The PROMPT approach: A meta-analysis of effects, efficacy and efficiency

Presenter | Aravind Namasivayam, Ph.D. S-LP (C)

Disclosure Statements

Aravind Namasivayam (Presenter)

Relevant Financial Relationships:

- Clinical Trials Research Grant: (2013-2018) - The PROMPT Institute, Santa Fe, NM.

- Research Associate: Oral Dynamics Lab, University of Toronto, Canada.

- Research Director - Speech Research Centre, Canada. Research consulting services to several clinics and programs:
  - Hanen Centre: Canada
  - KIDSSPEECH: Canada
  - PROMPT Institute: USA
  - Talk Moore Speech Services: USA
  - Maria de la Paz Institute: Argentina
  - Centro CIRCUS: Argentina
  - Pequeños Angeles: México
  - Speech Rehabilitation Institute: Greece
Aravind Namasivayam (Presenter)

Relevant Non-Financial Relationships:

- Adjunct Lecturer – Dept. of Speech-Language Pathology, University of Toronto.
- Adjunct Scientist – Toronto Rehabilitation Institute
- Adjunct Scientist - Toronto Western Hospital and Medicine - Neurology, Toronto Western Hospital, Toronto.
- Serves as reviewer for several peer-reviewed journals.
- Co-Founder Hear2Speak.org (non-profit).
The use of cameras, audio recording devices, and/or video recording devices, including cell phones, is prohibited at the 2019 National Conference on Childhood Apraxia of Speech. Participants found audio or video recording any portion of the Conference will be asked to leave immediately.
LEARNING OUTCOMES
Learning outcomes

By the end of the presentation, the audience will be able to do the following:

(1) Describe outcomes and effect sizes from PROMPT intervention studies.

(2) Identify possible mechanisms underlying therapeutic effects following PROMPT intervention.

(3) Identify how each intervention study fits the hierarchy of evidence quality framework and clinical-outcome testing models.
PURPOSE
Purpose

(1) Report **efficacy of PROMPT intervention** indexed at 2 levels (Robey & Schultz, 1998):
   
   (a) **Therapeutic effect**: Behavioral outcomes.
   
   (b) **Activity**: Potential means by which intervention achieves its intended therapeutic effect/action (i.e., neuroanatomical/neurophysiological Mode of Action).

(2) Report preliminary **meta-analysis** of single subject and group design studies.

(3) To evaluate the quality of PROMPT intervention studies using a **hierarchy of evidence quality framework**.

(4) Place PROMPT intervention studies within the **5-phase clinical-outcome testing model** (Robey & Schultz, 1998; Robey, 2004).
**What is PROMPT**

**Prompts for Restructuring Oral Muscular Phonetic Targets**

PROMPT is a motor-speech treatment approach framed within the principles of *Dynamic Systems Theory* (Kelso, 1995; Van Lieshout, 2004).

Normalized movement patterns are achieved by the use of systematic, coordinated multisensory inputs embedded into contextual (social-emotional/pragmatic) age-appropriate lexicon.

The ultimate goal is to maximize a client’s potential for functional, interactive & verbal communication.
What is PROMPT

Motor speech goals and intervention

Based on the non-uniform but interactive development of control of motor speech subsystems known as the Motor Speech Hierarchy (MSH).

There are seven key subsystems in MSH (Hayden et al. 2010; Green & Nip, 2010).
WHERE DOES PROMPT RESEARCH COME FROM?
BEHAVIORAL OUTCOMES
Behavioral Outcomes: Severe SSD (Square et al. 2014)

Speech Motor Accuracy for S2

Jaw/Lip – Set A

Auditory Accuracy for S2

Lingual – Set B
Behavioral Outcomes: Cerebral Palsy (Ward et al. 2013; 2014)

Speech Motor Accuracy

Perceptual Accuracy
Behavioural outcomes from the recent Randomized Controlled Trial (RCT) 2013-2018

Namasivayam et al. 2018
Behavioral Outcomes: Speech Motor Delay

- **Study Population**: Children with SSD who demonstrate moderate to profound speech articulation errors and difficulty with speech motor precision, stability and control, but do not meet criteria for CAS or DYS.

- SSD with motor speech involvement (SSD-MSI) or according to Shriberg’s classification system referred to as Speech Motor Delay (SMD; formerly MSD-NOS; Shriberg 2017, Shriberg & Wren, 2019).

- **Pathophysiology**: At level of neuromotor execution. Limitation or Delay in the development and maturation of speech motor skills required for precision and stability of speech output.

- Speech errors are not due to involuntary movements, deficits in muscle tone/reflexes or errors in higher level linguistic symbolic /phonological planning.
Behavioral Outcomes: Speech Motor Delay

- **The Need:** This population is resistant to traditional articulation & phonological treatment approaches.

- At greatest risk for persistent SSD. (Hayden et al., 2010; Shriberg et al., 2012; Strand et al., 2006).

- Due to the difficulty in treating this population, identifying clinically effective intervention is crucial to successful intervention.
Study Integrity and Monitoring

- Reporting requirements: CONSORT guidelines.

- Study Pre-Registered (April 2014) with the U.S. National Institutes of Health Clinical Trials Registry (https://clinicaltrials.gov/; Identifier: NCT02105402).

