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

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Citation: Namasivayam A. K. (2019, July). *The PROMPT approach: A meta-analysis of effects, efficacy and efficiency.* Apraxia Kids National Conference, Pittsburgh, PA.

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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

Disclosure Statements

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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.
- Editor – Special Edition – Journal of Speech-Language and Hearing research.
- Serves as reviewer for several peer-reviewed journals.
- Co-Founder Hear2Speak.org (non-profit).

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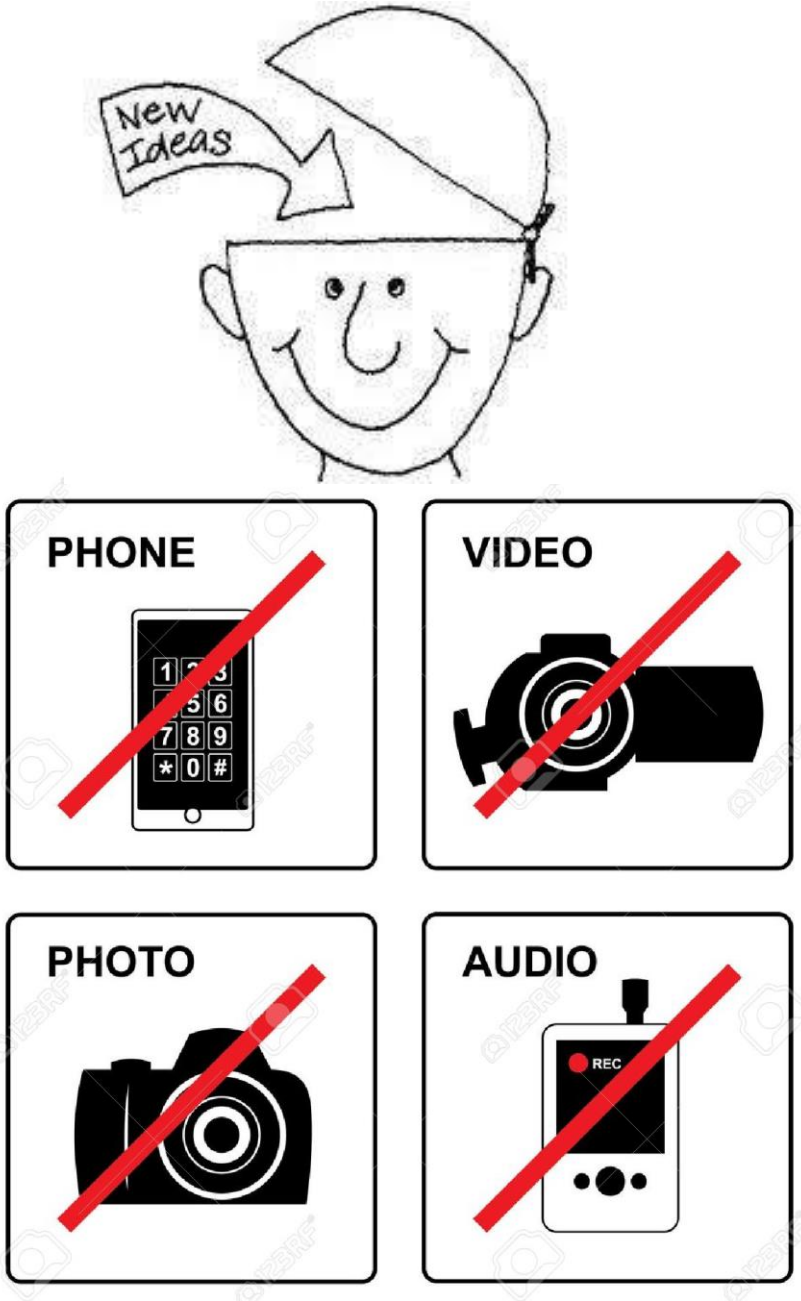


LEARNING OUTCOMES

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

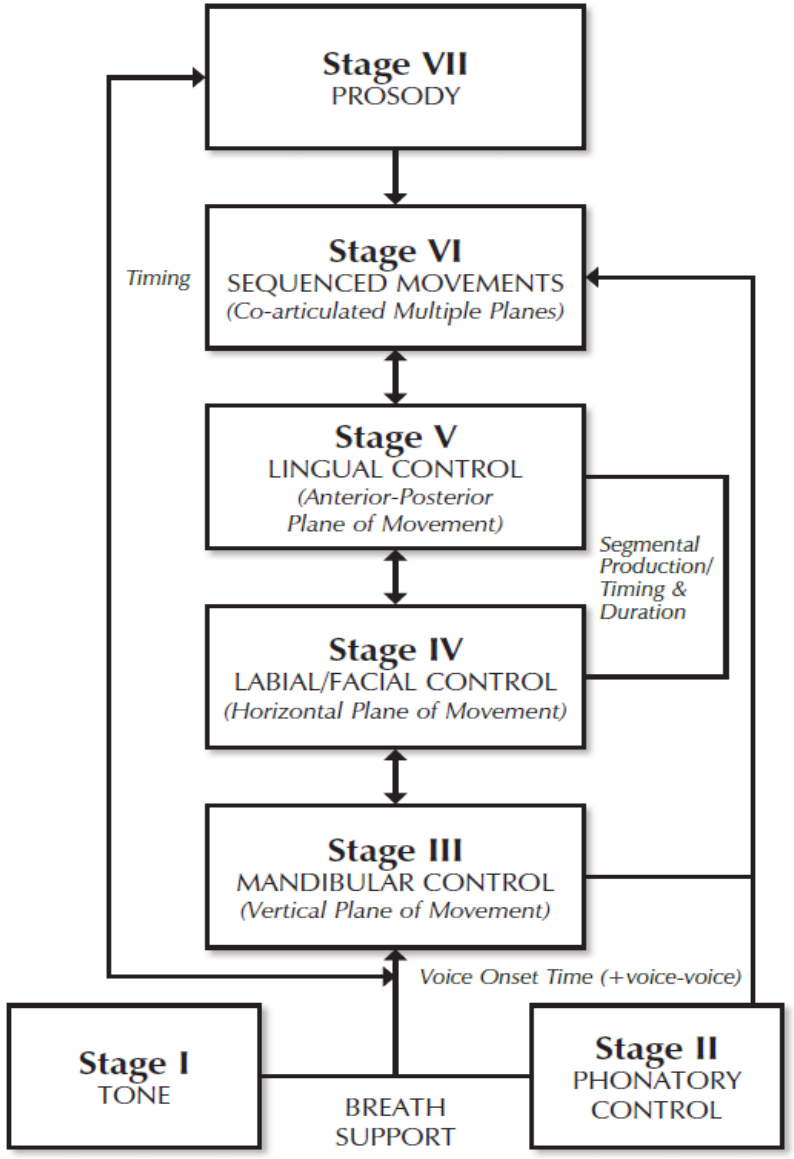
Targets

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 multi-sensory 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

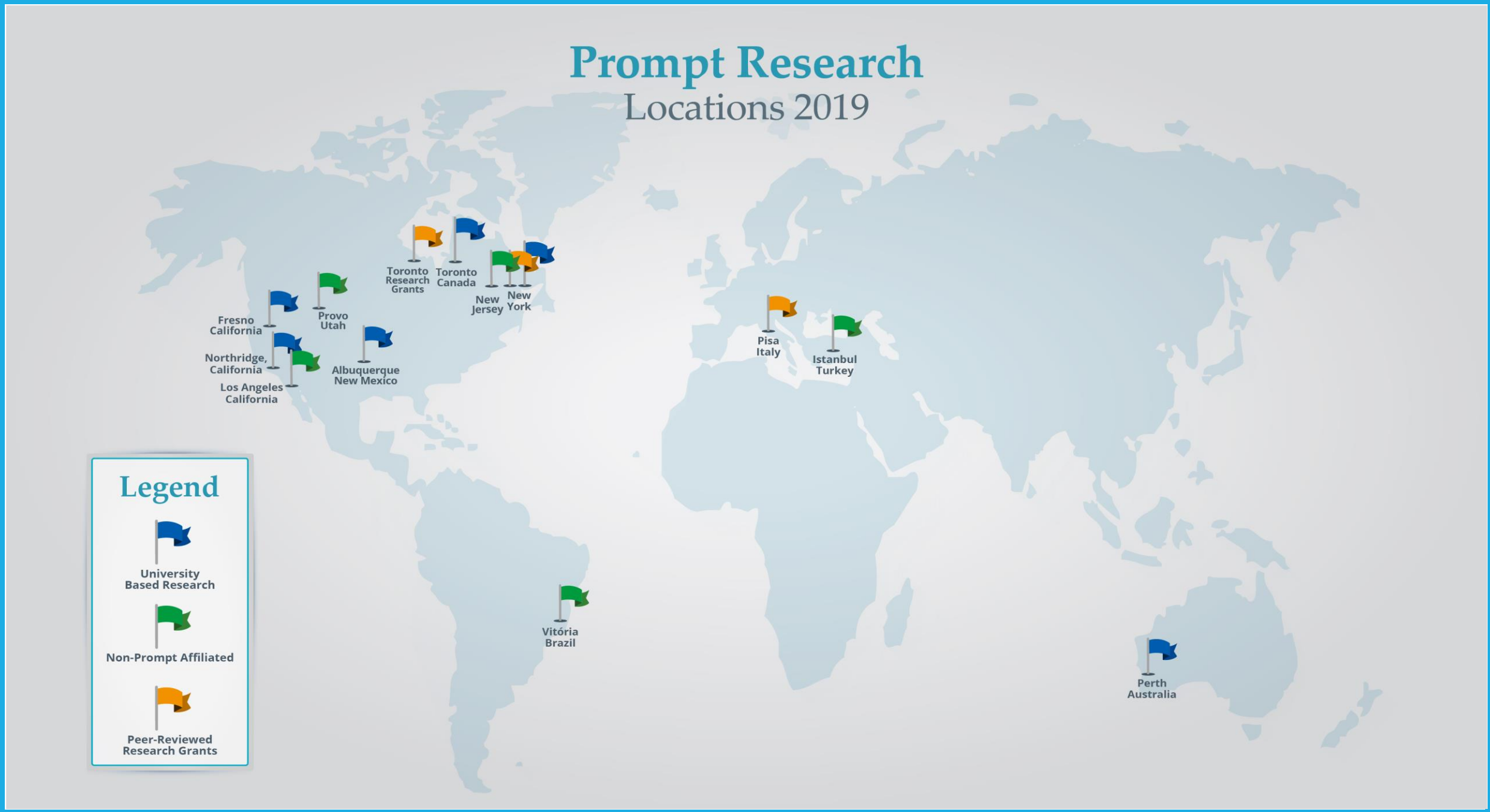
Based on the non-uniform but interactive development of control of motor speech subsystems known as the Motor Speech Hierarchy (MSH).

There are seven key subsystems in MSH (Hayden et al. 2010; Green & Nip, 2010).

PROMPT Research Locations

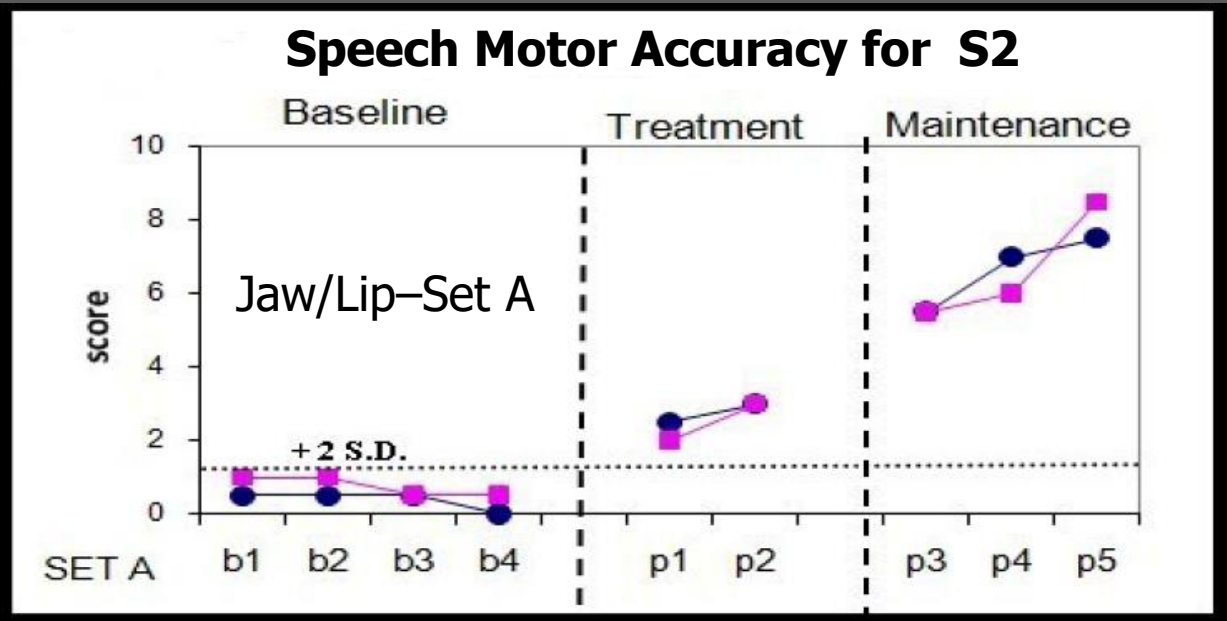
WHERE DOES PROMPT RESEARCH COME FROM?

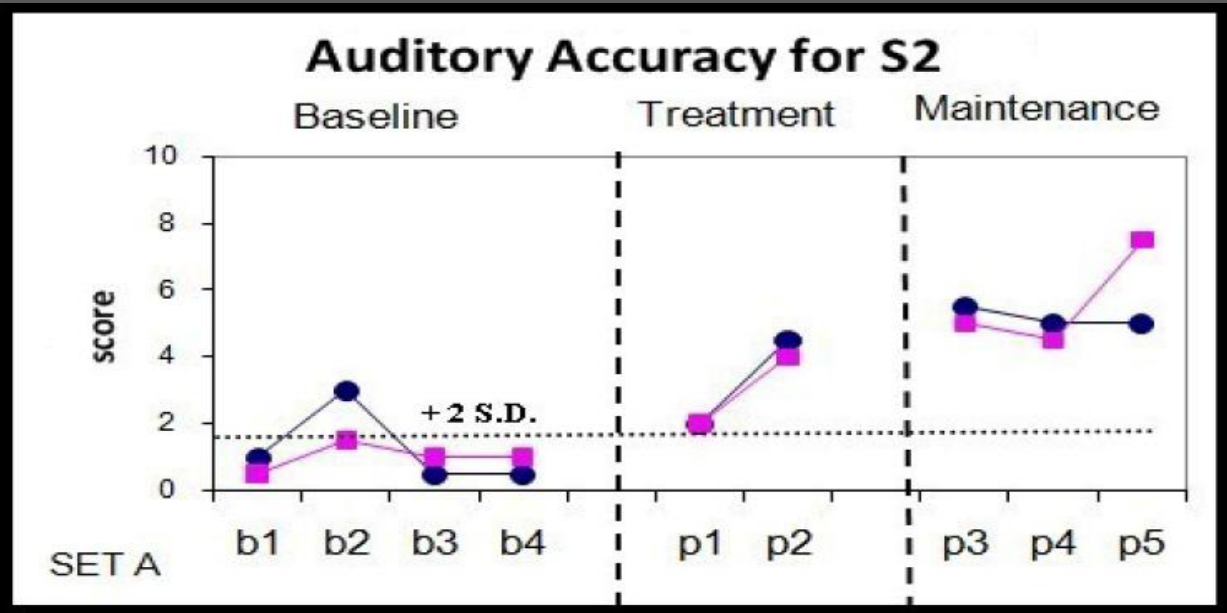
Prompt Research
Locations 2019

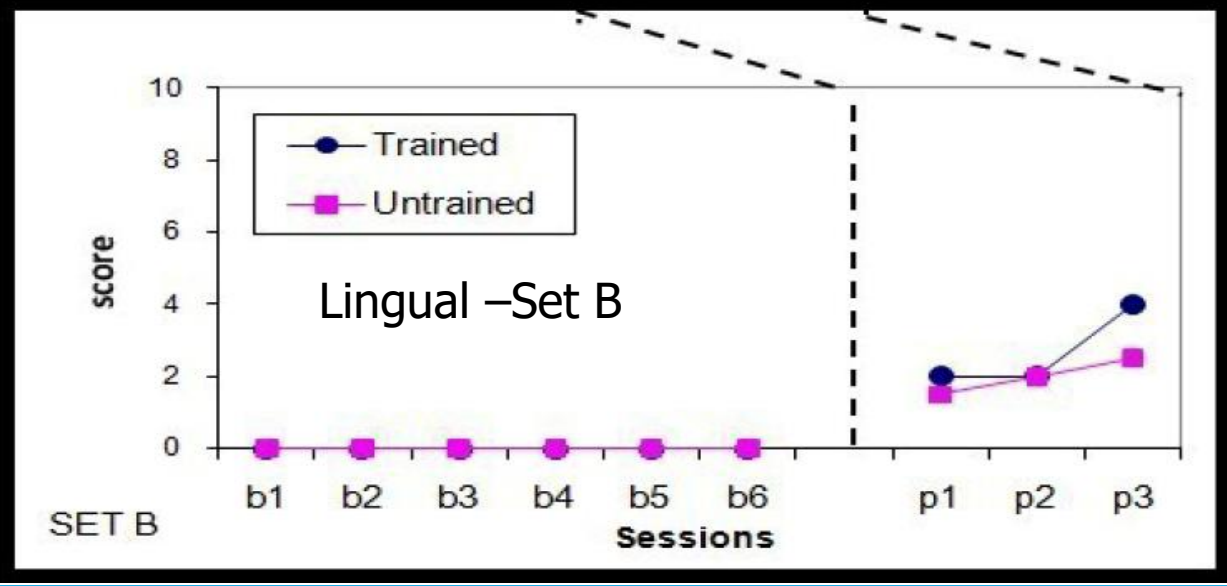


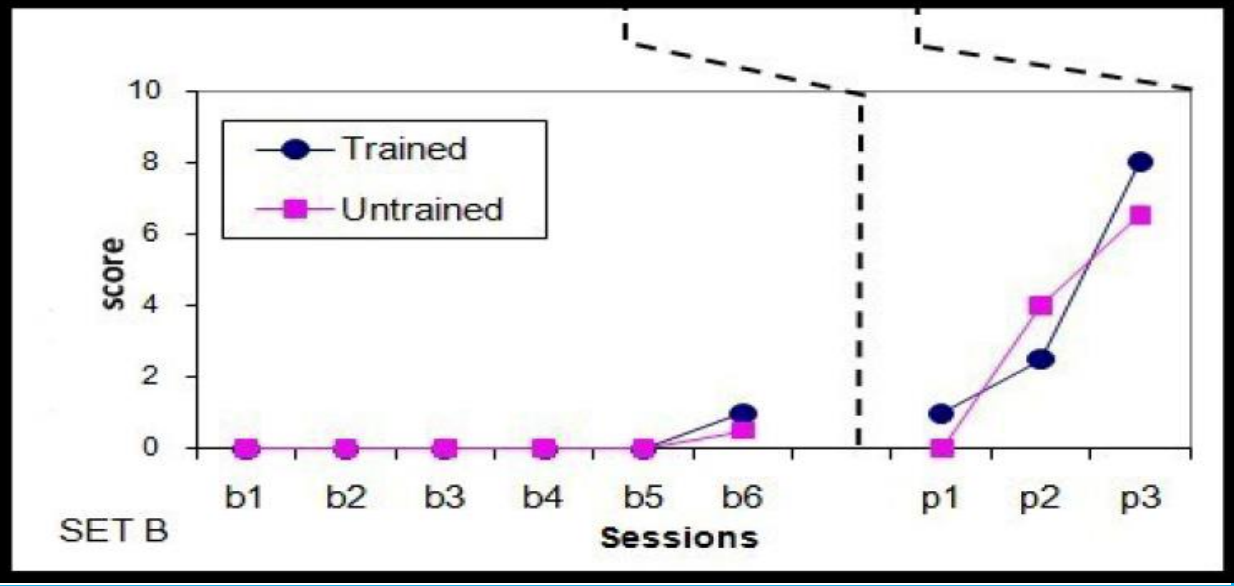
BEHAVIORAL OUTCOMES

Behavioral Outcomes: Severe SSD *(Square et al. 2014)*

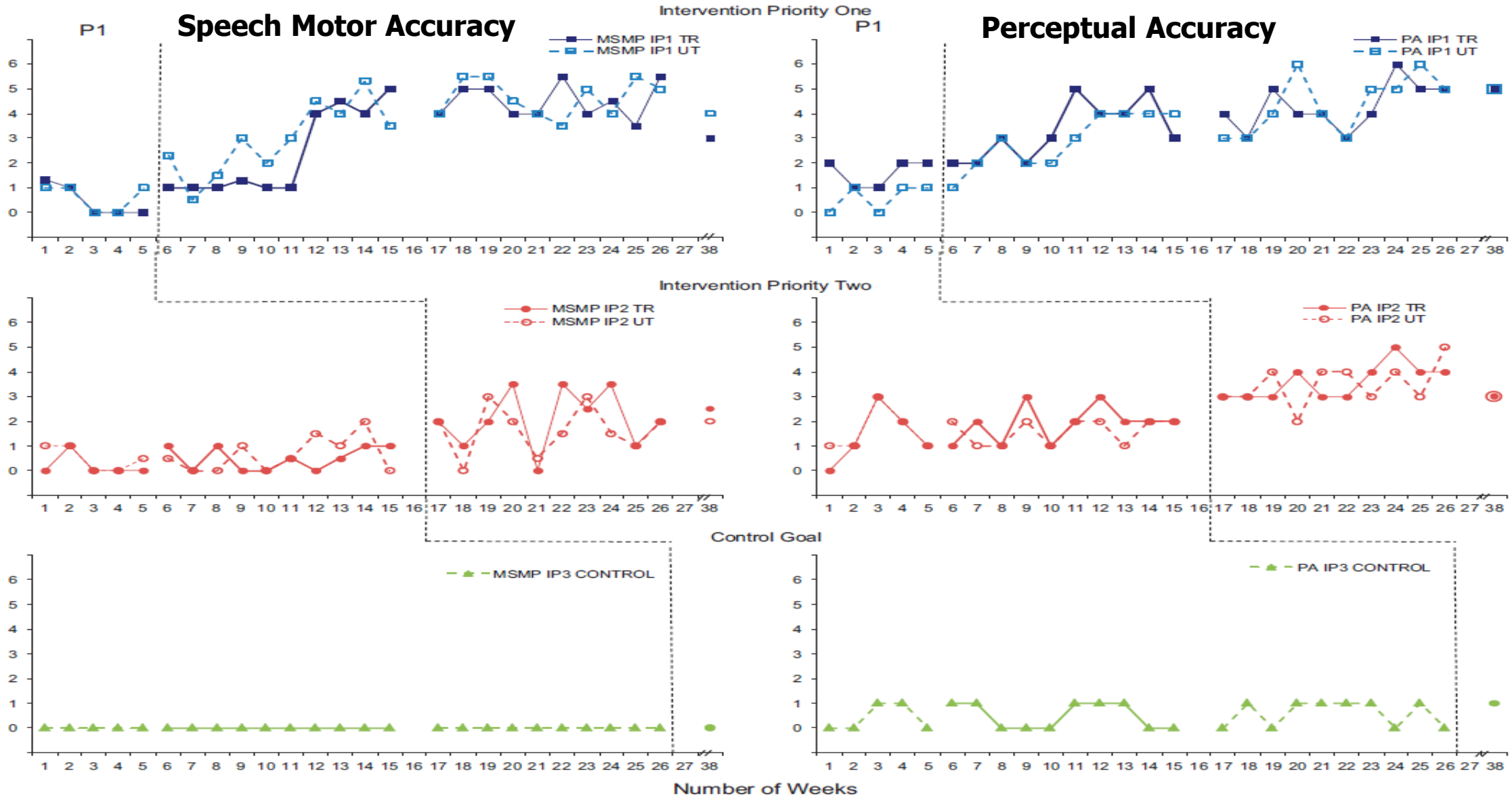








Behavioral Outcomes: Cerebral Palsy *(Ward et al. 2013; 2014)*



Behavioral Outcomes: Speech Motor Delay

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.

