



D5.3 – Independent Report on the performance of AULA on North American population



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VRMIND (GA 733901)

1. EXECUTIVE SUMMARY

VRMIND-AULA is a neuropsychological test for attention in children from 6 to 16 years old. It is a Continuous Performance Test (CPT) designed to evaluate attentional processes and support the diagnosis of attention disorders, it analyses the child's behaviour within a classroom. It is also valuable in other kind of disorders where attentional processes are essential like generalized developmental disorders, difficulties to learn or cognitive deficiencies. VRMIND-AULA offers scores about: sustained attention, divided attention (visual and auditory); impulsivity; excessive motor activity (hyperactivity); tendency to distraction, processing speed, focus on the task, attentional difference between visual and audio stimuli and between more and less stimulating tasks, sterile movement, motor activity and fatigue for tasks. Also distinguishes the tendencies to the internal or external distraction. The normative study of AULA with general population of Spain was published in Journal of Attention Disorders (Iriarte et al., 2012), and the convergent validity with Conners' Continuous Performance Test, the market leading test, has been recently published in Child Neuropsychology journal (Díaz et al., 2014).

This product was launched to the market on 2011 and it has been sold to 350 customers in 22 countries. From 2011 up to now both the professionals from Nesplora and also our customers have made different investigations with this tool.

Even though to continue researching with VRMIND-AULA it is always useful since these studies increase the visibility of the tool and its clinical value. This is the reason why it was planned to perform clinical studies with AULA in different countries at the beginning of the VRMIND Project.

This deliverable describes the contacts with potential collaborators made in section 3. The studies which were finally carried out are specified in section 4 while the main conclusions are drawn up in section 5.

A first version of this deliverable was sent in June but, as our collaborator in USA has shared with us more data some weeks ago, we have updated this deliverable.

2. RELATION WITH OTHER WPS AND DELIVERABLES

This deliverable is closely related with D5.1 (Independent report on the performance of AULA on European population) and D5.2 (Independent report on the performance of AULA on Latam population).

3. COLLABORATOR'S STUDIES

Several contacts were made basically with different experts in ADHD (Attention Deficit Hyperactivity Disorder). Unfortunately, our pool of current clients in USA it is not so big. We contacted with all of them, and also with some experts we identified, by mail and telephone. With some of them we could schedule a telco for giving more information. However, with some of them were not possible to reach an agreement for the reasons specified in the table below.

Table 1. Contacts done but not signed *(for confidentiality reasons, the columns including the name of the centers has been deleted in this version)*

CITY	REASON FOR NOT PARTICIPATING
Salt Lake City	Problems with the Ethical Committee
Chicago	Problems to carry out the collaboration in the time requested
Indiana	Problems regarding responsibility requested in the contract
USA (Austin)	Contact lost after exchanging basic Project information
USA (Portsmouth)	Contact lost after exchanging basic Project information
USA	Contact lost after first contact. Contact restored for buying Nesplora AULA but not in time for collaboration
USA	Retirement
USA	Contact lost after exchanging basic Project information

Canada	Problems to assume the cost of Ethical Committee
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As one of the main collaborators' complaints was to have the evaluations done by the deadline of the deliverable, we decided to offer the collaborators to participate with us and to share with us as much data as possible by month 2 of the project in order to be able to finish the deliverable by month 3, as expected in the DoA, and to continue collecting and exchanging data with us until they complete the total required sample.

But even with this more flexible criterion, we were able to get just one collaborator on board.

3.1 YourShrink

Collaborator's description: The licensed clinical psychologist, Mary Hynes Danielak Psy.D. has been practicing in the Atlanta area since 1990. She is one of the founders of The Counseling and Development Center, which has been located in Alpharetta since 1994, and she works alongside a group of multi-disciplinary clinicians. As part of her practice, Dr. Danielak conducts assessments and evaluations for learning disabilities such as: dyslexia, dyscalculia and dysgraphia, attention-deficit/hyperactivity disorder, Asperger's and autism.

Location: Alpharetta (USA)

Sample: 45 children between 6 and 16 years old.