- Approved by the Research Ethics Board at the University of Toronto (Protocol #29142)
Multi-Site RCT

John McGivney
Children’s Centre of Essex County

Data Monitoring & Randomization
(external agency)

Applied Health Research Centre
St. Michael's Hospital, Toronto

Erinoak Kids Centre
for Treatment and Development

The Speech & Stuttering Institute
<table>
<thead>
<tr>
<th><strong>Inclusion Criteria</strong></th>
<th><strong>Exclusion Criteria</strong></th>
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</thead>
<tbody>
<tr>
<td>3 to 10 yrs. mod to severe SSD.</td>
<td>Signs/Symptoms/Diagnosis of:</td>
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<tr>
<td>English spoken at home.</td>
<td>- Global motor involvement (Cerebral Palsy).</td>
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<td>Hearing/vision/non-verbal IQ WNL</td>
<td>- Autism Spectrum Disorders.</td>
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<td>Receptive language skills – WNL; Delays in expressive language</td>
<td>- Oral structural deficits.</td>
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<td>4 red flags for motor speech involvement (e.g., lateral jaw sliding, decreased lip rounding and retraction).</td>
<td>- Feeding impairments.</td>
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<td>- Dysarthric speech / drooling.</td>
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<td>- Prosodic and / or resonance disorders.</td>
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<td>- Childhood Apraxia of Speech</td>
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## Precision-Stability Index (PSI) & Speech Motor Control Profile

<table>
<thead>
<tr>
<th>ID</th>
<th>Stress Errors (&lt; 50)</th>
<th>Glides Correct (&lt; 90.8)</th>
<th>Epenthesis (&gt; 3.5)</th>
<th>HNR (&lt; 15.15 dB)</th>
<th>Syll. Dur (&gt; 370.37 ms)</th>
<th>VMPAC</th>
<th>Inconsistency (DEAP &gt; 40%)</th>
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### Speech Motor Delay

Reference:


Precision-Stability Index (PSI) & Speech Motor Control Profile (% for N = 49)

- Inconsistency (DEAP > 40%): 43.10%
- VMPAC: 73.90%
- Syll. dur (>370.37ms): 89.70%
- HNR (<15.15 dB): 83.60%
- % Epenthesis (> 3.5): 18.10%
- % Glides Correct (<90.8): 59.50%
- % Stress errors (< 50): 42.50%
A priori power and sample size calculations

- Data from 12 children with moderate to profound SSDs aged between 3:11 to 6:7 years (Namasivayam et al., 2013).

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Power Calculations</th>
<th>Required Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSIM (S.D. = 17)</td>
<td>ANCOVA analysis: 80% power</td>
<td>(N = 21) per group to detect difference of 10%</td>
</tr>
<tr>
<td>Functional outcomes (FOCUS: S.D. = 67)</td>
<td>Two-sided alpha of 5% Pre-Post Correlation 0.75</td>
<td>(N = 122) per group. To detect MCID of 16 point change.</td>
</tr>
</tbody>
</table>

- No reported meaningful differences (cut-off scores) to consider for power analysis for other variables (speech motor control, articulation).

\(~N = 22\) per group was chosen.
Waitlist (Home Strategies)

- Speech, Language and Literacy Strategies for Parents
  (4 page parent hand out; Justice et al 2009; Erinoak Kids Centre, Toronto)
  - Follow Your Child’s Lead/Play Interest and Join In.
  - Use activities that tempt child to communicate.
  - Get Face to Face. Cue your child to look at your mouth.
  - Turn taking.
  - Use simple language (matching child’s language level).
  - Model clear speech (louder, slower, stretched out, etc).
  - Appropriate reinforcements.
  - Early Literacy Skills (Book/Print organization, letters/Words).
Outcome Measures (Based on WHO ICF-CY framework)

Kearney et al., 2015

**Body structures and functions level:**
- Focal oro-motor control (FOC)
- Oro-motor Sequencing (SEQ)
- Criterion-referenced: probe words
- Single-word level articulation
- Percent consonants correct (PCC)
- Phonological process errors

**Activities and participation level:**
- Word-level Speech Intelligibility (CSIM; Wilcox & Morris, 1999).
- Sentence-level Speech Intelligibility (BIT; Osberger et al., 1994).
- Focus on the Outcomes of Communication Under Six tool (FOCUS; Thomas-Stonell et al., 2013).

Verbal Motor Production Assessment for Children (VMPAC; Hayden & Square, 1999)
Diagnostic Evaluation of Articulation & Phonology test (DEAP; Dodd et al., 2002).
All outcome measures and reliability procedures were assessed by S-LPs blind to group allocation and session (pre or post).

Inter-rater reliability *Kappa* coefficient was 0.73 based on approximately 20% of the data. (*kappa: 0.61-0.80 Good; Altman, 1991*)

Source data and data entry verifications (on-site) monitored by AHRC, St. Michael's Hospital in Toronto.

All outcome measures pre-registered prior to start of study in Clinical Trials Registry (*https://clinicaltrials.gov/; Identifier: NCT02105402*)
Outcome measures analyzed by Analysis of Covariance (ANCOVA) model using intent-to-treat principle, with baseline as covariate.

Effect size (ES) estimates with 95% confidence intervals of treatment on the primary measures.

Effect size calculated from the regression model in the original units of each variable.

All statistical analysis performed by AHRC.
**RCT – Key Design Features**

- Multi-site (3 sites), Double-Blind (Investigator, Outcomes Assessor).
- Two-arm parallel group RCT design.
- The study integrity was monitored by an arms-length, external agency, The Applied Health Research Centre (AHRC) at St. Michael's Hospital in Toronto.
Arms-Length External Monitoring

- **AHRC responsible for Study integrity:**
  - Verifying consent & Group allocation via randomization (sealed envelopes)
  - Conducting on-site data monitoring visits
  - Ensuring participants met study inclusion/exclusion criteria
  - Source data and data entry verifications (on-site)
  - Interim power analysis and all statistical analysis on outcome measures.

