

# Efficacy of saliva management interventions for children with cerebral palsy –

## A summary of the evidence

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## CAP

Critically Appraised Paper

A **CAP** includes a summary of a  
single study

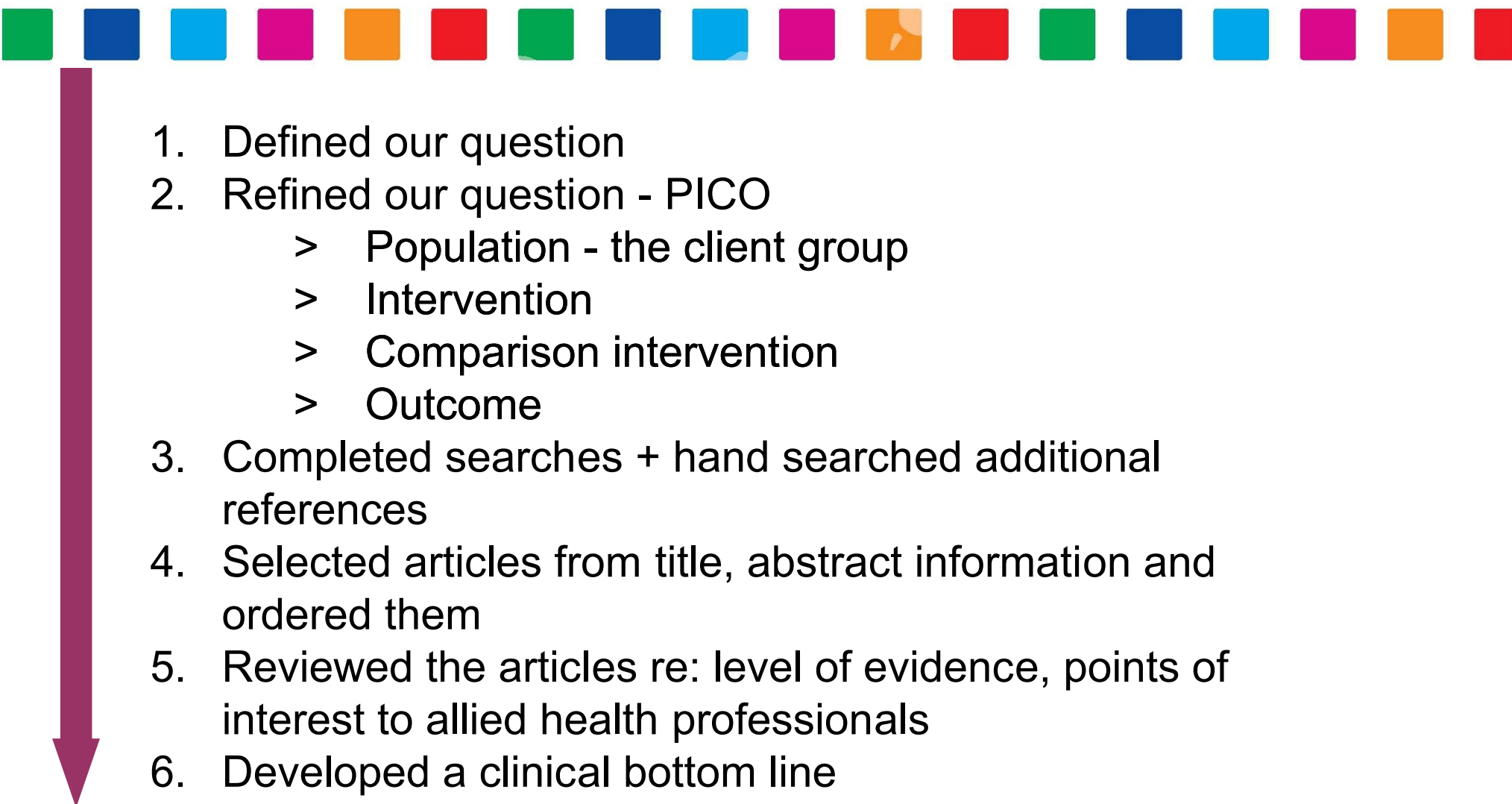
## CAT

Critically Appraised Topic

A **CAT** includes a summary of  
more than one study

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## Clinical Question

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1. Defined our question
  2. Refined our question - PICO
    - > Population - the client group
    - > Intervention
    - > Comparison intervention
    - > Outcome
  3. Completed searches + hand searched additional references
  4. Selected articles from title, abstract information and ordered them
  5. Reviewed the articles re: level of evidence, points of interest to allied health professionals
  6. Developed a clinical bottom line
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# Answerable question



Population	Intervention	Comparison	Outcome
Child	Oral motor	Nil	Saliva
Children	Oromotor		management
Paediatric	Behaviour		Increase control
Pediatric	Behavior		Decrease saliva
Infant	Medication		Efficacy
Cerebral palsy	Medicine		Effectiveness
Drool	Surgery		Improvement
Saliva	Botox		
Sialorrhea	Botulinum toxin type-A		
Dribble			