Sociodemographic data

	Number	Age average	Years of education (average)
Male	25	10.91	6.70
Female	22	10.89	6.32
Total	47	10.9	6.52

The diagnostic of the children were:

Diagnostic	Frequency	Percentage
ADHD (different subtypes)	34	72.34
Reading Disorder	12	25.53
Learning Disorder	1	2.12
Generalized Anxiety Disorder	1	2.12
Total sample	47	100

Measurements:

- Nesplora AULA:** AULA (Climent & Banterla, 2010) is a continuous performance test that takes place in a virtual scenario, very similar to a school classroom. During 20 minutes, the child is situated in a virtual context, shown through a head-mounted display with movement sensors and earphones and a single-button switch. Perspective places the child in one of the desks, facing the blackboard, where the stimuli appear. Stimuli are presented both on a visual and auditory basis, and, at the same time, previously randomized distractors of ecological nature appear progressively. The core of AULA is composed by two main exercises: (a) a NO-X paradigm-based exercise (i.e., "Press the button when you DO NOT perceive the target stimulus") and (b) an X paradigm-based exercise (i.e., "Press the button when you perceive the target stimulus").
- TOVA, Test of Variables of Attention** (Greenberg, 2011; Leark, Greenberg, Kindschi, Dupuy & Hughes, 2007) : The T.O.V.A. is a widely used Continuous Performance Test in USA. It uses geometric stimuli, and contains two test conditions: target infrequent and target frequent. In the first half of the test (the target infrequent half), the target:non-target ratio is 1:3.5, i.e.: a target is presented (randomly) only once every 3.5 non-target presentations. In this half which is

similar to most of the other Continuous Performance Tests (CPTs), the task is boring and fatiguing, and the subject must pay close attention to respond to the infrequent target correctly. When a subject does not respond to the target, it is called an error of omission and is a measure of inattention. In the second half of the test (target frequent half), the target:non-target ratio is 3.5:1, i.e: 3.5 targets are presented for every 1 non-target. In this half of the test, the subject expects to respond most of the time but occasionally must inhibit the tendency to respond.

- **WISC-V: Wechsler Intelligence Scale for Children®-Fifth Edition** (Wechsler et al., 2003): It is the latest version of the most proven trusted cognitive ability measure ever. It has been redesigned to give you a truly comprehensive picture of a child's abilities and it includes notable improvements to make identifying the issues—and finding the solutions—faster and easier.

Descriptive data:

WISC IV	
Description	Mean ± Standard Deviation
Verbal Comprehension Index	111.93 ± 10.182
Similarities	12.05 ± 2.202
Vocabulary	11.95 ± 1.987
Comprehension	11.36 ± 2.476
Information	11.83 ± 2.395
Perceptual Reasoning Index	109.66 ± 11.308
Block Design	10.66 ± 2.575
Picture Concepts	9.55 ± 2.791

Matrix Reasoning	12.12 ± 2.900
Picture Completion	9.37 ± 2.913
Working Memory Index	101.56 ± 13.107
Digit Span	10.24 ± 3.089
Arithmetic	10.95 ± 2.640
Processing Speed Index	98.61 ± 10.796
Coding	9.39 ± 2.575
Symbol Search	10.39 ± 2.626
Nesplora AULA	
Description	Mean ± Standard Deviation
Total omissions	28.81 ± 23.986
Total commissions	18.92 ± 20.481
Average reaction time on correct answers	910.3184 ± 151.040
Variability of reaction time on correct answers	440.264 ± 90.71
Motor activity	1.374 ± 1.020
TOVA, Test of Variables of Attention	
Response time average - total	94.19 ± 16.715
Commission errors - total	90.10 ± 18.623
Omission errors - Total	85.52 ± 21.5860
Attention Comparison Score (ACS) - Total variability	-1.3464 ± 1.74351
Attention Comparison Score (ACS)	-1.1417 ± ±.30918

Objectives of the study

The aim of this study is to explore the cognitive profiles of participants with different pathologies (mainly ADHD) with three different neuropsychological tests. Also, correlations between Nesplora AULA and TOVA will be analyzed in order to explore convergent validity of both tests.

