

Case Report Form (CRF)

Phase 1- Test 1

Selection and Inclusion

**Developmental dyslexia and method of remediation (DDMR)
Multimodal intervention in French-speaking children aged 8 to 13 years:
study protocol for a randomized multicentre controlled cross-over trial**

DDMR

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

Case Report Form (CRF)

Phase 1 - Test 1: Selection and Inclusion

Center no.: |_|_|

Patient no. (or patient code): |_|_|

Patient initials: |_| - |_|
(1st letter of last name – 1st letter of first name)

Sponsor:

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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: |_2_|_1_|_|_|

Correct: |_0_|_2_|_1_|

- **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.1121-1-1du CSP, 18th November 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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Experimental procedure

PHASES		Visits	Details and duration of the assement or intervention	
P h a s e 1	TEST 1	V 1 to V4	Information, consent, selection Baseline assessment	4 hr
	No intensive training 2 months	V 5 to V 12	Speech therapy sessions (STS): 30 min/week	STS: 4 hr
	TEST 2	V 13- V 14	Post-control assessment	2 hr
P h a s e 2	INTENSIVE TRAINING 1 2 months	V 15	Pre-training 1A baseline assessment	30 min
		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
		V 20	Post-training 1A baseline assessment	15 min
		V 21	Pre-training 1B baseline assessment	30 min
		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
		V 26	Post-training 1B baseline assessment	10 min
	TEST 3	V 27, V 28	Post-training assessment 1	50 min
Break	V 27, V 28	15 days without home training	1 hr	
P h a s e 2	INTENSIVE TRAINING 2 2 months	V 29	Pre-training 2A baseline assessment	30 min
		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
		V 34	Post-training 2A baseline assessment	15 min
		V 35	Pre-training 2B baseline assessment	30 min
		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
		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 h a s e 2	INTENSIVE TRAINING 3 2 months	V 43	Pre-training 3 baseline assessment	30 min
		V 44 to V 51	Home training (HT): 5 days/week-15 min/day Speech therapy sessions (STS): 30 min/week	HT: 10 hr STS: 4 hr
	TEST 5	V 52	Post-training 3 baseline assessment	10 min
P h a s e 3	No intensive training 2 months	V 53-54	Post-training assessment 3	2 hr
	TEST 6	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 min
Total		65 weeks	16 months	49 hr 20 min

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SELECTION VISIT- PHASE 1-Test 1-V 1

V1: first visit: 1 hour

Date : □□/□□/□□□□ (DD/MM/YYYY)

CONSENT COLLECTION

Mother and Father

on □□/□□/□□□□ on □□/□□/□□□□
DD/MM/YYYY *DD/MM/YYYY*

Or

The holder of parental authority on □□/□□/□□□□ (DD/MM/YYYY)

Note in the patient's source file the patient's participation in the study and the patient's consent.

In the absence of one of the parents, a prior oral agreement of the absent parent must be obtained and notified in the patient's medical file.

Contact information and written consent of the absent parent should be collected as soon as possible.

If one of the parents has not signed the consent form, the investigator must provide evidence in the child's source file of having tried to contact the parent.

Investigator's name: _____

Signature:

DEMOGRAPHICS

Born on: □□/□□/□□□□ (DD/MM/YYYY) Age: □□ years □□ months

Sex: Male Female Grade: □□□□

HISTORY

- Reason for speech therapy: Reading difficulties Spelling difficulties
- School difficulties
- Other.....

- Illnesses: Yes No If yes which ones? (allergies, frequent ear infections, cranial trauma, seizures, neurological or genetic disorders, other)
-
-

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Pathological birth Yes No

If so, why? (term, caesarean section, forceps, apgar, intensive care, other)

.....

Disorders during childhood Yes No

If so, which ones (sleep disturbance, eating, cleanliness, incessant crying, other)

.....

- Sitting age:
- Walking age:
- Age of first words:
- Age of first sentences:

Impaired global motor skills Yes No

If so, which ones (running, jumping, cycling, other)

.....

Impaired fine motor skills Yes No

If so, which ones (tie laces, fasten buttons, cut, embed, use cutlery, write, other)

.....

Impaired building skills Yes No

If so, which ones (puzzles, LEGO©, models, other)

.....

Language skill disorders Yes No

If so, which ones (vocabulary, sentences, narrative, other)

.....

Oral comprehension disorder Yes No

If so, in what context (simple language, elaborate language, school, home, multiple instructions)

.....

Impaired attentional abilities Yes No

If so, in what context (sustained activity, film, game, school, homework, other)

.....