- **Reporting requirements:** CONSORT guidelines; Pre-Registered (April 2014) with the U.S. National Institutes of Health Clinical Trials Registry (https://clinicaltrials.gov/; Identifier: NCT02105402). Approved by Research Ethics Board at the University of Toronto (Protocol #29142).
RANDOMIZED CONTROLLED TRIAL (RCT)

**RCT** is the **GOLD STANDARD** to establish causality between independent & dependent variables.

- **AHRC Arms Length** – Data monitoring, study integrity & Random allocation
  
  - N = 49
  - Severe SSD
  - PCC <50%
  - Sentence intelligibility 20%

- **M = 48.08 MONTHS**
  - SD = 12.33

  Blind Baseline assessments (PRE)

- **Immediate TX Group**
  - PROMPT intervention
  - N = 24
  - M = 48.70 MONTHS
  - SD = 11.77

  Blind Post 10 week assessment (POST)

- **Waitlist Group**
  - Waitlisted for 10 weeks
  - N = 25
  - M = 48.08 MONTHS
  - SD = 12.33
Intervention & Fidelity

- **Intervention Type:** PROMPT Intervention.
- **Dose Form:** Structured play
- **Dose (D):** Average 69.75 productions per goal per session.
- **Dose Frequency (DF):** Delivered 2x per week.
- **Session Duration:** ~ 45 minutes
- **Total Intervention Duration (TID):** 10 weeks.
- **Cumulative Intervention Intensity:** 1395 productions per goal (D x DF x TID).
- **Fidelity:** Therapists met treatment fidelity requirement >80% *(Treatment session video recordings & fidelity checklist; Hayden et al. 2015)*
<table>
<thead>
<tr>
<th>Variables</th>
<th>Levels</th>
<th>Significance</th>
<th>ES Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speech Motor control</td>
<td>VMPAC-FOC</td>
<td>$p = 0.016$</td>
<td>TX resulted in 6.27% greater FOC scores than waitlist</td>
</tr>
<tr>
<td></td>
<td>VMPAC-SEQ</td>
<td>Not Sig</td>
<td>Not Targeted in TX</td>
</tr>
<tr>
<td>Speech Artic (DEAP)</td>
<td>Standard Score</td>
<td>$p = 0.002$</td>
<td>TX resulted in 5.15 greater standard scores than waitlist. ~13 fewer raw score errors.</td>
</tr>
<tr>
<td></td>
<td>Percent Consonants Correct (PCC)</td>
<td>$p = 0.000$</td>
<td>TX resulted in 10.85% more consonants correct than waitlist. Change from Severe to Moderate-Severe.</td>
</tr>
<tr>
<td>Phonological Processes (DEAP)</td>
<td>DEAP-Test</td>
<td>Not Sig</td>
<td>Not Targeted in TX</td>
</tr>
<tr>
<td>Speech Intelligibility</td>
<td>Word Level</td>
<td>$p = 0.002$</td>
<td>TX resulted in 8.59% greater word level speech intelligibility scores than waitlist</td>
</tr>
<tr>
<td></td>
<td>Sentence Level</td>
<td>Not Sig</td>
<td>Groups had similar change (~10%)</td>
</tr>
<tr>
<td>Functional Communication</td>
<td>FOCUS</td>
<td>Not Sig</td>
<td>Groups had similar change (~12-14 point)</td>
</tr>
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</table>
Summary & Interpretation

- Effect size (ES) estimates with 95% confidence intervals of treatment on the primary measures

<table>
<thead>
<tr>
<th></th>
<th>Effect size</th>
<th>Lower 95%</th>
<th>Upper 95%</th>
<th>F-statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>VMPAC-FOC</td>
<td>6.270</td>
<td>1.223</td>
<td>11.318</td>
<td>83.105</td>
</tr>
<tr>
<td>VMPAC-SEQ</td>
<td>4.769</td>
<td>-3.050</td>
<td>12.587</td>
<td>89.523</td>
</tr>
<tr>
<td>Speech articulation</td>
<td>5.157</td>
<td>2.061</td>
<td>8.252</td>
<td>106.285</td>
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<tr>
<td>Phonological processes</td>
<td>1.858</td>
<td>-1.807</td>
<td>5.523</td>
<td>51.527</td>
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<tr>
<td>Word-level speech intelligibility</td>
<td>8.595</td>
<td>3.283</td>
<td>13.907</td>
<td>106.022</td>
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<tr>
<td>Sentence-level speech intelligibility</td>
<td>-1.632</td>
<td>-11.059</td>
<td>7.796</td>
<td>48.057</td>
</tr>
<tr>
<td>Percentage consonants correct</td>
<td>10.855</td>
<td>6.166</td>
<td>15.545</td>
<td>187.234</td>
</tr>
<tr>
<td>Functional communication</td>
<td>2.042</td>
<td>-14.971</td>
<td>19.056</td>
<td>116.151</td>
</tr>
</tbody>
</table>
Interpretation & Conclusion

- For Children ~4yrs old with severe SSD (PCC < 50%; intelligibility ~ 20%) with motor speech issues - 10 weeks of PROMPT intervention (2x week; 20 sessions; CII = 1395 productions per goal) we can expect the following (significantly more than home training + maturation effects combined):

  - **Significant change in:**
    - Oro-Motor Control Skills, Articulation, Speech Severity (PCC) and Word-Level Speech Intelligibility.