Hypotheses study

- 1) Correlation between the variables of Nesplora AULA and WISC IV would provide complementary data about the cognitive profiles on children with an ADHD diagnose.
- 2) Positive correlation between Nesplora AULA and the TOVA test are expected in order to prove convergent validity between both tests.

Results

The results in this section are presented according to the hypotheses previously formulated.

- 1) Some significant correlations are observed between the Nesplora Aula main scores and the WISC-IV indices. While total omission errors in Nesplora Aula correlates with Verbal Comprehension and Perceptual reasoning indices, the reaction time correlates with Verbal comprehension and working memory. These results suggest that, even both test are providing different and complementary information about the cognitive capacities, this functions can be related in the global cognitive profile of the person evaluated:

		Nesplora Aula			
		Tot_omission	Tot_commission	TR_correct_avg	TR_correct_sd
WISC IV	VCI	-.361*	.272	-.369*	-.263*
	PRI	-.397*	-.333	-.189	-.116
	WMI	-.280	-.063	-.376*	-.281
	PSI	-.217	-.222	-.150	-.042

2) Spearman correlation analysis has been applied between the main indices of Nesplora AULA and TOVA test. Significant correlations in main variables of TOVA test and visual variables of Nesplora Aula have been found as is shown in the following chart:

		Nesplora AULA			
		Vis_omission	Vis_commission	Vis_correct_avg	Vis_correct_sd
TOVA	OMISSION_ERRORS_TOTAL	-.420*	-.426*	-.409*	-.480**
	COMMISSION_ERRORS_TOTAL	-.339	-.524**	-.180	-.292
	RESPONSE_TIME_TOTAL_ms	-.340	-.141	-.454*	-.272
	RT_VARIABILITY_TOTAL_ms	-.398*	-.524**	-.365*	-.466**

Dissemination

The data collected in the study will be deeply analyzed and disseminated by Nesplora and the collaborator in different congresses and publications. One

of these congresses will be the Annual Conference of the American Academy of Pediatric Neuropsychology (AAPdN).

4. CONCLUSIONS

The aim of these validation clinical studies is to measure the accuracy, validity, sensibility and specificity, for the detection of pathologies, of the AULA test. From the commercial point of view, these tests are done in order to give value to the test in front of the market so the studies can open new markets in foreign countries.

AULA was deployed into the market in 2011 and from that moment until now several studies have been carried out by the R+D department of Nesplora but also by independent experts, mainly our clients.

For this report we expected to make studies with a total sample of 300 subjects in USA, and we have just been able to recruit 47 subjects. This reduction is due to the difficulties to find new collaborators to perform the studies in USA. Asking to the potential collaborators who have not finally joint us, the ethical constraints and the deadline of the studies have been the main reasons to not collaborate with us.

Even though, we have been able to close an agreement with just one collaborator. Her commitment was to recruit 50 participants but she finally managed to recruit a total of 47 patients. But with these 47 evaluations we can obtain reliable data about the convergent validity between TOVA and AULA that can be published in a journal with good impact factor. This study will help us to open the American market.

Currently we are talking to different potential collaborators. When we attended to the 6th ADHD World Congress to present the data obtained with the Latin American sample (see D5.2 for more information), we made some contacts with potential USA collaborators. At this time, we continue the conversations with the following contacts:

- Duke University (EEUU)
- Clínica Dra. Heithaus (EEUU)

- Coca Project (multinational project)

So we have presented them the project and they have been invited to collaborate with us. With some of them we are close to tying up a deal but we have not been able to do it yet. In fact, to close an agreement it is a process which takes an average of 5-6 months.

We have also another different via to identify collaborators. We have been talking to the Project and Research Manager of the European-American Business Organization, Inc. in New York. He says that they can help us identifying collaborators for our AULA studies, and in general for VRMIND studies, in USA, but also he thinks that they can help us to open the market there. Now we are in conversations with them and trying to accommodate the budgetary issues.

Anyway, we consider that it would be great to continue with clinical studies in USA since it is the more difficult region for us to start the commercialization and these studies can help us a lot with this purpose. For this reason we will continue with these clinical studies during the VRMIND lifecycle and beyond.

5. REFERENCES

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