofacial motor skills with the OMOK in healthy children between 2 and 8 years.

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

Summary

ID

NL-OMON45869

Source

ToetsingOnline

Brief title

Orofacial motor skills in children

Condition

- Other condition

Synonym

Orofacial skill problems

Health condition

Normaalwaardes gezonde proefpersonen

Research involving

Human

Sponsors and support

Primary sponsor: afdeling Logopedie (kinderen), Afdeling Revalidatie

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

Intervention

Keyword: Children, Orofacial Motor Observation in Kids (OMOK), Orofacial motor skills

Outcome measures

Primary outcome

Score (0 = not; 1 = moderate; 2 = normal) in typically developing children on the different items of the OMOK in consecutive age groups (normal values)

Secondary outcome

Differences between boys and girls on the scores of the different items

Interrater reliability of the various items

Study description

Background summary

The Department of rehabilitation/speech therapy of the Radboudumc (Amalia children's Hospital) is involved in the Outpatient Clinic *Zeldzaam* (*rare*). In this outpatient clinic children with rare genetic syndromes are seen. Based on the increased possibilities for DNA testing in which all genes can be mapped, young children with developmental problems are more and more diagnosed with a (relatively) unknown condition. The purpose of the Poli Zeldzaam is to identify the problems of children with a rare condition. In this way, children can be well described with a particular condition or syndrome. This might support the knowledge about the disorder and its possible treatment.

The assessments of these children, performed by the speech language therapist (SLT), are focused on the development of eating and swallowing, saliva control, language, speech and orofacial motor skills. The last item is related to the performance of conscious movements of face and mouth area, such as eye closing, pouting lips, sticking out the tongue, blowing and sucking. A list was composed: the Orofacial Motor Observation in Kids (OMOK) (see appendix 1 of the research protocol for the different items). This list is based on different assessments, such as the Dyspraxieprogramma [1] and other 'oral motor' assessments [2] [3]. In addition, elements from the Radboud Oral Assessment (adults) were incorporated [4].

Because the data from the various assessments (speech, eating and drinking, swallowing and orofaciale motor skills) give a complete picture of what a child can, all these elements are included in the SLT assessment. For most of those

parts normal values are available, so that the scores or results of the SLT assessment can be compared with these normal values. However, this is not the case for the development of the orofacial motor skills. Also for other groups of children it may be important to have these normal values.

Study objective

The collection of data of the orofacial motor skills with the OMOK in healthy children between 2 and 8 years.

Study design

1. In Nijmegen and surroundings day care centers, preschools and elementary schools will be approached with the question to announce the study in their newsletter or via their website. Via the email address, mentioned in this post (see appendix 2), parents can register their child, after they have read the information. Also Child health care centres will be asked to spread the information.
 2. The researchers (students of the SLT department of the HAN, Nijmegen) will make a planning in collaboration with the child care centers, preschools and elementary schools to assess the children, after receiving the mail and the permission statement from the parents (informed consent),
 3. The privacy of the participants is protected to the highest possible degree, based on The Persona Data Protection Act and privacy rules of the Radboudumc. Registration of research data takes place anonymously. A unique fictive code is used to trace back data. The encryption key is secured and only the coordinating researcher has access to the key.
 4. The OMOK is conducted by one of the researchers. In young children it is allowed that parents or caregivers are present at the investigation.
 5. The administration of the OMOK will take about 10 minutes. Children are asked to perform movements of face and oral area.
 6. To measure the interrater reliability 10% of the children (minimum N = 27), divided across the age groups, will be videotaped. Parents or caregivers are asked to agree with the making of a videotape (on the informed consent). The tapes will be numbered and be linked to the numbers of the children and be included in a data file. The video recordings are scored directly by the researcher, at a different time by one of the other researchers, and by one of the members of the research group
- Besides data of the OMOK data on age and gender are collected.

Study burden and risks

After the obtained information parents/caregivers decide whether their child might participate in the study. They are asked to send an email to the research group if they agree. The parents/caregivers will be asked to sign an informed consent. The data will be processed anonymously.

The children will be assessed according to the OMOK described in appendix 1. For the children it will take about 10 minutes. In young children the assessment can be performed at home, for other children the assessment will take place in the day care centers, preschools or elementary schools. Because this study is development related (when are young children able to perform these orofacial motor skills) the OMOK cannot be tested with adults.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Age between 2;0 and 8;0
Healthy children
Informed consent parents/caregivers

Exclusion criteria

Dysphagia
Feeding problems with the need for (additional) tube feeding
Neurological disease
Diagnosed with a syndrome
Anatomical deviances in oral area

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)
Control: Uncontrolled
Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 15-03-2019
Enrollment: 270
Type: Actual

Ethics review

Approved WMO
Date: 12-02-2019
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL68147.091.18