  - **10 weeks of therapy may be inadequate for:**
    - Changes in Sentence level intelligibility (BIT) and functional communication (FOCUS)

  - **Non-target variables in therapy Do Not Change:**
    - Oro-Motor Sequencing and phonological processes.

  - **Limitations:**
    - Statistical power / sample size issue for functional communication.
NEUROPHYSIOLOGICAL MECHANISMS

TMS Coil
Stimuli presented
EMG elect
EMG Gnd

We would like to thank Rami R. Garg, Research Coordinator, Dept of Neurology, Toronto Western Research Institute, for help in data collection.


Experiment in Progress
Sundara, Namasivayam & Chen 2001; Neuroreport
Neurophysiological mechanisms

- **Neuroscience of PROMPT Therapy**: Understanding *how and why* PROMPT intervention works.
  - **Kinematics**: Movement changes underlying PROMPT intervention.
  - **Coordination**: improved between phonatory & articulatory sub-systems.
  - **Key or active ingredient**: Tactile input underlying therapeutic effects / therapeutic action of PROMPT.
  - **Mode of Action**: Identification of potential neural target(s).
**Speech Movement (kinematic) changes in Children with Cerebral Palsy**

Ward et al., 2013, 2014

Single-subject multiple baseline across participants, 4 Phases (A, B, C & D).

A = baseline; B = first intervention priority; C = second intervention priority - one level higher on Motor Speech Hierarchy.
Kinematics (speech movements):

Systematic changes in mandibular and labiofacial sub-systems result in improved speech intelligibility.

Speech Movement (kinematic) changes in Children with Cerebral Palsy
Ward et al., 2013, 2014
How do changes in speech movements (kinematics) result in improved intelligibility?

What is the relationship between speech motor control & speech intelligibility.
What drives speech intelligibility?

- Oro-motor control & sequencing significantly correlated with intelligibility in SSD-MSD.
- 40-50% variance in intelligibility accounted for by VMPAC-FOC.
- 50-70% variance in Intelligibility accounted for by VMPAC-SEQ.
- Single-word articulation testing is a poor indicator of intelligibility.
- PROMPT possibly works because it targets underlying motor system.

** Correlation significant at 0.01 and * at 0.05. Namasivayam et al., (2013)

CSIM = Word-level speech intelligibility; BIT = Sentence-level speech intelligibility
Kinematics

What drives speech intelligibility?

• Participants: mod-to-severe articulation & phonological issues.

• Service Delivery: 8 weeks, 2x week 45 min, individual sessions –PROMPT treatment.

• Greater the speech motor control difficulty the lesser the progress/gains in connected speech intelligibility following treatment.

![Graph showing mean pre-post increase in sentence-level speech intelligibility for three groups: Group A = Artic + Phonology, Group B = Artic + Phonology + FOC, and Group C = Artic + Phonology + FOC + SEQ.](image)

Data from Namasivayam et al., (2013).
Voice onset time (VOT): Time between lip release for /p/ (articulation) and start of phonation for vowel /a/ e.g. in /pa/ production.

- VOT less 0 to 30 msec you hear /ba/
- VOT 30-100 msec you hear /pa/

VOT represents coordination between laryngeal and articulation speech sub-systems.
Speech Sub-System Coordination

PROMPT treatment improves coordination between phonation & articulation

Yu et al., (2014)

- VOT variability (CoV): significantly higher in MSD-PRE group compared to control group (p=.013) or MSD-Post treatment (p=.006)

- MSD-Post & Controls (p=.47) not significantly different.

Figure 1. Distribution patterns for VOT while producing /p/ for the control group, and children with MSD. Pre- and POST-therapy.
Most of the children with MSD in the study had jaw control issues. Stabilizing the jaw provides stable & reliable proprioceptive information from the masseter muscle to improve coordination between phonation and articulation!
**Active Ingredient**

**Treating speech subsystems in CAS with tactual input: the PROMPT approach.**

*Dale & Hayden, 2013*

**Population:** CAS (N = 4; 3;6 to 6 yrs), effectiveness Full PROMPT and PROMPT without tactile input.

**Design:** 2 children ABB and 2 children ACB design.

A = baseline; B = full PROMPT; C = Prompt Without TKP input. Each phase = duration 8 sessions (4 weeks).

**Research question:** What is the effectiveness of the initiation of Full PROMPT in the second four weeks in the children that started without tactile input?

**Results:**

a) Improved oro-motor control, sequencing & speech intelligibility

b) Improved quality of speech movements in untrained words (generalization)

*Dale & Hayden, 2013*
Active Ingredient

Treating speech subsystems in CAS with tactual input: the PROMPT approach.

Active Ingredient

Oro-Facial Tactile Cues Affect Phoneme Recognition & Retrieval

Namasivayam, Law, Yan, Hyunh, Bali, Hayden & Van Lieshout, 2016

Experiment:

Therapist delivered TKP inputs improve speech production accuracy.

Are the effects of TKP inputs simply arising from increasing orofacial awareness OR are they also being processed and utilized by the higher-order cognitive-linguistic system?

Can they facilitate phoneme perception & word retrieval?
Oro-Facial Tactile Cues Affect Phoneme Recognition & Retrieval

Namasivayam, Law, Yan, Hyunh, Bali, Hayden & Van Lieshout, 2016

Word frequency manipulation:
Low frequency words take longer to be recognized & harder to retrieve from memory. Low frequency words require greater cognitive effort.

TKP Congruency:
**Congruent:** Lip rounding target with lip rounding prompt.