PubMed, Google Scholar, Cochrane, CINAHL

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- 1a Systematic review of RCTs
  - 1b Individual high quality RCT
  - 1c All or none case series
- } A
- 2a Systematic Review of cohorts
  - 2b Individual cohort study; lower quality RCT
  - 2c Outcomes research
  - 3a Systematic review of case-control
  - 3b Individual case control
- } B
- 4 Case-series; lower quality cohort; lower quality case-control
- } C
- 5 Literature review; expert opinion paper; case study
- } D

## Outline of presentation of interventions



Behaviour programs – *“A descriptive analysis of studies on behavioural treatment of drooling (1970 – 2005)”*

Oromotor exercises – *“Management of drooling in children with neurological problems in Hong Kong”*


Medication – *“A systematic review for evidence of efficacy of anticholinergic drugs to treat drooling”*

Surgery – *“Efficacy of relocation of submandibular duct in cerebral palsy patients with drooling”*

Botulinum Toxin – *“Treatment of sialorrhea in children with cerebral palsy: a double-blind placebo controlled trial”*

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## Behaviour – Level of Evidence and Grades of Recommendations



Methodology of studies retrieved	#	Source of Evidence
Clinical guidelines	0	
Level A evidence <i>Systematic Review</i> <i>RCT</i>	0	
Level B evidence	0	Pubmed, CINAHL, Google Scholar, Cochrane Library
Level C evidence	3	
Level D evidence	0	

Sackett's Rules of Evidence & Grades of Recommendation (1986)

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**Objective:**

Descriptive analysis review of studies looking into behavioural treatment of drooling from 1970 until 2005.

Grade D

**Results:**


The authors of this paper reviewed 17 articles

All authors of the reviewed articles claimed positive results and many anecdotally described the related positive changes in quality of life of the participants.

Cannot draw a conclusion about the efficacy of behavioural interventions for drooling due to the methodological limitations of many studies in the review, although the approach is considered promising.

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## Behaviour programs key findings


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- Lack of behavioural intervention studies reported in the literature in the last decade
  - There have been no randomised control trials conducted that have investigated use of behavior interventions for saliva management for children with cerebral palsy
  - Time intensive intervention for clients and carers
  - No reported side effects which makes behavioral interventions a attractive option compared to surgery, Botox or pharmaceutical management
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- Tentative evidence that children with good cognitive ability and mild saliva management difficulties respond best to behavior interventions
- Need to consider behavior interventions in relation to medical management of drooling problem i.e. the role of behavior interventions both prior and after medical management such as Botox or surgery



## Oromotor exercises papers reviewed and levels of evidence



Methodology of studies retrieved	#	Source of Evidence
Clinical guidelines	0	
Level A evidence <i>Systematic Review</i> <i>RCT</i>	0	
Level B evidence	0	Pubmed, CINAHL, Google Scholar, Cochrane Library
Level C evidence	5	
Level D evidence	0	

Sackett's Rules of Evidence & Grades of Recommendation (1986)

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## Oromotor exercises article – Yam et al. (2006)



### **Objective:**

To report on the clinical outcome of oral-motor training used at a drooling clinic in Hong Kong.

Grade C

### **Results:**

Severity of drooling was rated using 10 point visual analogue scale.

An average decrease of 3.0 was rated on VAS at follow-up. It was noted that the effect gradually wore off with time after training had been stopped as on the VAS the rating was 1.9 four months after training was ceased.

Functional gains other than drooling control were achieved following oral-motor training.

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## Oromotor exercises key findings




- Drooling reduced whilst implementing oro-motor interventions.
  - No evidence of long term maintenance of saliva control. Short term gains only.
  - Outcome measures used in the papers reviewed were subjective and were non-standardised (e.g. Visual Analogue Scale).
  - All appraised papers were of low grade evidence
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- The oro-motor interventions described in the literature were time intensive.
- Interventions can be easily ceased and no side effects were reported.



## Medication papers reviewed and levels of evidence



Methodology of studies retrieved	#	Source of Evidence
Clinical guidelines	0	
Level A evidence <i>Systematic Review</i> <i>RCT</i>	1 0	
Level B evidence	1	Pubmed, CINAHL, Google Scholar, Cochrane Library
Level C evidence	9	
Level D evidence	0	

Sackett's Rules of Evidence & Grades of Recommendation (1986)

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## Medication article – Jongerius et al. (2003)



### **Objective:**

Systematic review to determine the efficacy of anticholinergic drugs in the treatment of drooling in children with multiple handicaps

Grade A

### **Results:**

Some evidence that Benztropine, Glycopyrrolate, and Benzhexol Hydrochloride were effective in the treatment of drooling but it could not be concluded which drug is preferable

Of seven studies that met the criteria 3 were RCT's, 3 were cohort studies, and 1 was an experimental design

All studies that were reviewed mentioned adverse side-effects

Studies were not exclusively discussing saliva management and cerebral palsy

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## Medication key findings



- *Anticholinergic drugs:* ( Benzhexol hydrochloride, Glycopyrrolate, benztropine, Transdermal Scopolamine)

High level evidence to support the efficacy of anticholinergic drugs. Grade A.