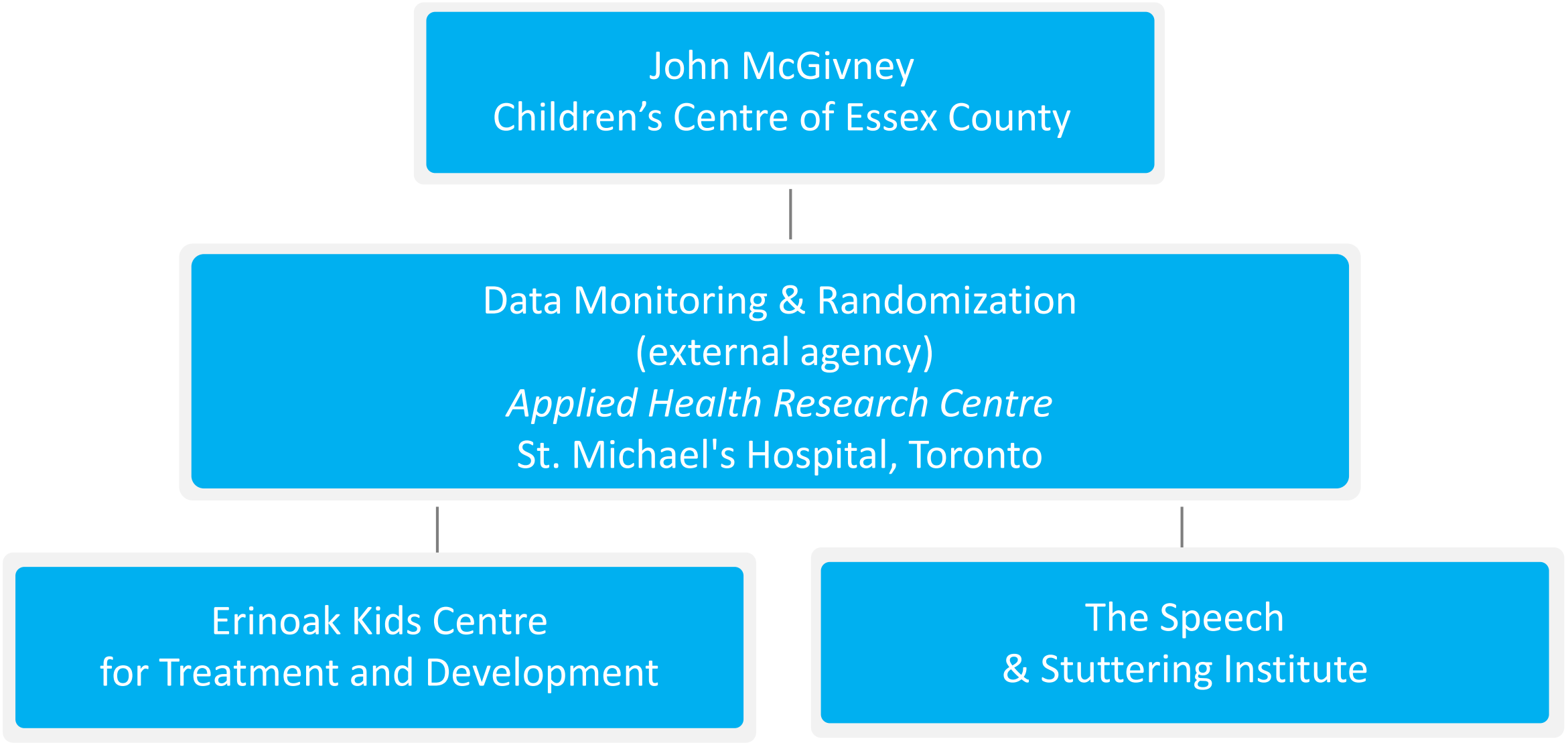
Behavioral Outcomes: Speech Motor Delay

- **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



Participants: Inclusion & Exclusion Criteria

Inclusion Criteria

- 3 to 10 yrs. mod to severe SSD.
- English spoken at home.
- Hearing/vision/non-verbal IQ WNL
- Receptive language skills – WNL; Delays in expressive language
- 4 red flags for motor speech involvement (e.g., lateral jaw sliding, decreased lip rounding and retraction).

Exclusion Criteria

Signs/Symptoms/Diagnosis of:

- Global motor involvement (Cerebral Palsy).
- Autism Spectrum Disorders.
- Oral structural deficits.
- Feeding impairments.
- Dysarthric speech / drooling.
- Prosodic and / or resonance disorders.
- Childhood Apraxia of Speech

Precision-Stability Index (PSI) & Speech Motor Control Profile

ID	% Stress Errors (< 50)	% Glides Correct (<90.8)	% Epenthesis (> 3.5)	HNR (<15.15 dB)	Syll.Dur (>370.37ms)	VMPAC	Inconsistency (DEAP > 40%)
1			X	X	X		
2	X	X		X	X	X	X
3			X	X	X	X	X
4				X	X	X	X
5		X		X	X		
6				X	X		
7				X		X	
8			-	X	-		-
9	X	X	X	X	-	X	X
10	-			X	X	-	X
11	-			X	X	X	X
12	X	X	X	X	X		
13	X	X				X	
14		X		X	-	X	
15	-	-	-	X	-	-	-
16		X		X	X	X	
17	X			X	-	X	
18	X	X	X	X	X	X	X

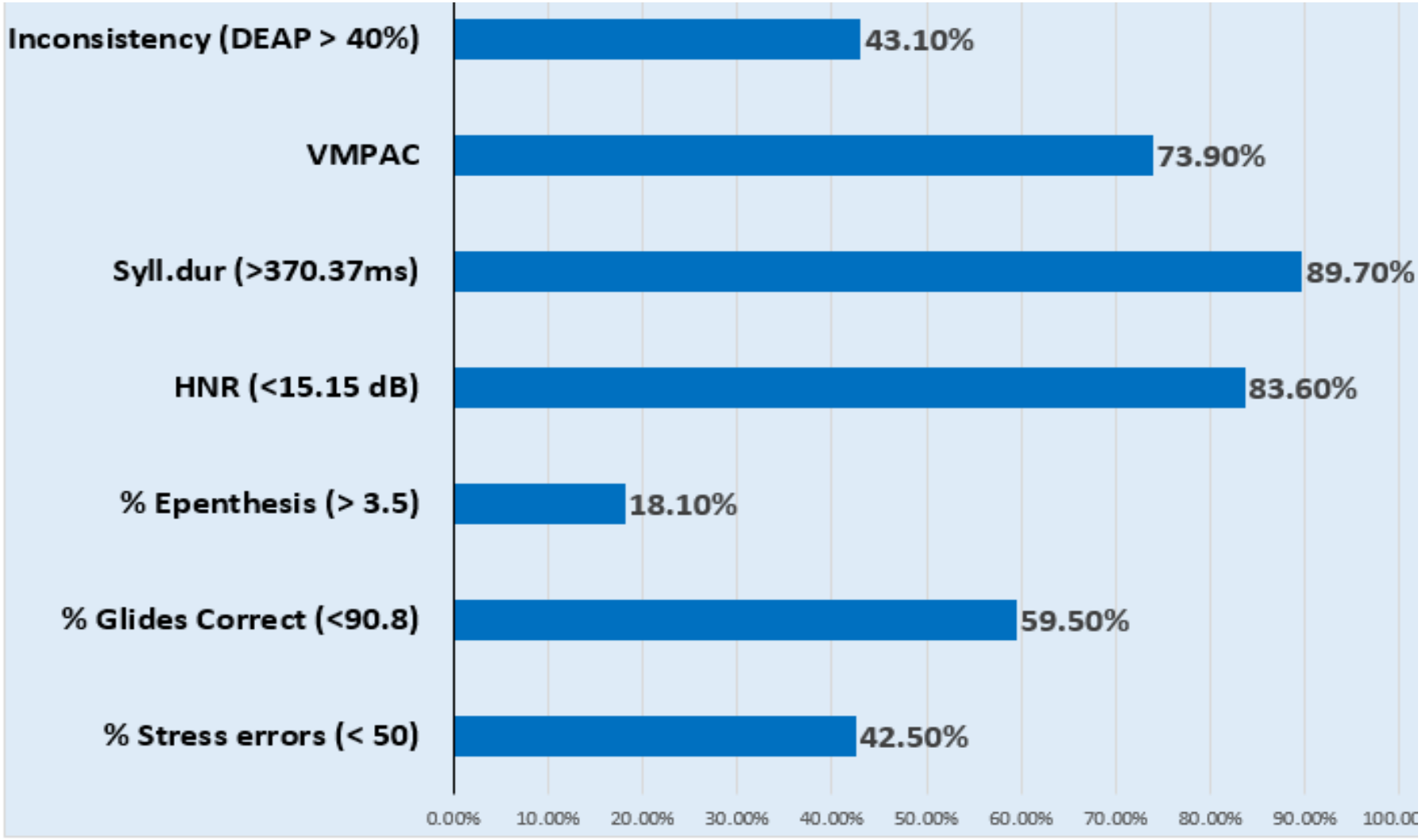
Speech Motor Delay

Reference:

Shriberg & Wren (2019). Clinical Linguistics & Phonetics 33(8):757-771

Shriberg et al., (2019). Estimates of the prevalence of motor speech disorders in children with idiopathic speech delay. Clinical Linguistics & Phonetics 33(8), 679-706.

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



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).

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

- 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:

Speech Motor Control

- Focal oro-motor control (FOC)
- Oro-motor Sequencing (SEQ)
- Criterion-referenced: probe words

Verbal Motor Production Assessment for Children (VMPAC; Hayden & Square, 1999)

Speech Articulation

- Single-word level articulation
- Percent consonants correct (PCC)
- Phonological process errors

Diagnostic Evaluation of Articulation & Phonology test (DEAP; Dodd et al., 2002).

Activities and participation level:

Speech Intelligibility

- Word-level Speech Intelligibility (CSIM; Wilcox & Morris, 1999).
- Sentence-level Speech Intelligibility (BIT; Osberger et al., 1994).

Functional communication

- Focus on the Outcomes of Communication Under Six tool (FOCUS; Thomas-Stonell et al., 2013).

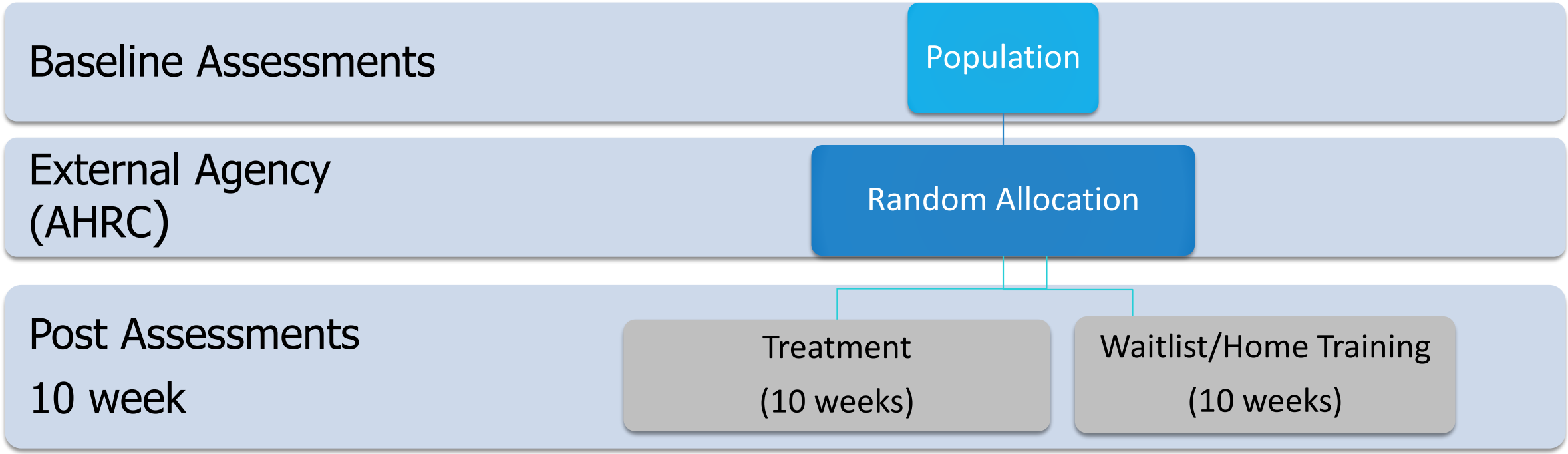
Data Integrity & Reliability

- 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)

Statistical Analysis

- 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

N = 49
Severe SSD
PCC <50%
Sentence intelligibility 20%

Blind Baseline assessments (PRE)

AHRC Arms Length– Data monitoring, study integrity & **Random allocation**

N = 24

Immediate TX Group
PROMPT intervention
M = 48.70 MONTHS
SD = 11.77

N = 25

Waitlist Group
Waitlisted for 10 weeks
M = 48.08 MONTHS
SD = 12.33

Blind Post 10 week assessment (POST)

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)*

Summary & Interpretation of PROMPT RCT

Variables	Levels	Significance	ES Interpretation
Speech Motor control	VMPAC-FOC	***p* = 0.016 (Sig)**	TX resulted in **6.27%** greater FOC scores than waitlist
	VMPAC- SEQ	*Not Sig*	*Not Targeted in TX*
Speech Artic (DEAP)	Standard Score	***p* = 0.002 (Sig)**	TX resulted in **5.15** greater standard scores than waitlist. ~13 fewer raw score errors.
	Percent Consonants Correct (PCC)	***p* = 0.000 (Sig)**	TX resulted in **10.85%** more consonants correct than waitlist. Change from Severe to Moderate-Severe.
Phonological Processes (DEAP)	DEAP -Test	*Not Sig*	*Not Targeted in TX*
Speech Intelligibility	Word Level	***p* = 0.002 (Sig)**	TX resulted in **8.59%** greater word level speech intelligibility scores than waitlist
	Sentence Level	*Not Sig*	Groups had similar change (~10%)
Functional Communication	FOCUS	*Not Sig*	Groups had similar change (~12-14 point)

Summary & Interpretation

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

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

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.**

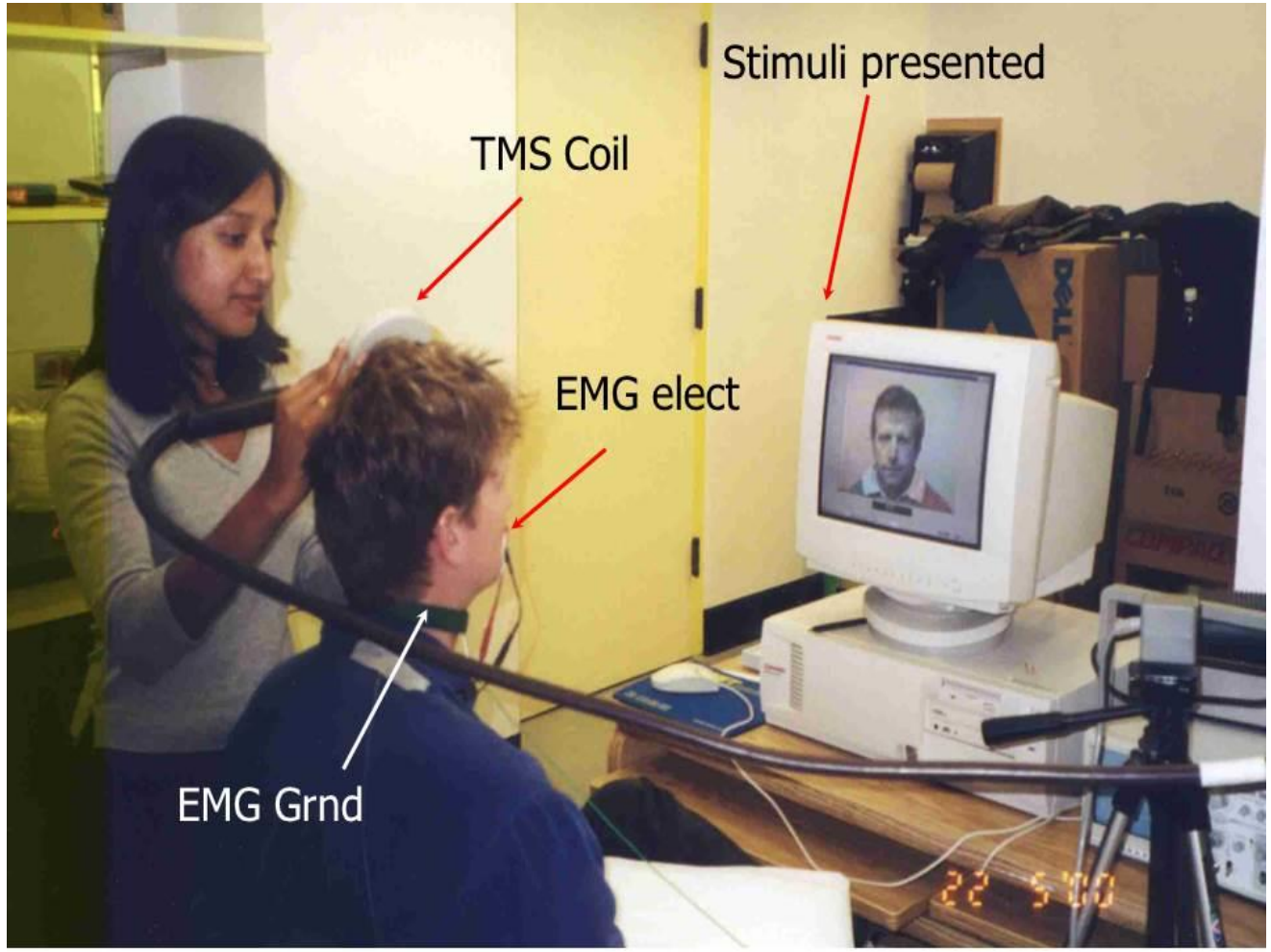
- **10 weeks of therapy may be inadequate for:**
  - Changes in Sentence level intelligibility (BIT) and functional communication (FOCUS)

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

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

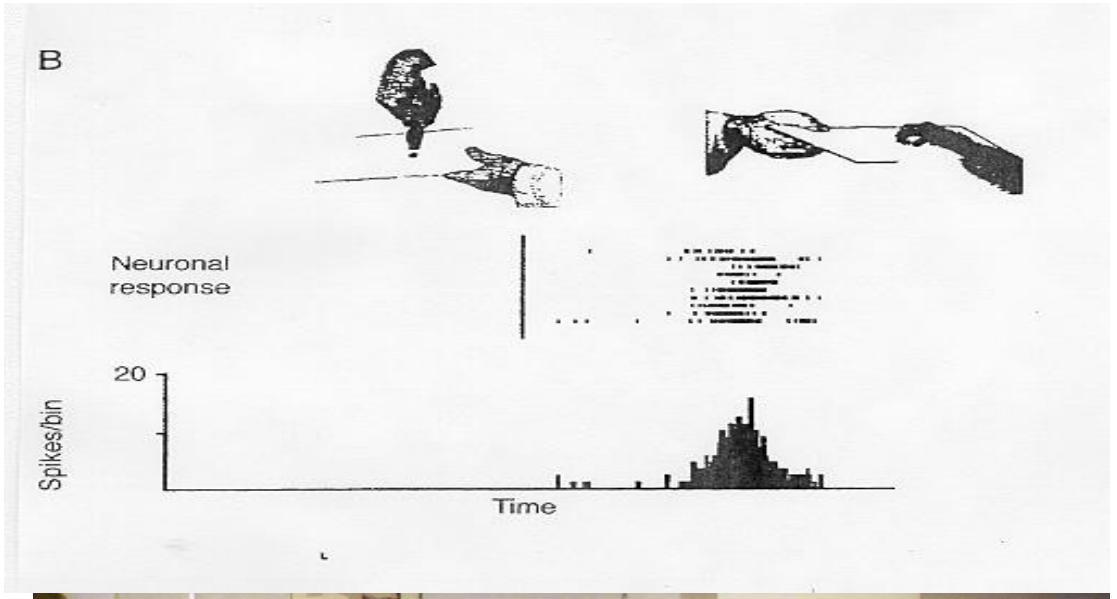
NEUROPHYSIOLOGICAL MECHANISMS

Mirror Neurons for Speech- First Report & Discovery in Toronto 2000-2001



Experiment in Progress

Sundara, Namasivayam & Chen 2001; Neuroreport



- We would like to thank Rami R. Garg, Research Coordinator, Dept of Neurology, Toronto Western Research Institute, for help in data collection.
- Paper published in *NEUROREPORT, vol 12, no 7,1341-1344, May 2001.*

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).