**Incongruent:** Lip rounding target with tongue tip elevation prompt.

Hypothesis:
Processing of low frequency words will benefit to a greater extent with TKP input relative to high frequency words.
Incorrect placement of TKP input significantly increases speech reaction time and decreases phoneme recognition only for low frequency words. Incorrect TKP input is detrimental to the cognitive-linguistic system.
How Therapy Changes the Brain
Mode of Action (MoA)

- **Mode of Action (MoA):** A functional or structural (anatomical) change, at the cellular level, resulting from the exposure of a living organism to a substance/intervention.

- **Mechanism of Action (MOA):** Changes at the molecular level. Specific biochemical interactions through which a drug substance produces its pharmacological effect. MOA mentions specific molecular targets to which the drug binds, such as an enzyme or receptor.

https://en.wikipedia.org/wiki/Mode_of_action
The Neuroscience of PROMPT Therapy

3 levels of Brain changes identified:

1. Brain structure: MRI data
   Kadis et al., 2014

2. Neuronal connectivity: MRI-DWI
   Chilosi et al., 2018; Fiori et al., 2018

3. Neuronal firing patterns: MEG
   Yu et al., 2018
Cortical changes following PROMPT in CAS
Kadis et al., 2014

Thinning of Wernicke’s area post PROMPT therapy?

• Wernicke’s area: Role in the formation “speech sound representation”.

• Lt. PSTG: speech perception and speech production.

• TKP inputs may facilitate the formation of more accurate speech sound representation.

• Which in turn allows the development of accurate & stable motor programs that can be retrieved and sequenced efficiently.

Left Post Superior Temporal Gyrus (Wernicke’s area):

Significant (p< 0.05) thinning Post PROMPT intervention
Mode of Action (MoA): Connectivity

**Tractography following PROMPT in CAS**

Chilosi et al., 2018; Fiori et al., 2018  
Fondazione Stella Maris, Calambrone, Pisa, Italy

10 CAS children - 30 therapy sessions (2x/week; approx 7 months):

(a) 5 CAS children (6;8 years) received language and non-speech oromotor intervention and

(b) 4 CAS children (5;7 years) received PROMPT.

Structural MRI using High Angular Resolution Diffusion Imaging (HARDI)
Diffusion weighted MRI (HARDI) can detect neuroplastic effects of intervention.

PROMPT treatment demonstrated neural connectivity changes in the (descending) dorsal cortico-bulbar tract. Corticobulbar system controls the muscles of the face, head and neck.
Magnetencephalography (MEG) in children with SSD receiving PROMPT
Yu et al., 2018

- 9 Children with SSD (4;2 years)
- Intervention: 2x/week x 8 weeks

- Significant post-therapy neural activity changes in brain regions related to oromotor control and speech production.
  - E.g. increased activity in inferior frontal gyrus (BA 44/45), motor cortex (precentral gyrus, BA 6) and insula (BA 13)
Neurophysiological mechanisms: Summary

Neuroscience of PROMPT Therapy: How & Why

- **Kinematics:** Systematic changes in mandibular and labiofacial sub-systems result in improved speech intelligibility.

- **Coordination:** PROMPT treatment may provide stable & reliable proprioceptive information from the masseter muscle which improves coordination between phonatory & articulatory sub-systems.

- **Key or active ingredient:** Tactile input underlying therapeutic action of PROMPT.

- **Mode of Action:** Identification of potential neural target(s). E.g. thinning of Wernicke’s area and neuroplastic changes in the dorsal cortico-bulbar tract.
META-ANALYSIS
What is Meta-analysis?

Defined as "the statistical synthesis of the data from separate but comparable studies, leading to a quantitative summary of the pooled results" (Chalmers, Hedges, & Cooper, 2002, p. 17).

Image source: https://www.cochrane.org
Meta-analysis

Example

### Key Information:
- Strength (effect size; ES)
- Direction (+/-)
- Consistency (cluster)
- Precision (confidence interval; CI)

### Forest plot – Big picture from individual studies!

### Common questions:
- Average effect of treatment?
- Where, with whom is treatment effective?
Meta-analysis: SSED

- **Data set:** Nine single-subject experimental research designs (SSED; LOE range II-A to II-B).

- Effect sizes derived from standard mean difference (SMD) measures (variation of Cohen’s $d$; Beeson & Robey, 2006; Busk & Serlin, 1992).

- Cohen’s $d = (\text{Mean intervention} - \text{Mean baseline})/\text{S.D. baseline}$ Pooled across participants.

- Effect sizes for SSED in PROMPT research are interpreted as follows: the first, second, and third quartiles for the $d$ statistic were computed to represent small (2.7 to 4.0), medium (4.1 to 6.6) and large effect sizes (>6.7; Beeson & Robey, 2006; Cohen, 1988).
Meta-Analysis: SSED

Single Subject Experimental Designs

Forest plot – Big picture from individual studies!
Meta-analysis: SSED Summary

- **Summary**: Positive medium effect sizes mean = 4.68 (SD = 1.77).


- Positive benefits for: children with severe to profound SSDs, Cerebral Palsy, Autism, CAS, persistent articulations issues resistant to treatment.

- Both group and individual treatment service delivery models were effective, when intervention duration ranged from 8 to 40 sessions.

Data set: Five peer-reviewed group studies including the recently completed randomized controlled trial (RCT) registered with the U.S. National Institutes of Health (NIH ClinicalTrials.gov Identifier: NCT02105402; Namasivayam et al., 2018).

