



D5.5 – Independent Report on the performance of ICSTEST on Latinamerican population



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1. EXECUTIVE SUMMARY

VRMIND-ICECREAM (Nesplora Ice Cream from now on) is a neuropsychological test for executive functions in people from 16 to 90 years old. It is a test designed to evaluate the main components of executive functions as working memory, planification, cognitive flexibility and processing speed to support the diagnosis and severity of any clinical condition which course with frontal lobe impairment. This assessment is carried out through the performance of the person within a virtual ice cream shop. The proper assessment of executive functions is a crucial issue in many conditions as different types of dementia, acquired brain injury, substance abuse disorder, adult ADHD, multiple sclerosis, psychotic disorders or anxiety and mood disorders.

This product is going to be launched to the market on 2019. For the commercialization of Nesplora Ice Cream we wanted to offer a scientific tool. That is why we have developed a normative study to a large extent by ourselves, but also with the help of some external collaborators. This way, the results obtained from the test, are automatically compared with the average of the person's reference group, where both age and sex are taken into account.

The performance of clinical studies researching with Nesplora Ice Cream 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 Nesplora Ice Cream in different countries at the beginning of the VRMIND Project. Also, collaborate with independent professionals, provides a better understanding of the interpretation of the measures obtained in the different clinical conditions.

This deliverable describes the contacts with potentials 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.

It is important to notice that our current collaborators in Latinamerica have not shared with us all the data and they will do it in the future. Besides, we are currently talking and trying to reach agreements with other potential collaborators in Latinamerica.

2. RELATION WITH OTHER WPS AND DELIVERABLES

This deliverable is closely related with D5.4 (Independent report on the performance of Ice Cream on European population) and D5.6 (Independent report on the performance of Ice Cream on N. American population).

3. COLLABORATOR'S STUDIES

Since the moment we received the approval of the VRMIND project we started looking for European collaborators. First of all we contacted with those members who signed an interest letter to collaborate with us and also with our current clients who have previously expressed interest in carrying out studies with Nesplora Ice Cream. Most of our contacts did not want to collaborate with us mainly due to agenda constraints and difficulties to achieve the ethical issues.

So we started inviting different experts in the neuropsychological field. These unsuccessful contacts are shown in table 1.

Currently we are also close to closing a collaboration agreement with Autonomous University of La Asunción / Randall Institute. In principle this agreement will aim to develop a study that proves the usefulness of the Nesplora Ice Cream tool for the characterization of the cognitive profile in people with Asperger's diagnosis or substance abuse disorder. It is expected that each of the two patient groups will consist of 20-25 people. In addition to Nesplora Ice Cream tests: (1) The Comprehensive Executive Function Inventory™ (CEFI®) ; (2) The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) will also be administered.

Finally the following three agreements with collaborators went ahead.

3.1 Neuraxis, centro de neuropsicología integral

Collaborator's description: Neuraxis is a clinical private practise specialised in Neuropsychology, evaluation, intervention and cognitive rehabilitation in neurodegenerative conditions, neurodevelopmental diseases, brain acquired injury, and mood disorders. María Victoria Isaacs is the director of Neuraxis and she's clinical Neuropsychologist. The collaborator agreement signed with this collaborator can be found in Annex 1 in this deliverable.

Location: Tolima (Colombia).

Sample's commitment: 30 adults from 60 to 75 years old with MCI diagnosis and 30 adults from 60 to 75 years old without cognitive impairment.

Sociodemographic data: The sample collected by this collaborator is still pending to be transferred to Nesplora. The deadline for the data collection is July 31st 2019.

Measurements:

- **Nesplora Ice Cream:** Nesplora Ice Cream (Climent 2018) is a neuropsychological test for executive functions in people from 16 to 90 years old. It is a test designed to evaluate the main components of executive functions as working memory, planning abilities, cognitive flexibility and processing speed to support the diagnosis and severity of any clinical condition which course with frontal lobe impairment. This assessment is carried out through the performance of the person within a virtual ice cream shop. The proper assessment of executive functions is a crucial issue in many conditions as different types of dementia, acquired brain injury, substance abuse disorder, adult ADHD, multiple sclerosis, psychotic disorders or anxiety and mood disorders.
- **MoCA:** The Montreal cognitive assessment (Nasreddine et al, 2005) has been conceived to evaluate mild cognitive disorders. This instrument examines the following skills: attention, concentration, executive functions (including the capacity for abstraction), memory, language, visuoconstructive abilities, calculation and orientation. The cutting point for DCL on this tool is 21 points.
- **MFE:** Memory Failures of Everyday Questionnaire was adapted for Spanish population by García-Martínez y Sánchez-Cánovas (1993). Using a 3 possible answer Likert type scale, cognitive complaints of the participant are collected.

Descriptive data: The sample collected by this collaborator is still pending to be transferred to Nesplora. The deadline for the data collection is June 30th 2019.

Objectives of the study:

The aim of this study is to test the sensitivity of Nesplora Ice Cream to detect the cognitive impairment associated to early stages of dementia. Also, correlation between Nesplora Ice Cream scores and MoCa and MSE test will be also analysed. The results of this study could potentially validate our tool to be administered in a wide clinical field as is the early detection and symptoms follow up of neurodegenerative processes.

Also, the control group of this study will be useful to compare Cyprus vs Spanish population and test the reliability of our norms.

Next steps:

After receiving the data at the end of June, Mann-Whitney U test will be carried out in order to analyse differences in the Ice Cream Scores between MCI group and the control group. The results will be disseminated in scientific journal publications.

3.2 Federico Gomez's Mexico Children Hospital (HIMFG).

Collaborator's description: The scientific and technological research of HIMFG, constitutes a substantive function carried out in a normative framework adapted to the characteristics of the promotion and development of research activities, with an institutional scientific policy that guarantees effectiveness and efficiency for research and quality, propitiating in HIMFG a general recognition of the research culture and its projection in undergraduate and graduate teaching, which revalue HIMFG as a medical institute of excellence at the service of Mexican society. Dr. Juan Carlos García Beristain is Neuropediatrician at the Neurology service of the HIMFG. The collaborator agreement signed with this collaborator can be found in Annex 2 in this deliverable.

Location: Mexico DF (Mexico).

Sample's commitment: 75 adults older than 16 years old with ADHD diagnosis.

Sociodemographic data: The sample collected by this collaborator is still pending to be transferred to Nesplora. The deadline for the data collection is December 31st 2019.

Measurements:

- **Nesplora Ice Cream:** Nesplora Ice Cream (Climent 2018) is a neuropsychological test for executive functions in people from 16 to 90 years old. It is a test designed to evaluate the main components of executive functions as working memory, planning abilities, cognitive flexibility and processing speed to support the diagnosis and severity of any clinical condition which course with frontal lobe impairment. This assessment is carried out through the performance of the person within a virtual ice cream shop. The proper assessment of executive functions is a crucial issue in many conditions as different types of

dementia, acquired brain injury, substance abuse disorder, adult ADHD, multiple sclerosis, psychotic disorders or anxiety and mood disorders.

- **Adult ADHD Self-Report Scale (ASRS-v1.1):** ASRS-v1.1 is an instrument consisting of the eighteen DSM-IV-TR criteria. Six of the eighteen questions were found to be the most predictive of symptoms consistent with ADHD. These six questions are the basis for the ASRS v1.1 Screener and are also Part A of the Symptom Checklist. Part B of the Symptom Checklist contains the remaining twelve questions.

Descriptive data: The sample collected by this collaborator is still pending to be transferred to Nesplora. The deadline for the data collection is December 31st 2019.

Objectives of the study:

The aim of this study is to test the sensitivity of Nesplora Ice Cream to detect the cognitive impairment associated to ADHD in adult population. The sample recruited for this study from parents of Children diagnosed of ADHD who also meet criteria of ADHD in the adulthood. For this reason, this study aims also to test the heritability of cognitive deficit in this disorder.

Next steps:

After receiving the data at the end of July, Mann-Whitney U test to analyse differences in the Nesplora Ice Cream scores between ADHD group and the control group. The results will be disseminated in scientific journal publications.

4. CONCLUSIONS

The clinical validation studies presented in this document are tackling different issues for a new neuropsychological test. As can be seen throughout the document, clinical studies are very heterogeneous in terms of type of population, objectives, etc... But all of them help us to advance in two lines: (1) obtaining scientific knowledge about cognitive functions; (2) positioning our tools in the market with a solid scientific base and contrasted not only by ourselves but also by independent collaborators.

With these studies, we want to test the convergent validity of our tool with other neuropsychological measures. Convergent validity is a desirable characteristic for our test, meaning our scores are targeting the same processes as other neuropsychological test in the market and already

accepted by the scientific community. To test this characteristic, we have available the data of the widely used MoCa and the CEFI tests.

Finally, we also want to test the sensitivity of our tool to detect cognitive impairment in clinical population, in this case, neurodegenerative processes associate to ageing and in ADHD in adult population. The results of this study could potentially validate our tool to be administered in a wide clinical field as is the early detection and symptoms follow up of neurodegenerative processes.

Although we have actively tried to obtain data from these studies by the time this deliverable is presented, we have not managed to obtain data from any of the collaborators.

Delays in the development of Ice Cream due to technical difficulties with the controller and the search for collaborators who meet the required requirements have been the main causes of not being able to submit data now.

However, what has been achieved has been to close 2 agreements and probably we will close another one in the next days. These studies, even if they continue and end outside the VRMIND project, are very interesting and necessary to be able to open the market for Nesplora, so they will continue throughout 2019 with Nesplora's own resources.

5. REFERENCES

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