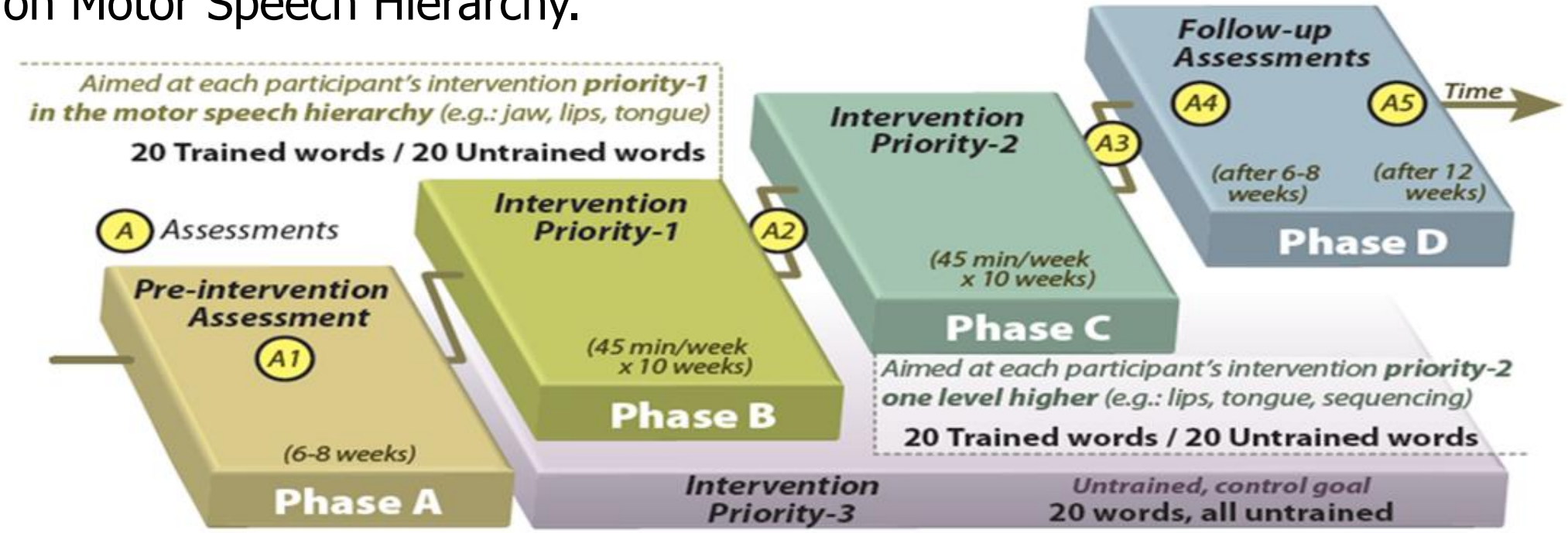
Kinematics

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

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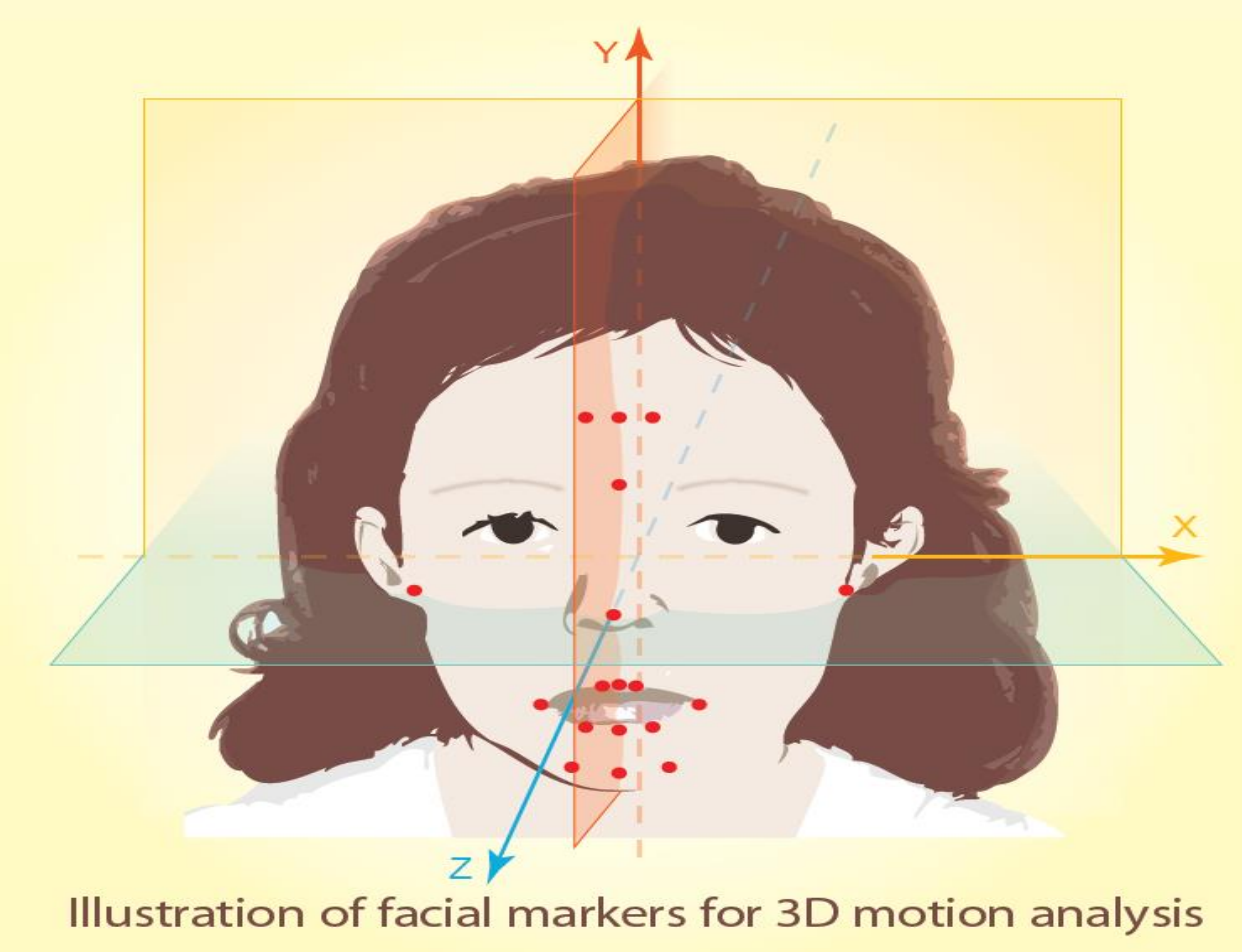


Illustration of facial markers for 3D motion analysis

Kinematics (speech movements):

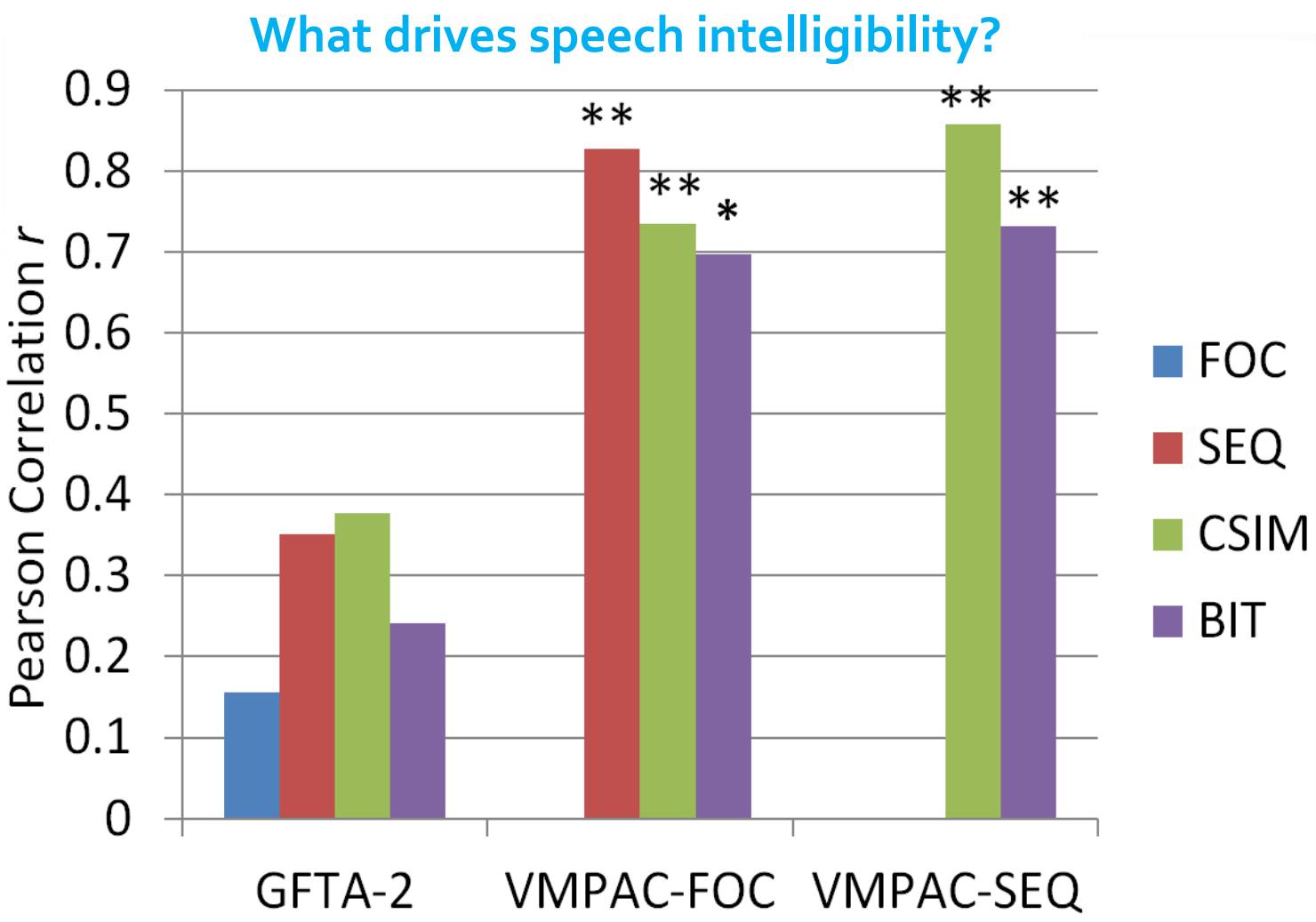
Systematic changes in mandibular and labiofacial sub-systems result in improved speech intelligibility.

Kinematics

How do changes in speech movements (kinematics) result in improved intelligibility?

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

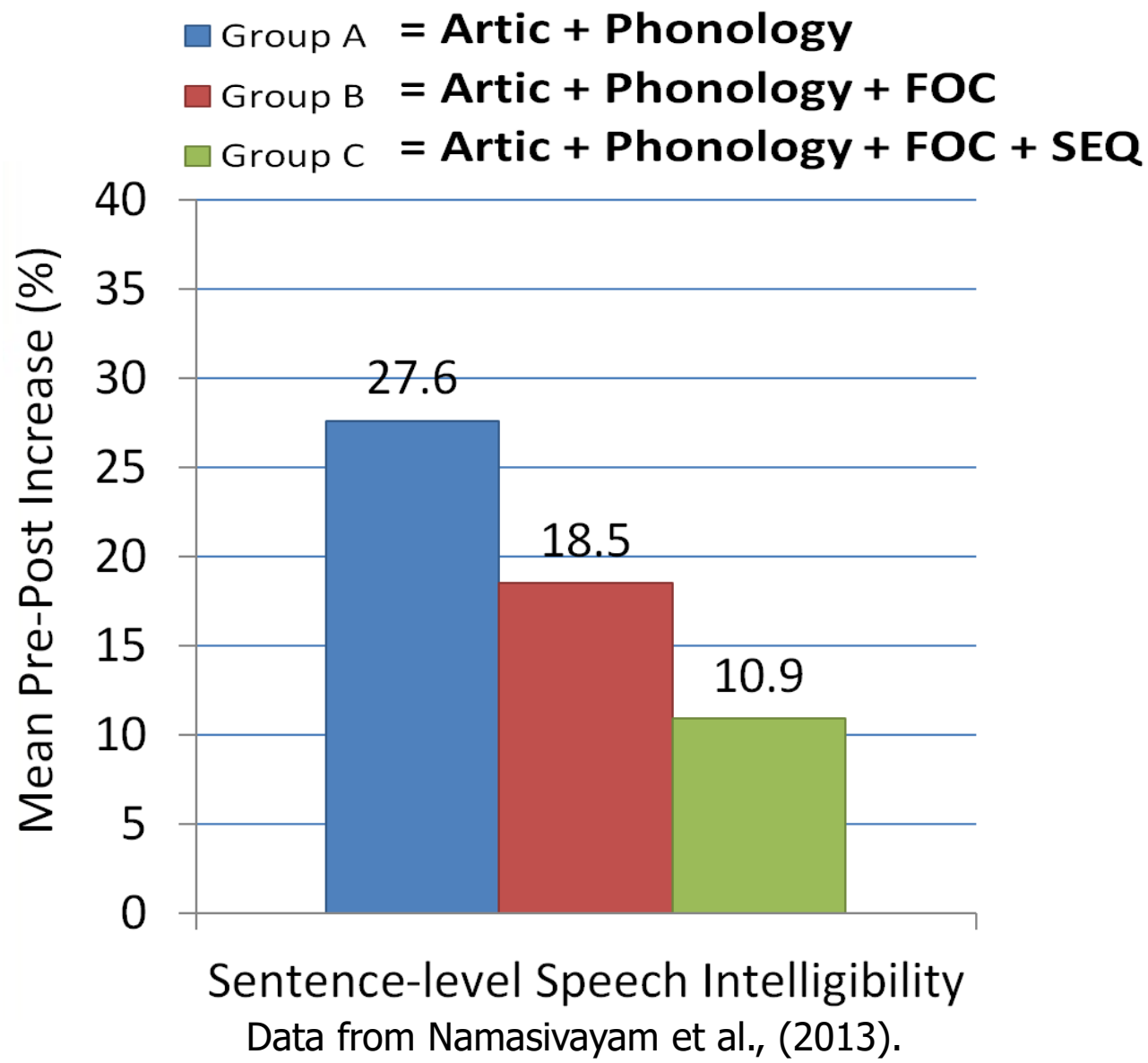
Kinematics



** Correlation significant at 0.01 and * at 0.05. Namasivayam et al., (2013)
CSIM = Word-level speech intelligibility;BIT = Sentence-level 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.**

Kinematics

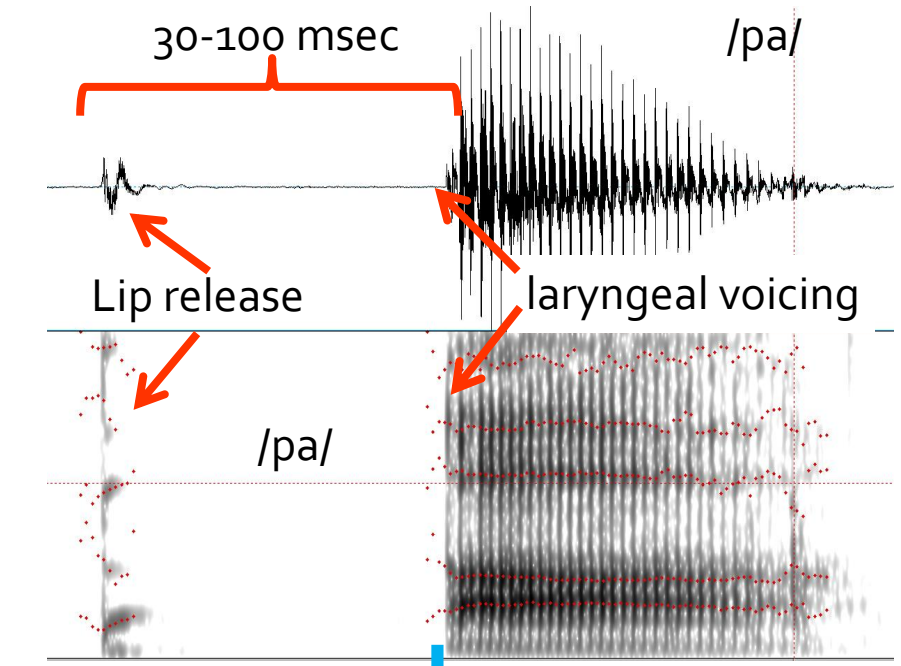


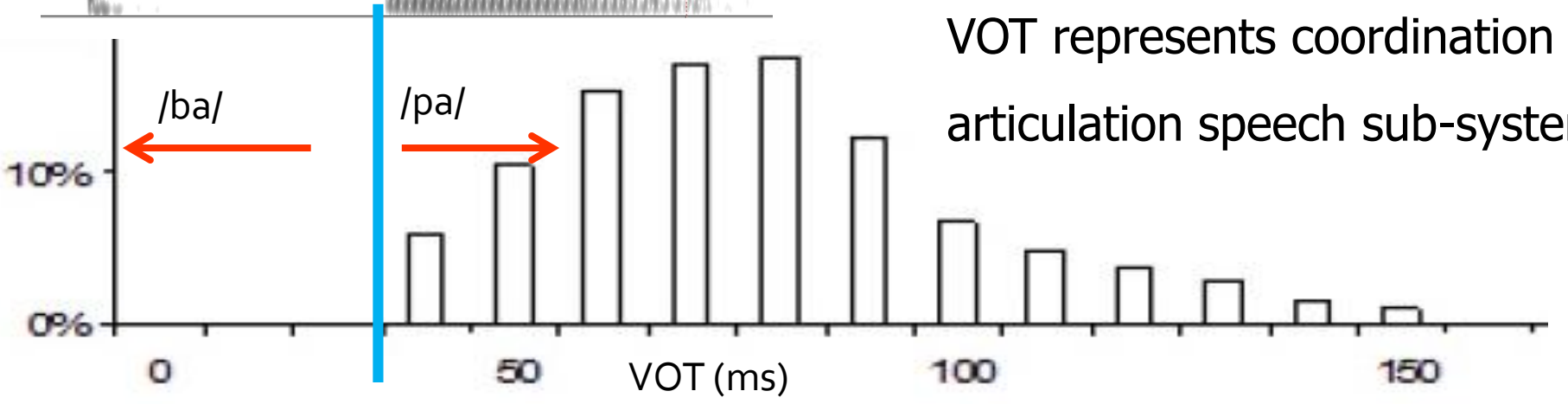
Data from Namasivayam et al., (2013).

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.