WHO ICF-CY (WHO, 2007) levels of measurement: Speech motor control (Focal oro-motor control (FOC) subsection of VMPAC test), speech articulation scores (DEAP or GFTA data) and word-level speech intelligibility.


Levels of Evidence: I-B to II-B
### Meta-Analysis: Oro-Motor Control

<table>
<thead>
<tr>
<th>Study name</th>
<th>Std diff in means</th>
<th>Statistics for each study</th>
<th>Std diff in means and 95% CI</th>
<th>Relative weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Namasivayam et al., 2018</td>
<td>0.695</td>
<td>0.096 0.505 0.884</td>
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<tr>
<td>Fiori et al., 2018</td>
<td>1.018</td>
<td>0.397 0.239 1.797</td>
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<td>8.24</td>
</tr>
<tr>
<td>Yu et al., 2014</td>
<td>1.411</td>
<td>0.231 0.959 1.863</td>
<td></td>
<td>16.33</td>
</tr>
<tr>
<td>Kadis et al., 2014</td>
<td>1.061</td>
<td>0.153 0.761 1.361</td>
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<td>22.65</td>
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<tr>
<td>Namasivayam et al., 2013</td>
<td>0.653</td>
<td>0.127 0.404 0.903</td>
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<td>25.02</td>
</tr>
<tr>
<td></td>
<td>0.911</td>
<td>0.132 0.652 1.169</td>
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-2.00 -1.00 0.00 1.00 2.00

- Treatment Not Beneficial
- Treatment Beneficial

- **Relative weight**
- **Total**
<table>
<thead>
<tr>
<th>Study name</th>
<th>Std diff in means</th>
<th>Standard error</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Z-Value</th>
<th>p-Value</th>
<th>Total</th>
<th>Relative weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Namasivayam et al., 2018</td>
<td>1.168</td>
<td>0.298</td>
<td>0.585</td>
<td>1.751</td>
<td>3.925</td>
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<tr>
<td>Fiori et al., 2018</td>
<td>1.632</td>
<td>0.683</td>
<td>0.294</td>
<td>2.971</td>
<td>2.390</td>
<td>0.017</td>
<td>5</td>
<td>6.06</td>
</tr>
<tr>
<td>Yu et al., 2014</td>
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<td>0.455</td>
<td>-0.193</td>
<td>1.592</td>
<td>1.536</td>
<td>0.125</td>
<td>6</td>
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<td>Kadis et al., 2014</td>
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<td>0.337</td>
<td>1.741</td>
<td>2.901</td>
<td>0.004</td>
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<tr>
<td>Namasivayam et al., 2013</td>
<td>0.756</td>
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<td>0.115</td>
<td>1.398</td>
<td>2.310</td>
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<table>
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<tr>
<th></th>
<th>Std diff in means</th>
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<th>Lower limit</th>
<th>Upper limit</th>
<th>Z-Value</th>
<th>p-Value</th>
<th>Total</th>
<th>Relative weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.995</td>
<td>0.168</td>
<td>0.666</td>
<td>1.325</td>
<td>5.921</td>
<td>0.000</td>
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</tbody>
</table>

-2.00  -1.00  0.00  1.00  2.00

Treatment Not Beneficial  Treatment Beneficial
### Meta-Analysis: Speech Intelligibility

<table>
<thead>
<tr>
<th>Study name</th>
<th>Std diff in means</th>
<th>Standard error</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Z-Value</th>
<th>p-Value</th>
<th>Total</th>
<th>Relative weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Namasivayam et al., 2018</td>
<td>0.599</td>
<td>0.121</td>
<td>0.361</td>
<td>0.837</td>
<td>4.933</td>
<td>0.000</td>
<td>24</td>
<td>43.85</td>
</tr>
<tr>
<td>Fiori et al., 2018</td>
<td>0.734</td>
<td>0.175</td>
<td>0.392</td>
<td>1.076</td>
<td>4.204</td>
<td>0.000</td>
<td>5</td>
<td>23.92</td>
</tr>
<tr>
<td>Namasivayam et al., 2013</td>
<td>0.393</td>
<td>0.147</td>
<td>0.105</td>
<td>0.681</td>
<td>2.677</td>
<td>0.007</td>
<td>12</td>
<td>32.23</td>
</tr>
<tr>
<td></td>
<td><strong>0.565</strong></td>
<td><strong>0.091</strong></td>
<td><strong>0.387</strong></td>
<td><strong>0.743</strong></td>
<td><strong>6.209</strong></td>
<td>0.000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

-2.00 -1.00 0.00 1.00 2.00

- Treatment Not Beneficial
- Treatment Beneficial
Meta-analysis: Group Studies Summary

Summary:

- Oro-motor control (VMPAC-FOC) and speech articulation: Significant and positive effect of intervention \((p < 0.001)\). Large mean SMD effect size >0.9

- Speech intelligibility: Significant and positive effect of intervention \((p < 0.001)\). Medium mean SMD effect size = 0.56

- Overall, meta-analysis suggests that the PROMPT intervention yields significant changes with robust effect sizes at the impairment, activities, and participation levels of the WHO ICF-CY (WHO, 2007).

