The development and evaluation of a behavioural program to treat drooling in children wit Cerebral Palsy

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Ethical review	Approved WMO
Status	Pending
Health condition type	Encephalopathies
Study type	Interventional

Summary

ID

NL-OMON30394

Source
ToetsingOnline

Brief title
Behaviour therapy for drooling in CP

Condition

- Encephalopathies

Synonym
cerebral palsy

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: nog onbekend

Intervention

Keyword: behaviour therapy, cerebral palsy, drooling

Outcome measures

Primary outcome

At baseline at least 10 or more 10-minute video recordings are made while the child is engaged in different daily activities such as watching television, playing a game, doing schoolwork, etcetera. Dependent measures are:

A) Drooling. Drooling behaviour is scored at two levels:

1. Latency recording: minutes/seconds the child manages to stay dry after the start of the activity.

2. Drooling severity: partial interval time-sampling during 40 intervals of 15 seconds with four categories: (a) new saliva below lower lip line, (b) old saliva below lower lip line, (c) string of dribble or (d) dry.

B) Wiping. The frequency of spontaneous wiping during 10 minute-sessions is scored.

During the training period post-tests for latency are scheduled at the end of each training session. When the 30-minutes interval is reached successfully, post-tests are only scheduled at the end of the last training session every day. In addition, to assess whether the training effects remain overnight, the first training session starts with a delayed post-test of latency.

At the end of the training period at least another 10 or more 10-minute video recordings are made while the child is engaged in different daily activities.

During generalisation and follow-up sessions drooling is only assessed with latency recording.

Interobserver reliability is determined for 10% of the video-recordings.

Secondary outcome

In addition to quantitative measures from behaviour observation, parents and teachers are asked to rate drooling severity on the TDS and a VAS for ten consecutive days before baseline-recordings and during follow-up periods. In addition, parents and teachers fill in questionnaires on practical, social and emotional consequences of drooling (Van der Burg et al., 2006) before baseline, during generalisation and follow-up periods.

Study description

Background summary

Reviews on the management of drooling unanimously conclude that behavioural treatment should be used before medication or surgery is considered. However, scientific evaluation of behaviour therapy for drooling is scarce: from 1970 to 2005, only 17 articles have been published, containing experimental data of only 53 patients. As a consequence, there is neither *evidence based* behavioural treatment nor *best practice* for drooling.

Study objective

The objective of this study is to develop an effective behavioural treatment for severe drooling. The hypotheses are:
1. A behavioural program containing instruction, goal setting, positive practice, self-management techniques, and positive and negative social reinforcement, leads to a reduction of drooling while the subject is performing daily activities in a one-to-one training.
2. The results generalize to natural settings at home and at school.

Study design

In a non-concurrent multiple baseline design across subjects (Watson & Workman, 1981) intervention is started after baseline. Once the training goal is reached, post treatment data are collected. Immediately after discharge, generalisation data are collected at school. After 6 and 24 weeks follow up

data are collected.

Intervention

The study is conducted in the clinical department of a rehabilitation centre, where participants are admitted during 3 weeks. During intervention three 1*-hour training sessions are scheduled daily.
During the training program the child learns to keep the mouth and chin dry and clean with increasing time-intervals while performing their daily activities.
The initial demanded intervals are 1, 2, 5, 10, 15, 20, 25, 30 minutes. After being dry for half an hour, time intervals are increased either with 5, 10 or 15 minutes, depending on the learning potential of the child.
Before training starts, the child is told that drooling is not good, because it makes you look bad. The child is convinced that other people don*t like the sight of drooling and he/she will be trained to swallow and wipe more often to prevent drooling. The training format is explained and a swallowing report on which stickers can be attached is introduced.
The time interval for the first training sessions is determined from baseline latency recordings. This is the interval that the child usually is able to stay dry during activity.
The training starts with instruction, positive practice, self-instruction, positive feedback for target behaviours and the introduction of the activity and the time interval. Whenever the child succeeds to stay dry during the entire interval, positive social reinforcement is given and a sticker is put in the swallowing report. If the child does not succeed, the activity is interrupted and the child is told that he/she has not succeeded the interval. Incidentally, a negative remark is added. The child is prompted to clean his/her face and a new trial is started. When the child succeeds at three successive trials, the next larger time interval is trained. When the child does not succeed three successive trials or three out of five trials, training is reinstated on the one step lower time-interval.

Study burden and risks

After inclusion the child is admitted to the clinical department of a rehabilitation centre during 3 weeks (except the weekends). Parents are offered the posibility of roomin-in. Parents and teachers fill in a questionnaire before intervention and at follow up at 6 and 24 weeks. In addition, they complete two ratingscales on drooling severity for 10 days. We will kindly ask hospitality for generalisation and follow-up recordings at the child's school.
There are no physical risks associated with participation. Psychological burden (homesickness, tiredness, disappointment or anger if not succesful) is carefully observed and discussed with the parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

· a confirmed diagnosis of CP, with detailed descriptions of movement impairment;
· drooling severity: Teacher Drool Scale (TDS: Camp-Bruno et al., 1989) score 3 (occasional drooling; intermittent all day) or more (4: frequent drooling; but not profuse; 5: constant drooling; always wet);
· developmental age >= 6 years; the child displays reasonable awareness of the practical and/or social consequences of drooling;
· the child has the ability to close his/her mouth and swallow on demand;
· the child has the ability to remain seated (or is able to correct seating position independently);
· the child has the ability to wipe the mouth/chin;
· the child is susceptible to social and/or material reinforcers;

· medication to treat drooling stopped at least 3 months before inclusion;
· the parents and teachers are willing to participate in the treatment program, i.e. to perform activities to maintain the training effect.
· the child and their parents and teachers are willing to participate in scientific research, including activities for data-collection (informed consent is obtained) and if significant positive changes are established are prepared to refrain from other medical treatment for 6 months after the end of the training.

Exclusion criteria

· the child has uncontrollable (epileptic) seizures;
· the child has severe aggressive or hyperactive behaviour;
· during 6 months before inclusion there has been surgery or botulinum toxin injection

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

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	NL14497.091.06