Speech Sub-System Coordination





<u>Voice onset time (VOT):</u>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

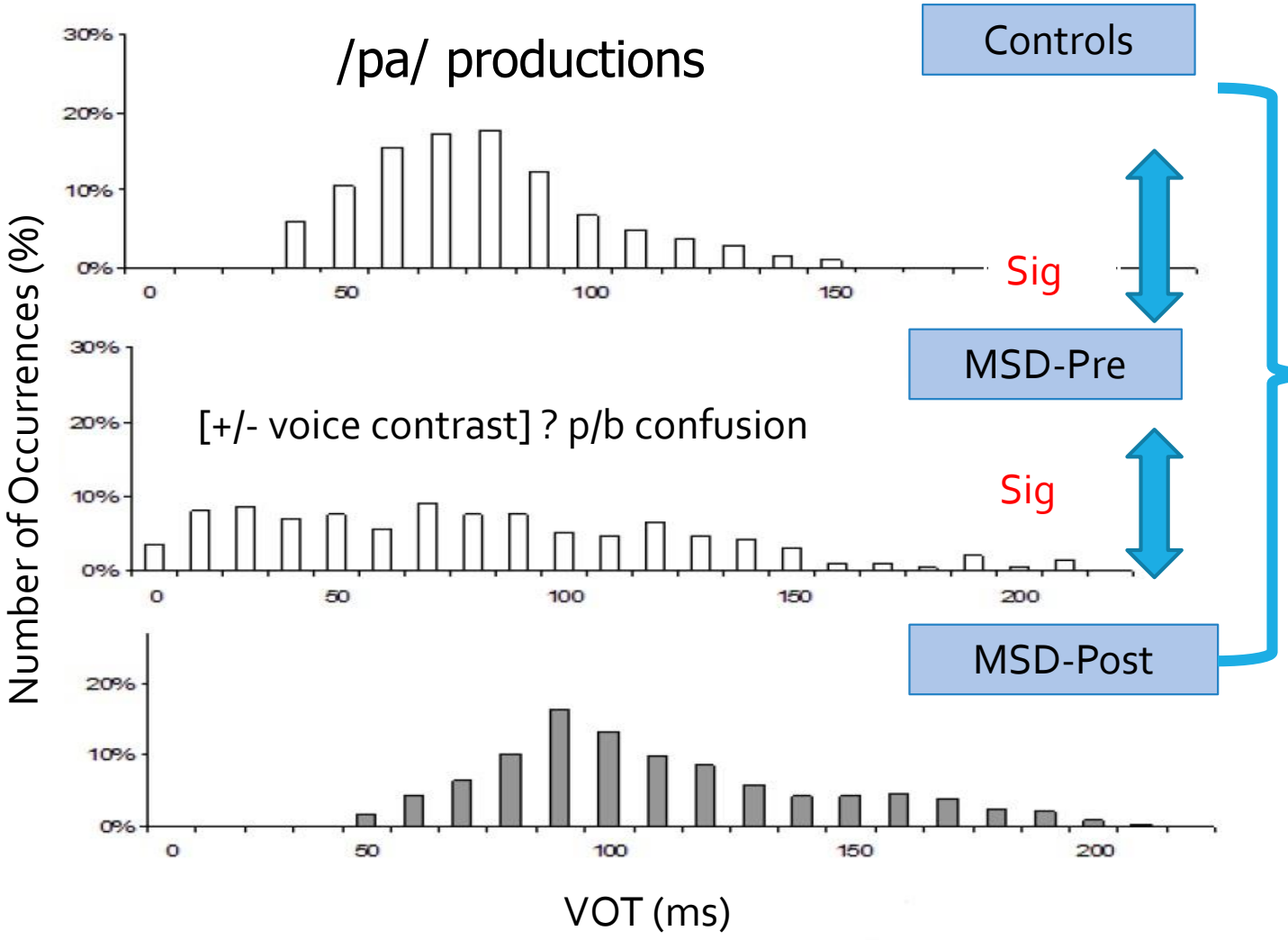


Figure 1. Distribution patterns for VOT while producing /p/ for the control group, and children with MSD, Pre- and POST-therapy.

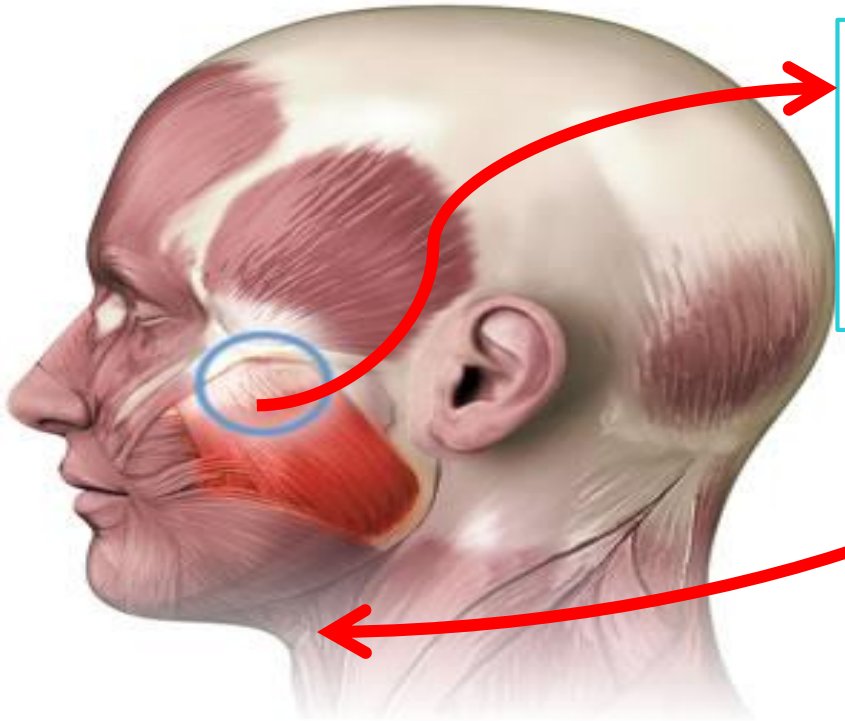
PROMPT treatment improves coordination between phonation & articulation

Yu et al., (2014)

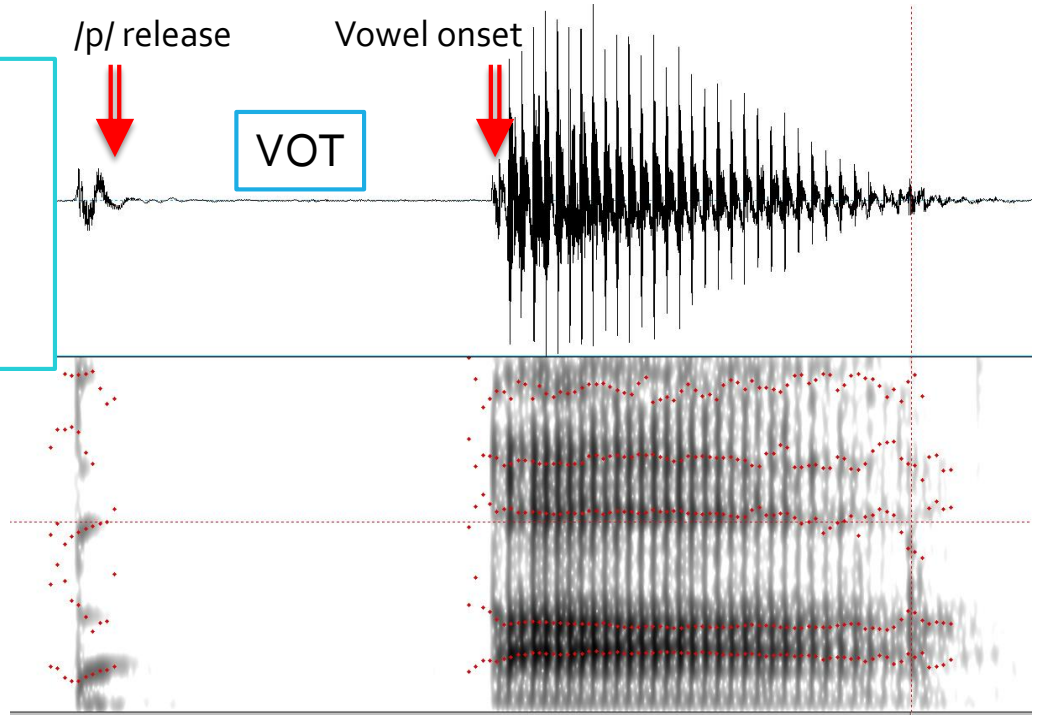
- VOT variability (CoV): significantly higher in MSD-PRE group compared to control group (p=.013) or MSD-Post treatment (p=.006)
- MSD-Post & Controls (p=.47) not significantly different.

Speech Sub-System Coordination

Relationship between Voice Onset Time (VOT) & PROMPT Therapy



Masseter spindle information controls:
-Jaw height (grading)
-Phonation onset
-Phonation variability



Data from: Neufeld, C., Namasivayam, A., Van Lieshout, P. (2013 a, b).

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?

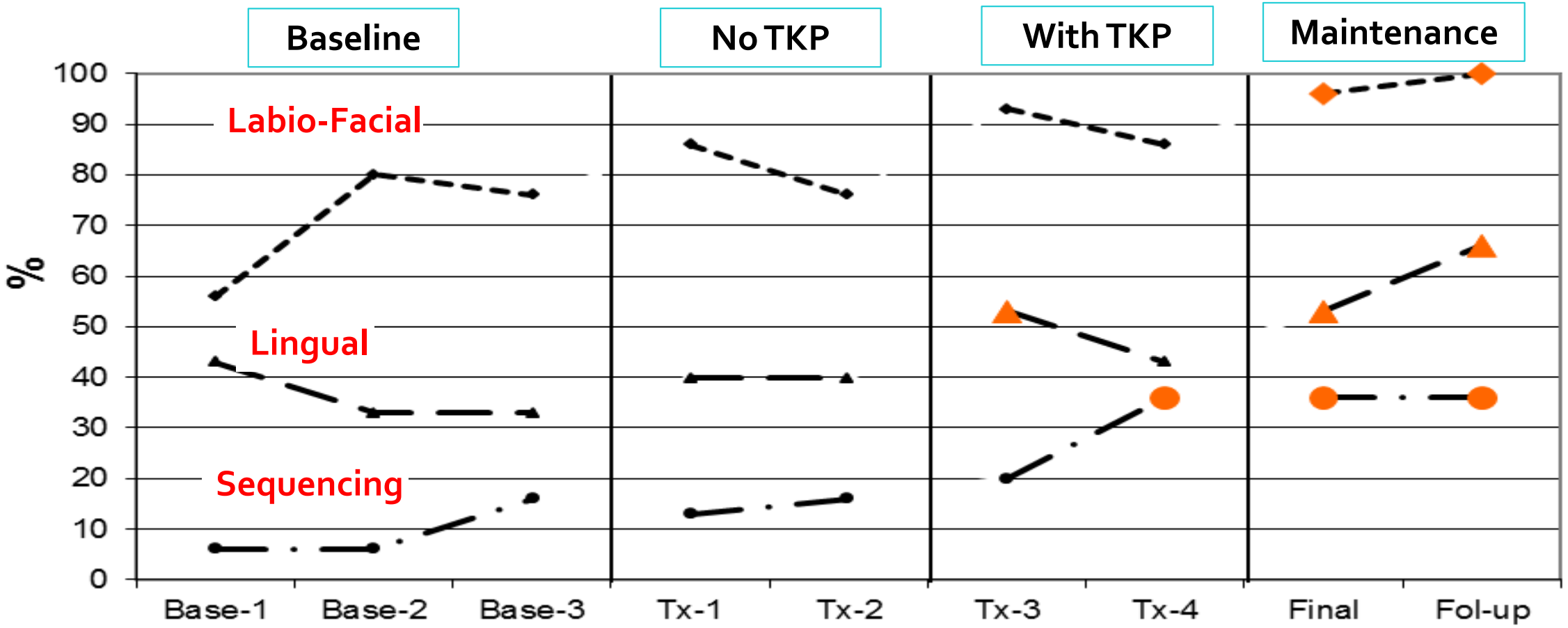
Results:

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

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

Active Ingredient

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



Participant B.B (Prompt Without TKP: Phase I) on Untreated Word Probes. Larger (orange) markers indicate performance > 2 SD above baseline. Y-axis = % score correct; From Dale & Hayden, 2013.

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?

Active Ingredient

Oro-Facial Tactile Cues Affect Phoneme Recognition & Retrieval

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

TKP Congruency:

Congruent: Lip rounding target with lip rounding prompt.

Incongruent: Lip rounding target with tongue tip elevation prompt.

Word frequency manipulation:

Low frequency words take longer to be recognized & harder to retrieve from memory.

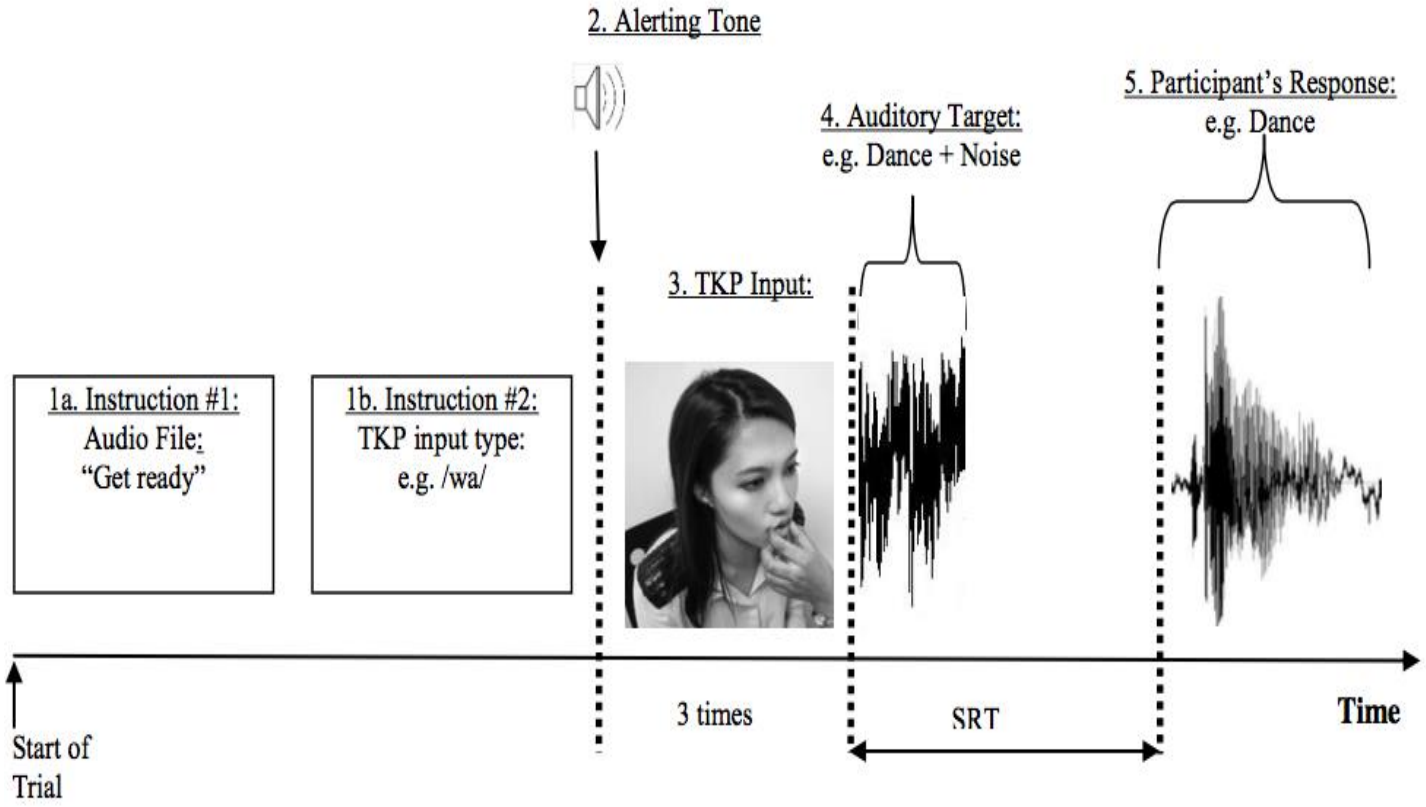
Low frequency words require greater cognitive effort.

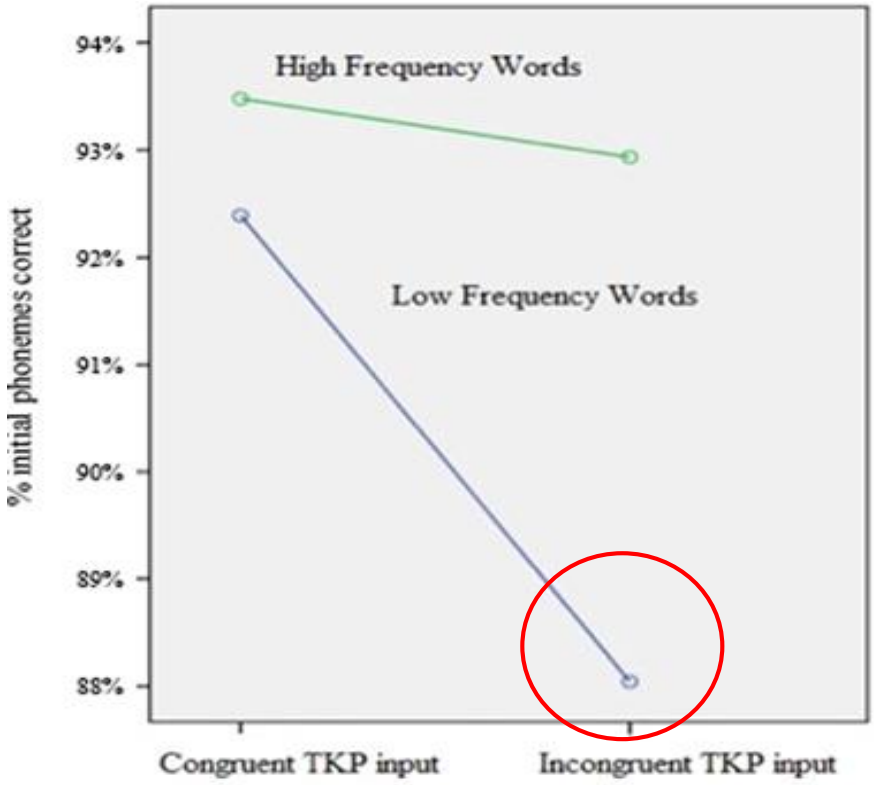
Hypothesis:

Processing of low frequency words will benefit to a greater extent with TKP input relative to high frequency words.

Active Ingredient

Oro-Facial Tactile Cues Affect Phoneme Recognition & Retrieval





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

Mode of Action (MoA)

The Neuroscience of PROMPT Therapy

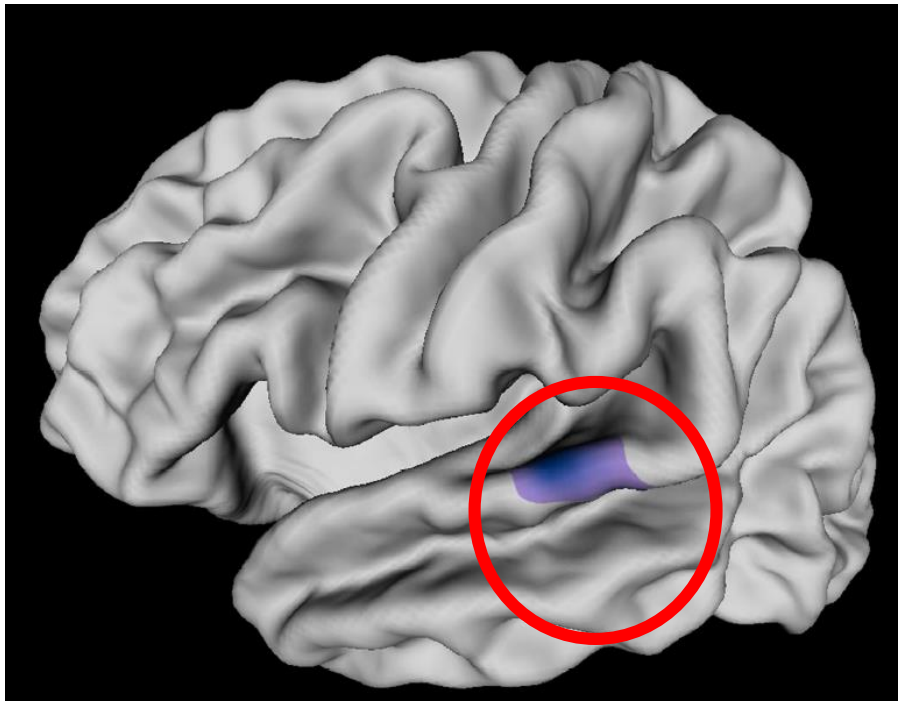
3 levels of Brain changes identified:

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

Mode of Action (MoA): Structure



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

Significant ($p < 0.05$) thinning Post PROMPT intervention

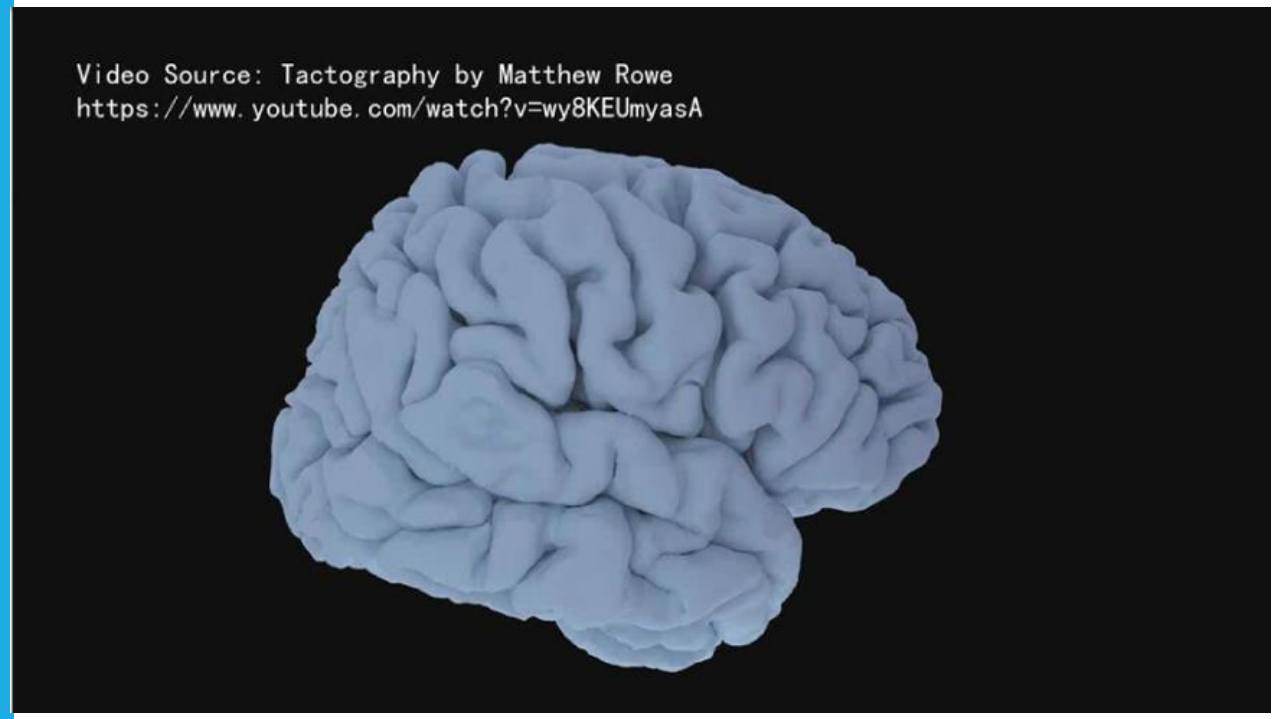
Cortical changes following PROMPT in CAS

Kadis et al., 2014

Thinning of Wernicke's area post PROMPT therapy?

- Wernickes 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.

Mode of Action (MoA): Connectivity



Structural MRI using High Angular Resolution Diffusion Imaging (HARDI)

IRCCS FONDAZIONE
STELLA MARIS
ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO

Tractography following PROMPT in CAS

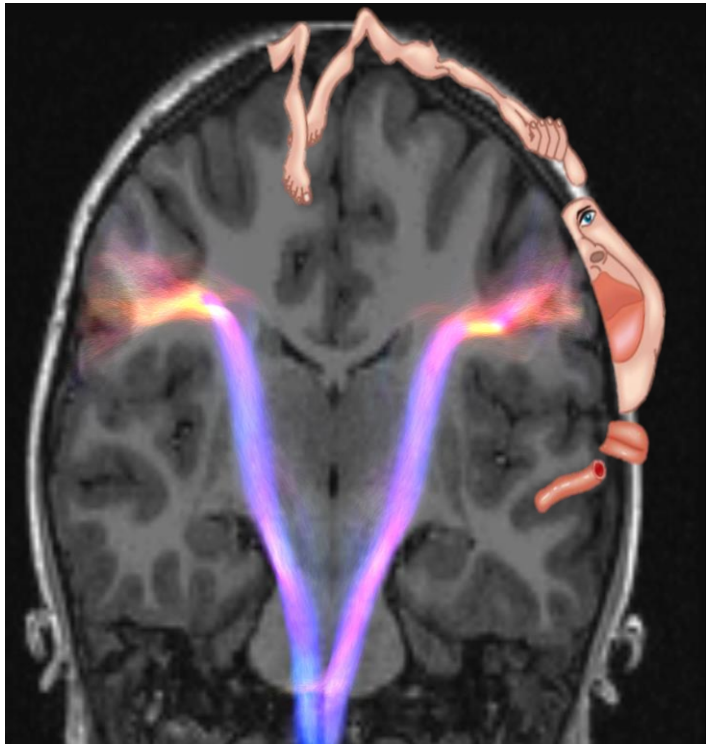
Chilosi et al., 2018; Fiori et al., 2018
Fondazione Stella Maris, Calambrone, Pisa, Italy

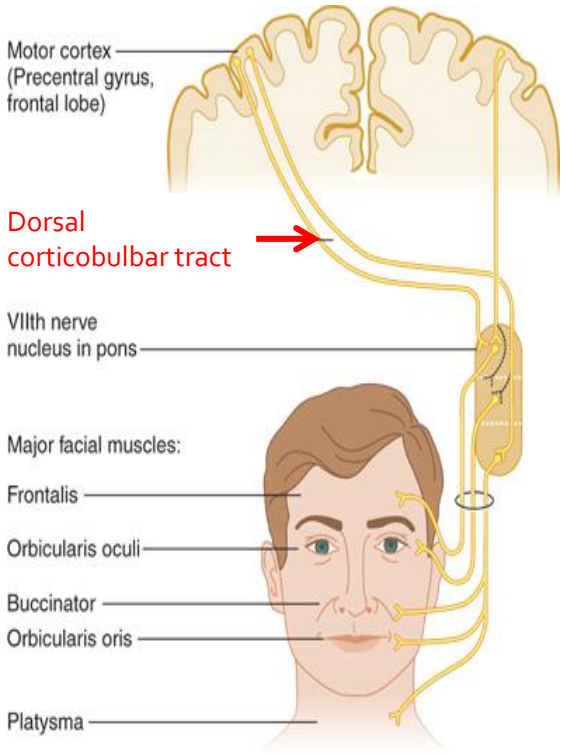
10 CAS children - 30 therapy sessions (2x/week; approx 7 months):

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

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

Mode of Action (MoA): Connectivity





RESULTS

PROMPT-treated

Tract FA	p-value	Cohen's d
Dorsal corticobulbar (lips, larynx)	.045	1.29
Ventral corticobulbar (tongue)	.071	-
Hand (control tract)	.150	-

L&OM-treated

Tract FA	p-value	Cohen's d
Dorsal corticobulbar (lips, larynx)	.283	-
Ventral corticobulbar (tongue)	.070	-
Hand (control tract)	.299	-

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.

Mode of Action (MoA): Neuronal firing patterns

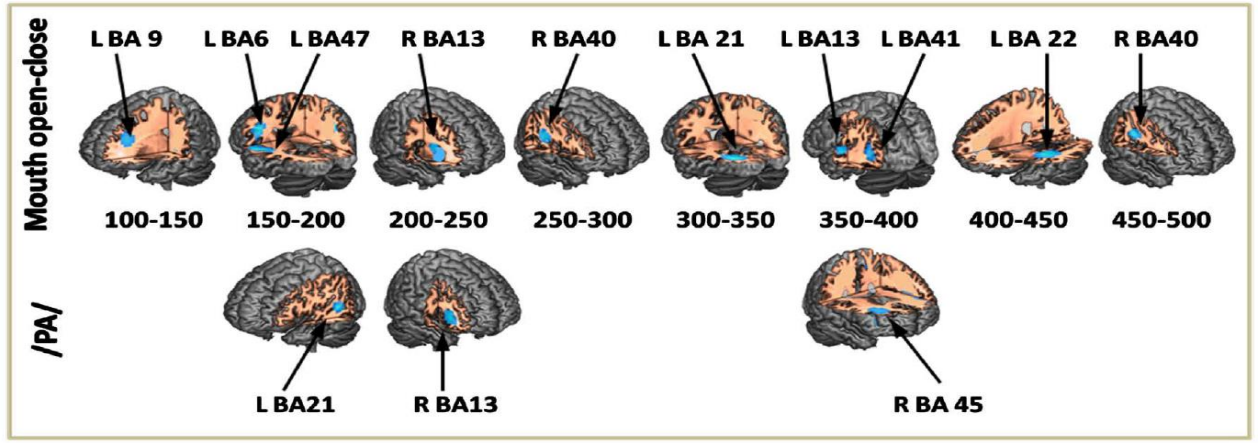


Figure 2. Three-dimensional brain images showing the areas that were significantly different between the pre- and post-intervention conditions for both the MOC task and the /pɑ/ production task.

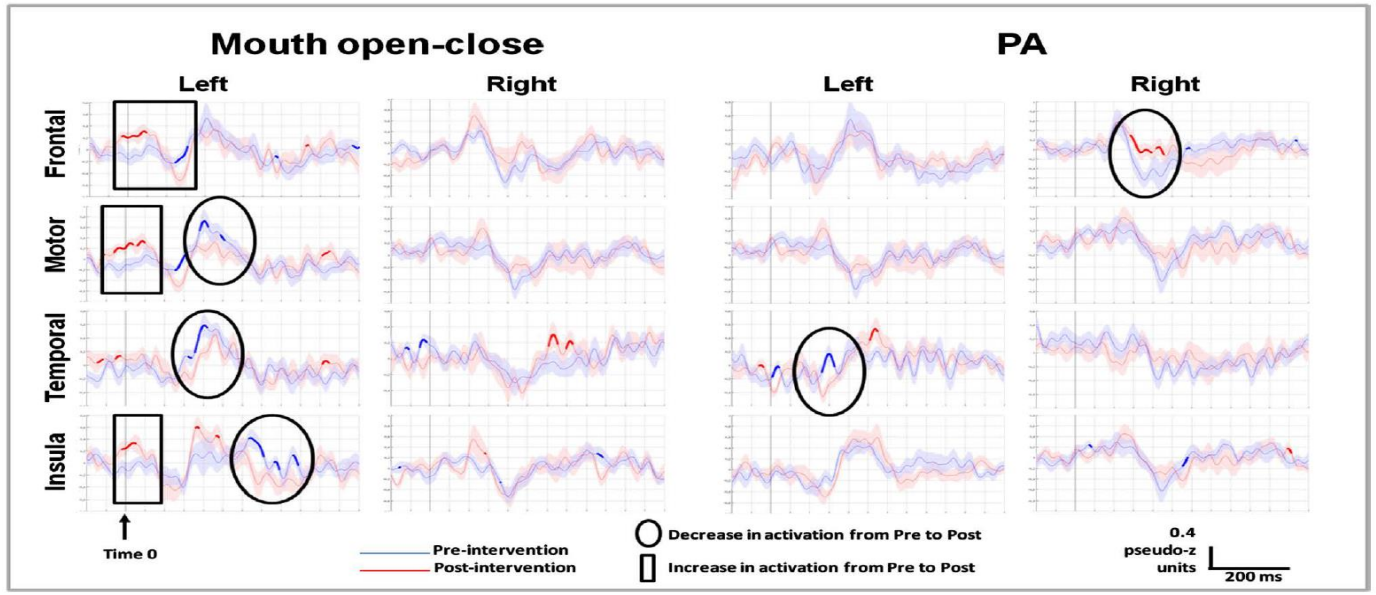


Figure 3. Virtual sensors for each task.

Magnetoncephalography (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

Meta-analysis

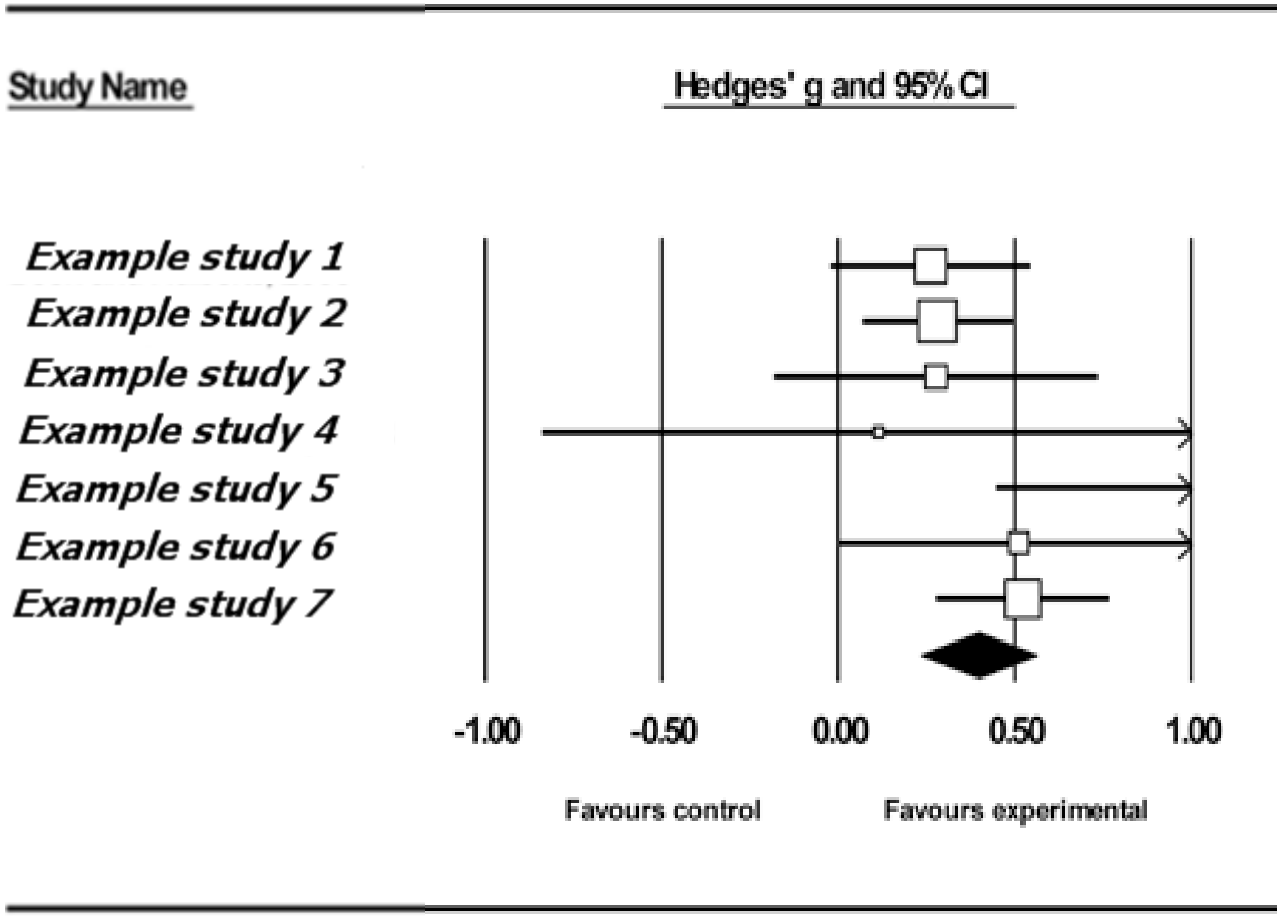
What is Meta-analysis?

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

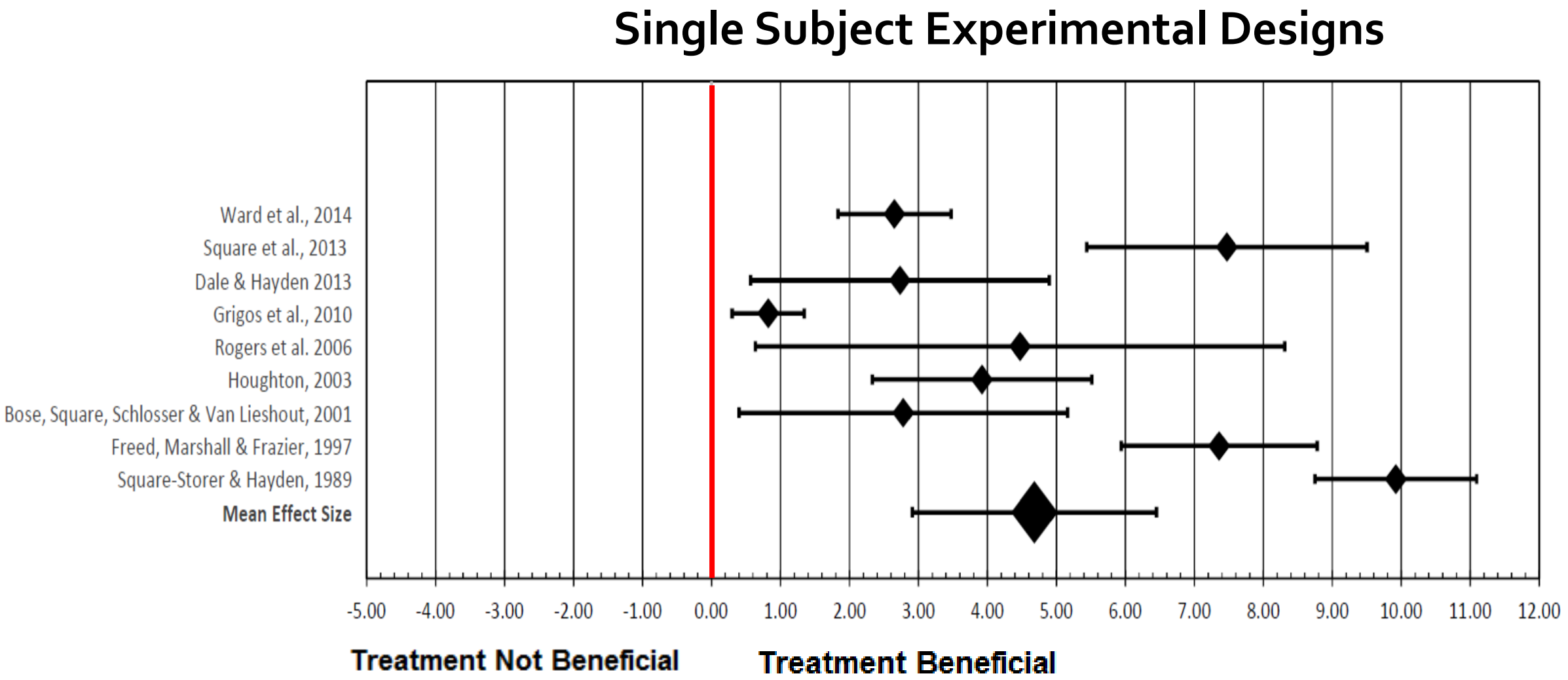
- **Data set:** Nine single-subject experimental research designs (SSED; LOE range II-A to II-B).

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

- Cohen's *d* = (Mean intervention – Mean baseline)/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



Forest plot – Big picture from individual studies!

Meta-analysis: SSED Summary

- **Summary:** Positive medium effect sizes mean = 4.68 (SD = 1.77).
- Adults studies (adult Apraxia and Aphasia) M = 6.68 > children with SSD (M = 3.67. Potential differences in dosage, outcome measurements, and population heterogeneity.
- 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.
- Positive changes at all WHO ICF-CY (WHO, 2007) levels: functional words acquired, accuracy of probe words, PCC, PVC, speech intelligibility and functional communication.

Meta-analysis: Group Studies

- **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.

- **Analyzed using:** Comprehensive Meta-Analysis; www.meta-analysis.com.

- **Levels of Evidence:** I-B to II-B

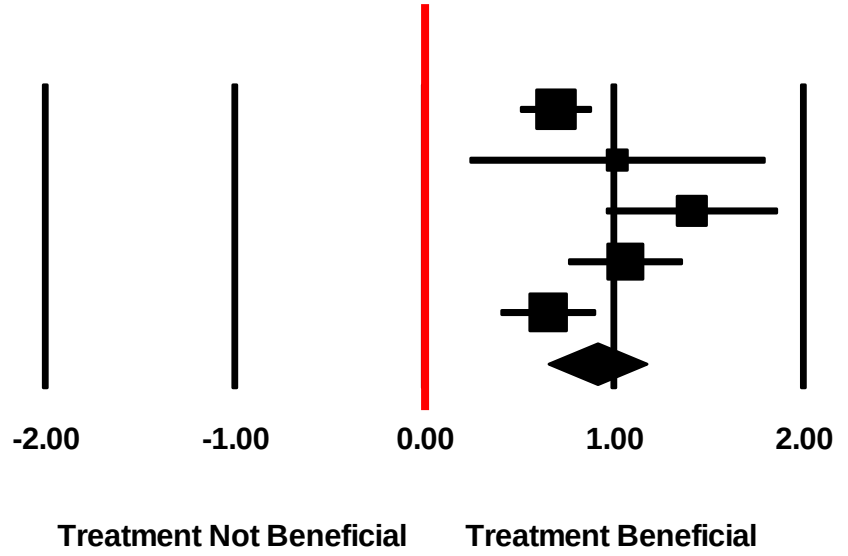
Meta-Analysis: Group

Meta-Analysis: Oro-Motor Control

Study name	Std diff in means	Standard error	Lower limit	Upper limit	Z-Value	p-Value	Total	Relative weight
Namasivayam et al., 2018	0.695	0.096	0.505	0.884	7.199	0.000	24	27.76
Fiori et al., 2018	1.018	0.397	0.239	1.797	2.562	0.010	5	8.24
Yu et al., 2014	1.411	0.231	0.959	1.863	6.117	0.000	6	16.33
Kadis et al., 2014	1.061	0.153	0.761	1.361	6.929	0.000	12	22.65
Namasivayam et al., 2013	0.653	0.127	0.404	0.903	5.137	0.000	12	25.02
	0.911	0.132	0.652	1.169	6.905	0.000		

Statistics for each study

Std diff in means and 95% CI



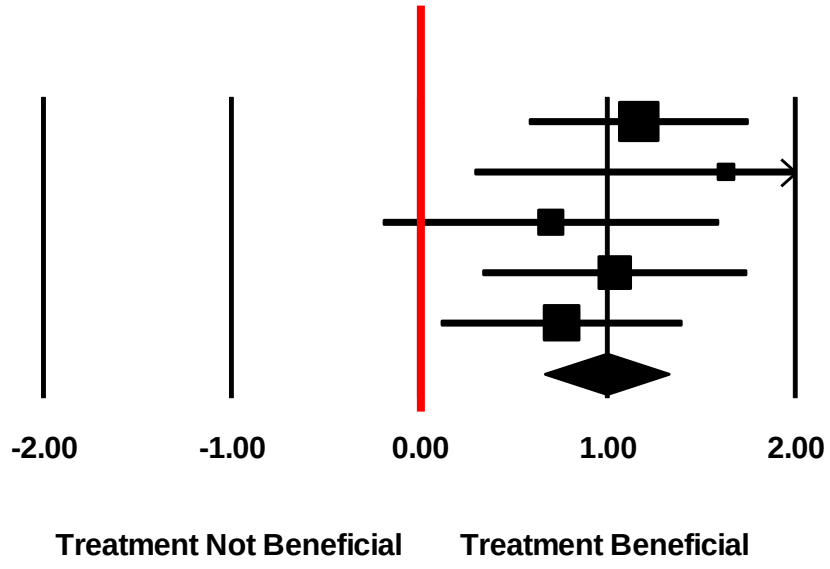
Meta-Analysis: Group

Meta-Analysis: Articulation

Study name	Std diff in means	Standard error	Lower limit	Upper limit	Z-Value	p-Value	Total	Relative weight
Namasivayam et al., 2018	1.168	0.298	0.585	1.751	3.925	0.000	19	31.93
Fiori et al., 2018	1.632	0.683	0.294	2.971	2.390	0.017	5	6.06
Yu et al., 2014	0.699	0.455	-0.193	1.592	1.536	0.125	6	13.62
Kadis et al., 2014	1.039	0.358	0.337	1.741	2.901	0.004	12	22.02
Namasivayam et al., 2013	0.756	0.327	0.115	1.398	2.310	0.021	12	26.37
	0.995	0.168	0.666	1.325	5.921	0.000		

Statistics for each study

Std diff in means and 95% CI



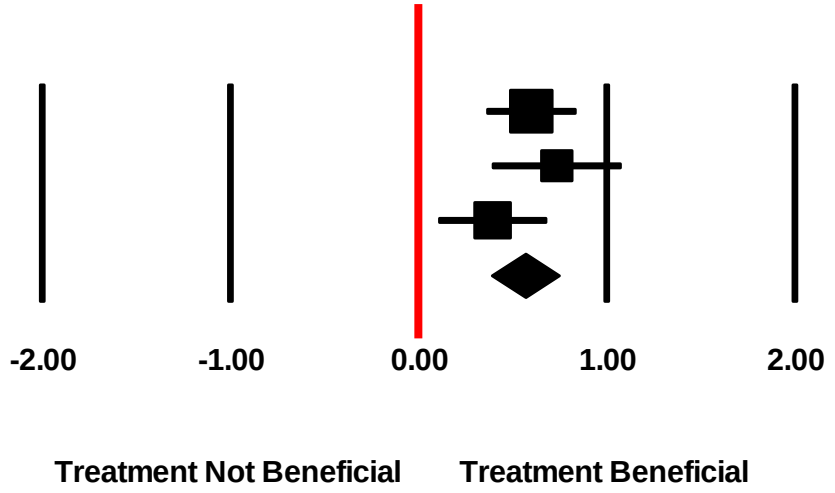
Meta-Analysis: Group

Meta-Analysis: Speech Intelligibility

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

Statistics for each study

Std diff in means and 95% CI



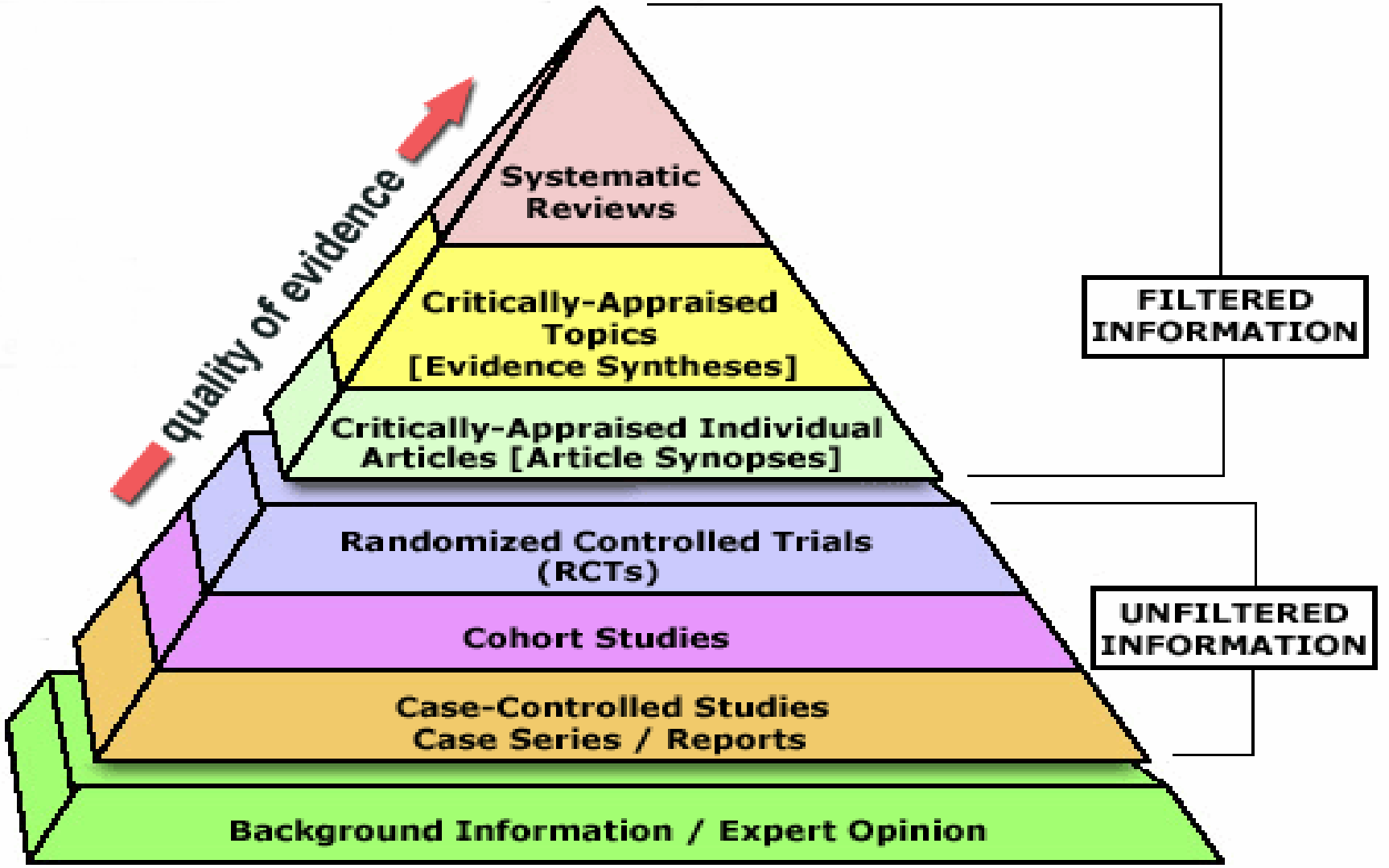
Meta-analysis: Group Studies Summary

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

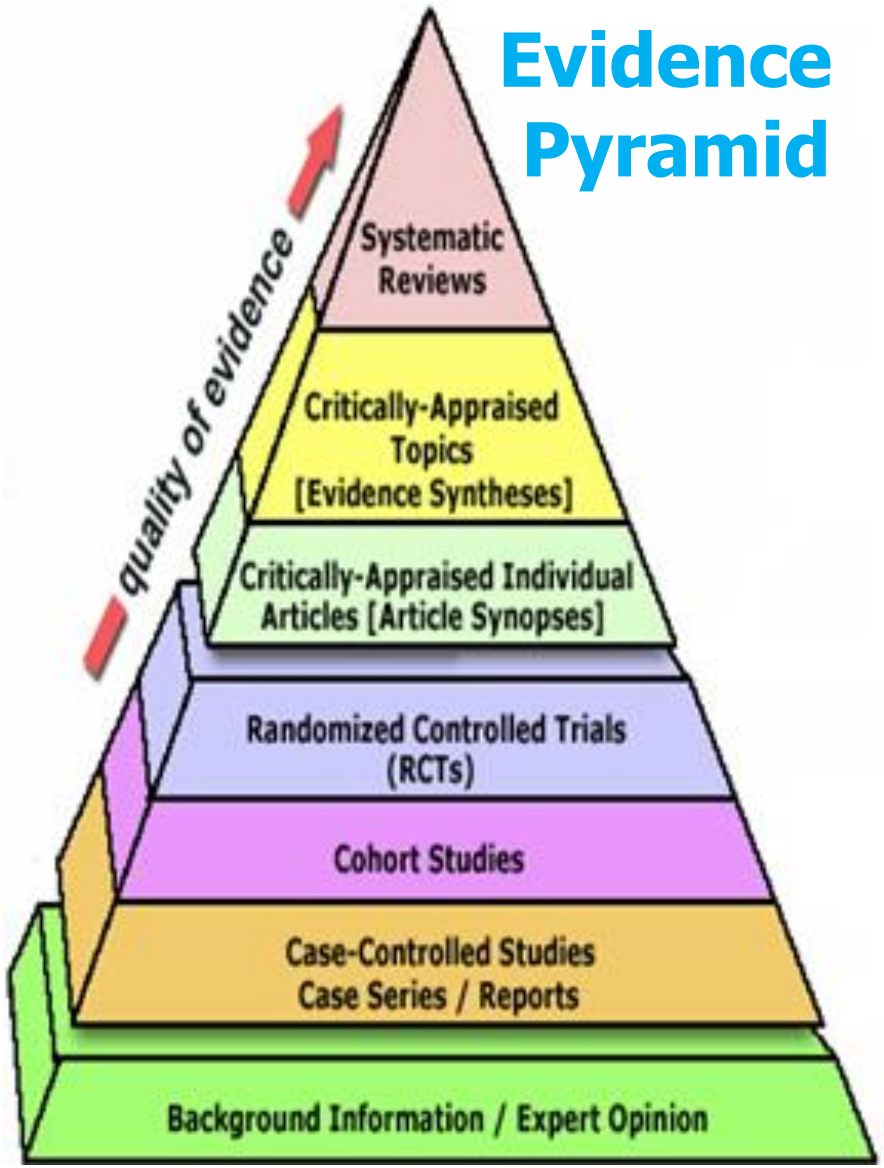


Source: http://www.dartmouth.edu/~biomed/resources.htmld/guides/ebm_resources.shtml

Hierarchy of Evidence Quality

Levels of Evidence	
Well-designed meta-analysis of > 1 RCT	Ia
Well-designed RCT	Ib
Well-designed controlled study without randomisation	IIa
Well-designed quasi experimental study	IIb
Well-designed nonexperimental studies (including correlation and case Studies)	III
Expert committee report, consensus conference and clinical experience of respected authorities	IV

Shekelle et al. Developing clinical guidelines. West J Med. 170(6):348-51, 1999 June



Hierarchy of Evidence Quality

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

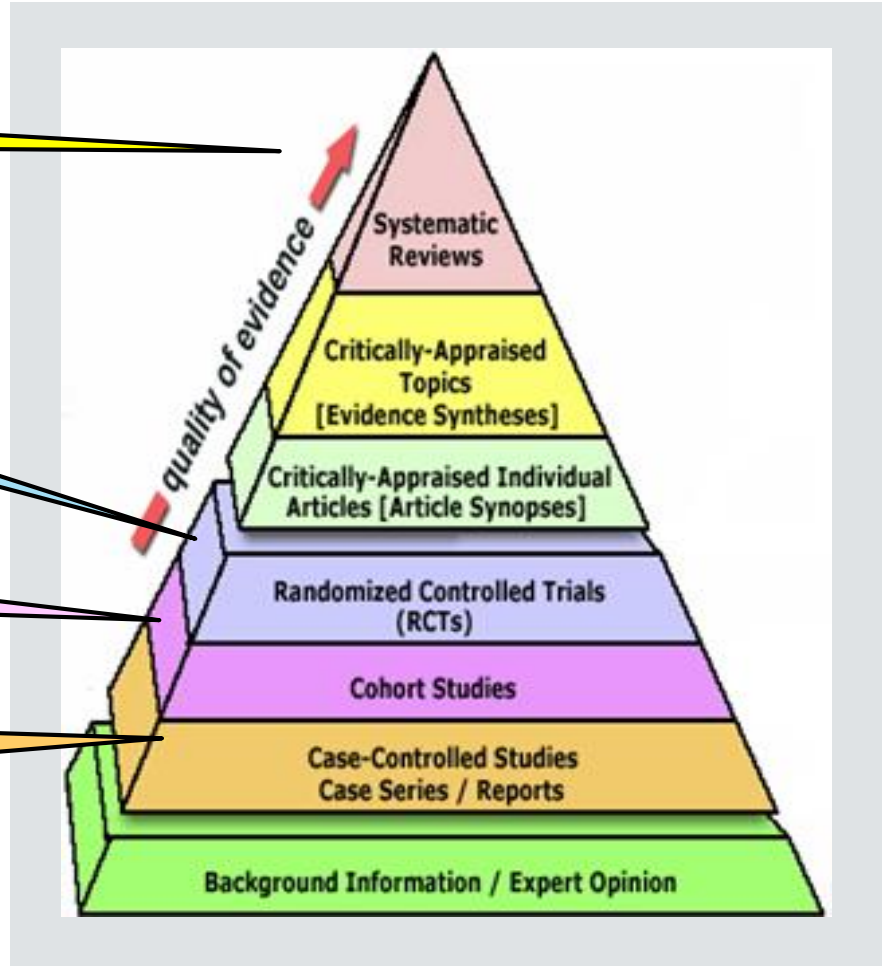
I-A **Meta-analysis**
Hayden et al. 2020

I-B **Multi-Centre RCT**
Namasivayam et al. 2018

II-A
II-B
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

II-A
II-B
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

Evidence Pyramid



CLINICAL OUTCOME RESEARCH

Clinical Outcome Research

Research studies are great but…

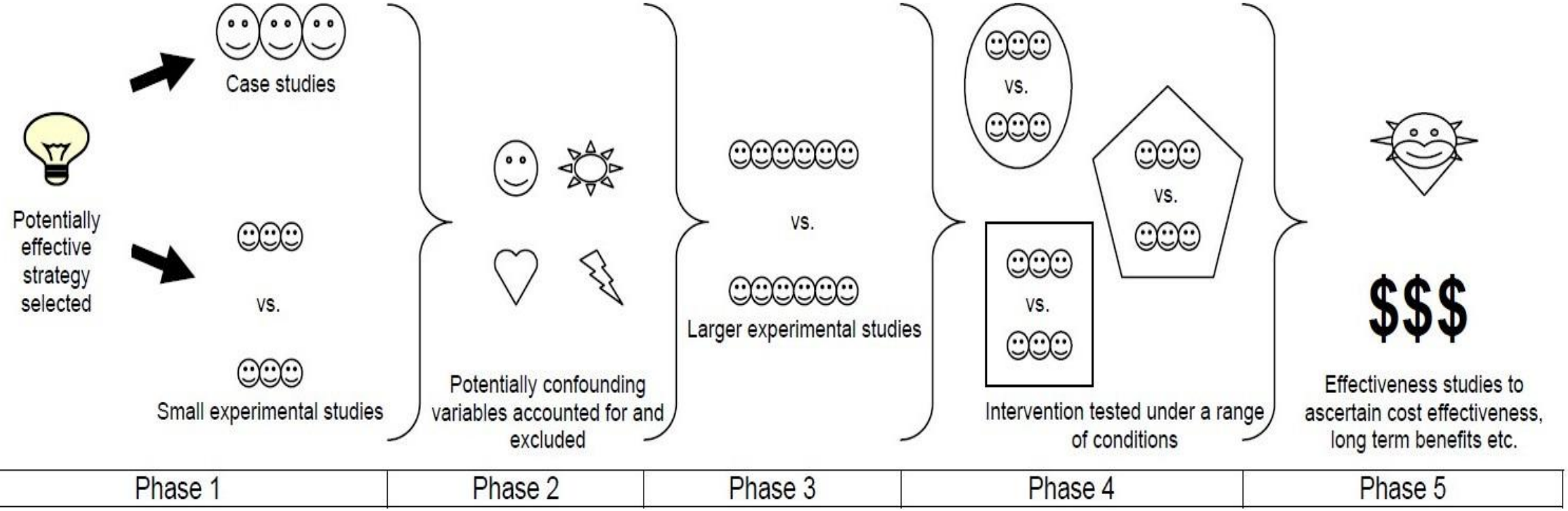
How do these studies fit the accepted standards for clinical-outcome testing used throughout the broader research community ? (e.g., by other disciplines, federal regulators, and third-party payers).

Robey, R.(2004). A five-phase model for clinical-outcome research, Journal of Communication Disorders, 401-411.

Clinical Outcome Research

5-Phase Outcome Research Model

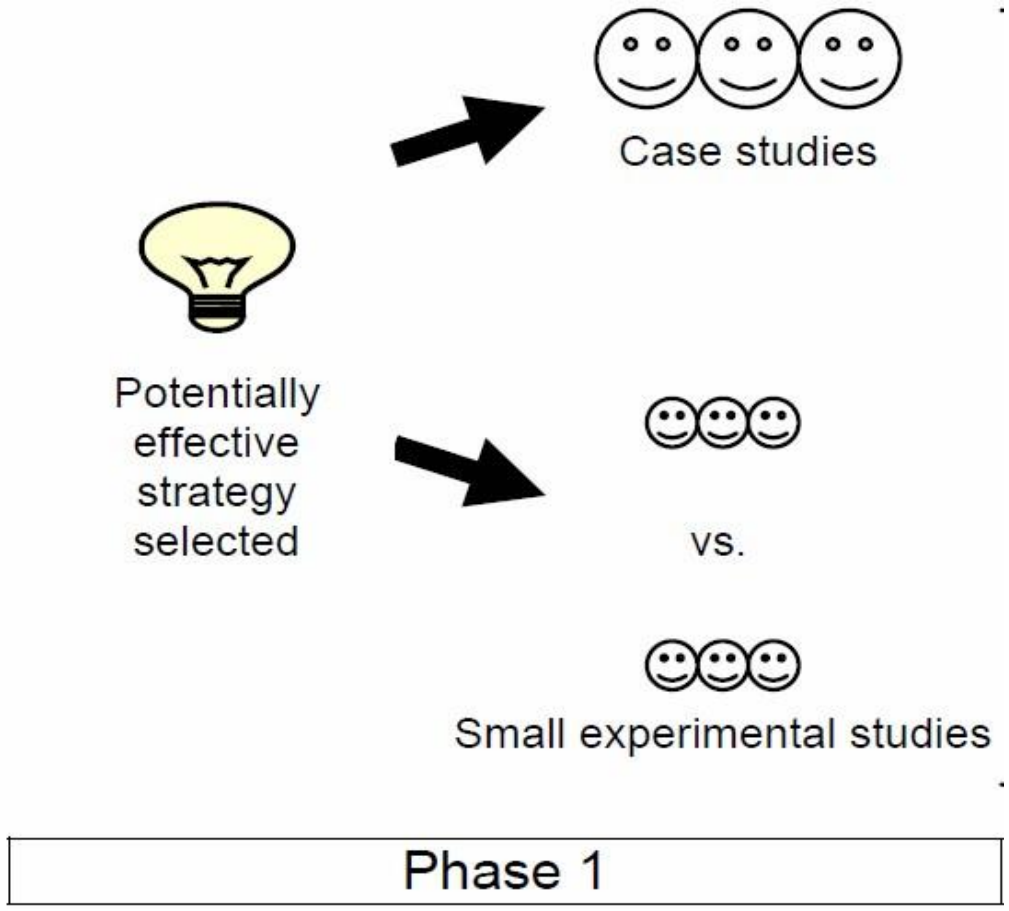
(Robey &Schultz, 1998; Robey, 2004)



Source: http://www.aare.edu.au/06pap/par06029.pdf

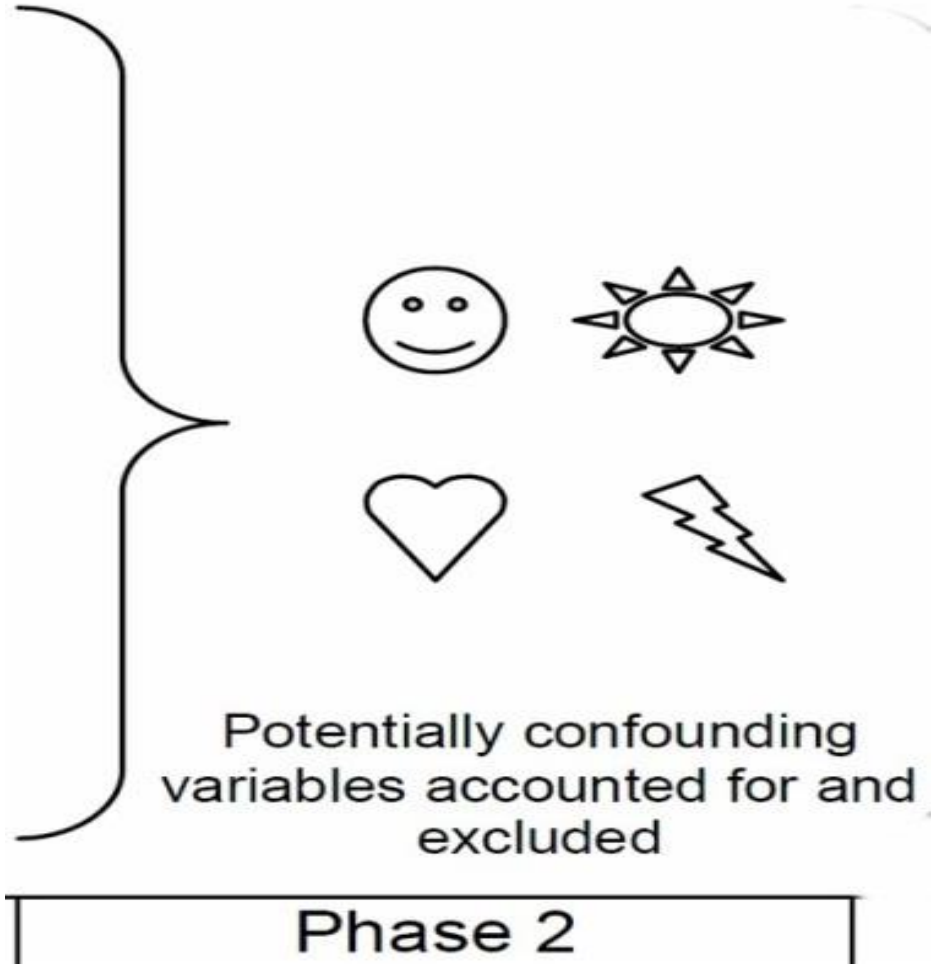
Clinical Outcome Research

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!)

Clinical Outcome Research



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	Speech, Language & Hearing (2015)
Outcome measures in Developmental Speech Sound Disorders with a motor Basis Kearney et al ., 2015	Current Developmental Disorder reports (2015)
Measuring & Training S-LPs Orofacial cueing: A Pilot Demonstration Namasivayam et al ., 2018	Journal of Healthcare Engineering, (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

Phase 2: Refine

EXPLORING QUANTIFIABLE MEASURES FOR THE EVALUATION OF SLP INTERVENTION FIDELITY

Namasivayam A. K., Ward., R, Bali, R., Davey, P., Strauss, G., Claessen, M., Hayden, D., & Van Lieshout, P.H.H.M (2017, July). *Exploring quantifiable measures for the evaluation of SLP intervention fidelity.* Poster presented at the 7th International Conference on Speech Motor Control, Groningen, The Netherlands

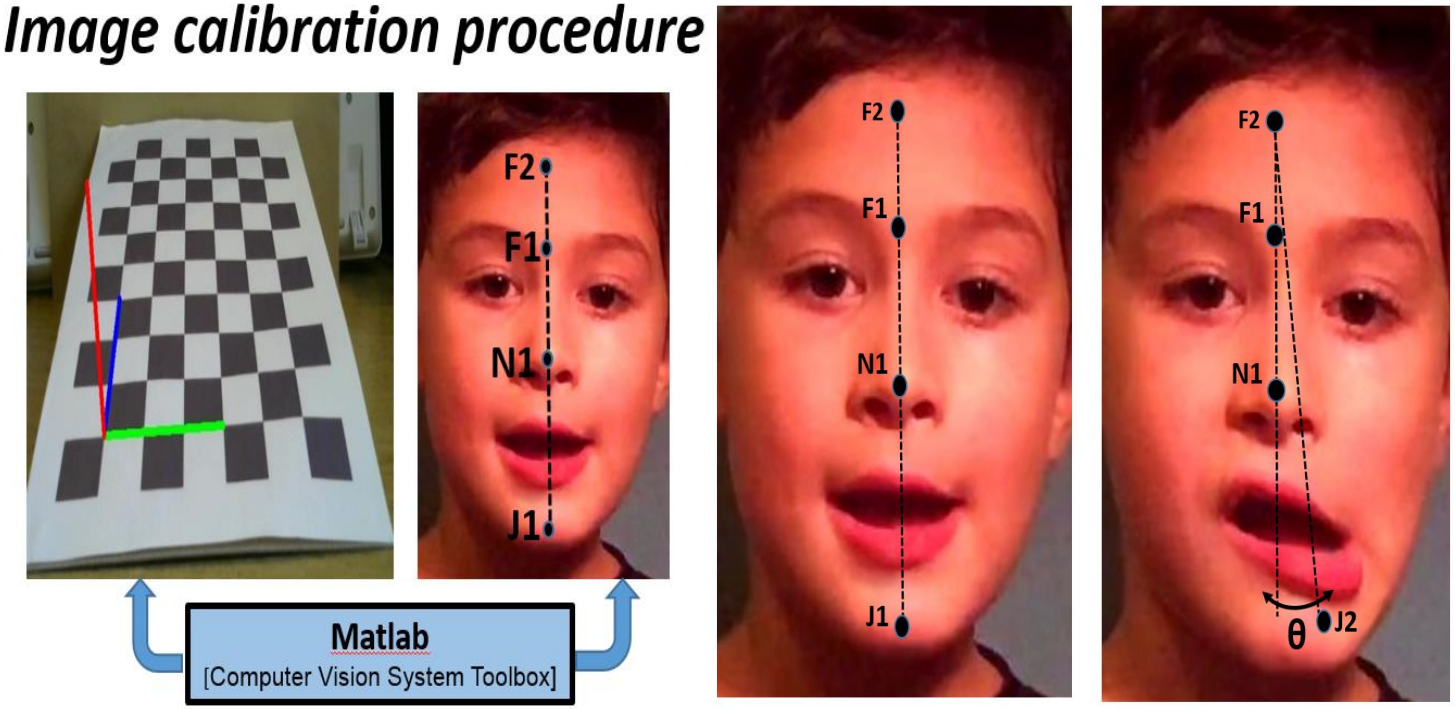
Phase 2: Refine

Assessment of a clinician's perceptual sensitivity to detect lateral jaw deviations

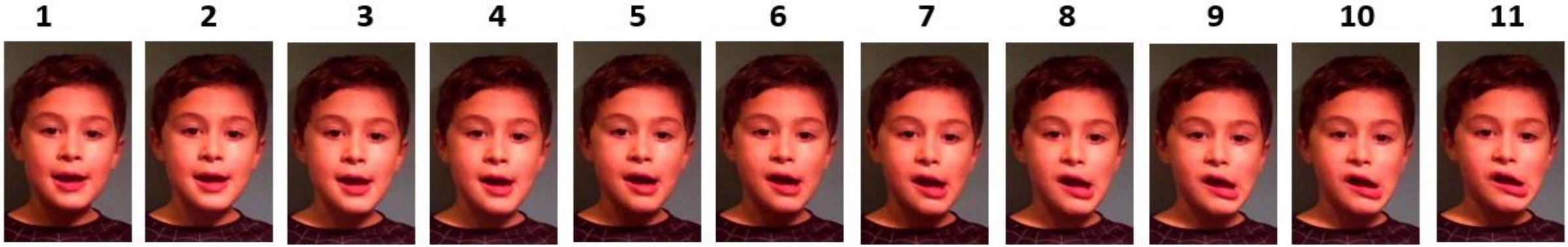
46 S-LPs with 2 different levels of clinical experience with MSD:

Novice = median 4 yrs
Expert = median 14 yrs
Controls = 7 non-S-LPs.

Image calibration procedure

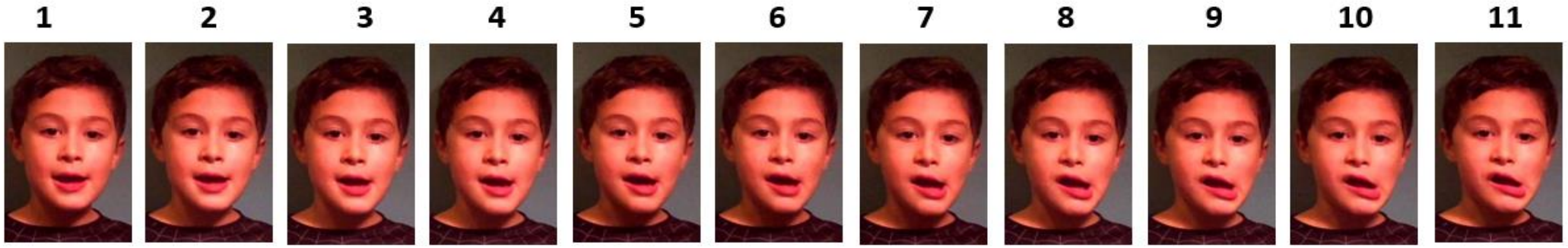


Clinical Outcome Research



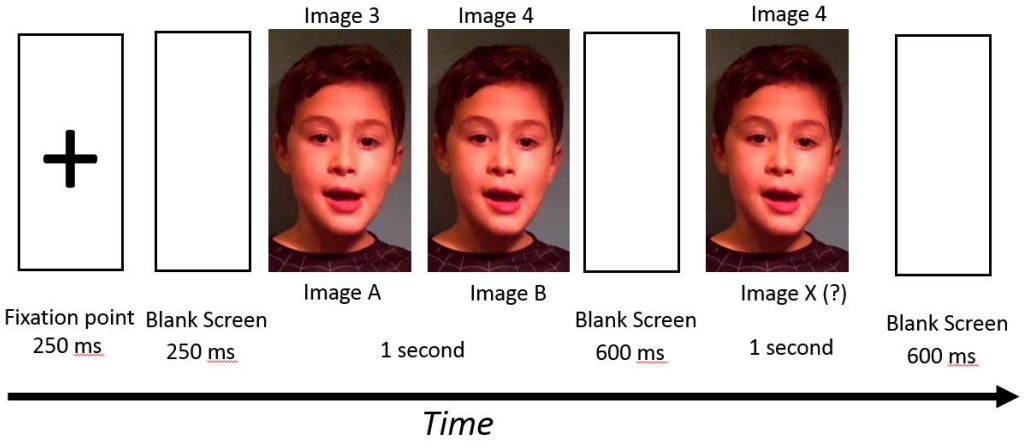
Stimuli: Linearly spaced continuum of 11 images (7-yr old child). Frame 1 = no lateral jaw deviation (0 radians), frame 11 = max jaw deviation (0.26 radians).

Task: Standard alternative forced choice identification procedure and ABX discrimination task using the 11 image stimuli set presented in random order.

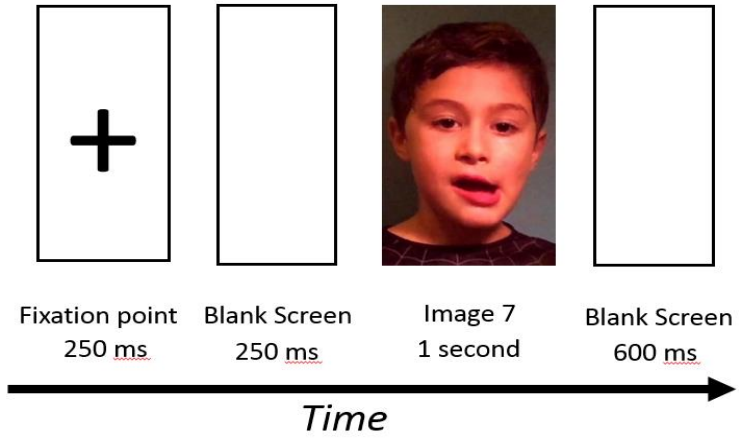


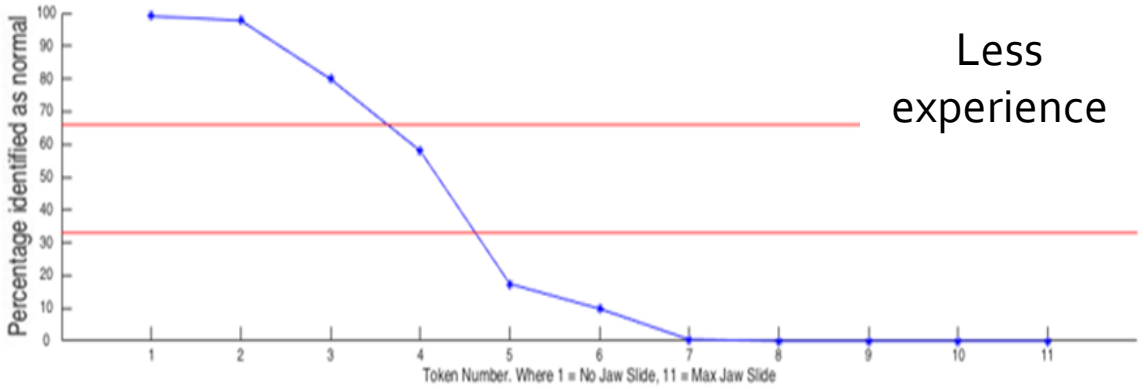
Frame	Image 1	Image 2	Image 3	Image 4	Image 5	Image 6	Image 7	Image 8	Image 9	Image 10	Image 11
Theta (radians)	0.01	0.03	0.06	0.08	0.11	0.14	0.17	0.19	0.21	0.24	0.26
Displacement (mm)	1	2.9	5.2	7.5	9.8	12.4	14.7	17.0	18.6	21.1	23

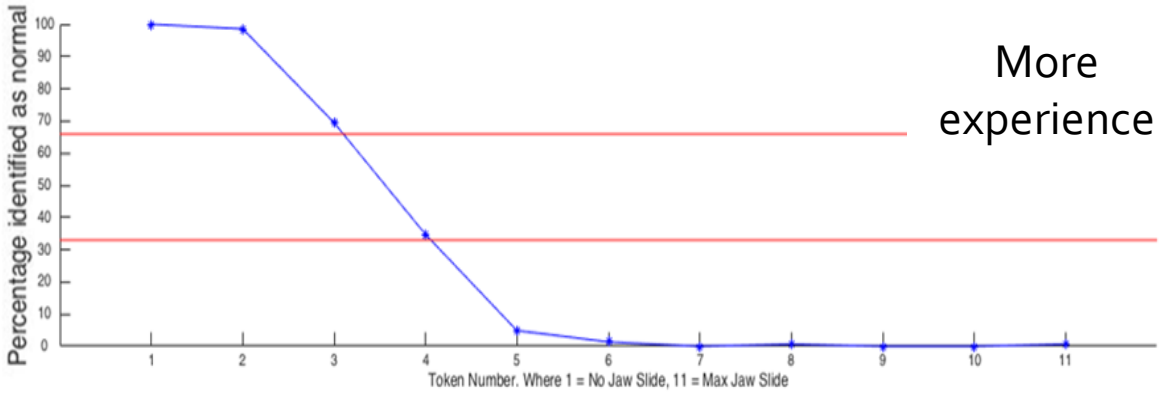
AB-X *perceptual discrimination task*

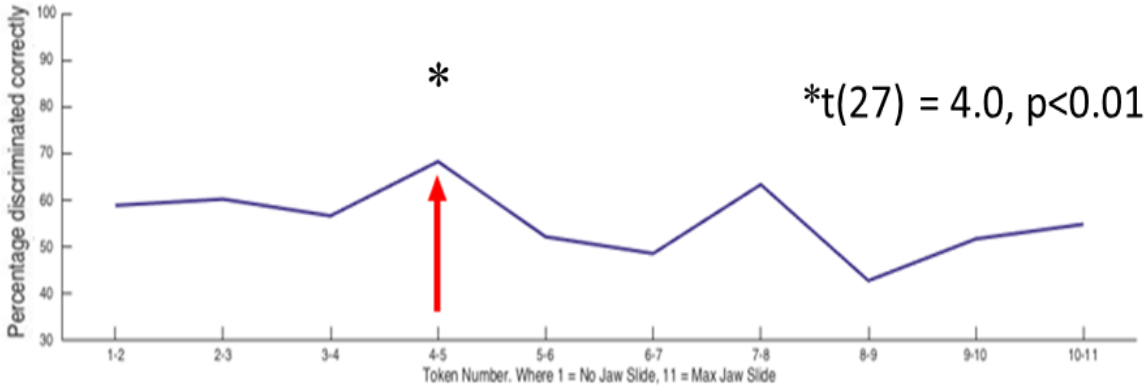


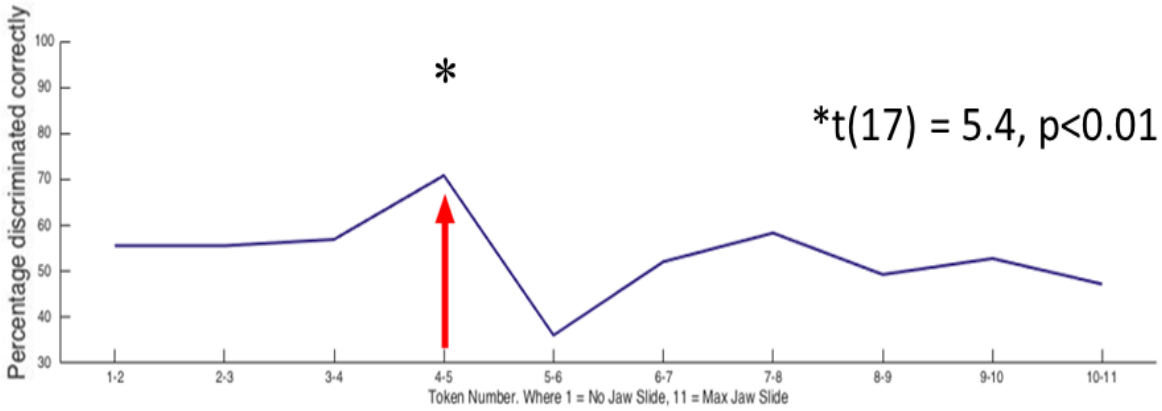
Alternative forced choice categorization (Identification) Task







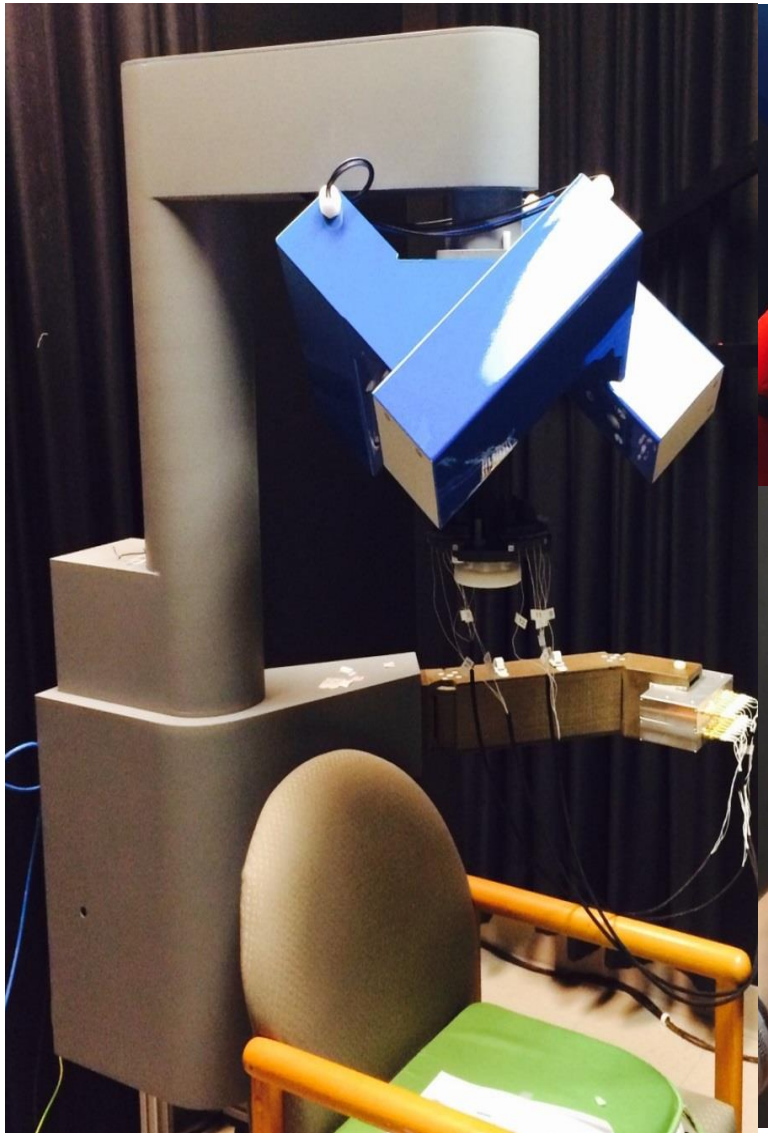




Results: Categorical perception mechanism for detection of typical Vs. Atypical. Experienced S-LPs relative to the novice group (experienced = 66% and novice = 35%; $Z = 2.051$ $p < 0.05$) were more sensitive than Controls (mean = 3.9) in the identification of jaw slide.

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)



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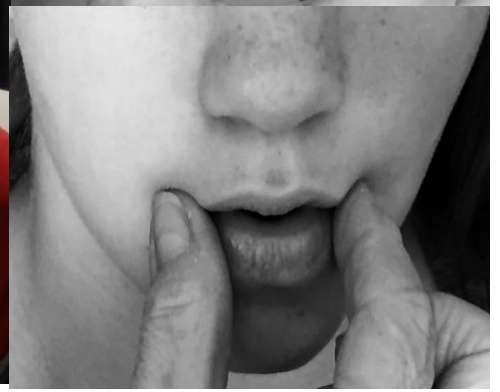

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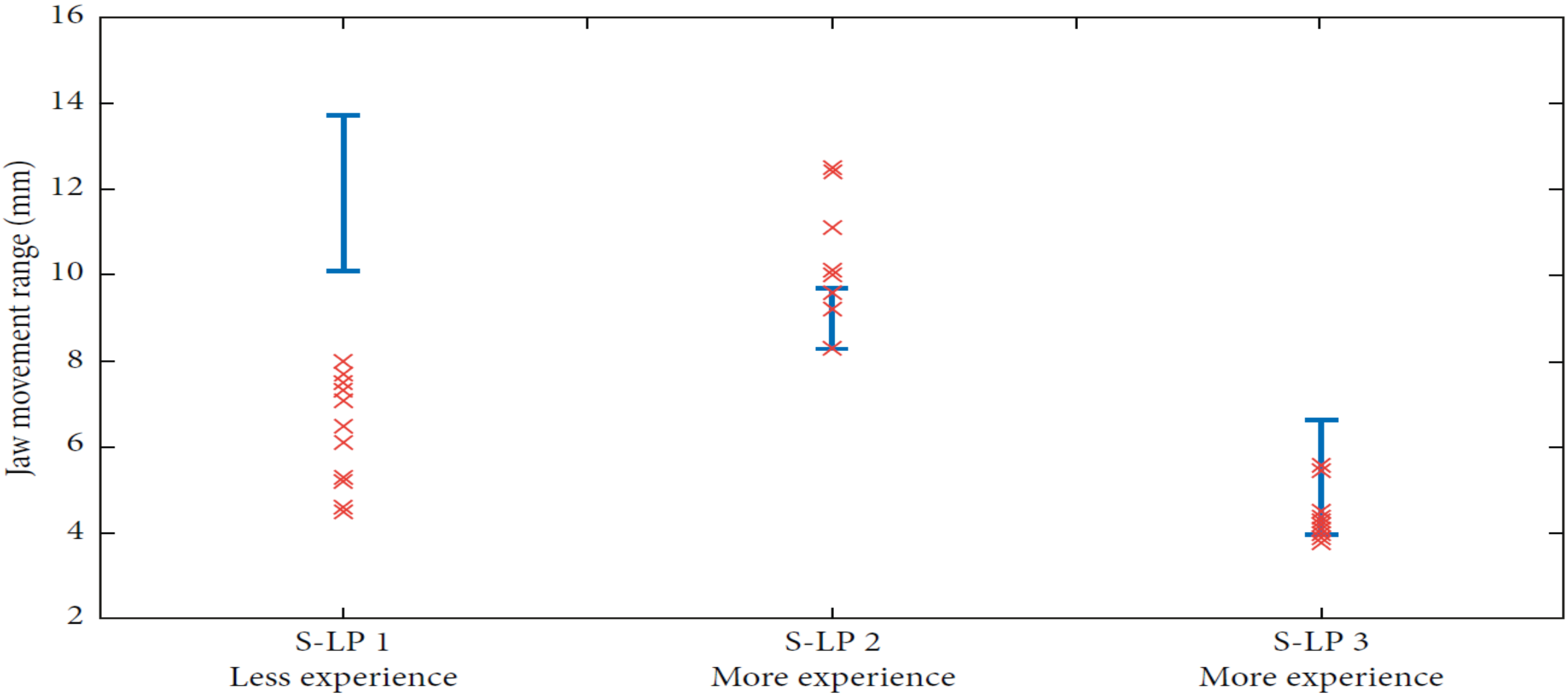
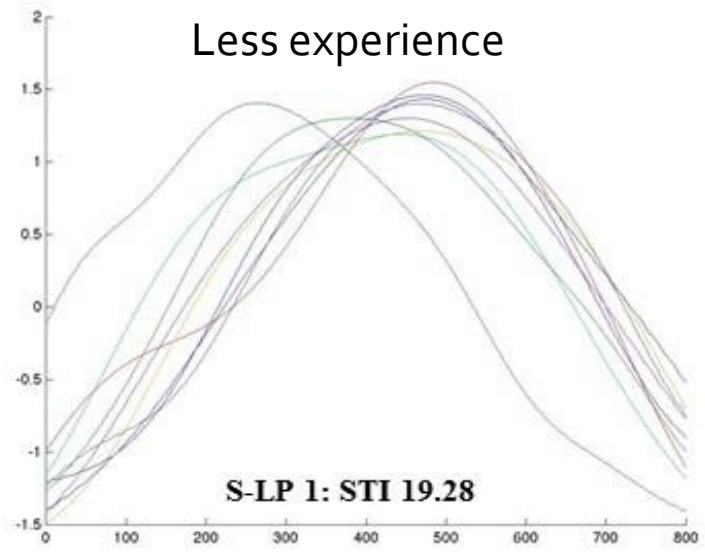
Clinical Outcome Research



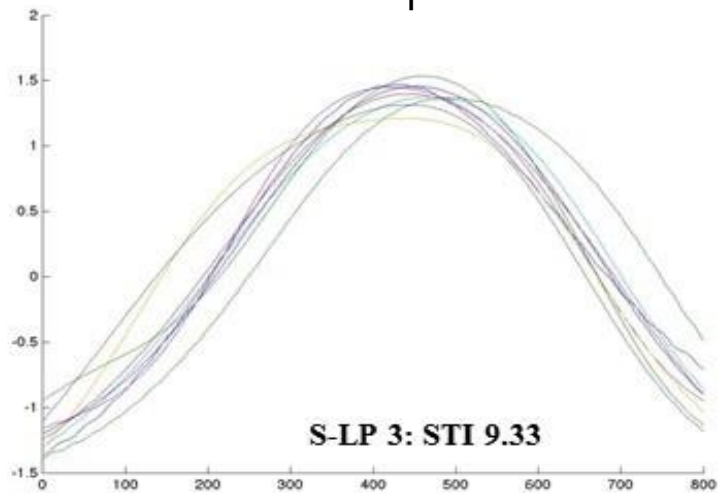
Kinematic consistency of upper lip movements (cyclic Spatial-Temporal Index (cSTI))

Less experience

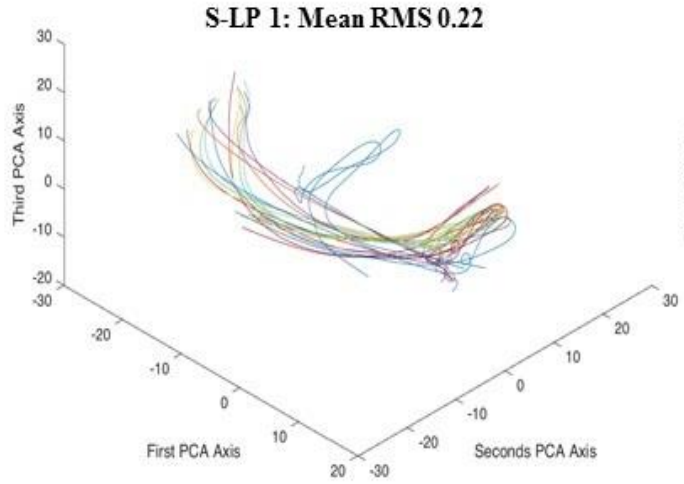


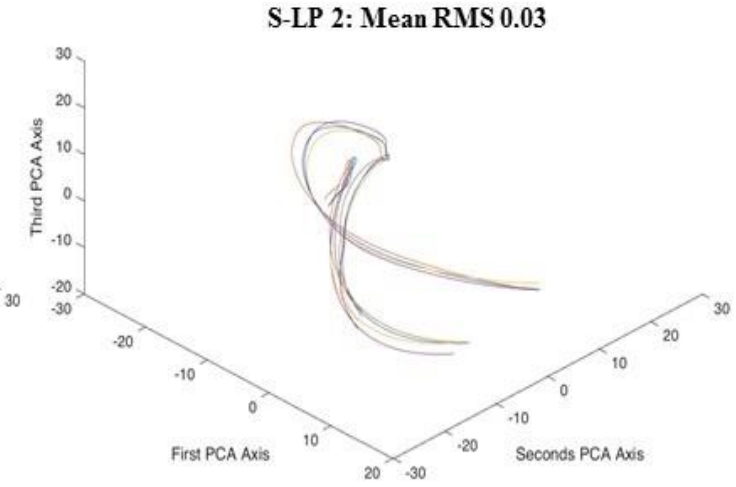
More experience

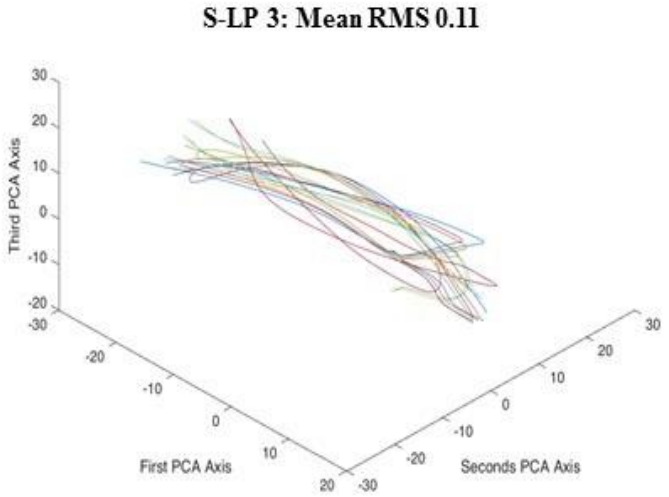
More experience

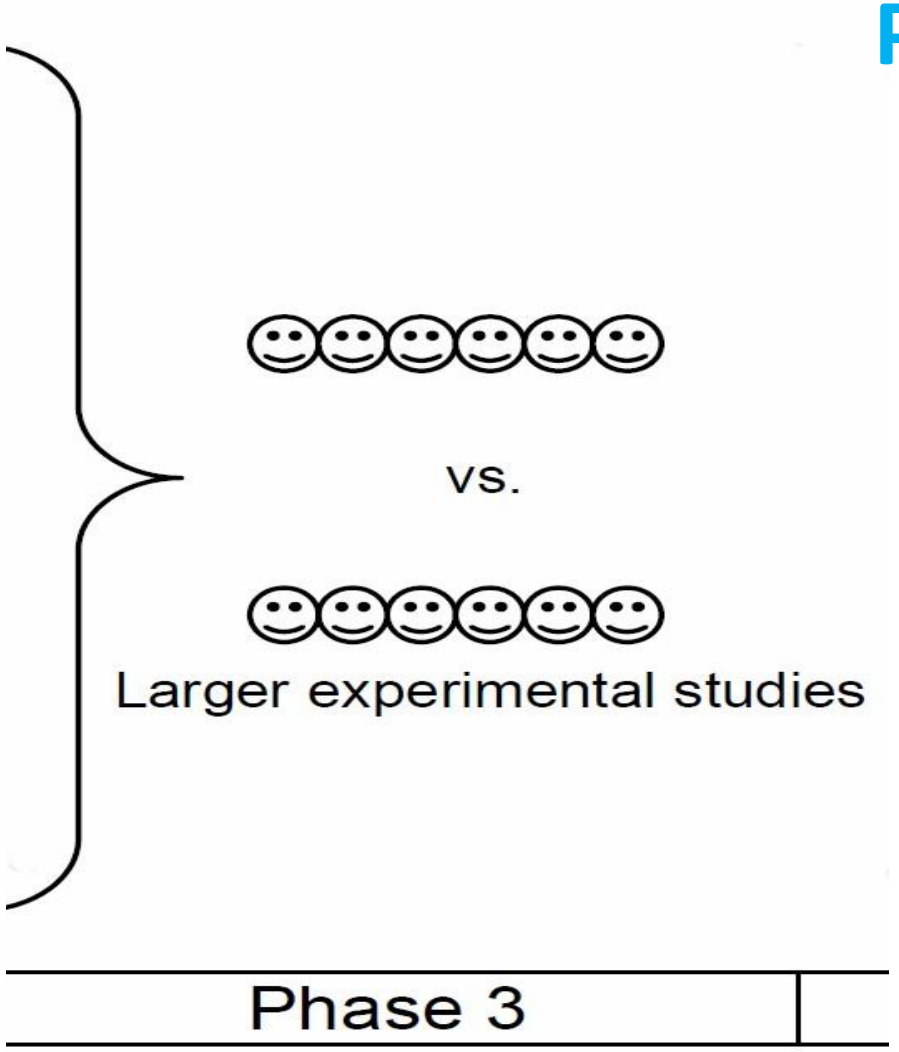


Consistency in shape of thumb finger movement trajectories (Generalized Orthogonal Procrustes Analysis).









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)

Phase 3: Efficacy

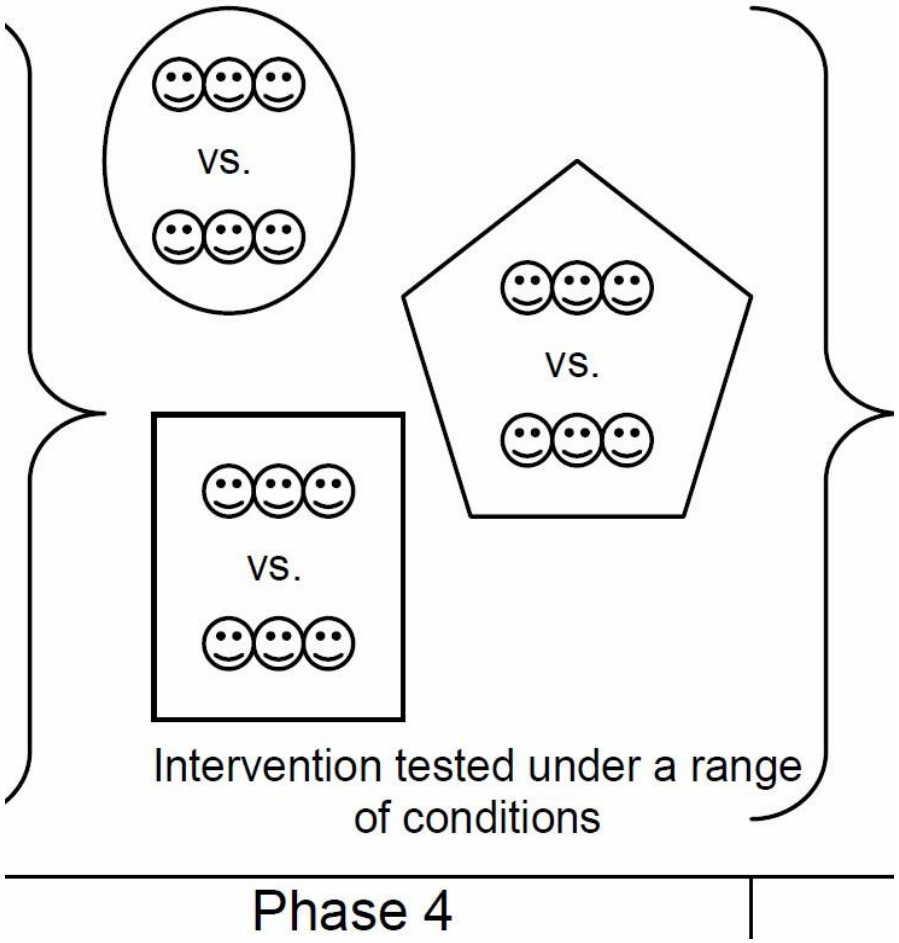
- **Aim:** to determine that observed outcomes are the direct result of treatment (i.e. to establish causality between independent and dependent variables)

ESTABLISHING CAUSALITY!

- **Methods:** require experimental control of extraneous variables that might affect outcomes
- Emphasize internal over external validity
- May not generalize to real-world conditions and clients

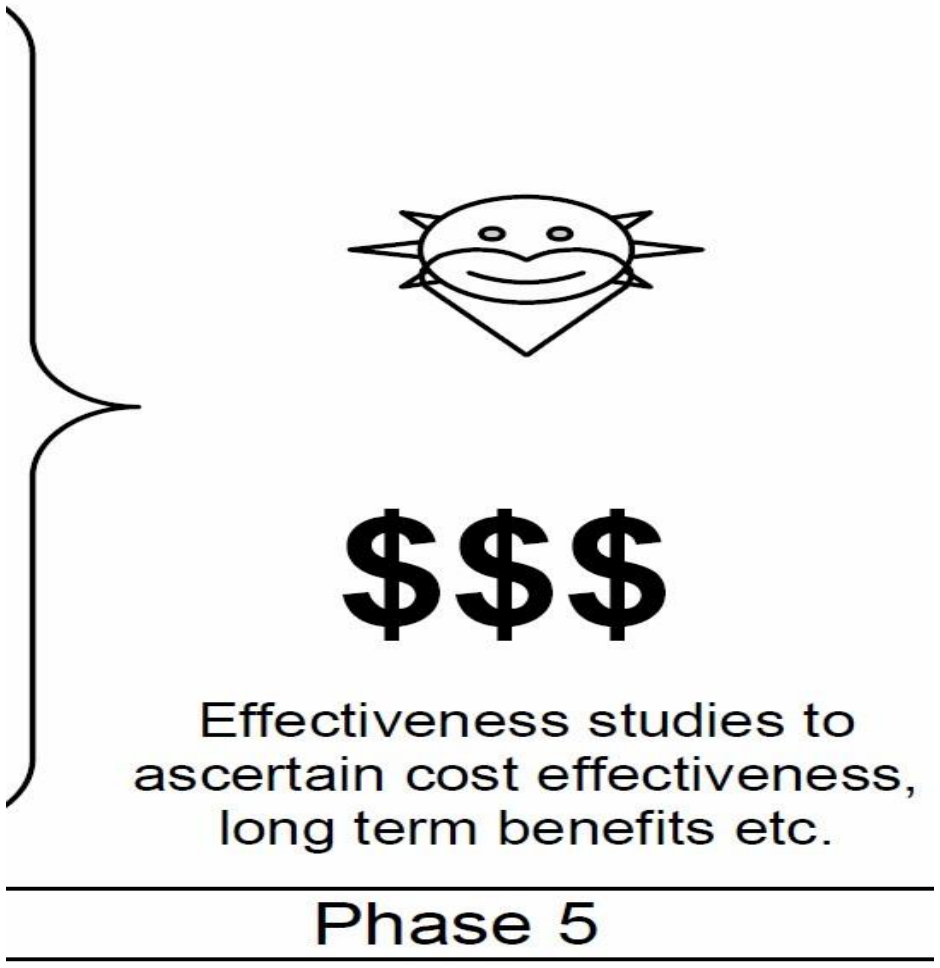
Clinical Outcome Research

Phase 4: Effectiveness



- Test <u>effectiveness after efficacy is established</u>.
- 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

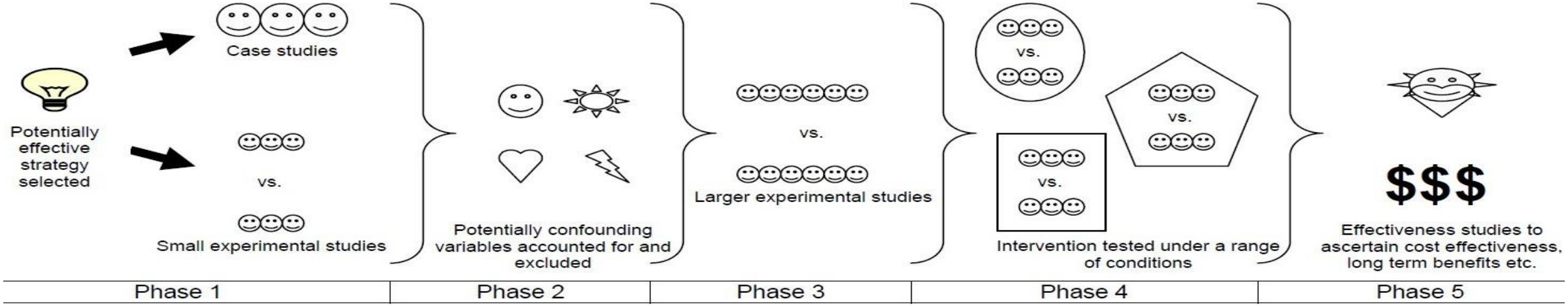


- Efficiency: cost-effectiveness/cost-benefit & long term benefits.
- Examination of patient and family satisfaction, quality of life
- Large samples required /external control not required (efficacy already established)
- Multiple single subject designs, single group designs

Clinical Outcome Research

5-Phase Outcome Research Model

(Robey &Schultz, 1998; Robey, 2004)



Exploration of Effects

Refine Efficacy

Ideal conditions

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

Effectiveness Efficiency

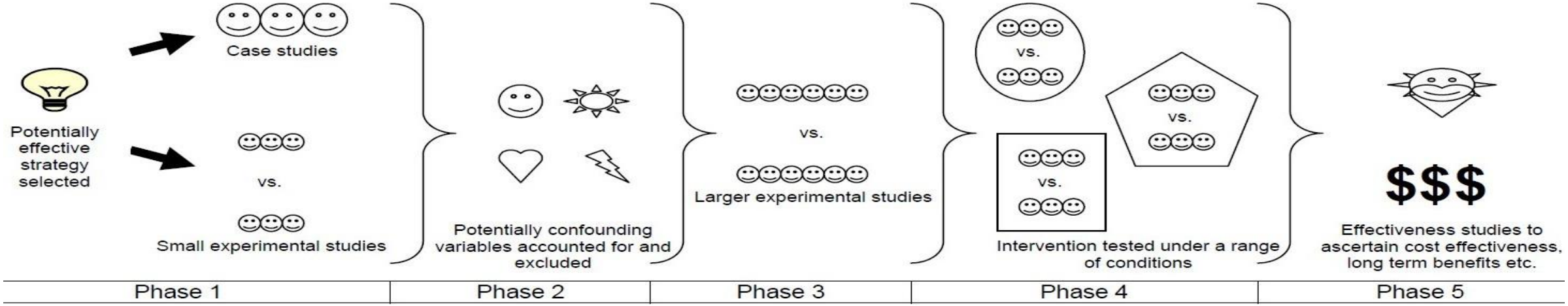
Average conditions

- *Does NOT establish causality.*
- *External validity*
- *Emphasize generalization*
- *Control group NOT needed!*

Clinical Outcome Research

5-Phase Outcome Research Model

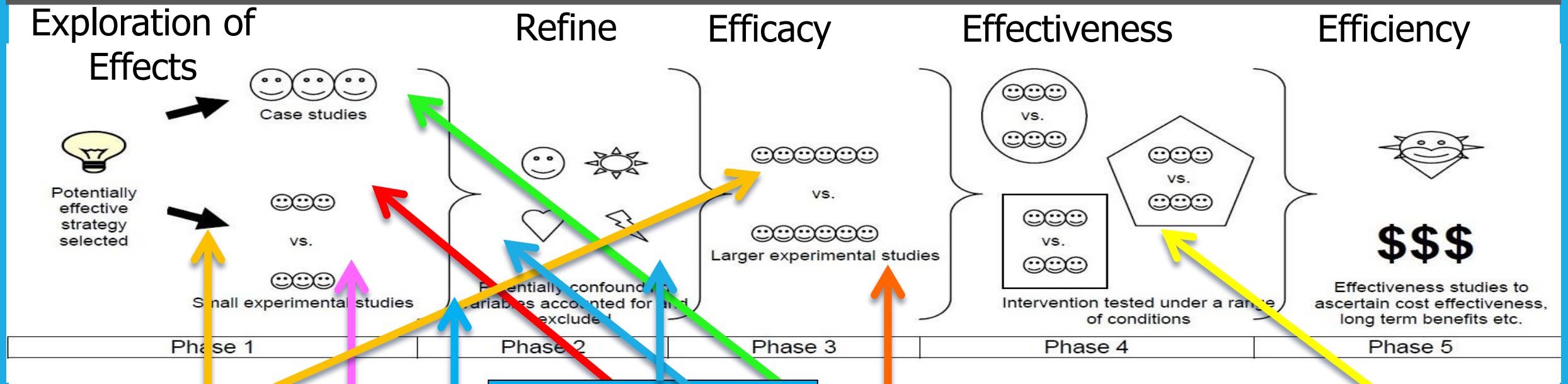
(Robey &Schultz, 1998; Robey, 2004)



Exploration of Effects | Refine | Efficacy | Effectiveness | Efficiency

Lets do a fun activity!

Clinical Outcome Research



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

Kearney et al., 2015 (outcomes measures)

RCT; Namasivayam 2018

Meta-analysis, 2020

Hayden et al 2015 Treatment Fidelity

Ward et al., 2013/14; CP

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

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.

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