- Effect sizes have to be interpreted with caution: (a) data were derived from studies that were not appraised for bias and (b) conducted on different populations.
HIERARCHY OF EVIDENCE QUALITY
Hierarchy of Evidence Quality

Source: http://www.dartmouth.edu/~biomed/resources.html# guides/ebm_resources.shtml
<table>
<thead>
<tr>
<th>Levels of Evidence</th>
<th>Evidence Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well-designed meta-analysis of &gt; 1 RCT</td>
<td>Ia</td>
</tr>
<tr>
<td>Well-designed RCT</td>
<td>Ib</td>
</tr>
<tr>
<td>Well-designed controlled study without randomisation</td>
<td>IIa</td>
</tr>
<tr>
<td>Well-designed quasi experimental study</td>
<td>IIb</td>
</tr>
<tr>
<td>Well-designed nonexperimental studies (including correlation and case Studies)</td>
<td>III</td>
</tr>
<tr>
<td>Expert committee report, consensus conference and clinical experience of respected authorities</td>
<td>IV</td>
</tr>
</tbody>
</table>

PROMPT intervention is a clinically effective treatment approach for children with severe SSD. Emerging evidence for adult Apraxia/Aphasia.

Hierarchy of Evidence Quality

Meta-analysis
Hayden et al. 2020

Multi-Centre RCT
Namasivayam et al. 2018

Yu et al. 2018-SSD
Fiori et al. 2018 - CAS
Yu et al., 2014 - SSD
Namasivayam et al. 2013-SSD
Kadis et al. 2014-CAS

Square et al., 2014- SSD
Dale & Hayden 2013- CAS
Ward et al., 2013 a,b - CP
Grigos et al., 2010- SSD
Rogers et al., 2006 - Autism
Bose et al. 2001- Adult apraxia
Freed et al. 1997- Adult apraxia
CLINICAL OUTCOME RESEARCH
Research studies are great but...

How do these studies fit the accepted standards for clinical-outcome testing used throughout the broader research community? (e.g., by other disciplines, federal regulators, and third-party payers).

Clinical Outcome Research

5-Phase Outcome Research Model
(Robey & Schultz, 1998; Robey, 2004)

- Phase 1: Potentially effective strategy selected
- Phase 2: Case studies vs. Small experimental studies
- Phase 3: Potentially confounding variables accounted for and excluded vs. Larger experimental studies
- Phase 4: Intervention tested under a range of conditions
- Phase 5: Effectiveness studies to ascertain cost effectiveness, long term benefits etc.

Clinical Outcome Research

Phase 1: Explore

- To develop hypothesis
- Feasibility: Is this promising?
- Establish safety
- Demonstrate treatment is active
- Refine methods/measures
- Small sample size, single-subject, single-group (external controls not required!)
Phase 2: Refine

- Only if Phase I is promising
- Refine hypothesis
- Establish patient selection criteria.
- Process standardization: standardize treatment protocol, fidelity, reliability and clinician training.
- Refine & establish outcome measures
- Small sample size, single-subject, single-group (external controls not required)
Clinical Outcome Research

**Phase 2: Refine**

Process standardization: fidelity, reliability, clinician training & outcome measures.

- The Assessment of fidelity in a motor speech treatment approach.
  Hayden, Namasivayam & Ward 2015

- Outcome measures in Developmental Speech Sound Disorders with a motor Basis
  Kearney et al., 2015

- Measuring & Training S-LPs Orofacial cueing: A Pilot Demonstration
  Namasivayam et al., 2018
Phase 2: Refine

PROMPT Fidelity Measure (PFM)
(Hayden, Namasivayam & Ward, 2015)

**Fidelity:** A set of procedures used to monitor & improve the validity and reliability of behavioral intervention.

Important for training of service providers and treatment delivery esp. when ‘active ingredients’ must be present in order for treatment to be effective.

**PFM integrates clinical skill & treatment delivery as a single quantifiable metric.** Pass = 100 of 144 points (~70%)

**Competence:**
- Standardized clinician training.
- Assessing clinician skill post training.

**Adherence:**
- Adherence to intervention protocol
- Receipt of treatment
EXPLORING QUANTIFIABLE MEASURES FOR THE EVALUATION OF SLP INTERVENTION FIDELITY

Phase 2: Refine
Assessment of a clinician’s perceptual sensitivity to detect lateral jaw deviations

46 S-LPs with 2 different levels of clinical experience with MSD:

Novice = median 4 yrs
Expert = median 14 yrs
Controls = 7 non-S-LPs.
**Stimuli:** Linearly spaced continuum of 11 images (7-yr old child). Frame 1 = no lateral jaw deviation (0 radians), frame 11 = max jaw deviation (0.26 radians).

**Task:** Standard alternative forced choice identification procedure and ABX discrimination task using the 11 image stimuli set presented in random order.
<table>
<thead>
<tr>
<th>Frame</th>
<th>Image 1</th>
<th>Image 2</th>
<th>Image 3</th>
<th>Image 4</th>
<th>Image 5</th>
<th>Image 6</th>
<th>Image 7</th>
<th>Image 8</th>
<th>Image 9</th>
<th>Image 10</th>
<th>Image 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theta (radians)</td>
<td>0.01</td>
<td>0.03</td>
<td>0.06</td>
<td>0.08</td>
<td>0.11</td>
<td>0.14</td>
<td>0.17</td>
<td>0.19</td>
<td>0.21</td>
<td>0.24</td>
<td>0.26</td>
</tr>
<tr>
<td>Displacement (mm)</td>
<td>1</td>
<td>2.9</td>
<td>5.2</td>
<td>7.5</td>
<td>9.8</td>
<td>12.4</td>
<td>14.7</td>
<td>17.0</td>
<td>18.6</td>
<td>21.1</td>
<td>23</td>
</tr>
</tbody>
</table>

**AB-X perceptual discrimination task**

**Alternative forced choice categorization (Identification) Task**
Results: Categorical perception mechanism for detection of typical Vs. Atypical. Experienced S-LPs relative to the novice group (experienced = 66% and novice = 35%; Z = 2.051 p < 0.05) were more sensitive than Controls (mean = 3.9) in the identification of jaw slide.