SCHOOL SITUATION

- In kindergarten, difficulties in carrying out activities Yes No
- Difficulties in learning to read Yes No
- Difficulties in learning to spell Yes No
- Difficulties in learning to write Yes No
- Difficulties in learning mathematics Yes No
- Current persistence of reading difficulties Yes No
- Difficulties in understanding written instructions Yes No
- Current persistence of spelling difficulties Yes No
- Current persistence of difficulties in mathematics Yes No

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- Recommendation to repeat the school year Yes No
- Repeated school year, which one Yes No
- Gifted student, in which areas..... Yes No
- Remedial assistance Yes No
- Help with homework Yes No
- Time devoted to homework in the evening

.....

- Additional comments

.....

.....

SELECTION TESTS, READING AND SPELLING

For the administration of the tests, refer to the instruction manual

- Reading meaningless text (Alouette©)
- Spelling (Chronosdictées©, version A)

SELECTION CRITERIA

SELECTION CRITERIA	Yes	No
Age ≥ 8 and ≤ 13	<input type="checkbox"/>	<input type="checkbox"/>
Diagnosis of dyslexia or difficulty in reading and/or spelling	<input type="checkbox"/>	<input type="checkbox"/>
Absence of perceptual, neurological or behavioral disorders	<input type="checkbox"/>	<input type="checkbox"/>
No oral language problems	<input type="checkbox"/>	<input type="checkbox"/>
Native language: French or early school in French	<input type="checkbox"/>	<input type="checkbox"/>
No attentional problems	<input type="checkbox"/>	<input type="checkbox"/>
No rehabilitation is underway	<input type="checkbox"/>	<input type="checkbox"/>
Home equipped with a computer connected to internet for daily training	<input type="checkbox"/>	<input type="checkbox"/>
Informed consent signed by both parents or the representative of the parental authority	<input type="checkbox"/>	<input type="checkbox"/>
Social Security affiliation or beneficiary	<input type="checkbox"/>	<input type="checkbox"/>

If one or more "NO" boxes are checked the patient is not selected for the study

Internal code	Patient number	PHASE 1 - Selection and inclusion TEST 1
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DATA COLLECTION-V 1

	Tests		Data	Raw scores	Rate + or -	Z scores (SD or percentiles)	Time (min)
	P H A S E 1	Anamnesia	Survey (CRF p.5 to 7)	"Don't enter anything here"			
Reading meaningless text		Alouette©	Number of errors	_ _		_ _ . _ _	3
			Number of words read	_ _ _		_ _ . _ _	
			Number of correct words	_ _ _		_ _ . _ _	
			Time in seconds	_ _ _		_ _ . _ _	
			Accuracy index	_ _ _		_ _ . _ _	
			Speed index	_ _ _		_ _ . _ _	
			Reading age	_ _ years _ _ months			
Spelling test		Chronosdictées© Version A	Number of phonetic errors	_ _		_ _ . _ _	10
			Number of lexical errors	_ _		_ _ . _ _	
	Number of grammatical errors		_ _		_ _ . _ _		
	Number of omissions		_ _		_ _ . _ _		
	Number of segmentation errors		_ _		_ _ . _ _		
	Total number of errors		_ _		_ _ . _ _		
V 1	Selection	Table CRF p. 8	"Don't enter anything here"				5
	Information	CRF	"Don't enter anything here"				20
	Consent	CRF	"Don't enter anything here"				5
	Total time (min)						58

Internal code	Patient number	PHASE 1 - Selection and inclusion TEST 1
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INCLUSION VISIT - PHASE 1- TEST 1- V 2 to V 4

To administer and determine the order of tests, refer to the manual sent to you that specifies the order to be followed.

INCLUSION VISIT V 2

V2: second visit: 1 hour

Date : □□/□□/□□□□ (**DD/MM/YYYY**)

- Reading aloud a meaningful text, La Mouette (Evaléo© 6-15)
- Phonological analysis, non-word repetition and rapid automatized naming (Evalec©)
- Visuo-attentional span (Evadys©)
- Oral comprehension (ECOSSE©) - only if oral language has not been tested or if there is still any doubt about a possible “specific language impairment”

Internal code	Patient number	PHASE 1 - Selection and inclusion TEST 1
19-HPNCL-02	□□/□□/□□□□	

	Tests		Data	Raw scores	Rate + or -	Z scores (SD or percentiles)	Time min	
	P	Reading meaningful text EVALEO©	"Mouette"	Number of words read	□□□□		□□	2
Number of correct words				□□□□		□□		
% correct/read				□□□□.□□		□□		
Degradation index				□□□□		□□		
h	Phonological awareness EVALEC©	Syllabe suppression	Accuracy (% errors)	□□□□.□□□		□□□.□□□	8	
			Time in seconds	□□□□.□□□		□□□.□□□		
		Phoneme suppression CVC	Accuracy (% errors)	□□□□.□□□		□□□.□□□		
			Time in seconds	□□□□.□□□		□□□.□□□		
	Phoneme suppression CCV	Accuracy (% errors)	□□□□.□□□		□□□.□□□			
		Time in seconds	□□□□.□□□		□□□.□□□			
	1	Non-word repetition	Span	□□		□□□.□□□		5
			Time in seconds	□□□□.□□□		□□□.□□□		
Rapid automatized naming		Color recognition, %	□□□□.□□□		□□□.□□□	2		
		Color recognition, time in seconds	□□□□.□□□		□□□.□□□			
	Reading names, %	□□□□.□□□		□□□.□□□				
	Reading names, time in seconds	□□□□.□□□		□□□.□□□				
T	Visuo- attentional span EVADYS©	Letter threshold	Threshold in ms	□□□□		□□□.□□□	20	
		Global Report GR	GR Score	□□□□		□□□.□□□		
			GR Span	□□.□□□		□□□.□□□		
		Partial Report PR	PR Score	□□□		□□□.□□□		
			PR Span	□□.□□□		□□□.□□□		
E	Oral comprehension	ECOSSE©	Number of errors	□□□		□□□	15	
			Total time (min)					

Internal code	Patient number	PHASE 1 - Selection and inclusion TEST 1
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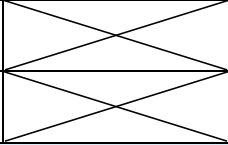
INCLUSION VISIT V 3

V3: third visit: 1 hour

Date: □□□/□□□/□□□□□□ (DD/MM/YYYY)

- Local/global analysis (SIGL©)
- Reading aloud regular, irregular words, and non-words (Evalect©)
- Matrix Reasoning (Wisc V©) - only if the neuropsychological check-up has not been performed or if it is not planned
- Perception of the evolution of the disorder, 2 questionnaires for parents and children (Likert scale)

Internal code	Patient number	PHASE 1 - Selection and inclusion TEST 1
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	Tests		Data	Raw Scores	Rate + or -	Z scores (SD or percentiles)	Time min
	P h a s e 1	Global/local analysis SIGL© "Drawings"	Response time (RT)	Local RT (ms)	_ _ _ _ . _ _ _		_ _ _ . _ _ _
Global RT (ms)				_ _ _ _ . _ _ _		_ _ _ . _ _ _	
Interference asymmetry RT (ms)				_ _ _ _ . _ _ _		_ _ _ . _ _ _	
Error Rate (ER)			Local ER (%)	_ _ _ _ . _ _ _		_ _ _ . _ _ _	
			Global ER (%)	_ _ _ _ . _ _ _		_ _ _ . _ _ _	
			Interference asymmetry ER (%)	_ _ _ _ . _ _ _		_ _ _ . _ _ _	
T E S T 1 V 3		Regular words (RW)	Accuracy (% errors)	_ _ _ _ . _ _ _		_ _ _ . _ _ _	15
			Time in ms	_ _ _ _		_ _ _ . _ _ _	
		Irregular words (IW)	Accuracy (% errors)	_ _ _ _ . _ _ _		_ _ _ . _ _ _	
			Time in ms	_ _ _ _		_ _ _ . _ _ _	
		Non-words (NW)	Accuracy (% errors)	_ _ _ _ . _ _ _		_ _ _ . _ _ _	
			Time in ms	_ _ _ _		_ _ _ . _ _ _	
	Short IW	Accuracy (% errors)	_ _ _ _ . _ _ _		_ _ _ . _ _ _		
		Time in ms	_ _ _ _		_ _ _ . _ _ _		
	Long IW	Accuracy (% errors)	_ _ _ _ . _ _ _		_ _ _ . _ _ _		
		Time in ms	_ _ _ _		_ _ _ . _ _ _		
	Short NW	Accuracy (% errors)	_ _ _ _ . _ _ _		_ _ _ . _ _ _		
		Time in ms	_ _ _ _		_ _ _ . _ _ _		
Long NW	Accuracy (% errors)	_ _ _ _ . _ _ _		_ _ _ . _ _ _			
	Time in ms	_ _ _ _		_ _ _ . _ _ _			
Wisc 5©	Matrix Reasoning	Correct items /32	_ _		_ _	10	
Surveys-Likert scale	Child pre-test	Total points	_ _			5	
	Parents pre-test	Total points	_ _				
Total time (min)							55

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V4 INCLUSION VISIT

V4: fourth visit: 1 hour

Date : □□□/□□□/□□□□□□ (*DD/MM/YYYY*)

- Short-term verbal memory and working memory, digit span (Evaléo©)
- Vocabulary (Evaléo©) - only if oral language has not been tested
- Visuo-spatial span (Corsi©)
- Reading comprehension (Orlec© L3)
- 2 minutes reading words, Eval2M (Evaléo©)
- Reading aloud a meaningless text (Deltatext© 1)

Internal code	Patient number	PHASE 1 - Selection and inclusion TEST 1
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P H A S E 1	Tests		Data	Raw Scores	Rate + or -	Z scores (SD or percentiles)	Time min
	Digit span	EVALEO©	Score forward span	_		_	8
			Forward span	_		_	
			Score backward span	_		_	
			Backward span	_		_	
	Vocabulary EVALEO©	Picture Naming	Accuracy (correct iERms)	_		_	15
			Total time, in seconds	_ .		_	
		Picture Designation	Accuracy (correct iERms)	_		_	
	Visuo-spatial span	Corsi©	Forward span	_		_ . _	8
			Backward span	_		_ . _	
WritERn comprehension	Orlec, L3©	Accuracy (correct items)	_		_ . _	5	
		Correct items (%)	_ . _		_ . _		
Reading meaningless text	Deltatext© 1	Number of words read	_		 _ . _ 	3	
		Number of errors	_		 _ . _ 		
		Time in seconds	_		 _ . _ 		
Words readi in 2 min	Eval 2M©	Number of words read	_		_	2	
		Number of correct words	_		_		
		% correct/read	_ . _		_		
Total time (min)							40

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INCLUSION AND NON-INCLUSION CRITERIA

INCLUSION CRITERIA	Yes	No
Age greater than or equal to 8 years and less than or equal to 13 years.	<input type="checkbox"/>	<input type="checkbox"/>
Diagnosis of dyslexia validated by performance lower than 1.5 standard deviation from the average developmental age on the Alouette© test and the reading tasks of irregular words and non-words (Evalec©)	<input type="checkbox"/>	<input type="checkbox"/>
Performance lower or equal to -1.5 standard deviation from the average in at least one phonological task (Evalec©) and at least one visuo-attentional task (Sigl©, Evadys©)	<input type="checkbox"/>	<input type="checkbox"/>
Home equipped with a computer connected to internet for daily training	<input type="checkbox"/>	<input type="checkbox"/>
Informed consent signed by one of the parents or the representative of the parental authority	<input type="checkbox"/>	<input type="checkbox"/>
Social Security affiliate or beneficiary	<input type="checkbox"/>	<input type="checkbox"/>

If one or more "NO" boxes are checked the patient is not included in the study

NON-INCLUSION CRITERIA	Yes	No
Intellectual delay or neurological disorders or global developmental disorder	<input type="checkbox"/>	<input type="checkbox"/>
Primary sensory deficit	<input type="checkbox"/>	<input type="checkbox"/>
Educational deficiencies	<input type="checkbox"/>	<input type="checkbox"/>
Attention Deficit Disorder with or without Hyperactivity (ADHD)	<input type="checkbox"/>	<input type="checkbox"/>
Specific oral language impairment	<input type="checkbox"/>	<input type="checkbox"/>
Previous daily phonological or visuo-attentional training	<input type="checkbox"/>	<input type="checkbox"/>

If one or more "YES" boxes are checked the patient is not included in the study

Is the patient included in the study? Yes No

If not, why:

Comments:

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RANDOMIZATION

At the end of the inclusion visits, send your randomization sheet to: karine.eskinazi@wanadoo.fr

The coordinating investigator will tell you whether participants are assigned to group 1 or group 2 and will send you the appropriate CRFs following the study.

- Group 1: PHONO 1 - VA 2- IM 3
- Group 2: VA 1- PHONO 2- IM 3

The participant is not informed of his or her attribution to group 1 or 2 and will follow the instructions given by the associate investigative speech therapist regarding the conduct of the study.

Rating: Treatment group: 1 2

Randomization No.:

Center No. :

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		Treatments			DIAGNOSIS	Start (DD/MM/YYYY)	End	
TYPES	CHECK-UP DATES (DD/MM/YYYY)	Rehabilitation		End Date (JJ/MM/AAAA)			Ongoing	
		Yes	No					
1	□□□/□□□/□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	□□□/□□□/□□□□□	□□□/□□□/□□□□□	<input type="checkbox"/>
2	□□□/□□□/□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	□□□/□□□/□□□□□	□□□/□□□/□□□□□	<input type="checkbox"/>
3	□□□/□□□/□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	□□□/□□□/□□□□□	□□□/□□□/□□□□□	<input type="checkbox"/>
4	□□□/□□□/□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	□□□/□□□/□□□□□	□□□/□□□/□□□□□	<input type="checkbox"/>
5	□□□/□□□/□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	□□□/□□□/□□□□□	□□□/□□□/□□□□□	<input type="checkbox"/>
6	□□□/□□□/□□□□□	<input type="checkbox"/>	<input type="checkbox"/>	□□□/□□□/□□□□□	□□□/□□□/□□□□□	<input type="checkbox"/>

Thank you for postponing all treatment received except treatment provided in the study