All have adverse side-effects and none of the drugs were identified as superior.

- *Intrathecal Baclofen Therapy:*


26 children with spastic cerebral palsy receiving drug for spasticity, 10/26 subjects drooling improved but 8/26 noticed an increase in drooling. Grade C

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- *Modafinil:*
    - Case study noticed decreased drooling in 2 clients who were using the drug for spasticity (2006) - Grade C.
    - Benign side-effects-not described
  - *Antireflux medication:* (Ranitidine & Cisapride)
    - This does not result in a clinically significant reduction in drooling for children with CP and pathological drooling-Grade C
  - *Alternate medications:* (Papaya and Grape seed extract)
    - Mentioned in literature as being used to dry secretions but no research in to their efficacy has been conducted.
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## Surgery papers reviewed and levels of evidence



Methodology of studies retrieved	#	Source of Evidence
Clinical guidelines	0	
Level A evidence <i>Systematic Review</i> <i>RCT</i>	0	
Level B evidence	0	Pubmed, CINAHL, Google Scholar, Cochrane Library
Level C evidence	11	
Level D evidence	0	

## Surgery article - Puraviappan et al. (2007)



### Objective:

To investigate the efficacy of bilateral submandibular duct relocation for the treatment of drooling in children with cerebral palsy

### Results:

The parents of seven of the children (87.5%) graded severity of their child's drooling as  $>7$  before the procedure. Following the procedure the same number of parents graded the severity of their child's drooling as  $\leq 2$ .

Therefore the authors concluded that 87.5% of the patients had a reduction in drooling of more than 5 points on VAS.

The patients who had a preoperative severity score of 10 had, on average, a postoperative score of 1.5.

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## Surgery key findings



- The studies appraised were of low evidence
  - Surgical procedures are irreversible and can have adverse side effects
  - Salivary flow is reduced and drooling can be significantly improved, often with immediate results – 3 studies noted that 80 – 89% of participants had improved in their control of their saliva.
  - 95% of daily salivary output produced by parotid and submandibular glands, therefore most surgical procedures have focused on these glands.
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- Two studies discussed changes in quality of life. One of these found that 80% of those who participated improved across a number of different measures including receiving affection from others and opportunities for communication and interaction



## Botulinum Toxin article papers reviewed and levels of evidence



Methodology of studies retrieved	#	Source of Evidence
Clinical guidelines	0	
Level A evidence <i>Systematic Review</i> <i>RCT</i>	0 1	
Level B evidence	3	Pubmed, CINAHL, Google Scholar, Cochrane Library
Level C evidence	9	
Level D evidence	0	

## Botulinum Toxin article – Alrefai et al. (2009)



### Objective:

RCT to prospectively study the efficacy and safety of intraparotid gland injection of Botulinum neurotoxin serotype A (Dysport) for the treatment of drooling in children with cerebral palsy.

Grade B

### Results:

Study was blinded to participants and investigators (Double blind)

The median frequency of drooling score, median severity of drooling score and the median of the total drooling score did not change in the placebo group.

Statistically significant reduction in drooling in the treatment group. The median frequency of drooling score declined ( $p=0.034$ ), the median severity of drooling score declined ( $p=0.026$ ), and the median total score declined also ( $p=0.027$ ).

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## Botulinum Toxin key findings



- Children with neurological disorders who received BoNT-A injections into submandibular and parotid glands showed a statistically significant effect from BoNT-A at 1 month post-injection, compared with control. Maintained significance at 6 months. Grade B.
  - Many children with CP and drooling show greater effect from intrasalivary gland BoNT-A than with scopolamine. BoNT-A has shown lower response rate (as % of participants) compared with scopolamine.
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- The effects of BoNT-A are time limited and this varies between individuals - Grade C.
  - Non-severe side effects seen with BoNT-A, compared with 71% of participants experiencing moderate-severe side effects with scopolamine - Grade C.
  - Ideal dosage not yet established.
  - General anaesthesia may be needed to administer BoNT-A.
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**Evidence Based Practice =**



## Concluding ideas:

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- Speech pathologists at The Spastic Centre are now able to access consolidated information that exists in regards to interventions for children with cerebral palsy who have difficulties with saliva management.
  - To date this CAT has been presented internally at a CAT Day for The Spastic Centre's staff. In addition to this a written word summary is available to staff on intranet, and The Spastic Centre has contracted a person to prepare parent friendly summaries of this CAT and other CATs developed by clinicians at The Spastic Centre.
  - In addition, clinicians at The Spastic Centre will further investigate particular interventions and their use, to direct therapists about their clinical implications.
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## Concluding ideas:



As clinicians we are unable to recommend any one approach over another. The importance of this CAT is that it allows us as clinicians to provide information to families that has been critically appraised, so that families can then consider what suits them best as individuals. Families can also use this information to delve deeper into intervention/s that they are interested in and contact specialists in those areas to gather further information.

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