Experienced clinicians: Greater sensitivity in detecting lateral jaw deviations.
Measuring & Training S-LP’s Oro-Facial Cueing: A Pilot Demonstration
(Consistency in the delivery of TKP inputs)
Kinematic consistency of upper lip movements (cyclic Spatial-Temporal Index (cSTI))

Consistency in shape of thumb finger movement trajectories (Generalized Orthogonal Procrustes Analysis).
Phase 3: Efficacy

- Tested under ideal conditions (i.e. ideal patients, ideal clinician, settings etc)
- Large sample/scale RCT studies (ext. control is required)
- Large sample with low incidence/rare disorders or stringent patient criteria = Multi-Centre RCT
- Efficacy = should be indexed at 2 levels (Therapeutic effects + Activity)
Aim: to determine that observed outcomes are the direct result of treatment (i.e. to establish causality between independent and dependent variables)

方法：require experimental control of extraneous variables that might affect outcomes

- Emphasize internal over external validity
- May not generalize to real-world conditions and clients
Phase 4: Effectiveness

- Test effectiveness after efficacy is established.
- Test under average conditions (e.g. typical patients, typical settings, etc)
- Test variations in dosage/intensity & clinician training levels.
- Superiority trials (treatment A vs B); Meta-analysis.
- Large samples req’d/external control not required (efficacy already established)
- Multiple single subject designs, single group designs
Phase 5: Efficiency

- Examination of patient and family satisfaction, quality of life
- Large samples required /external control not required (efficacy already established)
- Multiple single subject designs, single group designs
Clinical Outcome Research

**5-Phase Outcome Research Model**

(Robey & Schultz, 1998; Robey, 2004)

<table>
<thead>
<tr>
<th>Phase 1: Exploration of Effects</th>
<th>Phase 2: Refine</th>
<th>Phase 3: Efficacy</th>
<th>Phase 4: Effectiveness</th>
<th>Phase 5: Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exploration of Effects</td>
<td>Refine</td>
<td>Efficacy</td>
<td>Effectiveness</td>
<td>Efficiency</td>
</tr>
<tr>
<td>Ideal conditions</td>
<td>Average conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Establish causality.</em></td>
<td>- Does NOT establish causality.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Internal validity.</em></td>
<td>- External validity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Limited generalization.</em></td>
<td>- Emphasize generalization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Control group needed!</em></td>
<td>- Control group NOT needed!</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Establish causality.
- Internal validity.
- Limited generalization.
- Control group needed!

- Effectiveness studies to ascertain cost effectiveness, long term benefits etc.

---

Phase 1: Potentially effective strategy selected

- Case studies
- Small experimental studies

Phase 2: Potentially confounding variables accounted for and excluded

- Larger experimental studies

Phase 3: Intervention tested under a range of conditions

- vs.

Phase 4: Effectiveness studies

- vs.

Phase 5: Efficiency

- vs.

94
Clinical Outcome Research

5-Phase Outcome Research Model
(Robey & Schultz, 1998; Robey, 2004)

<table>
<thead>
<tr>
<th>Phase</th>
<th>Exploration of Effects</th>
<th>Refine</th>
<th>Efficacy</th>
<th>Effectiveness</th>
<th>Efficiency</th>
</tr>
</thead>
</table>

Lets do a fun activity!
Clinical Outcome Research

Exploration of Effects

- Case studies
- Potentially effective strategy selected
- Small experimental studies

Refine

- Efficacy
- Larger experimental studies
- Effectiveness
- Intervention tested under a range of conditions

Effectiveness

- RCT; Namasivayam 2018
- Meta-analysis, 2020

Efficiency

- $\text{\$\$\$}$

Fiori et al. 2018; Kadis 2014; Yu et al., 2018: Brain studies

Kearney et al., 2015 (outcomes measures)

Hayden et al. 2015

Treatment Fidelity

Namasivayam et al., 2013; Intelligibility and motor control relationship

RCT; Namasivayam 2018

Ward et al., 2013/14; CP

Square et al., 2014 (SSED)

Hayden et al., 2014 (Probe words Scoring)
CONCLUSION
Conclusions

- PROMPT intervention is a **clinically effective** treatment approach for children with severe SSD (e.g. SMD, CAS, CP). Emerging evidence for adult Apraxia/Aphasia.
- Published **fidelity, reliability, outcome measures & standardized** treatment protocols.
- Identified **active ingredient** (TKP inputs) and potential **Mode of Action** (neural targets) underlying therapeutic action of PROMPT.
- Experimental evidence for PROMPT is recognized as having been **conducted, replicated, and validated** by independent labs and researchers from around the world (McLeod & Baker, 2017, p.510).
- **Active program of research** in place to address current and future issues in **basic science & clinical efficacy** (internal and external research grants avail).
Special Thank You

- Families who participated.
- Staff: To 40+ Research Assistants, Independent contractors (S-LPs) and Volunteers from the University of Toronto and around the world.
- Lab Facilities: Dr. Pascal van Lieshout- Director, Oral Dynamics Lab. University of Toronto
- Collaborators and Partners:
  - John McGivney Children’s Centre of Essex County
  - The Speech & Stuttering Institute
  - Erinoak Kids Centre for Treatment and Development.
- Funding source: Clinical Trials Research Grant (2013-2018): PROMPT Institute, SF, NM.
References


References


References


References


Assessment / Classification References:


