

Case Report Form (CRF)

Group 1: PHONO 1 / VA 2 / C M 3 training

Coordinating center

Delegation for Clinical Research and Innovation

Developmental dyslexia and methods of remediation (DDMR). Multimodal intervention in French-speaking children aged 8 to 13 years: study protocol for a randomized multicenter controlled crossover trial

> DDMR Internal Code: ID No. RCB 2019-A01453-54 – No. 19-HPNCL-02

Case Report Form (CRF)

GROUP 1: PHONO 1 / VA 2 / IM 3 training

Center no.:					
Patier	nt no. <i>(or patient code):</i>				
Patient initials: $ _ - _ $ (1 st letter of last name – 1 st letter of first name)					
Sponsor:	Fondation LENVAL Hôpitaux Pédiatriques de Nice CHU-Lenval 57, Avenue de la Californie – 06200 Nice ≅: 04 92 03 03 92				
Coordinating Investigator:	Karine Harrar Eskinazi CERTA- Nice-CHU-Lenval 54 avenue de La Californie, 06200 Nice ≅: 04 92 03 92 00 ∃: 04 92 03 00 00 (@: karine.eskinazi@univ-cotedazur.fr				
Thesis director:	Pr Sylvane FAURE Laboratoire LAPCOS, UCA – MSHS – SE 24, avenue des Diables Bleus, 06357 NICE Cedex ≅: +33 4 89 15 23 72 @: sylvane.faure@univ-cotedazur.fr				
Thesis co-director:	Dr Bruno De Cara, MCF Laboratoire LAPCOS, UCA – MSHS – SE 24, avenue des Diables Bleus, 06357 NICE Cedex ≅: +33 4 89 15 23 72 @: bruno.de-cara@univ-cotedazur.fr				

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19-HPNCL-02	_ _ _ / / _ _ _	PHONO1/VA2/IM3 training

INSTRUCTIONS TO COMPLETE THE CASE REPORT FORM

1-GENERALITIES:

- Write in the designated space.
- Write in capitals.
- Use a black ballpoint pen.
- Do not use abbreviations.
- Complete the header on each page.

2-BOXES:

Open boxes (|__|_|): enter only one character per box. Closed boxes: check the corresponding answer

- Numeric values:
- Align the numerical values to the right
- Do not leave boxes empty, enter zero. E.g.: Incorrect: \[\(\bigcup_{\perp} \] \] Correct: \[\| \(\bigcup_{\perp} \] \]
- Dates: write dates in the day/month/year format (dd/mm/yyyy).

3-ERRORS:

In the event of an error, cross out the erroneous information with a single line so that it remains visible. Note the correction next to it, report, and date. Do not use correction fluid.

4-END OF STUDY:

When the patient's participation ends, whether at the end of the study or prematurely, complete the end-of-study sheet.

The end-of-study date:

It is the date of the last information collected as part of the study. No review related to the study, administration of the treatment under study, or data collection will be carried out after that date. The end-of-study date may be the date of the last visit or the date of the last information collected as part of the visit.

Early exit:

If the patient leaves the study before the end of the study, please specify the reason for this premature exit. If in doubt do not hesitate to contact the sponsor CRA (Clinical Research Associate) or the coordinating investigator. Premature exit by the patient: the patient may decide at any time to interrupt his or her participation in the study (refusal to continue / withdrawal of consent). All the data collected until the exit will be collected and analyzed (Jardé Law – Article L.1121-1-of the CSP, November 18, 2016 version).

5-CONTACT:

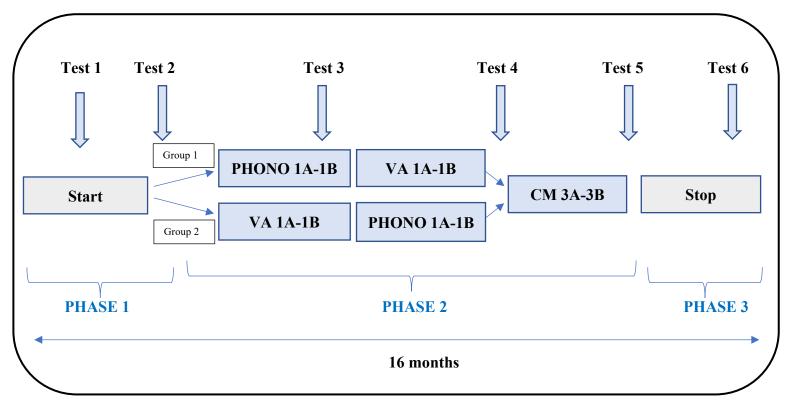
If any problems arise when filling out the CRF, please contact the sponsor (contact details mentioned on page 1).

6-Specific conventions for filling out the CRF:

- The data is collected in the tables included in this CRF in raw scores, Z scores and percentiles according to the instructions provided in the manuals for each test.
- For children with "high intellectual potential" the reading age must be compared with the age of development and not with the actual age.
- For Alouette©, two calibrations are used: the first calibration for the reading age and the second calibration dating from 2005.
- For DeltaText and Likert scales, there are no Z scores.
- Training is adapted to the cognitive profile of each child. For example, the child that does not have a visuo-attentional span disorder will complete 2 months of training with Switchipido© and will not practice with Maeva©. Therefore, the pre- and post-training baseline tables for Maeva© will not be used.

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Timeline and experimental procedure



PHONO: phonological; VA: visuo-attentional; CM: cross-modal

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	PHASES	Visits	Details and duration of the assement or interve	ntion
P	TEST 1	V 1 to V4	Information, consent, selection Baseline assessment	4 hr
h a s e	No intensive training 2 months	V 5 to V 12	Speech therapy sessions (STS): 30 min/week	STS: 4 hr
1	TEST 2	V 13- V 14	Post-control assessment	2 hr
		V 15	Pre-training 1A baseline assessment	30 min
P		V 16 to V 19	Home training (HT): 5 days/week-15 min/day Speech therapy sessions (STS): 30 min/week	HT: 5 hr STS: 2 hr
h	INTENSIVE TRAINING 1	V 20	Post-training 1A baseline assessment	15 min
а	2 months	V 21	Pre-training 1B baseline assessment	30 min
e e		V 22 to V 25	Home training (HT): 5 days/week-15 min/day Speech therapy sessions (STS): 30 min/week	HT: 5 hr STS: 2 hr
2			Post-training 1B baseline assessment	10 min
	TEST 3	V 26	Post-training assessment 1	50 min
	Break	V 27, V 28	15 days without home training	1 hr
		V 29	Pre-training 2A baseline assessment	30 min
P	INTENSIVE TRAINING 2	V 30 to V 33	Home training (HT): 5 days/week-15 min/day Speech therapy sessions (STS): 30 min/week	HT: 5 hr STS: 2 hr
h		V 34	Post-training 2A baseline assessment	15 min
а	2 months	V 35	Pre-training 2B baseline assessment	30 min
s e		V 36 to V 39	Home training (HT): 5 days/week-15 min/day Speech therapy sessions (STS): 30 min/week	HT: 5 hr STS: 2 hr
2		V 40	Post-training 2B baseline assessment	10 min
	TEST 4	V 40	Post-training assessment 2	50 min
	Break	V 41, V 42	15 days without home training	1 hr
P		V 43	Pre-training 3 baseline assessment	30 min
h a s e	a s INTENSIVE TRAINING 3 2 months		Home training (HT): 5 days/week-15 min/day Speech therapy sessions (STS): 30 min/week	HT: 10 hr STS: 4 hr
		V 52	Post-training 3 baseline assessment	10 min
2	TEST 5	V 53-54	Post-training assessment 3	2 hr
P h a s	No intensive training 2 months	V 56 to V 64	Stop home training Speech therapy sessions (STS): 30 min/week	STS: 4 hr
3	TEST 6	V 65	Follow-up assessment 15	
				_

Internal Code	Patient Number	Group 1
19-HPNCL-02		Training PHONO1/VA2/IM3

PHASE 1 – TEST 2 – V 5 to V 14

SPEECH THERAPY SESSIONS (V 5 TO V 12)

For two months, the children are seen once a week for 30 minutes at the speech therapist's office, by the therapist who carried

out the assessment. During these sessions, reading and spelling exercises are performed to compensate for the disorders. There is no daily home training during this phase.

	DATES (DD/MM/YYYY)	Reading	Spelling
V5	_ _ / _ / _		
V6	_ _ / _ / _ /		
V7	_ _ / _ / _ /		
V8	_ _ / _ / _		
V9	_ _ / _ / _		
V10	_ _ / _ / _		
V11	_ _ / _ / _ _		
V12	_ _ / _ / _		

POST-CONTROL ASSESSMENT – V 13 – TEST 2 (PART 1)

For the administration and order of the tests, refer to the "testing manuals". Tests must be administered in a random order to be different for each participant.

Date:	1/1 1	1/1 1	(DD/MM/YYYY)

- Reading meaningless text (Alouette©)
- Spelling (Chronosdictées© version B)
- Reading meaningful text: **Pingouin** (Evaléo© 6-15)
- Phonological analysis, non-word repetition, rapid automatized naming (Evalec©)
- Visuo-attentional span (Evadys©)
- Perception of the evolution of the reading disorder by the child and his parents evaluated by two questionnaires

(Likert scales)

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19-HPNCL-02		Training PHONO1/VA2/IM3

	т	ests	Data	Raw scores	Rate + or -	Z Scores (SD or percentiles)	Time (min)	
			Number of errors	111		111.11		
			Number of words read	111		111.11		
			Number of correct words	111		111.11		
	Reading meaningless text	"Alouette©"	Time in seconds	111		111.11	3	
			Accuracy index	111		111.11		
			Speed index	111		111.11		
			Reading age	_ yea	rs	months		
			Number of phonetic errors	111		111.11		
			Number of lexical errors	1_1_1		111.11		
		"Chronosdictées©	Number of grammatical errors	1_1_1		111.11	10	
P H	Spelling Test	" Version B	Number of omissions	111		111.11	10	
A			Number of segmentation errors	111		111.11		
E			Total number of errors	1_1_1		111.11		
1			Number of words read	111		11		
	Reading meaningful text	: "Pingouin"	Number of correct words	111		11	2	
	"EVALEO©"		% correct/read	1_1_1_1.1_1		11	2	
			Degradation Index	111		11		
		Syllable suppression	Accuracy (% errors)	1_1_1_1.1_1		111.11		
E			Time in seconds	111_1-1-11		111.11		
S T		Phoneme	Accuracy (% errors)	1111.11		111.11	3	
2		rness	Time in seconds	111_1-1-1		111.11		
			Accuracy (% errors)	1111.11		111.11		
	Phonological awarness		Time in seconds	111_1.11		111.11		
	"EVALEC©"	Non-word repetition	Span	11		111.11	1	
V 1		repetition	Time in seconds	111_1.11		111.11		
3			Color recognition, %	1_1_1		111.11		
		Rapid Automatized	Color recognition, time in seconds	111_1-11		111.11	- 2	
		Naming	Reading names, %	1_1_1_1.1_1		111.11	-	
			Reading names, time in seconds	111_1.11		111.11		
		Letter threshold	Threshold in ms	1_1_1_1		111.11		
	Visuo-	Global Report GR	GR Score	111		111.11		
	attentional span "EVADYS"		GR Span	11.111		111.11	20	
		Partial Report PR	PR Score	111		111.11		
			PR Span	11.111				
	Surveys-Likert scale	Child pre-test	Total points	111			5	
		Parents pre-test	Total points	1_1_1				
			Total tin	ne (min)			46	

Internal Code	Patient Number	Group 1
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POST-CONTROL ASSESSMENT – V 14 – TEST 2 (PART 2)

For the	administration	and order	of the tests,	refer to the	testing manuals.

Date: |__|_/|__|/|__|_| (DD/MM/YYYY)

- Global/local analysis (SIGL©)
- Reading regular, irregular words and non-words aloud (Evalec©)
- Short-term verbal memory and working memory, digit span (Evaléo©)
- Visuo-spatial span (Corsi©)
- Written comprehension (Orlec©)
- Reading meaningless text: DeltaText 2 (Bedoin©)
- Words read in 2 min, EVAL2M (Evaléo©)

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	т	ests	Data	Raw scores	Rate +	Z Scores	Time (min)
			Local RT (ms)	1_1_1_1-1-1		1_1_1-1-1_1	
	Global/local analysis	Response time (RT)	Global RT (ms)	1_1_1_1-1-1		111.11	
			Interference asymmetry RT (ms)	1_1_1_1-1-1_1		1_1_1.1_1_1	
	"SIGL© Drawings"		Local ER (%)	1_1_1_1-1-1_1		111.11	20
		Error Rate (ER)	Global ER (%)	1_1_1_1-1-1_1		111.11	
			Interference asymmetry ER (%)			_ .	
		Regular words	Accuracy (% errors)	- - - -		_ .	
		(RW)	Time in ms	_		_ .	
		Irregular words	Accuracy (% errors)	_ - - - -		_ .	
P H		(IW)	Time in ms	_ _		_ .	8
A		Non-words (NW)	Accuracy (% errors)	_ - - - -		_ .	
E		Non-words (NVV)	Time in ms			111-11	
1	Word reading	Short IW	Accuracy (% errors)	1_1_1_1-1-1_1		_ .	
	"EVALEC©"	SHOLLING	Time in ms			_ .	
		Long IW Short NW	Accuracy (% errors)	1_1_1_1.1_1_1		1_1_1-1-1_1	
			Time in ms	_ _ _		111-11	
			Accuracy (% errors)	1_1_1_1.1_1_1		1_1_1-1-1_1	
E			Time in ms	1_1_1_1_1		111-11	
S		Long NW	Accuracy (% errors)	1_1_1_1.1_1_1		111-11	- 5
2		Long IVV	Time in ms	1_1_1_1_1		111-11	
			Score forward span	II		1_1	
	Digit span	"EVALEO©"	Forward span	11		1_1	8
			Score backward span	II		11	
V 1			Backward span	II		1_1	
4	Visuo-spatial	"Corsi©"	Forward span	II		III · II	8
	span		Backward span	II		.	
	Written	"Orlec©, L3"	Number of correct items	111		.	5
	comprehension		Percentage of correct items	.		.	
			Number of words read	_			
	Reading meaningless text	"DeltaText© 2"	Number of errors	_			3
			Time in seconds	111			
			Number of words read	111		II	
	Words read in 2 min	"Eval 2M©"	Number of correct words	III		ll	2
			% correct/read	_ .		II	
	Total time (min) 59						

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PHASE 2 – PHONO 1 TRAINING – TEST 3 – V 15 to V 26

PRE-TRAINING PHONO 1A BASELINE ASSESSMENT, INSTRUCTIONS, V 15

Date: |__|_| / |__| / |__| (DD/MM/YYYY)

If the participant has been randomized to Group 1, she/he begins with phonological training. Phonological training
lasts two months and must be adapted by the clinician to the participant's cognitive profile based on the
results obtained in the Evalec test (phonological analysis, non-word repetition, rapid automated naming) and
Rapdys assessment.

For one month, the child will complete Phono 1A training if she/he obtains a score of less than -1.5 SD on at least one

Evalec test and a score of less than 70% in identification and/or discrimination in the Rapdys evaluation test. The exercises target phoneme fusion and categorical perception. Before starting the training, administer the following baseline tests and report the results in the table below.

NB: If the participant does not have a categorical perceptual disorder, complete Phono 1B training.

PHONO 1A training – first month – V 15				
Pre	Pre-training PHONO 1A baseline Raw scores			
	Phoneme fusion, accuracy out of 10	_ _		
BSL 1	Phoneme fusion, time in seconds	_ _	2	
Items seen	Rapdys, identification, %	_ _	5	
	Rapdys, discrimination, %	_ _	3	
	Phoneme fusion, accuracy out of 10		2	
BSL 2 Items not	Phoneme fusion, time in seconds	_ _	2	
seen	Spoonerism (Evaléo) accuracy	<u> </u>	5	
	Spoonerism (Evaléo) time	_ .	3	
BSL 3	Reading non-words, score out of 20	_ _	1	
	Reading non-words, time in seconds	_ _ . . .	1	
BSL 4	Fluidity drawings in 1 min		1	
Total time				

Give instructions to parents and children on how to complete 1A *phonological training* for 1 month at home (15 minutes a day, 5 days a week). See group 1 instruction manual.

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Internal Code	Patient Number	Group 1
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SPEECH THERAPY SESSIONS (V 16 TO V 19)

During the home training phase, the children are trained once a week for 30 minutes by the speech therapist, at the latter's office. They complete their exercises for 15 minutes with the speech therapist who checks the smooth

running of the training. The rest of the session is focused on reading and spelling exercises

	DATES (DD/MM/YYYY)	Reading	Spelling	Training
V16	_ _ / _ / _ _			
V17				
V18				
V19	/ / _			

Internal Code	Patient Number	Group 1
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POST-TRAINING PHONO 1A BASELINE ASSESSMENT, V 20

After one month of 1A phonological training, administer the same post-training baseline tests and report the results in the

table below.

	PHONO 1A training – first month – V 20		
Pos	st-training PHONO 1A baseline	Raw scores	
	Phoneme fusion, accuracy out of 10	_	
BSL 1	Phoneme fusion, time in seconds		2
Items seen	Rapdys, identification, %		5
	RapDys, discrimination, %		3
	Phoneme fusion, accuracy out of 10	_	2
BSL 2	Phoneme fusion, time in seconds		2
Items not seen	Spoonerism (Evaléo) accuracy		. 5
	Spoonerism (Evaléo) time	_ _ .	3
BSL 3	Reading non-word, score out of 20	_ _	1
	Reading non-word, time in seconds	_ _ . .	1
BSL 4	Fluidity drawings in 1 min	_	1
Total time			16

PRE-TRAINING PHONO 1B BASELINE ASSESSMENT, SECOND MONTH

Date: / /	(<i>DD/MM/YYYY</i>)
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After the first month of training, further exercises of the 1B phonological

training program are prescribed the second month if the participant achieves a score of less than 1.5 standard deviation in at least one Evalec test.

The exercises target phoneme segmentation and phonological memory.

Before starting training, complete the following baseline tests and report the results in the table below.

NB: Note: If the participant does not have a phonological short-term memory impairment, refer to the CRF G1 RAN/VA/CM for rapid automatized naming training.

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PHONO 1B training – second month – V 21				
	Pre-training PHONO 1B baseline	Raw scores		
	Phoneme segmentation, accuracy out of 10	_ _	2	
BSL 1 Items seen	Segmentation of phonemes, time in seconds	_ _	2	
	Comparisons of 5 sound sequences (Phonopidow)	_ _	2	
	Phoneme segmentation, accuracy out of 10	_ _	2	
BSL 2	Segmentation of phonemes, time in seconds		2	
Items not seen	Hearing acronyms (Belec), accuracy		2	
	Hearing acronyms (Belec), time	_ _ . .		
BSL 3	Reading non-word, score out of 20		1	
BSL 3	Reading non-word, time in seconds	_ _ . .	1	
BSL 4 Mathematical symbols, items completed in 1 min		1		
Total time			10	

Give instructions to parents and children on how to perform 1B phonological training for 1 month at home (15 minutes

a day, 5 days a week). See group 1 instruction manual.

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SPEECH THERAPY SESSIONS (V 22 TO V 25)

During home training, the children are seen by the speech therapist once a week for 30 minutes at the speech therapist's office. They complete their exercises for 15 minutes with the speech therapist who checks the smooth running of the training. The rest of the

session is focused on reading and spelling exercises (i.e. the automation of grapheme/phoneme matches for graphemes that have not yet been acquired, such as syllabic impregnation, Borel gestures, etc.).

	DATES (DD/MM/YYYY)	Reading	Spelling	Training
V22	_ _ / _ / _ _			
V23	_ _ / _ / _ _			
V24	_ _ / _ / _ _			
V25	_ _ / _ / _ _			

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POST-TRAINING PHONO 1B BASELINE ASSESSMENT, V 26
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Date: _ / /	(DD/MM/YYYY)
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After one month of training, administer the same post-training PHONO 1B baseline tests and report the results in the table below.

PHONO 1B training – second month – V 26						
	Post-training PHONO 1B baseline Raw scores					
	Phoneme segmentation, accuracy out of 10	_ _	2			
BSL 1 Items seen	Segmentation of phonemes, time in seconds	_ _	2			
	Comparison of 5 sound sequences (Phonopidow)	_ _	2			
	Phoneme segmentation, accuracy out of 10		2			
BSL 2	Segmentation of phonemes, time in seconds		2			
Items not seen	Hearing acronyms (Belec), accuracy		2			
	Hearing acronyms (Belec), time	_ _ . .	2			
BSL 3	Reading non-words, score out of 20		1			
DSL 3	Reading non-words, time in seconds	_ _ . _	1			
BSL 4	Mathematical symbols, items completed in 1 min	_ _	1			
Total time			10			

POST-TRAINING ASSESSMENT 1 – V26 – TEST 3

For the administration and order of the tests, refer to the "testing manuals". Tests must be administered in a random order to be different for each participant.

During the same session, V 26, administer Test 3 at the end of the two months of phonological training 1.

- Reading meaningless text, DeltaText© 3 (Bedoin)
- Reading meaningless text, Alouette©
- Reading meaningful text, La Mouette (Evaléo© 6-15)
- Words read in 2 min, EVAL2M (Evaléo© 6-15)
- Attentional focus local/global (SIGL©)
- Phonological analysis, non-word repetition, rapid automatized naming (Evalec©)
- Visuo-attentional span (Evadys©)

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	Tests		Data	Raw scores	Rate +	Z Scores (SD or percentiles)	Time (min)	
			Number of errors	111		111.11		
			Number of words read	1_1_1_1		111.11		
			Number of correct words	1_1_1_1		111.111	:	
	Reading meaningless text	"Alouette©"	Time in seconds	1_1_1_1		111.111	3	
			Accuracy index	1_1_1_1		111.111	:	
			Speed index	1_1_1_1		111.111		
			Reading age	_ yea	rs	months		
			Number of words read	1_1_1_1				
	Reading meaningless text	"DeltaText© 2"	Number of errors	1_1_1_1			3	
			Time in seconds	1_1_1_1				
			Number of words read	1_1_1_1		II		
	Words read in 2 min	"Eval 2M©"	Number of correct words	1_1_1_1		11	2	
			% correct/read	1_1_1_1-1-1		11	:	
			Number of words read	1_1_1_1		11		
P H	Reading		Number of correct words	1_1_1_1		11		
A	meaningful text "EVALEO©"	"Mouette"	% correct/read	1111.11		11	2	
E			Degradation Index	1_1_1_1		11		
2			Local RT (ms)	1111-11		111.11		
			Global RT (ms)	1111.11		111.11		
	Global/local analysis		Interference asymmetry RT (ms)	1111.11		111.11		
E	"SIGL© Drawings"		Local ER (%)	1_1_1_1-1-1		111.11	20	
S T			Error Rate (ER)	Global ER (%)	1_1_1_1-1-1		111-11	
3			Interference asymmetry ER (%) _ _ _ .			111.11		
		Letter threshold	Threshold in ms	111		111.11		
V 2		Global Report	GR Score	1_1_1_1		111.11		
6	Visuo- attentional span "EVADYS©"	(GR)	GR Span	11.111		111.11	20	
	"EVADYS@"	Partial Report	PR Score	111		111.11		
		(PR)	PR Span	11.111		111.11		
		Syllable	Accuracy (% errors)	1111		111.11		
		suppression	Time in seconds	1_1_1_1-1-1		111.11		
		Phoneme	Accuracy (% errors)	1111.11		111.11	3	
		Suppression CVC	Time in seconds	1111.11		111.11		
		Phoneme	Accuracy (% errors)	1111		111.11		
	Phonological awarness "EVALEC©"	suppression CCV	Time in seconds	1_1_1_1-1-1		111.11		
		rness	Span	1_1		111.11	1	
		repetition	Time in seconds	1_1_1_1-1-1_1		111.11		
			Color recognition, %	1_1_1		111.11		
		Rapid	Color recognition, time in seconds	1_1_1_1-1-1		111.11		
		Automatized Naming	Reading names, %	1111		111.11	2	
			Reading names, time in seconds	1_1_1_1-1-1		111.11		
			Total tin	ne (min)			51	

Internal Code	Patient Number	Group 1
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15-DAY BREAK WITHOUT TRAINING

A 15-day break without training is provided before moving on to 2 periods of visuo-attentional training. Weekly sessions continue at the office if the participant is not on vacation. In this case, please indicate it in the "comments."

	DATES (DD/MM/YYYY)	Reading	Spelling	Comments
V27	_ _ / _ / _ _			
V28	_ _ / _ / _ _			

PHASE 2 - VA 2 TRAINING - TEST 4 - V 29 to V 40

PRE-TRAINING VA 2A BASELINE ASSESSMENT-INSTRUCTIONS

Date:		/ _	_ /				(DD/MM/YYYY))
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After phonological training 1, the participants complete visuo-attentional training 2 for two months.

VA training *must* be adapted by the investigator to the participant's cognitive profile based on the results obtained on the Evadys test (global report and partial report) and SIGL (interference asymmetry, TE and TR).

For one month, the child will complete VA 2A training if she/he achieves a score of less than 1.5 standard deviation on at least one Evadys test. The exercises target the visuo-attentional span and spelling memory.

Before you start training, administer the following baseline tests, and report the results in the table below.

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ / _ _ / _ _ _	Training PHONO1/VA2/IM3

VA 2A training – first month – V 29								
	Pre-training VA 2A baseline Raw scores							
BSL 1	Maeva, score out of 10 (accuracy)		1					
DCI 2	VA global span numbers (Evaleo)	_ · _ _	4					
BSL 2	RC, EVA, out of 100 _							
BSL 3	Reading irregular words, score out of 20 _							
DSL 3	Reading irregular words, time in seconds	_ _ . .	1					
BSL 4	BSL 4 Codes, time in seconds							
Total time	e		7					

Then give instructions to parents and the child on how to complete the visuo-attentional training 2A for 1 month at home (15 minutes a day, 5 days a week). See the "testing manual" for instructions.

SPEECH THERAPY SESSIONS (V 30 TO V 33)

During home training, children are seen by the speech therapist once a week for 30 minutes at the speech therapist's office. They complete their exercises for 15 minutes with the speech therapist who checks the smooth running of the training. The rest of the session focuses on reading and spelling exercises (i.e. reading and transcribing graphemes).

	DATES (DD/MM/YYYY)	Reading	Spelling	Training
V30	_ _ / _ / _ _			
V31	_ _ / _ / _ _			
V32	_ _ / _ / _ _			
V33	_ _ / _ / _ _			

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ / _ / _ /	Training PHONO1/VA2/IM3

POST-TRAINING VA 2A BASELINE ASSESSMENT, V 34

After one month of training, administer the same post-training baseline tests and report the results in the table below.

VA 2A training – first month – V 34								
	Post-training VA 2A baseline Raw scores							
BSL 1	Maeva, score out of 10 (accuracy)		1					
BSL 2	VA global span numbers (Evaleo)	_ . _	4					
	RC, EVA, out of 100							
DGI 2	Reading irregular words, score out of 20		1					
BSL 3	Reading irregular words, time in seconds	_ _ . .	1					
BSL 4	BSL 4 Codes, time in seconds _							
Total Tim	ne		7					

After one first month of training, other exercises are given the second month. Before you start training, administer the following baseline tests, and report the results in the table below.

	VA 2B training – second month – V 35						
	Pre-training VA 2B baseline Raw scores						
		Good answer scores	_				
BSL1	Complex triplets Switchipido	Wrong answer scores	_	2			
		Average time in ms	_ _ _				
BSL2	VA global span number	rs, Evaléo	_ . _	4			
DSL2	RC, EVA, out of 100						
BSL3	Reading irregular word	s, score out of 20	_	1			
	Reading irregular word	_ _ . .	1				
BSL4 Mental calculation, items completed in 2 minutes _							
Total ti	me			7			

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Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ / _ / _ _ /	Training PHONO1/VA2/IM3

SPEECH THERAPY SESSIONS (V 36 TO V 39)

During home training, children are seen by the speech therapist once a week for 30 minutes in the speech therapist's office.

	DATES (DD/MM/YYYY)	Reading	Spelling	Training
V36	_ _ / _ / _ _			
V37	_ _ / _ / _ _			
V38	_ _ / _ / _ _			
V39	_ _ / _ / _ _			

POST-TRAINING VA 2B BASELINE ASSESSMENT- TEST 4 – V 40

Date:	l	l	/		I	/	l	l			(DD/MM/YYY	Y

After a month of training, administer the same post-training baseline tests and report the results in the table below.

	VA 2B training – second month – V 40						
	Post-training	VA 2B baseline	Raw scores				
		Good answer scores	_				
BSL1	Complex triplets Switchipido	Wrong answer scores	_	2			
	-	Average time in ms	_ _ _				
BSL2	VA global span number	_ . _	4				
DSLZ	RC, EVA, out of 100	_ _ _					
BSL3	Reading irregular word	s, score out of 20	_	1			
	Reading irregular word	_ _ . .	1				
BSL4 Mental calculation, items completed in 2 minutes _							
Total ti	me			7			

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Internal Code	Patient Number	Group 1
19-HPNCL-02		Training PHONO1/VA2/IM3

POST TRAINING ASSESSMENT 2 – V 40 – TEST 4

For the administration of the tests, refer to the "testing manuals". Tests must be administered in a random order to be different for each participant.

During the same session, V 40, perform Test 4 at the end of the 2 months of visuo-attentional training.

- DeltaText© 4
- Alouette©
- Pingouin (Evaléo© 6-15)
- EVAL2M (Evaléo© 6-15)

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ _ / _ _ /	Training PHONO1/VA2/IM3

	Tests		Data	Raw scores	Rate + or -	Z Scores (SD or percentiles)	Time (min)
			Number of errors	1_1_1		111.11	
P H			Number of words read	1_1_1_1		111.11	
S			Number of correct words	_		111.11	
E	Reading meaningless text	"Alouette©"	Time in seconds	_ _ _		111.11	3
2			Accuracy index	_ _ _		111.11	
			Speed index	1_1_1_1			
			Reading age	_ yea	rs	months	
		"DeltaText© 2"	Number of words read	_ _ _			
T E	Reading meaningless text		Number of errors	_ _ _			3
S			Time in second	_ _ _			
4			Number of words read	_ _ _		1_1	
	Words read in 2 min	l "Eval 2M©"	Number of correct words	_ _ _		1_1	2
			% correct/read	_ _		II	
			Number of words read	_ _ _		II	
V Reading 4 meaningful text "EVALEO©"	gful text "Pingouin"	Number of correct words	_ _ _		II	2	
		% correct/read	_ _ _ . _		1_1		
			Degradation Index	_ _ _		I <u></u> I	
			Total tin	ne (min)			10

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ / _ _ / _ _ _	Training PHONO1/VA2/IM3

15-DAY BREAK WITHOUT TRAINING

A 15-day break without training is provided before moving on to cross-modal training. During this break, weekly STS continue if the participant is not on vacation. In this case, please indicate it in the "comments."

	DATES (DD/MM/YYYY)	Reading	Spelling	Comments
V41	_ _ / _ / _ _			
V42	_ _ / _ / _ _			

PHASE 3 – CM 3 TRAINING – TEST 5 – V 43 to V 55

PRE-TRAINING IM 3 BASELINE ASSESSMENT – INSTRUCTIONS – V 43

Date: | | | / | | | | | | | (DD/MM/YYYY)

After the two periods of *phonological training* and the two periods of *visuo-attentional training*, the participant completes the third and final training period which is *cross-modal training* for two months. All participants (groups 1 and 2) have the same training.

CM 3A training – V 43				
	Pre-training IM 3 baseline	Raw scores		
DCI 1	Reading 20 words seen, accuracy		1	
BSL1	Reading 20 words seen, time in seconds _ .			
BSL2	Transcribing 10 words seen		2	
DCI 2	Reading regular words, accuracy	_	1	
BSL3	Reading regular words, time in seconds	_ _ . _	1	
BSL4	Labyrinth, time in seconds	_ _ . _	1	
Total Time			6	

Give instructions to parents and children on how to perform cross-modal training 3 with GraphoGame (10 *min* per day) and ARMAR training (5 minutes per day) for 2 months, 5 days/week. See the instruction book.

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Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ / _ / _ /	Training PHONO1/VA2/IM3

SPEECH THERAPY SESSION (V44 TO V 51)

During home training, children are seen by the speech therapist once a week for 30 minutes in the speech therapist's office.

011100	•			
	DATES (DD/MM/YYYY)	Reading	Spelling	Training
V44	_ _ / _ / _ _			
V45	_ _ / _ / _ _			
V46	_ _ / _ / _ _			
V47	_ _ / _ / _ _			
	DATES (DD/MM/YYYY)	Reading	Spelling	Training
V48	_ _ / _ / _ _			
V49	_ _ / _ / _ _			
V50	1 1 171 1 171 1 1 1 1			

V51

|_|_|/|_|/|_|_|

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ / /	Training PHONO1/VA2/IM3

POST-TI	RAINING	IM ₃	BASELINE	ASSESSMENT -	- V 51
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Date: / /	(DD/MM/YYYY)
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After two months of training, perform the same post-training baseline tests and report the results in the table below.

CM 3A training – V 43				
	Post-training IM 3 baseline	Raw scores		
DCI 1	Reading 20 words seen, accuracy	_ _	1	
BSL1	Reading 20 words seen, time in seconds _ .			
BSL2	Transcription of 10 words seen	_ _	2	
DCI 2	Reading regular words, accuracy _		1	
BSL3	Reading regular words, time in seconds	_ _ . _	1	
BSL4	Labyrinth, time in seconds	_ _ . _	1	
Total Time			6	

POST TRAINING ASSESSMENT 3 – TEST 5 – V52 AND V53

For the administration and order of the tests, refer to the "testing manuals". Tests must be administered in a random order to be different for each participant.
Date: _ / _ / _ (DD/MM/YYYY)

Same assessment as test 2.

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ _ / _ _ /	Training PHONO1/VA2/IM3

	т	ests	Data	Raw scores	Rate +	Z Scores (SD or percentiles)	Time (min)
			Number of errors	1_1_1		111.111	
			Number of words read	1_1_1_1		111.111	
			Number of correct words	1_1_1_1		111.111	
	Reading meaningless text	"Alouette©"	Time in seconds	1_1_1_1		111.111	3
			Accuracy index	_		111.11	
			Speed index	1_1_1_1		111.11	
			Reading age	yea	ars	months	
			Number of phonetic errors	1_1_1		111.11	
			Number of lexical errors	1_1_1		111.11	
	Spelling Test	"Chronosdictées©	Number of grammatical errors	1_1_1		111.11	10
	spening rest	" Version A	Number of omissions	111		111.11	10
P H			Number of segmentation errors	1_1_1		111.11	
S E			Total number of errors	111		111.11	
2			Number of words read	_		II	
	Reading	""	Number of correct words	111		1_1	2
	meaningful text "EVALEO©"	"Mouette"	% correct/read	1111.11		11	
т			Degradation Index	111		11	
E S		Syllable suppression	Accuracy (% errors)	_ . _		111.11	
T 5			Time in seconds	_ .		111.11	
	- -	Phoneme suppression CVC	Accuracy (% errors)	1111.11		111.11	
			Time in seconds	111_1-1-11		111.11	3
V 5		Phoneme suppression CCV	Accuracy (% errors)	1111.11		111.111	
2	Phonological awarness		Time in seconds	_ -		111.11	
	"EVALEC©"	Non-word	Span	11		111.11	1
		repetition	Time in seconds	111_1-11		111.111	
			Color recognition, %	1_1_1		111.11	
		Rapid	Color recognition, time in seconds	.		111.11	2
		Automatized Naming	Reading names, %	1111.11		111.11	
			Reading names, time in seconds	.		111.11	
		Letter threshold	Threshold in ms	111		111.11	
	Views	Global Report	GR Score	111		111.11	
	Visuo- attentional span "EVADYS©"	(GR)	GR Span	1_1.1_1_1		111.11	20
	EVADISO	Partial Report	PR Score	1_1_1		111.11	
		(PR)	PR Span	1_1.1_1_1		111.11	
			Total tim	ne (min)			51

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ / _ / _ /	Training PHONO1/VA2/IM3

	Te	ests	Data	Raw scores	Rate + or -	Z Scores (SD or percentiles)	Time (min)
			Local RT (ms)	_ _ .		_ _ . . _	
	Global/local analysis	Response time (RT)	Global RT (ms)	_ _ .		_ _ . . _	
			Interference asymmetry RT (ms)	_ _ .		_ _ . . _	20
	"SIGL© Drawings"		Local ER (%)	_ _ .		_ .	20
		Error Rate (ER)	Global ER (%)	_ _ . .		_ .	
			Interference asymmetry ER (%)	_ _ . .		_ .	
		Regular words	Accuracy (% errors)	_ _ .		_ _ . . _ _	
		(RW)	Time in ms			_ .	
P H	Word reading	Irregular words	Accuracy (% errors)	_ _ .		_ _ . . _	
A S	"EVALEC©"	(IW)	Time in ms			_ _ . . _	8
E			Accuracy (% errors)	_ _ .		_ _ . . _	
2		Non-words (NW)	Time in ms			_ _ . . _	
	Surveys-Likert scale	Child pre-test	Total points	1_1_1			-
т		Parents pre-test	Total points	1_1_1			5
E S	Digit span	"EVALEO©"	Score forward span	I_I		I_I	
Т			Forward span	I_I		II	_
5			Score backward span	I_I		I_I	5
			Backward span	II		II	
V 5	Visuo-spatial	patial	Forward span	I_I		_ .	
3	span	"Corsi©"	Backward span	I_I		_ _ . . _ _	8
	Written	"Orlec©, L3"	Number of correct items	1_1_1		_ _ . . _ _	. 5
	comprehension	Offece, L3	Percentage of correct items	_ _ .		_ .	5
			Number of words read	1_1_1_1			
	Reading meaningless text	"DeltaText© 1"	Number of errors	1_1_1_1			3
			Time in seconds	1_1_1_1			
			Number of words read	1_1_1_1		I_I	
	Words read in 2 min	"Eval 2M©"	Number of correct words	1_1_1_1		I_I	2
			% correct/read	_ _ . . .		I_I	
			Total tim	ne (min)			53

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ / / _	Training PHONO1/VA2/IM3

PHASE 3 – NO INTENSIVE TRAINING –TEST 6 – V 54 to 62

Training is interrupted for 2 months but weekly STS continue. A final evaluation is then carried out to check that the gains obtained during training remain stable.

SPEECH THERAPY SESSIONS (V 54 TO V 62)

	DATES (DD/MM/YYYY)	Reading	Spelling
V54	_ _ / _ / _ _		
V55	_ _ / _ _ / _ _		
V56	_ _ / _ / _ _		
V57	_ _ / _ / _ _		
In58	_ _ / _ / _ _		
At59	_ _ / _ / _ _		
V60	_ _ / _ / _ _		
V61	_ _ / _ / _ _		

FOLLOW-UP ASSESSMENT – TEST 6 – V 62

For the administration of the tests, refer to the "testing manuals". Tests must be administered in a random order to be different for each participant.

Date: |__|_/|__|/|__|_| (DD/MM/YYYY)

- Alouette©
- Delta text© 2
- Eval2M©
- Pingouin©
- Surveys (Likert scale)

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ / _ / _ /	Training PHONO1/VA2/IM3

	Tests		Data	Raw scores	Rate + or -	Z Scores	Time min	
			Number of errors	III		.		
			Number of words read	1_1_1_1		,		
			Number of correct words	1_1_1_1		.		
	Reading meaningless text	"Alouette©"	Time in seconds	1_1_1_1		.	3	
			Accuracy index	1_1_1_1		.		
P			Speed index	1_1_1_1		.	-	
h a s			Reading age	ye:	ars	months		
e 3		"DeltaText© 2"	Number of words read	1_1_1_1				
т	Reading meaningless text		Number of errors	1_1_1_1			3	
e s t			Time in seconds	1_1_1_1				
6	Words read in 2 min	"Eval 2M©"	Number of words read	1_1_1_1		II		
v \			Number of correct words	1_1_1_1		I_I	2	
6			% correct/read	_ _ _ .		II		
			Number of words read	lll		1_1		
	Reading meaningful text		Number of correct words	_ _ _		II	- 2	
ľ	"EVALEO©"	"Pingouin"	% correct/read	_ _ _ . _		II		
			Degradation Index	1_1_1_1		II		
	Surveys-Likert	Child pre-test	Total points	1_1_1			• 5	
	scale	Parents pre-test	Total points	1_1_1			, J	
			Total tin	ne (min)			16	

Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ / _ _ / _ _ _	Training PHONO1/VA2/IM3

UNWANTED / SERIOUS / ADVERSE EVENTS since the last visit (if applicable)

In this study, no adverse effects are expected since these are non-invasive tests and treatments. However, any occurrence of adverse events will be notified in the case report form and treated in accordance with current regulations.

TREATMENTS

- **Modified specific/experimental** treatment(s) (started, stopped, frequency) since the last check-up \$\&\tilde{s}\$ If YES, please fill or update the "Specific treatment sheet/experimental"
- **Modified concomitant** treatments (started, stopped, or frequency) since the last check-up \$\&\tilde{I}\$ If YES, fill or update the "Concomitant treatments sheet" (CRF test 1)

Note: The child's academic remediation (related to his pathology) is a concomitant treatment.

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Internal Code	Patient Number	Group 1
19-HPNCL-02	_ _ _ / _ _ / _ _ _	Training PHONO1/VA2/IM3

END-OF-STUDY SHEET

End-of-study	y date (DD/MM/Y	YYY):	_ /L_L /L	_L_L_l		
(last inforn				ıdy-related re ducted after th	views, treatment administro at date)	ation or
Study follow	wed to completion	on:	□ Yes	□ No		
If "No":						
Reaso	n for premature	exit:				
	Refusal to contin	ue/Withdrawa	al of patient co	nsent		
	Missing participa	nt				
	Daily training int investigate	_	nore than 15 da	ays without goo	d cause, subject to the judgm	ent of the
	I Irregular daily tr	aining, subjec	t to the judgm	ent of the inves	tigator	
	Other (to be spec	ified below)				
Accur	racy of the reason	-				
•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	•• •••••	•••••	•••••
•••••		• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	•••••	•••••
Last c	ontact date (DD/MI	M/YYYY)				
	rom protocol: yes, specify:	□ Yes	□ No)		
General co	mments:					
	• • • • • • • • • • • • • • • • • • • •					
	•••••					
Investigator	·'s signature					

Internal Code	Centre Nb.	Patient Nb.
XX-XX-XX	1_1_1	

SPECIFIC TREATMENT SHEET / EXPERIMENTAL

	Treatments			Treatments End Date (DD/MM/YYYY)			
	Phases 1, 2 or 3	Training 1, 2 or 3	PHONO 1 or 2 VA 1 or 2 IM 1 or 2	Visits	Start date (DD/MM/YYYY)	Note "Ongoing" if the treatment has not been completed at the end of the study	Reasons for change or termination
1						□ in progress	☐ Computer bug ☐ Sick leave ☐ Vacation ☐ Other, specify:
2						□ in progress	☐ Computer bug ☐ Sick leave ☐ Vacation ☐ Other, specify:
3						□ in progress	☐ Computer bug ☐ Sick leave ☐ Vacation ☐ Other, specify:
4						□ in progress	☐ Computer bug ☐ Sick leave ☐ Vacation ☐ Other, specify:
5						□ in progress	☐ Computer bug ☐ Sick leave ☐ Vacation ☐ Other, specify:

No. And Date